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

Office of AIDS Research Advisory Council
Sixtieth Meeting
June 23, 2022

Virtual
https://videocast.nih.gov/watch=45264

Meeting Minutes

Council Members Present: Dr. Blanton S. Tolbert (Chair), Dr. Tabia H. Akintobi, Dr. Margaret L. Brandeau, Dr. Kathleen L. Collins, Dr. Heidi M. Crane, Dr. Shruti H. Mehta, Dr. Veronica Miller, Dr. John W. Sleasman, Dr. Ivy Turnbull

***Ex Officio* Members Present:** Dr. Victoria J. Davey, Dr. Rohan Hazra, RADM Jonathan Mermin

Advisory Council Representatives Present: Dr. Francis Ali-Osman, Dr. Redonna Chandler, Dr. Monica Gandhi, Dr. Marguerita Lightfoot, Dr. Robert Yarchoan

Office of AIDS Research Leadership Present: Dr. Maureen M. Goodenow, Director; CAPT Mary T. Glenshaw, Office of AIDS Research (OAR) Advisory Council (OARAC) Designated Federal Official and Supervisory Senior Science Advisor; Dr. Julio Aliberti, Senior Science Advisor; Ms. Coretté Byrd, Health Science Policy Analyst

OAR Leadership, Invited Speakers, and Guests Present: Dr. Laura Cheever, Dr. Susan Gregurick, Ms. B. Kaye Hayes, Dr. Henry Masur, Mr. Anthony “Jin” Park

Welcome and Introductions

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

Dr. Blanton S. Tolbert welcomed participants to the sixtieth meeting of the National Institutes of Health (NIH) OARAC. A quorum was present. Meeting materials provided to Council members included the agenda, a conflict-of-interest form, and minutes from the fifty-ninth OARAC meeting, held on February 24, 2022.

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

Dr. Tolbert reviewed the sixtieth meeting agenda, noting the inclusion of time for public comments.

Report from the OAR Director

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

Dr. Maureen M. Goodenow welcomed attendees and invited them to reflect on the accomplishments of the OARAC at its sixtieth meeting. Dr. Goodenow thanked current and past OARAC members for providing their time and expertise to support the NIH OAR mission, as part of the OAR legislatively mandated Advisory Council.

OAR has been working to promote Pride Month throughout June and National HIV Testing Day on June 27. Dr. Goodenow acknowledged Dr. Ivy Turnbull, who joined OARAC as an *ad hoc* member in October 2021 and is now a voting member.

OAR recently restructured its communications and science policy activities into a new Policy, Legislation, Communications, and Engagement team, led by OAR Senior Policy Advisor Dr. Issel Anne Lim. Dr. Lim joined OAR in May and previous served at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD).

Dr. Goodenow provided an update on the NIH HIV research budget, reminding attendees that after significant budget increases through fiscal year (FY) 2005, NIH HIV funding was essentially flat from FY 2014 to 2018. From 2019 to 2021, the budget increased by $87 million, raising the total annual budget to just over $3 billion. In FY 2022, the congressional allocation to NIH OAR included an increase of more than $100 million for NIH HIV/AIDS research, which is 3.4 percent over the FY 2021 level. This is the largest increase for HIV research since FY 2014 and represents 13.4 percent of the estimated $775 million requested in the FY 2022 Professional Judgment Budget (PJ). This increase supports investments that align with the goals of the *NIH Strategic Plan for HIV and HIV-Related Research*, the *National HIV/AIDS Strategy* (NHAS)—including the Ending the HIV Epidemic in the U.S. (EHE) Initiative—and the FY 2022 PJ.

The annual *Professional Judgment Budget* (PJ), which NIH OAR is legislatively mandated to prepare, allows OAR to present an aspirational budget highlighting areas that would benefit from additional investment. OAR identifies investment areas through engagements with NIH Institutes, Centers, and Offices (ICOs), federal partners, and HIV community leaders. The FY 2023 PJ was released in June 2022 to Congress and the U.S. President; it estimates the need for $639 million in additional funds, a 20-percent increase in the HIV research investment over the FY 2022 enacted level. This additional funding would expand basic research in biomedical, behavioral, and social sciences; address HIV co-occurring conditions; develop transformative technologies, methodologies, and implementation approaches; and enhance diversity and strengthen the capacity of the HIV research workforce.

The NIH OAR coordinates HIV research across the NIH and partners with other agencies across the federal government. The NIH is one of the 11 operating divisions of the U.S. Department of Health and Human Services (HHS). OAR is the second oldest of the 14 NIH coordinating, planning, and strategic initiative offices. Communication and collaboration with other federal agencies are crucial to establishing effective strategies for HIV prevention, treatment, and care across national and global communities. These collaborations are essential to maximizing the return on public investment and facilitating a whole-of-government agenda to end the HIV pandemic globally and in the United States. OARAC provides advice on the planning, coordination, and evaluation of evolving HIV/AIDS research priorities. OARAC includes voting members and several *ex officio* members representing other federal agencies,

the NIH Office of the Director, and NIH Institutes and Centers (ICs) with the largest proportion of NIH HIV funding.

Links across federal agencies are facilitated by an interactive network of advisory boards and partnerships that provide critical information and expert advice to guide important decisions about the NIH HIV research enterprise. Shared membership by federal agencies on advisory boards promotes fluid communication and understanding of the perspectives of each agency's role in shaping HIV/AIDS policies. The guidance NIH OAR receives from OARAC and indirectly from other advisory councils contributes to the development of the NIH HIV research agenda and the budget requests presented to Congress and the White House.

Dr. Goodenow described examples of important NIH OAR interagency activities. In 2021, OAR coordinated NIH input to update the NHAS. In 2022, OAR convened partners from 19 ICOs and chaired the NIH HIV/AIDS Executive Committee (NAEC) NHAS Working Group to catalogue NIH NHAS implementation activities, which addressed focused areas of HIV workforce expansion and diversification, and stigma and disparities reduction among NHAS priority populations. OAR will continue to coordinate, monitor, and report on NIH-wide NHAS activities with NIH leadership and other partners. OAR currently provides staff support to the White House Office of National AIDS Policy (ONAP) and is participating in an interagency ONAP working group to develop quality-of-life indicators for the NHAS. OAR representatives recently attended an Operational Leadership Team retreat hosted by ONAP's director, Mr. Harold Phillips. Discussions focused on status-neutral and syndemic approach implications for EHE and the NHAS, as well as planning the start of Phase II of EHE in 2026. Although direct EHE funding has been allocated to Centers for AIDS Research (CFARs) in the first 3 years of the initiative, the NIH further leverages HIV funding to support and expand efforts to meet EHE objectives that also advance the NIH HIV research mission.

Ms. B. Kaye Hayes recently was appointed as the deputy assistant secretary for infectious disease and the director of the Office of Infectious Disease and HIV/AIDS Policy (OIDP). In this role, Ms. Hayes serves as executive director of the Presidential Advisory Council on HIV and AIDS (PACHA). Dr. Goodenow serves as the NIH *ex officio* member of PACHA. Recent PACHA engagements include a briefing on NIH HIV prevention, care, treatment, and cure research at a PACHA leadership planning session by OAR's deputy director and the National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS director, RADM Timothy Holtz and Dr. Carl Dieffenbach. Dr. Goodenow participated in the Molecular HIV Cluster Detection and Response Workgroup; suggestions for HIV cluster and detection policies and practices were submitted to the PACHA Stigma and Disparities Subcommittee for consideration for advising the President.

In early June, Ambassador-at-Large Dr. John Nkengasong officially assumed his new role as the U.S. Global AIDS Coordinator and Special Representative for Global Health Diplomacy at the U.S. State Department. He is the fifth person to hold this position since the President's Emergency Plan for AIDS Relief (PEPFAR) was created in 2003. NIH OAR will continue to work with PEPFAR leadership to accelerate progress on the global HIV response.

Dr. Goodenow emphasized that the NIH HIV research portfolio is truly global. International HIV research represents approximately 20 percent of total annual NIH HIV research funding. In FY 2021, $606 million was invested in more than 1,100 HIV research grants in 95 countries outside the United States. The international HIV research portfolio focuses on priority areas relevant for both the host nation and the United States, including multinational HIV clinical trials networks, initiatives focused on implementation science, and training and capacity-building

efforts. Bidirectional lessons learned from these international efforts will provide valuable models of real-life implementation to support EHE domestically. Similar to how NIH OAR leverages domestic EHE activities, NIH's PEPFAR work expands international collaborations to leverage and build upon networks and infrastructure, disseminate the clinical practice guidelines for HIV/AIDS prepared by the OARAC working groups, enhance the health workforce, and implement advanced diagnostic and clinical monitoring technologies.

Dr. Goodenow provided updates on key NIH OAR scientific and workforce priorities. OAR Listening sessions have continued during the travel restriction due to the COVID-19 pandemic. Virtual engagements have been effective in the absence of in-person meetings. A report summarizing findings from virtual listening sessions through July 2021 is available on OAR's website. In May, OAR participated in two virtual listening sessions hosted by the Texas Developmental CFAR and the Houston Health Department. These included researchers, clinicians, advocates, and community members in several Texas locations. Discussions touched on local concerns about specific issues, including high incidence of opioid and non-opioid substance use among people with HIV, difficulties accessing long-acting HIV treatment, and the need to address highly prevalent local comorbidities. OAR hosted a listening session at the annual meeting of the National Council of Urban Indian Health, which was the first OAR listening session focused specifically on Native American populations. In this community setting, OAR heard about the critical value of providing HIV clinical interventions within a cultural context that incorporates spiritual practices and family dynamics into HIV treatment.

In April, the OAR and NAEC Early Career HIV Investigators working group convened a Workshop for Early Career Investigators in HIV/AIDS with approximately 150 diverse graduate students, postdoctoral fellows, early-career investigators, and seasoned mentors in attendance. Workshop goals included stimulating scientific exchange, networking, and collaboration among the next generation of HIV investigators and increasing familiarity with the NIH review and funding processes. The workshop included a mock review session and offered the opportunity to demystify the scientific review process for new investigators. The workshop was well received, with significant and positive post-event feedback. Next steps include developing a follow-on workshop informed by participant feedback, enhancing and updating web content with resources for HIV early-career investigators, increasing networking opportunities, and developing a sustainability plan for a diverse HIV research workforce.

Among key NIH updates: Mr. Kevin Williams has been appointed as the new director of the NIH Office of Equity, Diversity, and Inclusion. The NIH recently launched a grant program aimed at closing the gap in funding rates between Black and white investigators. NIH OAR workforce activities with early-career investigators are aligned with the goals of the UNITE initiative and with the *NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility*, which is being finalized and includes strategies to strengthen the careers of women in the HIV research workforce. Within this context, OAR addressed women's representation in NIH HIV studies for the Women's Research Initiative on HIV/AIDS, which brings together leaders in HIV to identify key opportunities to accelerate the understanding of HIV in women. OAR participated in the Advisory Cabinet of the NIH Maternal Morbidity and Mortality Task Force to discuss the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative: Way Forward. In 2022, Congress approved the President's request for $30 million to enhance the program and provide innovative opportunities to improve the health of pregnant people, including those with HIV.

HIV and Aging continues to be a high priority of the NIH HIV research portfolio. NIH OAR was invited to present on the NIH HIV and aging research landscape at a recent meeting of the

Federal AIDS Policy Partnership, a national advocacy coalition focused on funding, legislation, and policy to end the HIV epidemic. One item discussed was OAR funding of several supplements through a Notice of Special Interest (NOSI) issued earlier this year in an ongoing collaboration with the National Institute on Aging (NIA). This NOSI expands current NIH aging research to include HIV objectives and explore health outcomes of people with HIV throughout the lifespan. In May, Dr. Goodenow met with NIA Director Richard Hodes to review HIV and Aging research priorities and expand HIV and Aging activities moving forward. Since the last OARAC, several NIH workshops have discussed the progress and future directions of HIV and aging research, including the Pathogenesis of Age-Related HIV Neurodegeneration Workshop and the NIH Intramural Neuro-HIV Research Workshop 2022.

The NIH OAR and several ICOs will lead and participate in workshops, symposia, presentations, and other activities at the upcoming AIDS 2022 conference in July. OAR will participate in a session on global and domestic bidirectional lessons learned, and OAR and the National Institute of Mental Health (NIMH) will launch a special issue in the *American Journal of Public Health* focusing on HIV-related intersectional stigma and discrimination to improve outcomes and inform public health. A satellite session will focus on implementation science related to EHE, and launch a special issue of the Journal of AIDS, which features an overview of the NIH role in EHE, authored by OAR staff and leaders. Other NIH sessions include a workshop on advancing HIV health communication science from the NIMH Division of AIDS Research; a session on the use of behavioral economics and conditional incentives in HIV treatment and prevention programs from Fogarty International Center and NIMH; and a session focused on recent evidence and optimal methods to evaluate neurodevelopmental outcomes in HIV.

Discussion Highlights

Dr. Goodenow elaborated on OAR's approach to develop listening session methodology and emphasized that OAR is open to hold a listening session interested partners and stakeholders.

When asked how NIH OAR coordinates HIV- and AIDS-related activities across ICOs to avoid duplicative efforts or leverage strengths, Dr. Goodenow explained that this aspect of OAR's activities is mandated in the legislation that created the Office. The NIH was funding HIV research before OAR was founded, and leadership came to realize that coordination among ICOs was needed. Over time, the Office model has expanded into other areas; now many Offices coordinate aspects of the NIH research portfolio. The Offices use similar methodologies, such as advisory committees (like OARAC) and internal coordinating commission executive committees, which include representatives from all ICOs participating in the HIV research agenda. Dr. Goodenow emphasized that many parties have the opportunity to provide input; OAR's job is to triangulate input from the HIV community and advocates and find ways to move the HIV research agenda forward. Maintaining nimbleness and agility also is important given the rapid advances in the field. Dr. Goodenow commented that OAR must balance needs with resources and ensure that the resources remain fluid to accommodate those needs.

Dr. Goodenow noted almost all of the 27 NIH ICs have HIV research programs and receive part of the NIH HIV allocation. Out of 14 NIH Offices, about 8 engage in programmatic work, and almost all are involved in HIV research. HIV research is very interactive and widespread, but the depth of investment and involvement is variable. For some ICs, such as NIAID and the Fogarty International Center, HIV research funding forms a large proportion of their budget. Dr. Goodenow pointed out that one important consideration is how the budgets fluctuate over time

as the overall HIV research enterprise receives new input and expands into newly identified priorities.

Connecting Data, Enhancing Software, and Creating a Data and Digital Health Ecosystem

Susan K. Gregurick, Ph.D., Director, Office of Data Science Strategy (ODSS), NIH

Dr. Susan Gregurick explained that ODSS's vision has been built on the *NIH Strategic Plan for Data Science*. The goals are to support common infrastructure and architecture for data science; leverage commercial tools, technologies, and services; enhance the nation's biomedical data science research workforce through improved training programs and novel partnerships; enhance data sharing, access, and interoperability; ensure the security and confidentiality of patient and participant data; improve the ability to capture, curate, validate, store, and analyze data for biomedical research; and develop, promote, and refine data standards, including standardized data vocabularies and ontologies. ODSS provides leadership and coordination for the *NIH Strategic Plan for Data Science*, develops and implements NIH's vision for a modernized and integrated biomedical data ecosystem, enhances a diverse and talented data science workforce, and builds strategic partnerships with other federal agencies, nonprofits, and international partnerships to develop and disseminate advanced technologies and methods.

The final *NIH Policy for Data Management and Sharing* was released in October 2020 and becomes effective January 25, 2023. The NIH requires applicants to prospectively plan how scientific data will be preserved and shared through submission of a data management and sharing plan outlining how scientific data and any accompanying metadata or standards will be managed and shared, considering any potential restrictions or limitations. The plan is part of the budget justification section of the application for extramural awards and part of the technical evaluation for contracts. The policy applies to all funded research at the NIH that generates scientific data but does not include activities that do not generate data, such as training or infrastructure.

Shared data types include all NIH-supported research generating scientific data, including recorded factual material of sufficient quality to validate and replicate research findings; these may be published or unpublished. Laboratory notebooks, preliminary analyses, case report forms, and physical objects do not need to be shared. Data should be accessible as soon as possible but no later than publication or the end of an award.

The plan should include the data type or data to be preserved and shared; related tools, software, and code needed to access or work with the data; standards to be applied to scientific data and metadata; data preservation, access, and timeline information, including the repository to be used, persistent unique identifier, and when or how long data will be available; access, distribution, and reuse considerations or other factors; and oversight of data management or how compliance with the plan will be monitored or managed by the funding institution that manages the award. This information is available on the NIH Data Sharing site. Webinars will be provided to help the community understand and prepare for the policy. Dr. Gregurick emphasized that the requirements of the policy are impactful and culture-changing.

Dr. Gregurick explained that no universal solution to sharing data exists because researchers have different expectations and experiences. Investigators can share smaller amounts of data as supplemental material with publications on PubMed Central; larger data sets can be shared in generalist repositories. The largest and highest-priority data sets can be stored with NIH's

cloud partners through the Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) program. Data often must be enhanced to make them findable, accessible, interoperable, and reusable (FAIR), which frequently is a challenge. Making data ready for artificial intelligence and machine learning requires more enhancement than making them FAIR. Dr. Gregurick emphasized the importance of understanding the persistence of noise and uncertainty of labels, as well as the amount of data. These principles affect computational model performance. Dr. Gregurick noted that ODSS has several supplemental programs and funded many awards, with more planned for the next year. For example, one grantee is working to improve sepsis outcomes by using electronic health records (EHRs) to estimate a patient's risk of multidrug resistance. Dr. Gregurick pointed out that EHR data are difficult to use and particularly challenging when data are related to people in minority populations because the data often are sparse, the metadata are inconsistent, and descriptors—including race and ethnicity—often are misrepresented.

ODSS has been working to enhance NIH-supported data repositories to align with TRUST factors, including transparency of function, responsibility of data stewardship, user- and community-driven capabilities, and sustainability, as well as alignment, and attention to capabilities. ODSS supported 17 awards in 2021. Several programs that support data repositories and knowledge bases are available. These typically are R01 grants, supporting repositories as biomedical resources with dedicated funding and special emphasis panels overseen by the Center for Scientific Review. Applicant repositories must align with a particular IC's mission, support data management and sharing with demonstrated scientific impact within the community, address the quality of data services and methods that will increase the efficiency of operation, engage with their scientific community and the journals that align with their focus, and establish transparency of governance. Providing support for repositories encourages good data management and lifecycle practices. This year ODSS is developing metrics that can be shared openly for use and utility of data repositories. The program will continue for the next 3 years and may shift to include newly emerging data knowledgebases and repositories.

ODSS encourages researchers to explore domain-specific repositories first, but many generalist repositories also are available. The new Generalist Repository Ecosystem Initiative supports collaboration among generalist repositories to make it easier for researchers funded by the NIH to share data in compliance with the new policy. This initiative also should improve the ability to find data across repositories and increase rigor and reproducibility. ODSS is developing a set of core metrics across repositories that enhance use and usability of repositories, as well as core metadata to enhance discoverability. The expected outcomes are making data sharing easier, improving discoverability, increasing the reproducibility of research, and encouraging the secondary use of data.

The DataWorks! Prize is a partnership with the Federation of American Societies for Experimental Biology that highlights the power of data sharing and reuse in the biological and biomedical sciences. The $500,000 prize will be used to recognize up to 12 teams for their achievement in data sharing or reuse practices. Entries opened in May and will close in July 2022.

Dr. Gregurick explained that data can be shared in many ways, including in cloud-based servers. The NIH has partnered with Amazon Web Services, Google, and Microsoft Azure through the STRIDES program to provide discounts on cloud storage and compute, as well as professional services and training. The program currently supports 173 petabytes of data, 50 of which are genomic data. Dr. Gregurick emphasized the challenges of managing this amount of

data and the interesting questions that arise, such as how to search across genomic sequence data. Cloud analysis is not always straightforward and may include concerns about cost, persistence, and utility. Dr. Gregurick provided an overview of the NIH Cloud Laboratory, which allows researchers to explore cloud environments before using a full STRIDES account for research. Researchers can use this service to strengthen their cloud training, build proof-of-concept solutions to specific scientific tasks, or test configurations to optimize research analyses.

Software is an important part of the data ecosystem. ODSS has a long-standing partnership with the National Science Foundation (NSF) to connect computer scientists and biomedical researchers. All ICs partner with ODSS to improve smart and connected health, which began as a device program but now has extended to include data science, artificial intelligence, imaging, EHRs, and electronic health care. Applications are funded by the NIH, NSF, or both and co-funded by ODSS. ODSS offers supplements to existing NIH researchers to enhance software tools for open science.

Researchers increasingly need to understand the Fast Healthcare Interoperability Resources (FHIR) standard, which enables data sharing and interoperability by mapping electronic health care structures across systems. The NIH plan for modernizing its biomedical data science ecosystem includes FHIR to integrate clinical data into biomedical science. ODSS has supported three FHIR trainings since December 2021 and is working with ICOs to explore increased training capacity. The NIH Data Sharing and Reuse Seminar Series is held on the second Friday of every month to highlight data science activities at the NIH, data reuse by NIH-funded researchers to answer novel research questions, and the value of data sharing. The seminars have been well attended, including by international participants. The talks are archived online.

Discussion Highlights

Dr. Gregurick acknowledged the need for significant institutional resources to comply with the new data sharing guidelines and hoped that researchers would explore existing repositories before considering whether additional repositories need to be created for the community. *Ad hoc* sharing strategies—such as personal FTP sites—are difficult for other researchers to find and access, so Dr. Gregurick encouraged participants to look at existing resources within the community and institutions. Regarding resource disparities at institutions that support underrepresented researchers, Dr. Gregurick explained that ODSS is working with the National Institute of Minority Health and Health Disparities and the National Institute of General Medical Sciences to enable greater data capabilities in minority-serving institutions (MSIs). Dr. Rohan Hazra added that the NICHD has a long-standing population dynamics research data program that, in its most recent cycle, required centers to have an established relationship with an MSI, which can help increase capacity at less-funded institutions.

When asked what the future holds in this field, Dr. Gregurick explained that past predictions of how cloud storage would work have not provided realistic solutions for the very diverse biomedical research community. Current explorations include data capabilities that are not only federated but also interoperable—significant capabilities currently exist in several fields, but they are specific to those teams. To create interoperability, metadata need to be defined across systems; sophisticated ways to find and search data are needed, as well. New training options must be created; some innovative training strategies already have been created in response to the COVID-19 pandemic.

In response to a question about considerations when training the future generation of data scientists, Dr. Gregurick emphasized the need to begin data science training early in the undergraduate years, regardless of whether students focus on bench or computer science. She pointed out that data science concepts really are statistics and computer science concepts. Use cases often are helpful in training students. The NIH Cloud Laboratory aims to be a training program. Dr. Gregurick noted that recruitment of underrepresented populations can be enhanced with program flexibility. For example, for candidates that cannot travel to the NIH, ODSS has designed training programs that allow remote work. She added that when fully remote options are offered, the best candidates apply, because the programs fit their needs, not ODSS's needs.

Dr. Gregurick elaborated on barriers in data science. Many data sets have thousands of common or similar elements, but different metadata and measurements. Data harmonization is a significant struggle. She commented that although a comprehensive solution remains out of reach, the problem is well known at the leadership level, including IC directors. Data cannot be fully utilized until this issue is resolved, but the issue must be resolved carefully.

HHS Partner Agency Updates

HHS Office of the Assistant Secretary for Health (OASH) OIDP

B. Kaye Hayes, M.P.A., Deputy Assistant Secretary for Infectious Disease and Director of OIDP, OASH, HHS

Ms. Hayes explained that OIDP provides strategic leadership and management while encouraging collaboration, coordination, and innovation among federal agencies and stakeholders to reduce the burden of infectious diseases. It has five federal advisory committees—PACHA, the National Vaccine Advisory Committee, and committees on antimicrobial resistance, blood and tissue safety and availability, and tick-borne diseases. It develops, coordinates, and supports a range of HIV-related initiatives, such as EHE, the Minority HIV/AIDS Fund, and HIV.gov. OIDP coordinates with federal and nonfederal stakeholders to develop, implement, and monitor national strategies for HIV, sexually transmitted infections (STIs), viral hepatitis, and vaccines. Ms. Hayes explained that OIDP is using a syndemic approach to reduce silos among strategies for HIV, STIs, viral hepatitis, and vaccines, as well as considering the effects of the opioid crisis and the importance of mental health across these areas.

The NHAS, which was re-released on December 1, 2021, has four goals: (1) prevent new HIV infections, (2) improve HIV-related health outcomes of people with HIV, (3) reduce HIV-related disparities and health inequities, and (4) achieve integrated, coordinated efforts that address the HIV epidemic among all partners and interested parties. The updated NHAS includes several key changes, it:

- Recognizes racism as a serious public health threat and acknowledges the ways in which racism drives disparities and affects HIV outcomes
- Strengthens emphasis on better integrating responses to the intersection of HIV, viral hepatitis, STIs, and substance use and mental health disorders (i.e., the syndemic approach)
- Puts greater emphasis on the important roles of harm reduction and syringe service programs in the national response to HIV, viral hepatitis, and substance use disorder
- Adds a new focus on the needs of the growing population of people with HIV who are aging

- Calls for expanding the engagement of people with lived experience in the research, planning, delivery, assessment, and improvement of HIV prevention, testing, and care services
- Acknowledges populations living with or experiencing risk for HIV under unique circumstances.

HIV research activities are integrated more broadly across the NHAS objectives. It encourages the reform of state HIV criminalization laws. It enhances the focus on quality of life for people with HIV, which Ms. Hayes emphasized is an important developmental measure. It calls for sustaining innovations implemented during the COVID-19 public health emergency that can continue to support and improve access to and engagement in HIV services. It expands the focus on addressing the social determinants of health that influence an individual's HIV risk or outcomes. It adds a new focus on opportunities to engage the private sector. A working group of federal partners has been convened to address the quality-of-life indicator. Designation as a developmental indicator means that data sources, measures, and targets will be identified and have their progress monitored thereafter.

Ms. Hayes noted that the four EHE pillars—diagnose, treat, prevent, and respond—remain relevant. EHE alignment with the new NHAS includes acceleration of existing approaches and increased focus on syndemic and status-neutral approaches. Despite COVID-19, EHE jurisdictions have shown tremendous progress during the EHE initiative. The Ryan White HIV/AIDS Program (RWHAP) served 11,139 new clients and reengaged an additional 8,282 clients in EHE's first year. The initiative assisted community health centers in scaling up pre-exposure prophylaxis (PrEP) access to 389,000 people. The administration has indicated continued support for the initiative in the FY 2023 budget funding and policies. A new national viral suppression campaign, I Am a Work of ART, has been designed in collaboration with the community to encourage people who have been diagnosed with HIV to seek care, remain in care, and achieve viral suppression with antiretroviral therapy (ART).

Ms. Hayes explained that PACHA was created in 1987 and includes a diverse group of members, such as prominent community leaders with expertise in public health, global health, or population health; leaders of faith communities; and business professionals and other leaders held in high esteem. Guidance from these HIV/AIDS experts has been crucial to administrative leaders. Ten new members were appointed in August and November 2021; the roster now more accurately reflects the racial, ethnic, sexual and gender minority, and geographic diversity of the HIV epidemic in the United States today. Expertise is sought in certain areas: men who have sex with men with HIV, substance misuse and syringe exchange, HIV and aging, women and HIV, young people and HIV, and HIV and housing. PACHA recommends increased uptake in the Ready, Set, PrEP program; ensuring equity and justice in ending the HIV epidemic; studying the impact of COVID-19 on HIV prevention and treatment; encouraging the involvement of private-sector partners in HIV efforts; and supporting the creation of a national PrEP program. Because working with the community is crucial for successfully implementing EHE, OIDP created the PACHA-to-the-People series and convened it in several high-priority EHE areas. The series also included site visits to community-based organizations with members and federal partners to learn firsthand about the best interventions that make the biggest impact on the ground. The next event will occur in Los Angeles in September.

Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee (CHAC) on HIV, Viral Hepatitis, and Sexually Transmitted Disease (STD) Prevention and Treatment

Laura W. Cheever, M.D., Sc.M., Associate Administrator for the HIV/AIDS Bureau (HAB), HRSA, HHS

RADM Jonathan Mermin, M.D., M.P.H., Director, National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis (TB) Prevention (NCHHSTP), CDC, HHS

Dr. Laura Cheever provided an overview of HAB, explaining that its vision is optimal HIV care and treatment for all to end the HIV epidemic in the United States. The HAB mission is to provide leadership and resources to advance HIV care and treatment to improve health outcomes and reduce health disparities for people with HIV and affected communities. RWHAP, which has an FY 2022 appropriation of $2.5 billion, provides a comprehensive system of HIV primary medical care, medications, and essential support services for people with low incomes with HIV. It funds grants to states, cities, counties, and community-based organizations to improve health outcomes and reduce HIV transmission. Recipients determine service delivery and funding priorities based on local needs. RWHAP has a payor of last resort statutory provision: RWHAP funds may not be used for services if another state or federal payer is available. RWHAP served nearly 562,000 people in 2020; and more than half the people with diagnosed HIV in the United States receive care through RWHAP each year. Almost 90 percent of RWHAP outpatient ambulatory health care clients were virally suppressed in 2020, exceeding the national average of 64.6 percent.

RWHAP is a federal program that provides grants across the country to establish and maintain a comprehensive system of care and treatment for people with HIV who are low income. The largest segment of appropriations is directed to state recipients—designated as Part B—because some states may not have large cities. In 2020, the RWHAP served more than half a million people in the United States and three territories, with no reduction in services resulting from the COVID-19 pandemic. A high proportion of clients are from minority populations, are more than 50 years of age, or live below the poverty line. Significant progress has been made in viral suppression among priority populations, but disparities remain, particularly among Black/African American clients, transgender clients, youth ages 13 to 24 years, and clients with unstable housing. Viral suppression increased nationally by 19.9 points between 2010 and 2020.

Dr. Cheever outlined ways the HAB is promoting health equity and reducing disparities. One is by engaging the community directly, so it has developed a community engagement framework; RWHAP legislation also requires community engagement and partnership. HAB supports continuous quality improvement by helping recipients set goals, monitor performance measures, and oversee quality improvement projects. For service delivery, RWHAP addresses social determinants of health—such as access to stable housing, food, and transportation—in addition to clinical services. HAB uses data to inform decision-making to address health disparities; the RWHAP legislation requires the same of recipients. HAB uses implementation science in practice, program, and policy. This includes collating and disseminating evidence-informed interventions and building capacity of community-based organizations.

HAB is working to achieve the EHE goals. To get people with HIV into care, it is working to improve viral suppression rates and decrease disparities. For people with newly diagnosed HIV, it is enhancing linkage to care and engagement in care. For people with HIV who are out of care, it is expanding reengagement in care and improving retention in care. EHE recipient activities for linkage to care and reengagement include low-barrier clinics, coordinated protocols

that streamline the client experience, and rapid reengagement protocols after missed appointments. For rapid ART, HAB aims to introduce a dedicated Rapid Linkage to Care Coordinator, provide treatments within 7 days of diagnosis from at-home or self-testing kits, and supply ART starter packs or a 30-day supply at the conclusion of the first client interaction. Some of the many roles of peer navigators and community health workers include addressing social determinants of health, enrolling clients in health care coverage and scheduling appointments, and providing technology and educational services to help navigate online medical record access.

The CHAC advises HHS, CDC, and HRSA on activities related to prevention and control of HIV, viral hepatitis, and other STDs; support of health care services to people with HIV; education of health professionals and the public; and the agencies' responses to prevention and health service delivery needs of affected communities and the needs of people with HIV or those at risk for HIV, viral hepatitis, and other STDs. CHAC's Telehealth Workgroup recommends that health equity in relationship to telehealth be studied. CDC PrEP guidance—as well as PrEP services—should be expanded, and virtual services to enhance routine STI screening should be explored. Workforce considerations include trauma and burnout, roles and standards of practice, and retention and recruitment.

RADM Jonathan Mermin reported on the CDC's NCHHSTP, which envisions a future free of HIV, viral hepatitis, STDs, and TB. Because many of these issues are chronic and associated with stigma, NCHHSTP always has incorporated social determinants of health when considering how to address these issues. NCHHSTP focuses on high-impact prevention and control efforts to reduce incidence, morbidity, mortality, and health disparities related to these infections. A syndemic approach is used to cluster social and economic issues that affect health on the population level.

NCHHSTP emphasizes that people matter. Seeing disparities in disease invigorates a robust response by reflecting public health injustice and emphasizing the opportunity to focus efforts on serving the people most affected. Men who have sex with men account for 70 percent of HIV diagnoses, 42 percent of primary and secondary syphilis cases, 42 percent of gonorrhea cases, and 17 percent of chlamydia cases. People who inject drugs are the population with the highest proportion of acute hepatitis C virus (HCV) and a substantial proportion of hepatitis B virus (HBV) infections, 11 percent of HIV diagnoses, and a large proportion of overdose deaths. Some racial and ethnic groups are disproportionately affected—African Americans are eight times and Hispanic/Latinos are three times more likely to acquire new HIV infections than white populations. More than a third of TB and HBV diagnoses are among Asian Americans. Justice-involved populations have higher incidences of all communicable infections; RADM Mermin emphasized that public health efforts must include this population.

Many EHE priority areas overlap with counties that have a high burden of other infections. RADM Mermin suggested that focusing efforts in those areas with disproportionate effects will make a bigger difference faster. He emphasized that every state can consider how resources are distributed and how to improve that distribution.

One benefit of a syndemic approach is holistic service delivery—RADM Mermin pointed out that patients want their care providers to care about their entire self. Taking a syndemic approach at the population level is necessary to address social and economic determinants of health. RADM Mermin emphasized that if the syndemic approach is implemented effectively, it increases efficiency and cost-effectiveness, reduces stigma, and supports a focus on the policy and social determinants of health that drive infections. This approach increases flexibility by

enabling partners to adapt, implement, and modify integrated services to increase responsiveness to evolving epidemics or changing contexts and gives implementing partners increased control and ability to provide comprehensive services.

High-impact syndemic strategies include multi-pathogen testing, , venue- and program-based multi-disease prevention interventions, outbreak response, outbreak response, data sharing and analyses, digital communication campaigns and interventions, and ultimately, policy change. Key actions to address syndemics include putting people first, focusing on equity, directing funding to epidemic hotspots, leveraging policy as a public health tool, and prioritizing innovation.

RADM Mermin pointed out that although HIV incidence has declined slightly in recent years in the United States, this change has occurred too slowly to eliminate HIV; additionally, the prevalence of HIV has increased as PWH live longer and healthier lives. However, innovations have been developed, including self-testing, STI clinic investments, pharmacy data to care, PrEP, and cluster detection and response. The NIH collaborates with the CDC in many areas of funding, research, and partnerships.

RADM Mermin provided highlights from the April CHAC meeting related to leveraging policy to advance HIV, viral hepatitis, and STI priorities. For example, Medicaid HVC treatment has been restricted to patients with liver damage and applies sobriety and prescriber restrictions. Removing those restrictions would be beneficial, because they contribute to excess morbidity and mortality.

Overview of the HHS Office of Global Affairs and Its Role in PEPFAR

Anthony "Jin" Park, M.A., Director, PEPFAR, Office of Global Affairs, HHS

Mr. Jin Park explained that PEPFAR is a U.S. government global initiative to control the HIV/AIDS pandemic. PEPFAR is unique because its programs are implemented by several US agencies working internationally. It is coordinated by the U.S. State Department's Office of the Global AIDS Coordinator; the Global AIDS Coordinator has a rank of Ambassador-at-Large to ensure collaboration, diplomacy, and effective work by US-funded HIV programs around the world. Ambassador John Nkengasong recently was welcomed as the U.S. Global AIDS Coordinator and leader of PEPFAR.

PEPFAR has had unwavering bipartisan Congressional and Presidential support. PEPFAR has supported at least 20 countries that have recently achieved epidemic control of HIV or reached the 90-90-90 HIV treatment targets established by the Joint United Nations Programme on HIV/AIDS (UNAIDS). This year, 19 million people are on life-saving treatment through PEPFAR, up from 17 million last year. The fact that this increase occurred simultaneously with the COVID-19 response demonstrates PEPFAR's impact and flexibility. Despite flat budgets in recent years, PEPFAR has been able to expand services and increase the number of people receiving treatment.

The Country Operational Plan (COP) is a process that engages multilateral stakeholders across society to discuss a country's PEPFAR program, evaluate the data, consider the unique contributions of partners, and make any necessary course corrections to ensure that the COP addresses the current needs of the epidemic. Core operating principles and values highlighted in the 2022 COPs include a focus on being person centered, evidence based, data driven, and gender responsive; diversity, equity, inclusion, and accessibility; collaboration and partnership; agility and adaptability; resilience; and linkage and integration.

Mr. Park outlined out the interagency nature of PEPFAR projects. The Office of the Global AIDS Coordinator primarily serves to coordinate PEPFAR. Although HHS provides overarching support, on-the-ground implementation is conducted by the CDC, HRSA, NIH, U.S. Food and Drug Administration (FDA), and UNAIDS. The PEPFAR principals—representatives of key agency partners—meet quarterly to discuss policy issues. The deputy principals, a group of senior programmatic leaders, meet weekly to ensure strong coordination. Oversight is managed by the Country Accountability and Support teams, with interagency representatives providing direct support.

The Office of Global Affairs (OGA) has leadership in PEPFAR; the OGA's primary function is to provide diplomatic outreach to ensure PEPFAR is promoting good science to support its partners. The OGA participates in the World Health Organization (WHO) with a range of activities in support of PEPFAR. The HHS PEPFAR principal contributes to PEPFAR policy and strategy at PEPFAR principals meetings and represents at the principals level the FDA, NIH, and other HHS agencies that do not have an on-the-ground presence.

OGA's PEPFAR goal is an AIDS-free generation through public health diplomacy, strategic leadership, and cooperative engagement across the U.S. government that fully leverages the scientific and technical expertise of HHS. OGA manages PEPFAR funds and advances HHS scientific, technical, and financial assets toward PEPFAR goals and priorities. It also advises senior HHS leadership in their engagement with PEPFAR, the Global Fund, and other HIV/AIDS policy dialogue. OGA ensures that PEPFAR funding moves efficiently from the U.S. State Department to HHS PEPFAR-implementing operating divisions. OGA supports bidirectional learning at the intersection of global and domestic HIV issues, such as coordinating an International AIDS Society satellite session and working in such areas as mental health and regulatory capacity building. Mr. Park emphasized that PEPFAR wants countries to think more holistically as they achieve epidemic control.

Panel Discussion

When asked whether RWHAP resources have been fully implemented for EHE activities, particularly given HRSA's partnership with the NIH, Dr. Cheever commented that HRSA has worked closely with the NIH in the past and has had some success developing practical strategies. EHE funding often requires CFARs to work with local health departments, which often use HRSA funding to facilitate linkage to care. Work with CFARs has been successful, but implementation remains challenging. Dr. Cheever expressed hope that the NIH could, ideally, develop an HIV vaccine and expand HIV implementation science.

In response to a suggestion that the NIH consider expanding its portfolio to increase healthcare delivery in EHE focus communities, Dr. Cheever emphasized the importance of addressing challenges between HIV diagnosis and entry into care. Barriers are numerous and include difficulties associated with navigating insurance and the health care system. She commented that the NIH has helped HRSA better understand how to engage with people using trauma-informed care.

RADM Mermin commented that firm organizational boundaries can create problems. In HIV research, the NIH primarily conducts basic and applied research, RWHAP focuses on implementation and evidence-based program strategy, and the CDC conducts applied research and program evaluation. He suggested that sharing ideas and talking to the people experiencing health issues are the best ways to improve health. OARAC members pointed out the need to continue pushing for bidirectional community engagement.

RADM Mermin confirmed that opioid addiction is the most commonly discussed syndemic condition but wondered whether a broader concept—such as mental health—could encompass opioid addiction when discussing the many environmental factors that affect health, in addition to such factors as poverty and racism. He commented that public health sometimes is slow to adopt changing approaches, but considering only discrete diseases may cause important factors to be overlooked. Ms. Hayes added that OIDP incorporates the opioid crisis in its work but also considers housing, mental health, and many other issues that affect the outcomes of its efforts.

Dr. Goodenow commented on the trajectory of HIV research needs, from early basic research to the development of clinical trial networks and the increasing need for implementation science. She noted that a "one-size-fits-all" solution will not be found, so ways to improve care delivery in many types of communities are needed. Mr. Park commented that communities can be local or global; HRSA's knowledge tended to be gathered domestically and shared globally, which can expand the community.

When asked about the most effective component of the syndemic approach, RADM Mermin commented that the best approaches for many specific, small-scale problems are known, which has led to such policies as standing orders for multi-infection screening. On a larger scale, one of the most important considerations is ensuring that policies are changed, which is the final step in implementation.

RADM Mermin commented on research as a tool for equity—when the problems that prevent people from leading their healthiest lives are known, research can be conducted to overcome those problems. Many current innovations in HIV treatment were developed to address specific issues; although these innovations were developed through science, they ultimately will help address implementation and treatment barriers in HIV and other infections.

HIV Clinical Guidelines Working Groups of OARAC Updates

Prevention and Treatment of Opportunistic Infections (OIs) in Adults and Adolescents with HIV

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

Dr. Henry Masur explained that the Adult and Adolescent OI Guidelines continue to receive a significant number of page views and noted that the Panel makes an effort to keep them current. Usage has remained steady over the last 5 years; these Guidelines have a reputation for being useful and unbiased. The most-viewed chapters continue to be those focused on more common OIs, but maintaining chapters on rarer OIs also is important because clinicians need to know where to turn for guidance when these OIs are seen in practice. The Panel's section group leads meet quarterly to discuss whether updates are needed. Co-chairs represent the NIH, Infectious Disease Society of America, HIV Medicine Association, and CDC.

Recent updates include expanded discussion of management and treatment of *C. difficile* disease. Upcoming changes include an update to the section on the HBV vaccine to recommend the double-dose recombinant vaccine and updated recommendations regarding PPSV23 and PCV20 to include booster doses for people with HIV ages 18 and older for the new pneumococcal vaccine. Dr. Masur noted that any differences in recommendations between the Guidelines and the recommendations of other groups are noted in the text. The sections on immunization, HBV, community-acquired pneumonia, and varicella-zoster virus are scheduled for update soon.

Antiretroviral (ARV) Agents in Pediatric HIV Infection and Prevention and Treatment of OIs in HIV-Exposed and HIV-Infected Children

Rohan Hazra, M.D., Associate Director of Extramural Research, NICHD, NIH

Dr. Hazra explained that the full Pediatric ARV Guidelines were published on April 11, 2022. Three sections shared with the Perinatal ARV Guidelines were published on December 30, 2021. The Guidelines were updated to address ARVs in line with FDA recommendations, including new dosage strengths of ARVs approved for pediatric use by the FDA in 2021. Some updates for drugs approved in 2022 are in process and will be published as real-time updates later this year.

Dr. Hazra elaborated on the updated pediatric formulations, all of which can be found in the What's New section of the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. The Special Considerations in Antiretroviral Therapy for Adolescents section now includes additional content about substance use concerns. The Adherence to Antiretroviral Therapy in Children and Adolescents with HIV section was revised to provide recent data about the following: smartphone-based reminders, peer-support interventions, modified directly administered ARV therapy, and a multicomponent intervention—including remote coaching, electronic dose monitoring, and tailored outreach.

Tables for ART-Associated Adverse Effects and Management have been updated. Recommendations have been reviewed with updates regarding associated ARVs, onset and clinical manifestations, estimated frequency, risk factors, prevention and monitoring, and management where indicated.

All drug sections in Appendix A: Pediatric Antiretroviral Drug Information were reviewed and updated, when indicated, to include those updates described.

Dr. Hazra reminded attendees that the Pediatric OI Guidelines engaged in a rescoping process, which has resulted in new standard operating procedures with an updated section revision frequency based on epidemiology and new advances. This Panel has expanded its membership and editorial support infrastructure. Revisions currently are underway for the Vaccine-Preventable Diseases, *Mycobacterium tuberculosis* (MTB), and Cytomegalovirus sections. Additional Leadership Group and section authorship candidates have been recruited and are being interviewed. Dr. Hazra pointed out that the Pediatric OI Executive Secretary, Dr. Bill Kapogiannis, serves as a liaison to the American Academy of Pediatrics Committee on Infectious Diseases, leading the Panel to critically review 13 chapters of the Red Book. The Pediatric OI Guidelines are downloaded less frequently than the adult Guidelines sections, but Dr. Hazra noted that the population of children with HIV is about 10 percent that of adults with HIV. Similarly to the Adult OI Guidelines, the sections on more common OIs are visited more frequently, and the sections on rarer OIs remain an important resource.

Updates from the NIH Advisory Council Representatives

AIDS Research Advisory Committee (ARAC)

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

Dr. Monica Gandhi provided updates from the June 6, 2022 ARAC meeting, including remarks on the NIAID budget and paylines. Funding earmarked for the EHE supports CFAR supplements; other supported research includes developing a universal influenza vaccine, studying tick-borne diseases, and researching antimicrobial resistance. Although COVID-19 funding remained flat, an immunity laboratory is planned. Funding for regional biocontainment and food allergy research has increased.

NIAID has established a Diversity, Equity, Inclusion, and Accessibility (DEIA) Council to work internally and externally on developing a diverse and inclusive workforce and workplace. NIAID's Workplace Civility Task Force has been created to provide input on and champion workplace civility and anti-harassment efforts across the Institute. Dr. Gandhi noted the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Diversity Initiative, which requires those applying for BRAIN Initiative funding to incorporate diverse perspectives and support the culture change necessary to address inequities and systemic biases in biomedical research. NIAID research opportunities include an R01 specifically for researchers from diverse backgrounds, 135 EHE projects across CFARs, renewal of CFARs grant awards, and a new initiative to enhance DEIA at CFARs for early pipeline investigators.

Several requests for applications (RFAs) are available. One is focused on defining the mechanisms of HIV-induced inflammation and immune activation during suppressive ART, which includes 3 years of basic research to determine the landscape of various cellular subpopulations followed by 2 years of applied research to develop therapeutics. Another aims to analyze early events in TB and TB/HIV infection to identify interventional targets; it encourages mechanistic studies of MTB/HIV or MTB infection before full development of adaptive immune functions.

A Cellular Immunology Core Laboratory is planned as a central laboratory to conduct assays that measure cellular immunity; Dr. Gandhi noted that identifying cellular immune responses from candidate HIV vaccines will be essential. The MTB Quality Assessment Program will ensure that laboratories can perform study-specified MTB tests proficiently. Key tasks are performing external quality assurance and assay validation; the program will be available to all supported investigators. The External Quality Assurance Program Oversight Laboratory, which serves external laboratories involved in HIV research, has been renewed.

National Advisory Council on Drug Abuse (NACDA)

Redonna Chandler, Ph.D., Director of the HIV Research Program, National Institute of Drug Abuse, NIH

Dr. Redonna Chandler provided updates from NACDA and thanked Dr. Carlos del Rio for his service as NACDA representative to OARAC. NIDA is working to approve a new council member with HIV expertise to serve as an OARAC Ex-Officio. Dr. Chandler noted a recent publication that demonstrates the importance of intervening on social determinants of health when addressing HIV and other infectious diseases, especially HCV. Among people who inject

drugs, HIV and HCV infections are common; many people who inject drugs are unstably housed, which increases the risk of HIV and HCV infection. This study used modeling to estimate the proportions of HIV and HCV infections that occur as a result of housing instability in 58 countries. Dr. Chandler noted that this was the first study to estimate the global contribution of unstable housing to any infection; it adds to the growing body of evidence showing the effect of social determinants of health on infectious diseases. The study predicts that unstable housing will contribute 8 percent of new HIV infections and 11 percent of new HCV infections among people who inject drugs. The median transmission population attributable fraction for HIV ranged from 2.2 percent in Eastern Europe to 21.6 percent in North America; for HCV, this measure ranged from 2.8 percent in Eastern Europe to 26.2 percent in North America. For both HIV and HCV, the rates in high-income countries were more than double the rates in low- and middle-income countries. Dr. Chandler emphasized that this highlights the importance of developing interventions that will affect social determinants of health.

At its May 2022 meeting, NACDA approved concepts on a range of topics, including mechanistic and basic science studies and a focus on the criminal justice population. Newly published funding opportunity announcements (FOAs) address the intersection of stimulant use and HIV, implementation of comprehensive HIV services in syringe service programs, increasing engagement and retention in HIV treatment with people using substances, and assessing pathogenic mechanisms that influence blood–brain barrier function in HIV and substance use disorders.

National Advisory Mental Health Council

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 provided an update from the NIMH National Advisory Mental Health Council. As part of the Unity Agenda, President Biden announced a bipartisan strategy to respond to the substance use and mental health crisis. The FY 2023 budget request for NIMH includes $5 million for research on innovative treatment models and $5 million toward advancing research on social media effects. The Senate Committee on Health, Education, Labor, and Pensions held a hearing on strengthening mental health and substance use disorder programs. The NIMH director testified before the Senate Appropriations Subcommittee on Labor, Health, and Human Services–Related Agencies on the proposed FY 2023 NIH budget. NIMH participated in a virtual fireside chat with OSTP representatives to discuss adolescent brain development, especially the impacts of stress, the COVID-19 pandemic, and social media; Dr. Lightfoot confirmed that designated funds are available for this research. The $1.5 trillion omnibus spending package provided the NIH with $45 billion, $2.2 billion of which was provided to NIMH. HHS representatives currently are engaging in a national tour to strengthen mental health.

NIMH's 2021 strategic plan update included expanding information on DEIA efforts, linking the plan to NIMH's approach to mental health disparities research, providing information on the new NIH climate change and health initiative, and addressing new interest areas focused on economic factors. As part of the update process, NIMH released the *2021 Strategic Plan Progress Report*. The NIMH director recently outlined NIMH activities in alignment with NIH's racial and ethnic equity plan. NIMH is focusing on leveraging existing data to improve new initiatives and support systems to apply a racial and equity lens to ICs, workforces, structures, and systems. To identify and dismantle any racial and ethnic disparities in the workforce, NIMH is using staff feedback to address racial disparities related to leadership, trust, reprisals, and

anti-harassment. NIMH aims to improve its recruitment and retention to enhance the diversity of the workforce.

NIMH's Division of AIDS Research is creating a strategic plan to align with the NHAS, EHE, and the *NIH Strategic Plan for HIV and HIV-Related Research*. This plan would focus on prevention through biomedical and behavioral health strategies and treatment to improve health outcomes and prevent further transmission. Several intervention targets are planned at the community health level to address key populations at risk. The plan includes a focus on implementation science, as well as neuroHIV and cure research. One key population the plan focuses on is transgender people; NIMH efforts to align with and focus on this population involve mobile technologies, peer navigation, and PrEP delivery. Recently reviewed Division of AIDS Research RFAs address expansion of differentiated care approaches for adolescents with HIV and deciphering immune–central nervous system interactions in people with HIV on ART.

National Cancer Advisory Board (NCAB)

Robert Yarchoan, M.D., AIDS Coordinator, Director, Office of HIV and AIDS Malignancy; Chief, HIV and AIDS Malignancy Branch; Senior Investigator, National Cancer Institute (NCI), NIH

Dr. Robert Yarchoan shared NCAB updates. An RFA for basic and translational research on health disparities in HIV/AIDS and cancer will focus on the biological interactions of cancer health disparities in marginalized populations with an underlying HIV/AIDS infection through basic mechanistic or translational studies to investigate how HIV interacts with the disparities to promote cancers. A disparities RFA will support studies of how health disparities interact with HIV to cause cancer through investigations of (1) causal drivers of accelerated onset of cancer; (2) genetic and epigenetic cancer susceptibility differences; (3) host responses to cancer; (4) microbiome analysis; and (5) studies that investigate the role of oncogenic viral coinfections on cancer development, treatment, and outcomes in marginalized populations that have health disparities and are severely and disproportionately affected by HIV. This RFA covers an R01 for 5 years or an R21 for 2 years, with an anticipated release date of December 2022 and receipt date of December 2023. Anticipated funding is seven or eight R01s and five or six R21s per year for 2 years. They will be funded by July 2023 or July 2024 with a proposed budget of $5 million per year and $25 million in total costs.

A Kaposi sarcoma (KS)–associated herpesvirus (KSHV) vaccine workshop was held in October 2021 to explore the possibility, approaches, and practicality of vaccine development. It included 65 invited participants and was open to the research community. Some of the areas covered included transmission and epidemiology, immunity to herpesviruses, lessons learned from vaccine development for other viruses, and practical issues related to developing and implementing a KSHV vaccine. In the United States, KS disproportionately affects African American men in the South, particularly young men; these populations have a worse prognosis when they develop KS. KS causes morbidity and mortality in sub-Saharan Africa and remains the most common tumor overall in men in some countries. KS is almost exclusively a disease of HIV-infected patients and occasionally patients with other immunodeficiencies. While acknowledging the scientific, practical, and implementation challenges, the participant consensus at the meeting was optimistic about the feasibility of developing a KSHV vaccine, based in part on the observation that the virus is much less transmissible than other herpesviruses, such as Epstein-Barr virus.

Dr. Yarchoan reported on the Anal Cancer High-grade Squamous Intraepithelial Lesion (HSIL) Outcomes Research (ANCHOR) trial, which showed that treatment of HSIL, an anal cancer

precursor, can prevent anal cancer. In the United States, the incidence of anal cancer in people with AIDS increased dramatically between 1991 and 2005, then remained steady at a high level. More than 4,000 people entered the ANCHOR trial and were randomized to observation or treatment of HSIL. Results were statistically significant showing that treatment prevented anal cancer, which likely will affect the guidelines for HSIL screening in people with HIV, as well as other groups. Dr. Yarchoan noted that this was the largest cancer trial in people with HIV to date; he thanked the participants and OAR for their support. Next steps include correlative studies with the samples collected in the trial, research on improved treatment for anal HSIL, and research to determine the best algorithm to prioritize high-resolution anoscopy.
Dr. Yarchoan noted that more practitioners must be trained in high-resolution anoscopy.

Discussion Highlights

When asked about potential correlations between KS and prostate cancer in Black males, Dr. Yarchoan explained that although both diseases occur disproportionately in Black males, the reasons are not well understood. KS largely occurs because of acquisition during life; genetic factors have not been shown to be important. He pointed out that Black males have high prevalence of HIV acquisition and often do not receive adequate treatment for many reasons, such as stigma. Dr. Yarchoan pointed out that more research on sociological reasons is needed.

NAEC

Julio Aliberti, Ph.D., Health Scientist Administrator, Senior Science Advisor, OAR, NIH

Dr. Julio Aliberti reviewed concepts and FOAs related to HIV cleared by IC advisory councils and published since the previous OARAC meeting. Between February 2022 and June 2022, 19 HIV-related concepts were cleared by the advisory councils of NIAID, NIDA, NIMH, NCI, and the Office of Research Infrastructure Programs, comprising 12 new concepts and 7 reissues. One FOA has been published since the previous meeting through NIDA, NIMH, and the National Institute of Neurological Disorders and Stroke. Dr. Aliberti referred to the DataWorks! Prize and noted the importance of data sharing and reuse in biomedical science.

Public Comment

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

CAPT Mary Glenshaw confirmed that no public comments had been received.

Closing Remarks and Adjournment

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

Dr. Goodenow thanked the Council members and speakers and noted the retirement of Dr. James Anderson, director of the NIH Division of Program Coordination, Planning, and Strategic Initiatives.

Dr. Tolbert added his thanks, reminded attendees that the next meeting, scheduled for October 27, may be virtual or hybrid and adjourned the meeting at 4:41 p.m. EDT.

Certification

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

Blanton Tolbert

Blanton Tolbert, Ph.D.
Chair, OARAC

11/01/2022
Date

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Date: 2022.11.02 18:16:18 -04'00'

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

Date