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

Office of AIDS Research Advisory Council
Fifty-First Meeting

June 27, 2019
5601 Fishers Lane, Room 1D13
Rockville, Maryland

Meeting Minutes

Council Members Present: Dr. Charles R. Wira (Chair), Dr. Jay R. Radke (Executive Secretary), Dr. Tricia H. Burdo, Dr. John J. Chin, Ms. Lynda M. Dee, Dr. Jennifer Kates, Dr. Lynne M. Mofenson, Dr. William G. Powderly,* Dr. Scott D. Rhodes, Dr. Kimberly K. Scarsi, Dr. Bruce R. Schackman, Dr. Babafemi Taiwo

***Ad Hoc* Members Present:** Dr. Maureen M. Goodenow (Director, Office of AIDS Research), Dr. Ingrid Basset, Dr. Heidi M. Crane, Dr. Jonah Sacha, Dr. David M. Smith

***Ex Officio* Members Present:** Dr. Julie A. Ake, Dr. Victoria Davey, Dr. Carl Dieffenbach, Dr. Roy M. Gulick, Dr. Jonathan Mermin

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

Invited Speakers and Guests: Dr. Jose A. Bauermeister, Dr. Stacy Carrington-Lawrence, Dr. Rohan Hazra, Dr. Miroslaw "Mack" Mackiewicz, Dr. Karen L. Parker, Dr. Dianne Rausch, Dr. Robert Yarchoan,

Council Members Absent: Ms. Dázon Dixon Diallo

* Participated remotely.

Welcome and Introductions
Charles Wira, Ph.D., Geisel School of Medicine at Dartmouth

Dr. Charles Wira welcomed participants to the fifty-first meeting of the National Institutes of Health (NIH) Office of AIDS Research Advisory Council (OARAC). Meeting materials provided to Council members included the agenda, a conflict-of-interest form, and minutes from the fiftieth OARAC meeting, held on March 28, 2019. Dr. Lynne Mofenson moved to accept the draft minutes from the fiftieth OARAC meeting; the motion was seconded by Dr. Scott Rhodes. Members of the Council voted to approve the minutes. Dr. Wira reviewed the fifty-first 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 noted that the meeting occurred on National HIV Testing Day, on which people of all backgrounds and sexual orientations are encouraged to get tested for HIV; know their status; and seek prevention, care, and treatment

services. She introduced the new Deputy Director of OAR, Dr. Timothy Holtz, who officially joined the Office on June 17. Dr. Goodenow informed attendees that Dr. Jay Radke accepted a position at the National Institute of Allergy and Infectious Diseases (NIAID); Dr. Mary Glenshaw will assume the role of OARAC Executive Secretary.

The NIH is addressing its culture regarding sexual harassment (Harassment doesn't work here), emphasizing the importance of this priority for NIH Director Dr. Francis S. Collins. Initiatives include surveys to assess the effects of current policies, an anti-sexual harassment website, and an interim report. This report recommended that the NIH treat professional misconduct—including sexual harassment—as seriously as research misconduct; require all principal investigators to attest that they have not violated and will not violate their institutional code of conduct; develop mechanisms to recapture lost talent and provide restorative justice for survivors; and consider novel approaches to address investigator independence from mentors. These recommendations include reporting requirements to ensure that the NIH does not unknowingly fund researchers found guilty of sexual harassment. A final report from the Office of the NIH Director will be developed and posted online, with additional tools for the public.

Dr. Goodenow noted Dr. Collins' recent declaration that he would no longer participate in panels at meetings that do not demonstrate inclusiveness with regard to speakers. Dr. Goodenow intends to promote inclusion similarly when considering speaking engagements. In addition, OAR will review policies for meetings, conferences, and workshops funded with NIH HIV funds and actively promote inclusiveness in their agendas.

Dr. Goodenow mentioned recent conferences and described the increases in funding for research on HIV and aging. The distribution of HIV/AIDS funding across all Institutes, Centers, and Offices (ICOs) reflects the complexity of the research. In addition to biomedical research, behavioral aspects of HIV regimens are important to ensuring the implementation of treatment and prevention among older populations.

In May 2019, OAR responded to a request from the Office of Management and Budget (OMB) to understand how NIH research can support efforts to treat and cure HIV/AIDS, how the portfolio has changed with advancements in antiretroviral drug formulations, and research avenues the NIH seeks to fund in 2019 and 2020. OAR presented an overview of the distribution of HIV funding across ICOs and the percentage of each ICO's budget allocated to HIV research, as well as examples of new data analytics approaches. This meeting was the second OAR/OMB meeting; the initial meeting occurred in September 2018. Future annual meetings were requested by the OMB.

Dr. Goodenow noted the July 2019 International AIDS Society (IAS) conference in Mexico City, Mexico, at which OAR will convene a behavioral and social sciences symposium to inform and update IAS conference attendees on NIH-supported priorities and opportunities in HIV/AIDS-related behavioral and social sciences research.

Dr. Goodenow provided an update on progress and goals related to the development of the Fiscal Year (FY) 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research. OAR will present Dr. Collins with a draft for his review and feedback in the coming months.
Dr. Goodenow commented on OAR's recent listening sessions with community members, which were addressed in more detail later in the OARAC meeting agenda.

In response to questions from Dr. Mofenson during the March 2019 OARAC meeting, Dr. Goodenow reported on data related to National Heart, Lung, and Blood Institute (NHLBI)

support for research among exposed but uninfected children. The NHLBI has invested almost $13.5 million over the past 10 years in HIV-related pediatric and neonatal cardiovascular and pulmonary health projects. In addition, over the past 10 years NHLBI has provided $6 million co-funding to the Pediatric HIV/AIDS Cohort Study (PHACS) and a one-time $1.1 million allocation to support supplements.

The NIH launched the Next Generation Researchers Initiative in 2017 to address the challenges in embarking upon independent research careers and promote the growth, stability, and diversity of the biomedical research workforce. In FY 2018, the NIH set a goal to fund 1,100 early stage investigators (ESIs), which was surpassed. In FY 2019, the NIH seeks to fund at least 1,100 ESIs. OAR is analyzing the data to determine the extent that ESIs in HIV research received funding. A follow-up report is anticipated at the October 28, 2019, OARAC meeting.

Dr. Goodenow provided an update on the *Ending the HIV Epidemic: A Plan for America* initiative. Supplements are available to currently funded eligible Centers for AIDS Research (CFARs) and AIDS Research Centers (ARCs) and provide 1 year of pilot funding to identify and design a targeted implementation science project that addresses one of the four *Ending the HIV Epidemic: A Plan for America* (EHE) pillars: Diagnose, Treat, Prevent, and Respond. Dr. Goodenow emphasized that the existing treatment and prevention strategies could theoretically end the epidemic today, but implementation strategies are needed to expand access and use. The CFAR/ARC supplements will determine areas to invest for further long-term projects.

Discussion Highlights

Dr. Goodenow clarified that although the *Ending the HIV Epidemic: A Plan for America* initiative has made significant progress in planning for implementation in the 3 months since the initiative was announced, most funding is intended to begin in FY 2020.

When asked whether the community would receive information in return for participating in listening sessions, Dr. Goodenow explained that the sessions are intended to inform OAR and will culminate in a forthcoming public report.

When asked about guidelines for ICOs on what percentage of their portfolio should be dedicated to HIV, Dr. Goodenow explained that although ICOs provide input that helps define the distribution of the HIV research budget, ICOs are not obligated to have an HIV research agenda. The distribution of HIV research funds varies by ICO and can shift annually depending on a variety of factors.

In response to a question about NHLBI's support for PHACS, Dr. Rohan Hazra clarified that the program currently is in a recompete phase.

Updates to the U.S. Department of Health and Human Services (HHS) HIV/AIDS Treatment and Prevention Guidelines from the Working Groups of the OARAC

Rohan Hazra, M.D., Chief, Maternal and Pediatric Infectious Diseases Branch, Eunice Kennedy Shriver *National Institute of Child Health and Human Development (NICHD), NIH*

Dr. Rohan Hazra explained that the HHS HIV/AIDS Treatment and Prevention Guidelines are used extensively, accumulating more than 2 million page-views over the past year.

- Adult antiretroviral therapy (ART) guidelines have not been updated since the previous OARAC meeting.

- Updates for the opportunistic infection (OI) guidelines include alphabetizing sections, removing the "Preventing Exposure" section, renaming pathogens, and providing updated information or references. Additional updates for both adult and pediatric OI guidelines are pending clearance or editing by the Centers for Disease Control and Prevention (CDC).

- The working group for the pediatric ART guidelines is planning a rapid update around dolutegravir and bictegravir.

Dr. Hazra explained that the working groups review the pages of the pediatric guidelines with the most views each year, which helps with prioritization of updates. On one such call, they questioned how much international traffic the guidelines receive, leading to an assessment that showed that two-thirds of the page views are international. The majority of children with new HIV diagnoses in the United States are foreign-born. Adoptees or migrant children often are being treated in locations that may not be major urban centers with strong HIV expertise. Dr. Hazra emphasized that although the guidelines are designed for U.S. users, the guidelines' writers should be aware of the increasing importance of international treatment settings.

The perinatal guidelines are updated once per year. Dr. Hazra updated the attendees on an NICHD Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC), which was created in response to the 21st Century Cures Act. The group met four times in less than a year and developed a 400-page report that was sent to the HHS Secretary and Congress in the fall of 2018. One recommendation was to continue the Task Force, so PRGLAC 2.0 will meet in August 2019 and begin implementing the recommendations.

Discussion Highlights

Attendees commented that, because the OI guidelines are very useful, clinicians caring for non-HIV individuals frequently consult them. The guidelines thus provide a broad service to the community, particularly when many experts in the field are retiring. Additionally, attendees discussed the responsibility to prioritize U.S. concerns despite the international reach.

Dr. Hazra explained that the NIH and CDC are collaborating to reduce review times for updated sections. Dr. Jonathan Mermin added that although the clearance process timeline varies for each case, the process is beneficial. However, he recommended an examination of causes of protracted review times.

Dr. Hazra clarified that the PRGLAC website is not designed for end-users or health care workers but presents a research plan for PRGLAC 2.0 developed using experience from the HIV field and perinatal guidelines.

Updates from the NIH Advisory Council Representatives

AIDS Research Advisory Committee (ARAC)
Richard Chaisson, M.D., Professor of Medicine, Epidemiology, and International Health, Johns Hopkins School of Medicine, Baltimore, MD

Dr. Richard Chaisson explained that the National Institute of General Medical Sciences (NIGMS) HIV portfolio has moved to NIAID.

The NIAID HIV/AIDS Clinical Trials Networks are in a recompete stage, with applications due soon. The CFAR and ARC supplement applications, at the forefront of the *Ending the HIV Epidemic: A Plan for America* effort for FY 2019, are under review. The ARAC approved a proposal for reissuing a funding opportunity announcement (FOA) for CFARs, which are P30 grants. Major changes include an increase in funding for developmental CFARs, expansion of the basic science cores and justification for concierge cores, encouragement for microgrants, additional clarification for scientific working groups, and a new requirement for community engagement plans. The estimated return on investment for CFARs is very high.

Dr. Chaisson reported on the Martin Delaney Collaboratories for HIV Cure Research program, which was approved by ARAC for recompetition. While the program has been very successful over the past half-dozen years, proposed changes include increased focus on basic research and elimination of clinical trials. A new, separate initiative, the Martin Delaney Collaboratory for Pediatric HIV Cure Research, will be awarded to one program to focus on the unique aspects of cure research in young children and neonates.

The International epidemiologic Databases to Evaluate AIDS (IeDEA) network also will be recompeted, with seven awards anticipated for existing grantees. IeDEA cohorts have 1.7 million individuals, including children with HIV and children who are exposed but uninfected. Changes to IeDEA include the addition of people with tuberculosis, study of comorbidities and non-AIDS morbidities, and collaboration with the National Library of Medicine to improve the data metrics and standards. Additional recompeting programs will address key co-infection therapeutics, an immunology quality assessment program, and a new initiative on tuberculosis vaccine development for individuals with HIV.

National Advisory Mental Health Council (NAMHC)

Dianne M. Rausch, Ph.D., Director, Division of AIDS Research, National Institute of Mental Health (NIMH), NIH

Dr. Dianne Rausch explained the significant barrier posed by stigma to testing, prevention, and care, particularly for the disadvantaged populations in which the epidemic remains challenging to address. Although interventions frequently address one component of stigma, intersectional solutions are needed to address the very complex factors that influence stigma. Applications received to the Promoting Reductions in Intersectional StigMa (PRISM) to Improve the HIV Prevention Continuum request for applications (RFA) incorporate a wide variety of creative approaches to intersectional stigma and a broad range of key populations.

As part of NIMH's response to the *Ending the HIV Epidemic: A Plan for America* initiative, the NIMH also plans to study implementation in Health Resources and Services Administration (HRSA) Ryan White HIV/AIDS Program (RWHAP) clinics regarding screening for and treating mental illness. Although RWHAP sites demonstrate successful rates of HIV suppression overall, gaps remain among some populations. Research for this initiative will focus on transdiagnostic approaches to address the multiple aspects of mental health that often occur simultaneously..

Another initiative will adapt immunotherapy strategies to target HIV reservoirs in the central nervous system. The brain is a unique challenge because access is difficult; antibodies do not easily cross the blood-brain barrier and can set off toxic inflammatory reactions. This initiative aims to stimulate research using new technologies without activating inflammatory pathways. Dr. Rausch reminded attendees that almost every component of the HIV/AIDS treatment cascade is related to the NIMH's work.

National Cancer Advisory Board (NCAB)
Robert Yarchoan, M.D., Director, Office of HIV and AIDS Malignancy, National Cancer Institute, NIH

Dr. Robert Yarchoan explained an RFA called the U.S. and Low- and Middle-Income Country HIV Malignancy Research Networks. Cancer and HIV complicate treatment of both conditions. HIV-related cancers persist in low- and middle-income countries (LMICs). Previous collaborations between investigators in LMICs and in the United States on high-priority research questions in HIV-associated cancers have focused on improving research infrastructures and training investigators. The new phase of the project will continue and expand the HIV-associated cancer efforts in scientific knowledge, research capacity, collaborations, and early-career investigators. The program supports the full range of research except treatment-oriented trials, which are conducted by the AIDS Research Malignancy Consortium. Dr. Yarchoan emphasized that institutions will need to demonstrate previous research collaborations to ensure future success.

Discussion Highlights

Dr. Rausch elaborated on the effects of stigma, such as the difficulty of encouraging patients to take prevention drugs given concerns that HIV prevention medication can be misinterpreted as HIV treatment.

Dr. Geraldina Dominguez commented that training young investigators to become mentors can occur through journal clubs, project critiques, and other peer-to-peer mentoring, to help build capacity.

Dr. Chaisson clarified that the Martin Delaney Collaboratories maintain the ability to conduct early clinical work, but formal clinical trials would be conducted by the HIV/AIDS Clinical Trials Network.

Attendees emphasized the importance of evolving research strategies over time and including community engagement to ensure that local needs are defined and met.

FY2021/2025 NIH Strategic Plan for HIV and HIV-Related Research
Stacy Carrington-Lawrence, Ph.D., Health Science Administrator, OAR, NIH

Dr. Stacy Carrington-Lawrence reviewed two recent requests for information (RFIs) released by OAR. The first RFI, published in March 2018, sought feedback on the NIH HIV/AIDS research priorities; most respondents supported increasing technologies in research and at-home HIV testing, as well as methods to detect drug adherence and cure-related technologies to assess viral suppression. Training and recruitment of new investigators was mentioned frequently, as was the need for collaborations given the multidisciplinary nature of HIV research. The second RFI was released in 2019 and asked whether NIH HIV research priorities remained relevant and whether alignment with priorities should be assessed differently. Respondents overwhelmingly indicated that the priorities remained relevant, but research should be assessed in terms of “aligned” versus “not aligned.”

OAR held listening sessions with a diverse set of stakeholders across the United States to provide an open and transparent forum for communicating current and future research opportunities, making informed decisions regarding the HIV research agenda, and identifying and prioritizing the research supported by the NIH. Attendees at the Seattle listening sessions

suggested disseminating information about the benefits and outcomes of trial participation; increasing the attention on rural and suburban populations, particularly given the geographic shift in the epidemic caused by the increasing cost of living in the city; and supporting efforts to treat and prevent comorbidities, such as substance abuse. In the Atlanta area, topics of focus included basic and translational research to develop a cure and a vaccine, access to a variety of prevention options, more research on sexually transmitted infections (STIs), health care capacity issues, and stigma in rural populations. The most recent sessions, in New York, included discussion of inclusive studies with women and adolescents, aging—including the effects of social isolation and other stigma related to age—and how HIV affects the lives of children born with HIV who now are adults with children of their own. Other foci included research on health inequities and their effect on HIV prevention, treatment, and care; development of an implementation tool kit; better communication on NIH's microbicide research agenda; and how the new study section organization may have limited enthusiasm from younger investigators.

Common themes across all the listening sessions focused on differentiated, integrated, and coordinated prevention treatment and care services, as well as delivery models that address specific needs of specific individuals and populations. Attendees discussed intersectional stigma and medical mistrust as well. Dr. Carrington-Lawrence noted the importance of "knowing your epidemic"—understanding all relevant factors and building relationships long before a planned study. Attendees at listening sessions recommended additional strategies, such as expanding the population and diversity of trial participants, increasing implementation science research efforts beyond pre-exposure prophylaxis (PrEP), and expanding the research capacity and diversity of the HIV workforce.

Dr. Carrington-Lawrence concluded by noting the importance of federal collaboration to facilitate care, as well as the importance of increasing communication within and outside the HIV fields.

Discussion Highlights

Dr. Carrington-Lawrence clarified that many of the concerns raised by the community are synergistic with current work at OAR, but a disconnect remains between that work and how the community is informed of its existence and progress.

Attendees pointed out structural barriers that may hinder implementation science and training, such as underfunded awards and specific requirements for patient-oriented research. Additionally, attendees noted recruitment and retention issues for ESIs.

Dr. Goodenow elaborated on the value of structuring the listening sessions in a way that supports granular insights. For example, women's groups in New York felt left out of the effort, and tribal groups in Seattle expressed mistrust in research. She reiterated that the CFARs are the obvious place to start, but future sessions will continue to engage various stakeholder groups in different ways and in different regional locations with distinct epidemics.

OARAC members commented on the U.S. focus of NIH research and recommended that HIV research funding address populations of women of childbearing potential, children who are HIV-exposed and uninfected, and transgender and other gender minority individuals, as well as collaborations with long-term survivors.

Age and HIV-Related Neurodegeneration Workshop Updates
Miroslaw "Mack" Mackiewicz, Ph.D., Program Officer, National Institute on Aging, NIH

Dr. Mack Mackiewicz explained that data increasingly show shared pathologies among multiple dementias of aging and that researchers are interested in determining whether this concept applies to neuro-HIV. He reviewed information from the Age and HIV-Related Neurodegeneration Workshop in May 2019, at which researchers from the HIV field collaborated with those who study Alzheimer's and other related dementias. Each presenter was challenged to address another view of the field. Session topics included the effects of aging on HIV biology, the effects of HIV on the process of aging, and the mechanisms of neurodegeneration in Alzheimer's and HIV; the conference also included an RFA investigators' forum. Additionally, participants discussed risks of acquisition and age-related changes in the immune system and the effect of these on the HIV reservoir. Dr. Mackiewicz proposed improving the definition of aging to understand the effects of HIV. He commented on potential biomarkers for HIV- and age-related neurodegeneration and outlined potential approaches. The attendees at the conference have agreed to convene again in the future.

Discussion Highlights

When asked about community representation, Dr. Mackiewicz explained that while there is some degree of community engagement, this could be improved.

Attendees commented that most work on HIV and aging has been concentrated on those infected in adulthood and asked whether there was any effort to conduct research with those who were infected at a younger age. Dr. Mackiewicz agreed that this area needs further study, particularly related to how neurodegenerative illnesses manifest earlier in the life course. Dr. Goodenow suggested that Dr. Mackiewicz discuss this question with Dr. Hazra.

Sexual and Gender Minority (SGM) Research at the NIH: Past, Present, and Future Directions

Karen L. Parker, Ph.D., M.S.W., Director, Sexual & Gender Minority Research Office (SGMRO), NIH

Dr. Karen Parker explained that NIH leadership is very supportive of the SGMRO. The NIH uses the term SGM to be as inclusive as possible. Dr. Parker clarified that the mission of the SGMRO includes persons with differences in sex development (DSD), sometimes known as intersex. When considering research with SGM populations, Dr. Parker explained that certain constructs must be understood: sex is biological and not binary, whereas gender identity, which also is not binary, is a social construct. Sexual orientation research may require assessment of such components as identity, attraction, and behavior that can be difficult to measure. Estimating the size of SGM populations is difficult, particularly because language used to ask the questions can lead to different answers. Dr. Parker noted that high school students increasingly identify in a nonbinary way or as transgender. Young SGM individuals have specific health concerns, such as an increased risk of suicide. Generally, health disparities are present across the life course for SGM populations, as well as across varying disease areas and health conditions.

Dr. Parker explained the history of SGM research at the NIH, beginning with the 2009 commission of the first comprehensive report on LGBT health from the Institute of Medicine, released in 2011 and titled *The Health of Lesbian, Gay, Bisexual, and Transgender (LGBT) People: Building a Foundation for Better Understanding*. After release of the report, the NIH developed the NIH SGM Research Strategic Plan and established the SGM Research Coordinating Committee. In 2015, the NIH established the SGMRO, which is housed in the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), as is OAR. This organization allows the SGMRO to work intersectionally with all ICOs.

The SGMRO's activities include coordinating SGM-related initiatives across the NIH, representing the NIH at conferences and meetings, and serving as a resource for the NIH community. The small size of the Office necessitates careful consideration of whether an initiative could fit under another ICO's mission prior to the SGMRO taking the lead. The SGMRO collaborates with ICOs on reporting, manages information dissemination across the NIH and with the extramural research community, and develops initiatives across the NIH to ensure that SGM research is not siloed. The SGMRO accomplishes its goals through the SGM Research Coordinating Committee, which includes representation from across the NIH, as well as the Research Working Group of the DPCPSI Council of Councils.

Dr. Parker reviewed the Strategic Plan, which focuses on FYs 2016 to 2020 and covers SGM research across the entire NIH, and progress to date on its goals. For Goal 1—to expand the knowledge base of SGM health research—the NIH has released several SGM-specific FOAs and administrative supplements from the SGMRO. In September 2017, the SGMRO released an FOA on the health of transgender and gender nonconforming populations. In April 2018, the Office held a workshop focused on SGM measurement and later released a report with research opportunities and an RFI. The SGMRO now is considering next steps related to measurement. A portion of the website that is focused on measurement was released in December 2018.

Goal 2—to remove barriers to planning, conducting, and reporting NIH-supported research—includes establishing the SGMRO, which has been successful. The Office works with the NIH Clinical Center to develop training, collect gender identity data, and remove the sex marker from wristbands. SGMRO and Clinical Center staff now are discussing how to collect sexual orientation data and add them to the electronic health record. In October 2016, SGM populations were declared a health disparity population for research, which many researchers say helps validate their work within their institutions and otherwise remove barriers to conducting SGM research.

Goal 3—to strengthen the community of scholars and researchers who do this work—the SGMRO supports both researchers conducting SGM-related work regardless of the researcher's identity and researchers who identify as SGM regardless of their research field. Dr. Parker emphasized that science is not always a welcoming place for SGM individuals, so ensuring that talent is not lost and scientists can study their desired field regardless of their SGM status is critical. The SGMRO holds regional workshops focused on grantspersonship for SGM health research and has instituted non-monetary investigator awards in SGM health research.

Goal 4—to evaluate progress in advancing SGM research—is accomplished by releasing a yearly portfolio analysis and an annual report. Dr. Parker noted that the FY 2017 portfolio analysis and the 2018 annual report were released earlier that day on the website.

The SGM Research Working Group convened in September 2018 to conduct a mid-course strategic plan review and make recommendations. For Goal 1, the recommendations focus on training and communicating to the research community that SGM research can be funded and is a priority for the NIH. To follow up on the measurement workshop, the working group recommended releasing an FOA or notice on measurement. To remove barriers as part of Goal 2, the working group recommended expanding the SGMRO by two people; Dr. Parker reported that three staff members were added, demonstrating NIH's support for the Office. She added that one of the staff members is a communications specialist and will help the Office to focus on the communications-related goals of the strategic plan. Under Goal 3, the working group suggested holding a regional workshop focused specifically on DSD and intersex

research. Such a workshop would help researchers working in this field to come together and build the community. The working group also recommended further collaboration with the Office of Scientific Workforce Diversity. Dr. Parker explained the challenge posed by the lack of data on whether SGM populations are underrepresented in biomedical research and explained that the National Science Foundation will pilot questions about sexual orientation and gender identity in its many surveys, which hopefully will provide data within a few years on the representation of SGM individuals in research. For Goal 4, the working group recommended expanding the next strategic plan to include both operational and scientific priorities.

Dr. Parker explained that the grants portfolio increased to 379 projects in FY 2017. About 67 percent of the projects are related to HIV/AIDS—a slight decrease from previous years that reflects the increasing diversity of the SGM portfolio. Dr. Parker emphasized that although HIV/AIDS is a critical research area, the SGMRO supports balancing the portfolio to address other research areas of concern to SGM populations. Currently, 72 percent of projects are research projects, but individual training and institutional training need to be increased. Dr. Parker explained that the 21st Century Cures Act has SGM-specific provisions included, which led to a Public Health Service Act amendment for SGM health research.

Dr. Parker outlined plans for future regional workshops, expanding investigator awards, communicating the importance of SGM research to the community, improving the environment in the Clinical Center to make the facilities more affirming, and working with *All of Us*℠ to collect data on sexual orientation, gender identity, and intersex identity. The Office also plans to convene a workshop on bisexual health, which is an area covered by no other ICOs and is appropriate for SGMRO to lead. The next strategic plan will cover FY 2021 through FY 2025 and will be released in September 2020.

Discussion Highlights

Dr. Parker explained that research tracking is limited by how investigators choose to code their work. The recent addition of staff members to the SGMRO will allow the Office to assess the portfolio more comprehensively, as recommended by the working group.

When asked about community involvement, Dr. Parker noted that the Office involves the community heavily in all of its activities, including on the working group. A listening session is planned for later in 2019 to gather additional community input.

In response to a question about the inclusion of SGM populations in training and program grant applications, Dr. Parker explained that the NIH workplace climate survey showed that SGM individuals generally experience more harassment. She added that although more data are needed to understand the scientific climate as a whole, workplaces must be environments in which SGM individuals feel safe being authentic.

In response to a suggestion that racial and ethnic minority career paths could serve as frameworks for SGM individuals navigating their careers, Dr. Parker commented on collaborations with the Office of Scientific Workforce Diversity as a starting point for SGM career development.

When asked about gaps in research related to SGM health, Dr. Parker pointed out the lack of information on chronic diseases and long-term hormone effects. Minority stress, cancer rates, and youth suicide risk are known to be higher for SGM individuals, but more research is needed. Dr. Parker stressed the need to think of people as human beings rather than in terms of

a single disease, such as HIV, particularly given the known areas of health research important to SGM populations.

In response to a question about cultural taxation for mentors, Dr. Parker acknowledged that this is a known issue and suggested that the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program could serve as a model.

When asked about risks related to disclosing SGM status in the absence of legal protections, Dr. Parker suggested that the workplace equality index used by the Human Rights Campaign could serve as a model to review NIH's policies. She added that although providers are hesitant to ask about sexual orientation and gender identity, SGM individuals mostly are willing to disclose. At the Clinical Center, no complaints have been logged since instituting this question, and the non-response rate is very small. However, Dr. Parker cautioned that legal protections are not equally present for SGM people across all 50 states. Although this is a challenge, SGMRO staff are aware that "if you're not counted, you don't count"; in other words, disclosure is the first step toward the measurement research needed before SGM health can be improved.

Barriers and Opportunities to End the HIV Epidemic Among SGM Youth
Jose A. Bauermeister, Ph.D., M.P.H., Penn Presidential Professor and Penn Fellow, Department of Family and Community Health, School of Nursing, University of Pennsylvania

Dr. Jose Bauermeister emphasized that the key components needed to end the HIV epidemic are in place, but the technology must be implemented effectively and fairly. For example, an individual encouraged to use PrEP must be provided with the necessary tools and support to use it effectively. Dr. Bauermeister recommended thinking of the HIV space in terms of cultural competency and cultural humility. Cultural competency is a set of behaviors, attitudes, and policies that allow professionals to work effectively in cross-cultural situations. Cultural humility, however, requires providers to remain open to the possibility that cultural competencies may change over time for different populations or for different individuals.

Dr. Bauermeister presented several case studies, noting that although providers long have assumed "one size fits all" for HIV testing, in reality individuals have varying needs to feel safe getting tested. In one initiative, Dr. Bauermeister and his team explored ways a young man who has sex with men (MSM) might find a place to get tested and sent "secret shoppers" to assess the cultural competency of providers. If a young MSM has a negative experience with an HIV test, they might be less likely to get tested again in the future. Dr. Bauermeister and his team followed up with providers assessed in this study, heard about many external factors influencing how the providers interacted with patients, and provided technical assistance in line with the results. Dr. Bauermeister emphasized the need to be more innovative with both virtual and real support for testing, prevention, and treatment implementation.

In the second study, a number of possible testing sites were researched online, but when the sites were called to confirm the availability of services, the number of possible sites decreased. Although the sites with available services are located in areas where HIV is most prevalent, sites were not providing service as successfully as possible. These sites are given their scores periodically via the Get Connected service, which also provides free technical assistance. Dr. Bauermeister emphasized that these case studies show the need to improve services for young SGM clients, which requires booster sessions for the workforce. He suggested developing a quality assurance agenda as part of the *Ending the HIV Epidemic: A Plan for America* initiative.

Dr. Bauermeister described a coalition called Michigan Forward in Enhancing Research and Community Equity (MFIERCE) through which steering committee members, youth advisory board members, and community members convened to discuss how to strengthen and expand services for young MSM and transwomen. Themes from initial discussions were refined to shape community dialogues, after which two priorities emerged. First, as a micro-enterpreneurship program, the youth advisory board will act as expert consultants for community agencies. Second, the Health Access Initiative was established as a quality improvement program that will train providers and front desk staff in cultural competency, then provide technical assistance to improve implementation.

Dr. Bauermeister emphasized the importance of community engagement and noted that incentivizing participation can increase uptake. He added that the models presented could be scaled up to other jurisdictions to improve SGM cultural humility training broadly and ensure sufficient implementation of PrEP and treatment as prevention as part of ending the HIV epidemic. Dr. Bauermeister noted the importance of monitoring implementation through quality assurance and quality improvement indicators.

Discussion Highlights

When asked about the differentiation between attraction and behavior, Dr. Bauermeister explained the need to reach MSM at younger ages. Questions that address only behavior may miss the initial attraction, before the individuals start having sex.

Dr. Goodenow and Dr. Mermin discussed the creativity of these initiatives and the possibility of implementing them at CDC.

Update from the NICHD on Dolutegravir
Rohan Hazra, M.D., Chief, Maternal and Pediatric Infectious Diseases Branch, NICHD, NIH

Dr. Hazra updated the attendees on the ongoing assessment of data related to dolutegravir's connection to neural tube defects. He noted the challenges posed by the high percentage of relevant data that are confidential. With the flexibility of the OAR Innovation Fund process, the relevant study was quickly expanded in FY 2018 after the signal was identified; a number of related projects also were expanded to study the issue. In FY 2019, NIH HIV strategic funds were used to develop a pharmacovigilance cohort for pregnant women.

Dolutegravir has been shown to act as a partial antagonist of folate binding, which could explain the neural tube defect signal. Dr. Hazra emphasized that the signal has not been confirmed across all groups. Additional studies are being conducted on bictegravir and cabotegravir.

Despite the rapid response and expansion of studies, none were accepted for presentation at the Conference on Retrovirals and Opportunistic Infections (CROI) in March 2019. Dr. Hazra and his colleagues were able to convene a 1-day meeting to present data confidentially at the end of April 2019, with representatives from many institutions in attendance. Dr. Hazra commented that although the data from this meeting cannot be shared publicly, the results are likely to influence the subsequent research priorities in critical ways.

Discussion Highlights

Attendees discussed the release of data anticipated during the IAS meeting. Dr. Hazra emphasized that any results with a clearly actionable public health indication would be shared

immediately. The folate signal has not yet shown sufficient strength to mandate such an action as an ethical imperative; however, this situation can be used as an opportunity to recommend folate fortification generally. Implications for the HHS guidelines can be discussed in greater detail when the data are released at the IAS conference. Attendees also discussed potential considerations in peer review for releasing data from these studies. Dr. Hazra emphasized that an emergent health situation should not require good scientific practices to be set aside.

Public Comment
Charles Wira, Ph.D., Geisel School of Medicine at Dartmouth

Dr. Wira stated that no written public comments had been received.

Closing Remarks/Adjournment
Maureen M. Goodenow, Ph.D., OAR, NIH
Charles Wira, Ph.D., Geisel School of Medicine at Dartmouth

Dr. Goodenow thanked the Council members, guidelines working groups, and speakers. She acknowledged the end of the OARAC term for Drs. Wira, Mofenson, and Rhodes. The October meeting will occur on October 28, 2019, but no orientation meeting will occur until February 2020.

Dr. Wira expressed his pleasure at serving as Chair and thanked Dr. Radke. Dr. Jennifer Kates will take over as Chair.

Dr. Wira thanked the attendees and adjourned the meeting at 3:30 p.m. EDT.

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

- S - 9 / 24 / 19
Charles Wira, Ph.D. Date
Chair, Office of AIDS Research Advisory Council

- S - 9 / 24 / 19
Jay Radke, Ph.D. Date
Executive Secretary, Office of AIDS Research Advisory Council