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

Office of AIDS Research Advisory Council
64th Meeting
October 26, 2023

Virtual (Videocast Link)

Meeting Minutes

Council Members Present:
Dr. Kathleen L. Collins
Dr. Omar Galarraga
Dr. Shruti Mehta
Dr. Veronica Miller
Dr. Luis J. Montaner
Dr. Mojgan H. Naghavi
Dr. Anne M. Neilan
Dr. John W. Sleasman
Dr. Ivy E. Turnbull

***Ex Officio* Members Present:**
Dr. Victoria J. Davey
Dr. Carl W. Dieffenbach
Dr. Monica Gandhi
Dr. Rohan Hazra
Dr. Marguerita Lightfoot
RADM Jonathan Mermin
Dr. Melanie Ott

Office of AIDS Research (OAR) Leadership:
Dr. Bill G. Kapogiannis (Chair),
RDML Timothy Holtz, Deputy Director (Executive Secretary)
CAPT Mary Glenshaw

Invited Speakers and Guests:
Dr. Courtney Aklin
Dr. Christopher Barnhart
Dr. Kendall J. Bryant
Ms. Coretté Byrd
Dr. Redonna K. Chandler
Mr. Gabriel Maldonado
Dr. LaRon Nelson
Dr. Alice K. Pau
Dr. Eliseo J. Pérez-Stable
Dr. Dianne M. Rausch
Dr. Karina Walters

Welcome and Introductions

RDML Timothy H. Holtz, M.D., M.P.H., OARAC Executive Secretary, Assistant Surgeon General, U.S. Public Health Service, Deputy Director, OAR, NIH
Bill G. Kapogiannis, M.D., FIDSA, OARAC Chair, Acting Associate Director for AIDS Research and Acting Director, OAR, NIH

RDML Timothy H. Holtz and Dr. Bill G. Kapogiannis welcomed participants to the 64th meeting of the NIH OARAC. A quorum was present. Meeting materials provided to Council members included the agenda, a conflict-of-interest form, and minutes from the 63rd OARAC meeting, held on June 22, 2023. Dr. Kapogiannis reviewed the 64th meeting agenda, noting the inclusion of time for public comments.

Report from the Acting OAR Director

Bill G. Kapogiannis, M.D., FIDSA, OARAC Chair, Acting Associate Director for AIDS Research and Acting Director, OAR, NIH

Dr. Kapogiannis noted this OARAC meeting is focused on health disparities, one of the most pressing challenges in the HIV field. Although the science of preventing and treating HIV has progressed significantly, not everyone benefits equally from these advances. Dr. Kapogiannis emphasized the need to address biomedical, behavioral, and social science aspects of health disparities simultaneously—and in better and smarter ways.

Dr. Kapogiannis recognized the recent death of Dr. Stephaun Wallace, who worked to increase positive health outcomes for minoritized populations as Director of External Relations for the Fred Hutchinson Cancer Center's HIV Vaccine Trials Network, among many other roles. Dr. Kapogiannis noted that challenges persist regarding disparities, particularly in the context of HIV. Most new HIV diagnoses in the United States occur among Black and Latino populations, despite these groups representing a minority of the U.S. population. The majority of new HIV diagnoses occur in populations of men who have sex with men (MSM), and Black and African American MSM are most affected. Within that population, young Black and African American MSM are the most affected subpopulation—three of four new HIV diagnoses in Black and African American MSM are among those ages 13 to 34.

NIH recently announced that “people with disabilities” is now an officially designated population experiencing health disparities. This has implications for NIH-supported research and the ability to address this population’s needs. People with disabilities are the single largest minority group in the United States, and worldwide, more than 1 billion people have disabilities. An estimated one in four people with HIV has at least one disability, and the co-occurrence of disabilities and HIV compounds disparities. Models from Tanzania and South Africa estimate that people with HIV who are disabled are less likely than their nondisabled counterparts to be diagnosed or receive adequate HIV care.

Dr. Kapogiannis commented that achieving and maintaining health depends on a confluence of factors. Developing effective and well-tolerated therapies and other biomedical technologies is vital but insufficient. Individuals, groups, populations, and societies live and function within complex socio-structural and behavioral realities; identifying and addressing the full spectrum of and fulcrum points within those realities are key challenges. To continue making progress in addressing the HIV pandemic, strategies must be developed that address the many detrimental and interacting factors—including health disparities, social determinants of health, intersectionality, and syndemics—that together influence health outcomes.

Dr. Kapogiannis outlined ways that OAR is working to address these challenges. The first is through the *Ending the HIV Epidemic in the U.S.* (EHE) initiative, which aims to reduce the number of new HIV infections in the United States by scaling up prevention and treatment strategies in key jurisdictions. NIH awarded 201 EHE implementation science projects between 2019 and 2022; most projects include more than one priority population, and the investments follow the proportional burden of disease. In 2023, NIH solicited and funded EHE implementation science projects in four areas—Syndemic Approaches, Leveraging Pharmacies, Post-Incarceration Linkage to Care, and Cluster Detection Response—for a $25 million total investment. Syndemic approaches were intentionally prioritized for a larger proportion of the investment because syndemic interactions can negatively affect health outcomes across the HIV prevention and care continuum.

OAR's NIH-wide multidisciplinary signature programs are another way OAR is addressing the challenges of ending the HIV pandemic. The last OARAC meeting featured the HIV and Women Signature Program. Dr. Kapogiannis noted that the Technology for HIV Research program has been renamed Advancing Technologies to Improve HIV Diagnosis and Care. On November 1 and 2, OAR and the NIH AIDS Executive Committee (NAEC) will host a community-oriented virtual workshop focusing on advancing the development of HIV diagnostics and technologies, titled "Community Voices: Forging the Path Forward for HIV Self-Testing and Personalized Viral Load Monitoring."

OAR, with the National Institute of Mental Health (NIMH), also supports a pharmacy-centered HIV research initiative. Pharmacies present a game-changing opportunity to decentralize patient care and make it more accessible. Pharmacies often are seen as places where people can go for health care support without feeling judged or stigmatized, and pharmacies have longer hours and more locations than many clinics, which helps expand the ways people can access necessary care at critical times. In June, OAR and NIMH—along with several other institutes, centers, and offices (ICOs)—held a meeting to discuss pharmacy-centered HIV research.

Dr. Kapogiannis highlighted an important two-part event -- an HIV and Aging virtual research workshop and a later panel discussion held at the 2023 U.S. Conference on HIV/AIDS (USCHA), co-led by OAR in partnership with several ICOs, the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA). One important message from the workshop was that aging with HIV includes considerations for older adults as well as those with longer cumulative exposure to the virus after having acquired HIV earlier in life, including children born with HIV. Thus, HIV and aging must be considered across the life span.

The 2023 USCHA featured an HIV and Women workshop, co-hosted by OAR and the NIH Office of Research on Women's Health, exploring ways to identify gaps and priorities at the intersection of HIV and women's health and gather input from the community. Participants at a listening session within the workshop emphasized that HIV is not the defining feature of their lives and called for more meaningful engagement with research that centers on the complexity of Black women's experiences. OAR received feedback and ideas for future research priorities for HIV and women to inform the next NIH Strategic Plan for HIV and HIV-Related Research.

Dr. Kapogiannis emphasized that basic discoveries still are progressing, and that basic science remains a vital tool in the fight against HIV. In September, OAR presented its inaugural Innovation in HIV Research Symposium as part of the NIH Research Festival and intends this to be an annual event. The symposium highlighted research supported by the NIH OAR Innovation Fund, a program that provides 1--year funding for meritorious projects that use innovative approaches to address high-priority scientific opportunities in HIV research. In the first symposium, nine NIH intramural Innovation Fund recipients presented their findings, covering a broad range of topics.

Dr. Kapogiannis pointed out that this is the last OARAC meeting before World AIDS Day on December 1. This year is the 35th anniversary of World AIDS Day and the 35th anniversary of OAR. OAR is coordinating a virtual NIH event that will align with the U.S. government theme of "Remember and Commit" and anticipates the release of a National HIV/AIDS Strategy Interim Action Report on that day from the White House Office of National AIDS Policy (ONAP).

The next OARAC meeting is on February 22, 2024, and will be a virtual event. Dr. Kapogiannis thanked the participants for making the meetings a priority. He informed members that OAR had

transitioned the role of OARAC Designated Federal Officer from CAPT Mary Glenshaw, OAR's Senior Science Advisor, to RDML Holtz, OAR's Deputy Director. The transition aligns OARAC's leadership structure with standard NIH practices and enables CAPT Glenshaw to focus on the revision of the NIH HIV research priorities and NIH Strategic Plan for HIV and HIV-related Research. He also announced that Dr. Francis Ali-Osman would step down as National Cancer Advisory Board representative and that Dr. Christopher Friese would assume the role. Dr. Tabia Akintobi has completed her term as a voting OARAC member, and several members have extended their terms.

Dr. Kapogiannis announced that Dr. Jeanne Marrazzo has started her position as the new Director of the National Institute of Allergy and Infectious Diseases (NIAID). Dr. Marrazzo is a longtime champion of women, minoritized populations, and HIV and sexually transmitted infection care. Other new NIH staff include Dr. Karina Walters, Director of the Tribal Health Research Office (THRO); Dr. Jane Simoni, Director of the Office of Behavioral and Social Sciences Research; Dr. Andrew Bremer, Director of the Office of Nutrition Research; and Dr. Tara Schwetz, who will become Director of the Division of Program Coordination, Planning, and Strategic Initiatives. The search for the next OAR Director is ongoing.

Dr. Kapogiannis commented on the future of the NIH HIV research program for enhancing how multifaceted, complex challenges are addressed. OAR will coordinate the development of the next NIH Strategic Plan for HIV and HIV-related Research and is taking preliminary steps to prepare for that update. Ideas will be vetted through internal channels, including the NAEC, which represents all ICOs with HIV funding. An OARAC working group will be launched to assist with efforts to incorporate external input; a presentation is anticipated for the next OARAC meeting. Dr. Kapogiannis concluded his remarks by emphasizing that OAR recognizes the challenges posed by health disparities, social determinants of health, syndemics, and other intersectional factors to achieving the goal of ending the HIV epidemic.

Discussion Highlights

In response to a question about community-based health disparities research, Dr. Kapogiannis commented that the syndemic approach intentionally addresses the need for this type of research and that EHE projects are intended to be conducted within the community. Dr. Dianne Rausch added that Centers for AIDS Research have ongoing community-based projects and currently are developing 2026 initiatives. Drs. Kapogiannis and Rausch clarified that although aging populations are not highlighted in EHE research, they continue to be included in and a focus of the initiatives. Dr. Kapogiannis noted that the next version of the strategic plan will offer an opportunity to adjust the funding portfolio after reviewing needs across all sectors.

Ending the HIV Epidemic Starts With Addressing Health Disparities

Eliseo J. Pérez-Stable, M.D., Director, National Institute on Minority Health and Health Disparities (NIMHD), NIH

Dr. Eliseo Pérez-Stable commented on the significant progress in HIV care since the beginning of the epidemic. Although the tools now exist to treat HIV, outcomes remain lower in minority populations. Multilevel approaches are needed to address disparities and health inequities in prevention and care. Community engagement must be cultivated, and trust must be built to support sustainable partnerships. Known successful strategies must be implemented, and NIH must promote diversity in the scientific and clinical workforce.

Among NIH's designated health disparities populations, one unifying characteristic is the social disadvantage that results from being subject to discrimination or racism and from being underserved in health care. Discrimination based on race, ethnicity, and socioeconomic status influence health and predict life expectancy in ways that have not been fully explained. Most chronic diseases are more common in people of less privileged socioeconomic status because of structural factors. Racial and ethnic disparities also account for many excess health care costs. NIMHD research prioritizes race and ethnicity and socioeconomic status as fundamental pillars of health disparities science and studies the intersectionality of race and ethnicity and socioeconomic status with rurality, sexual and gender minority status, disability status, and other demographic factors. NIMHD has focused on standardized measurement, especially around social determinants of health, such as by adding structural and social factors to the PhenX toolkit.

HIV health disparities and housing instability intersect significantly, especially in racial and ethnic minority populations and youth and young adults. Those who experience homelessness and housing instability are less likely to be linked to treatment and may have poorer HIV outcomes, which suggests the need for targeted interventions in local areas. There are stark differences by state in rates of death for people diagnosed with HIV.

Dr. Pérez-Stable emphasized the need for scientists to consider how discrimination affects medical outcomes. Most research on racism has focused on interpersonal interactions, but racism is also systemic, structural, internalized, perceived, or secondhand. In recent years, NIMHD has conceptualized racial inequality as cumulative stress that is harmful to health in many ways. Historical redlining policies have influenced social segregation and the trajectory of health outcomes. Strategies to mitigate the effects of racism require long-term investments.

Promoting health equity is critical and begins with expanding access. The COVID-19 pandemic has reiterated that community-engaged research is necessary to reduce health disparities, and Dr. Pérez-Stable emphasized that the RADx (Rapid Acceleration of Diagnostics) model should be sustained. NIMHD's recommended future research directions include developing multilevel interventions, emphasizing intersectionality, identifying mechanisms, assessing communication strategies that promote trust between patients and clinicians, and implementing structural change to modify individual and group behaviors.

The Epistemology of Ignorance: Normal Science, Inevitable Inequities, and Audacious Antidotes for the HIV Epidemic

LaRon Nelson, Ph.D., RN, FNP, FNAP, FNYAM, FAAN, Associate Dean for Global Affairs and Planetary Health, Independence Foundation Professor of Nursing, Yale University

Dr. LaRon Nelson pointed out that social inequities in HIV are alarming but predictable, reflecting the patterns of social organization in U.S. communities across multiple social, economic, and health burdens. Patterns of disease are socially and politically determined, and people often are minoritized based on their placement within the social hierarchy, leading to a devaluation of minoritized communities that leaves them disadvantaged and overexposed to risk. For example, interventions are often designed to be successful for White MSM, but those benefits will not necessarily translate to Black MSM and, thus, must be redesigned.

Dr. Nelson posited that "normal science" supports the status quo, including embedded blind spots that render minoritized groups easy to miss and ignore. Racism is embedded in scientific

infrastructure, and racist logic is embedded in scientific processes. Inequities persist because "normal science" supports them, so improving inequities requires a disruption of existing patterns to shift to a revolutionary type of science. When science can no longer address the questions of the day, a new way of thinking is needed; these paradigm shifts eventually become the "new" normal. Dr. Nelson commented that from a researcher perspective, the HIV field is already at a crisis point because new strategies have not worked, so the field may be on the cusp of a revolution. Generating new knowledge does not improve systems, so the revolution may involve putting evidence into action.

The new epoch of the HIV epidemic is driven by multiple behaviors and systems rather than individual behavior; if science is to address HIV, it must also address other relevant behaviors and systems that affect individual and population-level outcomes. Research is needed to understand and better address the complex drivers of HIV outcomes. Interventions must be more agile to be successful and relevant in the current phase of the epidemic, which might require suspending normal rules without sacrificing scientific rigor.

These new complexities require novel research designs and mathematical methods; Dr. Nelson emphasized that NIH should invest in developing and testing new methods that can be successful in new paradigms and are informed by people with a variety of lived experiences. Research infrastructure development should be supported, especially in Historically Black Colleges and Universities, Hispanic Serving Institutions, Indigenous schools, and other Minority-Serving Institutions. Training grants must be provided in the places where people with lived experiences similar to the focus population receive their education.

Dr. Nelson emphasized the need to address these issues quickly and treat HIV as an emergency. The COVID-19 pandemic demonstrated how agencies behave differently in an emergency setting, and the existing HIV processes can be made more responsive using these models. Diversity supplements should be increased, cooperation should be incentivized, and collaboration should be rewarded to maximize research impact by sharing resources. Dr. Nelson commented on the epistemology of ignorance, pointing out that ignorance is popularly understood as a gap in knowledge resulting from insufficient information and remedied through provision of data, but a critical assessment suggests that ignorance is a refusal of knowledge and prevention of learning to maintain bliss, power, and order. He reiterated that the widening gap in HIV incidence demonstrates the need to do something dramatically different to address inequities.

Defeating Stigma and Advancing Health Equity

Gabriel Maldonado, M.B.A., Chief Executive Officer, TruEvolution, Inc.

Mr. Gabriel Maldonado outlined TruEvolution's supportive housing program, which houses homeless people with HIV. Because this program was implemented during the COVID-19 pandemic, it showed the type of innovation possible without burdensome regulations. The program is a 24-month transitional housing program focused on those at highest risk of COVID-19 and HIV acquisition. It offers 48 beds, and a majority of these are offered to LGBTQI+ people and those with HIV. A strong population of seniors also is represented. The program operates five residential homes, as well as recreational and wellness programs and a community park, in Riverside, California.

Mr. Maldonado outlined strategies that can be implemented through other programs and opportunities for science. Programs should focus on establishing low barriers of entry to

services, which simplifies access. Comprehensive service delivery, with housing as its nexus, allows the best opportunity to support staying in care because people whose core survival and quality of life needs are addressed are more willing to participate in treatment. The program also integrates wellness and nonclinical services, and it offers a balance between guided experiences and self-determination. Some modules are required, but the program also provides security and information technology services to help residents develop areas of their lives beyond survival, allowing fluidity, flexibility, and freedom.

Mr. Maldonado recommended that NIH let the community see the people involved in research—not just their scientific results—to build trust. Community-based research initiatives should be expanded, and more innovative ways to evaluate research opportunities are needed. Implementation science models that address social determinants of health should be better supported by federal resources. Mr. Maldonado also recommended dismantling silos and exploring possibilities for blending funding and other activities among government departments and agencies.

Discussion Highlights

Dr. Luis Montaner commented that study sections often have trouble identifying health disparities research that is significant and innovative, and that addressing one-size-fits-all requirements and meeting the needs of communities often are at odds. The new guidelines for scientific review include an opportunity to emphasize the importance of health disparities research.

When asked why new methods are needed when disparities often seem to stem from implementation challenges, Dr. Nelson clarified that many current methods have good efficacy but unequal impact, so the effects of interventions in the real world must be studied rigorously. Dr. Rohan Hazra commented on the challenges some community-based organizations face in acquiring research funding, noting that the NIH Improve Program has a challenge competition to encourage community organizations to develop the capability to address research needs for improving maternal health among populations experiencing health disparities.

Dr. Pérez-Stable commented that NIMHD is charged with monitoring and assessing investments in minority health and health disparities research across NIH, but determining which research is counted can be difficult. He added that one implementation science challenge is getting people from minority communities to participate in clinical trials; trials for COVID-19 treatments accrued many White volunteers despite the disproportionate impact on minority communities.

RADM Jonathan Mermin emphasized the need to consider methods that would allow implementation of critical applied research questions, pointing out that knowing who is included in research is essential to knowing whether research answers the intended question.
Dr. Kathleen Collins pointed out that academic pipeline programs often struggle to expand their applicant pools, and few NIH funds are available for such programs. Dr. Nelson suggested that the NIH Pioneer Awards could serve as a creative model for training program applications.

Panel Discussion: Integrating Syndemic Models in HIV Health Disparities Research

Courtney Aklin, Ph.D., Deputy Director, National Institute of Nursing Research (NINR), NIH
Christopher Barnhart, Ph.D., Health Science Policy Analyst, Sexual & Gender Minority Research Office (SGMRO), NIH
Kendall J. Bryant, Ph.D., Director, HIV/AIDS Research, National Institute on Alcohol Abuse and Alcoholism (NIAAA), NIH
Redonna K. Chandler, Ph.D., Director, HIV Research Program, HEALing Communities Study, National Institute on Drug Abuse (NIDA), NIH
Eliseo J. Pérez-Stable, M.D., Director, NIMHD, NIH
Dianne M. Rausch, Ph.D., Director, Division of AIDS Research, NIMH, NIH
Karina Walters, Ph.D., M.S.W., Director, THRO, NIH

Panelists offered opening remarks on integrating syndemic models in HIV health disparities research. Dr. Courtney Aklin pointed out that because nurses are everywhere, NINR has a broad reach and can bridge disciplines. Dr. Christopher Barnhart noted that SGMRO works across NIH and the federal government to promote equitable outcomes across the HIV care continuum for all sexual and gender minority (SGM) people. Dr. Kendall Bryant explained that alcohol use disorders and drinking patterns directly affect prevalence of HIV infection and several aspects of HIV treatment, and NIAAA examines the complex role of alcohol use with a person-by-environment approach that has evolved throughout the HIV epidemic. Dr. Redonna Chandler commented that NIDA recognizes the syndemic nature of substance use disorder and HIV, as well as the disproportionate burden of substance use disorder on minority populations, therefore, HIV is integrated in all NIDA initiatives. Dr. Pérez-Stable reiterated that NIMHD focuses on interventions that reduce viral load and pre-exposure prophylaxis (PrEP) uptake promotion, adding that NIMHD has received fewer competitive R01 applications in recent years. Dr. Rausch noted that NIMH prioritizes interdisciplinary neuroscience and behavioral science across multiple populations, with strong attention to diversity, equity, inclusion, and accessibility. Dr. Walters pointed out that American Indian and Alaska Native (AI/AN) populations tend to be invisible and misclassified in systems, making it difficult for their needs to be met. In response, THRO consults and collaborates with tribal partners and Native-serving organizations to generate Native science and a workforce to build lives and communities.

When asked what research methodologies are most likely to yield results with a direct effect on the health outcomes of minoritized populations, Dr. Pérez-Stable commented that community-engaged research is critical and that an adaptable network based on sustainable partnerships, mutual respect, equality, and trust should be built and sustained. NIMHD also supports implementation science because of the difficulty in delivering effective approaches to the people most in need. Standardized measures also are critical for the scientific community as more data are collected.

With regard to next steps and best practices to advance intersectionality research, Dr. Rausch noted that NIMH supports basic behavioral and social sciences research aimed at ending the pandemic and improving health for people with HIV across all populations and has prioritized intersectionality, with special attention to key populations, for many years. Dr. Barnhart pointed out that creating, validating, and improving measures of intersectionality and related constructs will allow researchers to link relevant factors to health more clearly. Validation should be performed with the intended audience, and statistical methods for rigorous analysis of complex intersectional data must be developed. For SGM people, when appropriate, sexual orientation and gender identity (SOGI) data should be collected as demographic data in studies that do not

focus on these communities, and data not related to SOGI should be collected in SGM-focused studies. He emphasized the importance of addressing needs more holistically and investigating a broader range of health drivers, identities, and structural and social determinants of health that more accurately approximate a person's circumstances. Dr. Barnhart also pointed out that communities should be full partners in all phases of research. Implementation and dissemination research also is critical, and cross-pollination between researchers in different fields should be encouraged, as should transparency.

Dr. Chandler elaborated on how NIDA uses the syndemic approach, noting that both HIV and substance use amplify the impact, burden, disease, and health outcomes of the other. She cited examples, noting the nonmedical use of opioids is three times higher among people with HIV, and fentanyl increases HIV replication. She emphasized the need to address these issues simultaneously. Dr. Chandler also commented that NIH needs to begin considering how the effects of climate change disproportionately affect the parts of the country that already have the greatest disparities.

When asked which interventional studies address specific drivers that might have significant effects on HIV health outcomes, Dr. Walters pointed out that in AI/AN communities, HIV is not always the most pressing issue. Further, few efficacy studies have been conducted in AI/AN communities, but related work such as land-based healing approaches, may allow researchers to step outside typical frameworks and shift the conversation to community-level change. Pathology-oriented research often stigmatizes Native communities, and identity-based interventions that increase connectedness, feeling seen, and a sense of belonging are critical. Dr. Walters added that many successful interventions pass through the AI/AN community rather than the LGBTQI+ community, and virtual interventions often provide safer ways for people to connect with others without being outed to their community.

Dr. Bryant pointed out that alcohol use disorders are the most prevalent substance use disorder among people with HIV and remain under identified and under addressed, so more active engagement from the government is needed. He emphasized the need to transfer knowledge from high-income communities to their developing counterparts to address alcohol-related issues in people living with HIV. Conjoined screening and adaptive models have been tested, and upcoming concepts will look for biomarkers for alcohol-related conditions.

In response to a question about methods and approaches for the AI/AN community and other populations with less access, Dr. Walters pointed out that the majority of AI/AN and SGM people are in urban settings, which poses unique demands around sampling and prevalence when communities are not clustered. Many measures do not adequately capture some of the constructs that are meaningful to the community, and constructs that focus more on well-being are needed. The complexity of identity is difficult to capture. Researchers also must assess trauma and violence in relation to substance use and the effects of boarding school trauma on knowledge of healthy sexual practices. Culturally driven interventions are needed that explore original instructions around healthful behaviors and restore relational ways of being in the world.

Dr. Barnhart commented on the need to increase research on how policies affect health, especially in light of the current threats to the health of SGM people. More qualitative and mixed-measure strategies are needed to form a richer picture of the inequities faced by LGBTQI+ people, and research must shift from its traditional individual focus to examinations of social and structural drivers. Community-based research that empowers LGBTQI+ people to tell their stories and be heard as partners is needed. Dr. Barnhart added that each LGBTQI+ subpopulation has unique care needs and faces unique barriers, so research must be tailored to

specific focus populations. Existing data, such as the LGBTQI+ data set collected by the *All of Us* Research Program, should be leveraged.

Dr. Aklin pointed out that NINR encourages research on social determinants of health among minoritized populations, addressing relevant questions without considering social determinants of health is almost impossible. NINR is working to break down barriers in nomenclature to support a shared understanding and has helped establish the NIH-Wide Social Determinants of Health Research Coordinating Committee to support this effort. NINR also supports initiatives to increase awareness across nursing and complementary disciplines and address social determinants of health among youth and has supported research on unmet needs related to antiretroviral therapy (ART) and Black individuals using a community-engaged approach.

In response to a suggestion that OAR advocate for greater availability of information about NIH's disparities research portfolio, Dr. Kapogiannis shared that although NIH invests substantially in health disparities research, more data need to be added to RePORTER to characterize this broad portfolio more accurately. The Center for Scientific Review currently is reviewing its processes, and OAR can provide feedback.
Dr. Montaner commented on the challenges faced by applicants from minority institutions and encouraged developing a new, more effective paradigm, including populating study sections with appropriate investigators, using existing networks that know their candidates well, and synergizing with people already in the community.

RADM Mermin suggested that OAR consider whether it is funding the most strategic scientific research that would reduce disparities if implemented. He pointed out that small demonstration projects and niche research often is not as useful in the long term, so past research that did not translate into public health success should be assessed.

Dr. Rausch commented that implementation research is complicated but essential. Researchers must engage community partners to identify which social determinants of health and HIV outcomes are relevant to that particular community so that interventions can be tailored. A hybrid approach also can be helpful because built-in checkpoints allow the research to change if the approach is not working as expected.

In response to a question about unexplored real-world approaches to reducing transmission, Dr. Bryant commented that NIAAA has looked closely at prevention, including policy research, geospatial considerations, PrEP and post-exposure prophylaxis availability, risk management, and training for health professionals to deliver brief messaging interventions in many settings.
Dr. Chandler pointed out that despite the overwhelming evidence demonstrating the effectiveness of syringe service programs, they are being shut down in many areas of the country. Health communications must be effectively tailored to meet people where they are in terms of health expertise, culture, and language. In many instances, health communications must convince both the patient population and the community in which the intervention will take place. People also face discrimination within the health care system from those who are supposed to provide necessary care.

When asked how NINR fosters community-driven research, Dr. Aklin pointed out that the Community Partnerships to Advance Science for Society (ComPASS) program provides the opportunity to support community organizations as they lead research, which will help NINR understand barriers and further address them at the community level.

Updates From the NIH Advisory Council Representatives

National Advisory Mental Health Council (NAMHC)

Marguerita Lightfoot, Ph.D., Associate Dean for Research at the Oregon Health & Science University and Portland State University School of Public Health

Dr. Marguerita Lightfoot outlined the most recent NAMHC meeting, noting NIMH's initiative to advance precision medicine in psychiatry, including projects related to precision diagnostics and biomarker development. HIV-related funding opportunities currently are available in such areas as social disconnection and suicide risk in later life, care and treatment for adolescents, mental health comorbidities, intersectional stigma, and implementation science to advance global prevention and treatment targets. The last NAMHC meeting included concept clearances on advancing HIV testing, prevention, and care through pharmacists and pharmacies and streamlining mental health interventions for youth living with HIV in low- and middle-income countries. Proceedings are available for two NIMH-sponsored meetings from summer 2023: Violence and the HIV Care Continuum and Pharmacy-Centered HIV Research.

Dr. Lightfoot highlighted recent research showing that the brain microglia may serve as a persistent HIV reservoir. She pointed out that NIMH strongly supports the ComPASS program, which includes some HIV-related studies. ComPASS is part of the NIH Common Fund and focuses on health equity, supporting structural interventions and multisectoral partnerships. Dr. Lightfoot noted that the fiscal year 2023 (FY23) budget allocation includes an increase for NI MH that would support more than 600 new and renewed project grants. She pointed out that the House and Senate appropriations committees differed in their allocations for FY24, so the next year of funding remains in question.

National Advisory Council on Drug Abuse (NACDA)

Melanie Ott, M.D., Ph.D., Director, Senior Investigator, Gladstone Institute of Virology and Immunology, Professor of Medicine, University of California, San Francisco

Dr. Melanie Ott reiterated that the NIDA HIV research portfolio is broad and intertwined with HIV research, supporting both clinical and implementation science research. NIDA's focus is on understanding the synergistic impact of HIV and substance use and examining the contributions of substance use to HIV and the pathogenesis of HIV-associated comorbidities and persistence. The most recent NACDA meeting included an update on federal efforts to address the national HIV epidemic highlighting that 1 in 10 infections continues to be diagnosed in people who inject drugs; drug use, overdoses, and homelessness also continue to be driving factors in new HIV infections and poor health outcomes in people with HIV. The meeting also highlighted that PrEP is effective in people who inject drugs—the U.S. Preventive Services Task Force gave PrEP an "A" grade and recommended prescribing it for people at increased risk for HIV acquisition, including people who inject drugs.

Dr. Ott commented on the implicit bias of primary care providers toward people who inject drugs, which highlights the need to continue supporting research on discrimination and intersectional stigma regarding the provision of guideline-concordant care for people who use drugs and are at risk for or living with HIV. Current funding opportunities from NIDA include research into microglial pathophysiology, comorbid substance use disorder and HIV, and development of *ex vivo* models for studies at the intersection of HIV and polysubstance use.

NIH HIV/AIDS Executive Committee

Coretté Byrd, R.N., M.S., Health Science Policy Advisor, HIVinfo Program Manager, OAR, NIH

Ms. Coretté Byrd reviewed 15 HIV-related concepts cleared by ICO advisory councils and published since the previous OARAC meeting. The 10 new concepts and 5 reissues were cleared by the advisory councils of NIAID, NIMHD, the National Cancer Institute, the National Institute on Aging, and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

AIDS Research Advisory Committee (ARAC)

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

Dr. Monica Gandhi provided updates from the recent ARAC meeting, including remarks on the NIAID budget. Although NIAID had strong funding in the most recent budget period, Dr. Gandhi highlighted the effects of political polarization on NIAID and infectious disease research. The House Appropriations Committee proposed a funding cut of 23 percent, and the Senate proposed a flat budget. Although these budgets were not passed, they show that NIAID has been particularly affected by this budget climate, so NIAID has proposed a conservative financial management plan for the near future, with lower-than-normal paylines.

Recent successes include approval of cabotegravir every 8 weeks as a preventive agent; the U.S. Preventive Services Task Force "A" grade for PrEP, which will pave the way for insurance approval; and many advances through the AIDS Clinical Trials Group and ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines) platforms, work that is ongoing. Recently approved concepts include such topics as global patterns of HIV incidence, strategies for eliminating HIV proteins, controlled release of HIV vaccines to increase immunogenicity, and strategies to make vaccine responses more durable.

Dr. Gandhi commented on the need for more research on gender-affirming hormone therapy, resilience, immunology, and pharmacokinetics in the context of ART. Other recently approved concepts include research on more creative long-acting drug delivery systems for ART optimization in children and a collaborative biomedical research program between the United States and Brazil.

HIV Clinical Guidelines Working Groups of OARAC Updates

Guidelines for the Use of Antiretroviral (ARV) Agents in Adults and Adolescents With HIV

Alice K. Pau, PharmD, Staff Scientist and Clinical Pharmacist, NIAID, NIH

Dr. Alice K. Pau provided updates on the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, which are celebrating their 25th anniversary in a significantly different HIV landscape from when they began. The panel recently held its first retreat since 2019; topics discussed included ART guidelines around the world, weight change and adiposity, how the Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE) results may affect the Guidelines, HIV and transplant, drug–drug interactions, and new ART drugs in development.

The Adult ARV Guidelines page views dipped during the early part of the COVID-19 pandemic but now are increasing again. Although the What to Start page has always been the most

viewed, Dr. Pau pointed out that the drug–drug interactions section is the second most popular and is used by many people around the world. The increased number of drugs in use and the difficulty of assessing the effects of long-acting agents has complicated this section; the Panel currently is reviewing drugs approved in the last several years that may be relevant to HIV.

The COVID-19 and HIV section will be retired soon, and users will be referred to the NIH COVID-19 guidelines, which contain information on treatment of COVID-19 in people with HIV. New sections under development include an HIV and transplant section and a section on weight and adiposity changes and ART. Following the results of REPRIEVE, the Panel is seeking cardiology and lipidology experts to work with the Panel on developing recommendations on the use of statins in people with HIV. Dr. Pau pointed out that statin guidance may not be appropriate for the Adult ARV Guidelines, but that remains under consideration. She added that updates on a number of sections are scheduled for early spring 2024.

Public Comment

RDML Timothy H. Holtz, M.D., M.P.H., OAR, NIH

RDML Holtz reported that no public comments had been received.

Closing Remarks and Adjournment

Bill G. Kapogiannis, M.D., OAR, NIH

A motion to accept the minutes of the 63rd OARAC meeting was approved unanimously by email; the minutes of this meeting also will be approved using that method. Dr. Kapogiannis thanked the Council members and speakers and adjourned the meeting at 4:57 p.m. EDT.

Certification

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

Bill G. Kapogiannis -S Digitally signed by Bill G. Kapogiannis -S
Date: 2023.12.13 17:17:47 -05'00'

Bill G. Kapogiannis, M.D.
Chair, OARAC

Date

Timothy H. Holtz -S Digitally signed by Timothy H. Holtz -S
Date: 2023.12.14 11:05:05 -05'00'

RDML Timothy H. Holtz, M.D., M.P.H.
Executive Secretary, OARAC

Date