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

# Office of AIDS Research Advisory Council (OARAC)
**63rd Meeting**
**June 22, 2023**

**Hybrid Meeting (Videocast Link)**

## Meeting Minutes

**Council Members Present:**
Dr. Ivy E. Turnbull (Acting Chair)
Dr. Kathleen L. Collins
Dr. Omar Galarraga
Dr. Luis J. Montaner
Dr. Mojgan H. Naghavi
Dr. Anne M. Neilan
Dr. John W. Sleasman

***Ex Officio* Members Present:**
COL Julie A. Ake
Dr. Francis Ali-Osman
Dr. Victoria J. Davey
Dr. Carl W. Dieffenbach
Dr. Monica Gandhi
Dr. Rohan Hazra
Dr. Melanie Ott

**Office of AIDS Research (OAR) Leadership:**
Dr. Bill G. Kapogiannis
RDML Timothy Holtz
CAPT Mary T. Glenshaw

**Invited Speakers and Guests:**
Ms. Rahel Abebe
Dr. Geetanjali Bansal
Dr. Elizabeth Barr
Ms. Coretté Byrd
Dr. Janine A. Clayton
Mr. Robert Cregg
Dr. Seble G. Kassaye
Dr. Leslie Marshall
Dr. Henry Masur
Dr. Alice K. Pau
Dr. Dianne M. Rausch

## Welcome and Introductions

*Ivy E. Turnbull, D.L.P., Ed.M., M.A., Acting OARAC Chair, Deputy Executive Director, AIDS Alliance for Women, Infants, Children, Youth and Families, The AIDS Institute*
*CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary and Supervisory Senior Science Advisor, OAR, National Institutes of Health (NIH)*

Dr. Ivy E. Turnbull welcomed participants to the 63rd meeting of the NIH OARAC. A quorum was present. Meeting materials provided to Council members included the agenda, a conflict-of-interest form, and minutes from the 62nd OARAC meeting, held on March 2, 2023. A motion to accept the minutes of the 62nd OARAC meeting was approved unanimously. Dr. Turnbull reviewed the 63rd meeting agenda, noting the inclusion of time for public comments.

**Report from the Acting OAR Director**

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

Dr. Bill G. Kapogiannis welcomed attendees and recognized the transition of former OAR Director Dr. Maureen Goodenow to Senior Advisor in the NIH Office of the Director. Dr. Goodenow, the first woman to direct OAR, assumed leadership in 2016. Her accomplishments include coordinating a $250 million increase in the NIH HIV research budget over the last 5 years, implementing the first 5-year *NIH Strategic Plan for HIV and HIV-Related Research*, and working with the White House Office of National AIDS Policy to ensure strong research representation in the revised *2022–2025 National HIV/AIDS Strategy*. Dr. Kapogiannis welcomed Dr. Turnbull as the incoming OARAC Chair and noted new voting members Drs. Omar Galarraga, Luis Montaner, Mojgan Naghavi, and Anne Neilan.

The *Fiscal Year 2025 NIH HIV/AIDS Professional Judgment Budget*, now available on OAR's website, highlights accomplishments in HIV and AIDS research during the previous year and estimates the amount of additional funding needed in the following year to advance progress in priority areas of science as outlined in the *FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research*. OAR has accelerated the development of the fiscal year 2024 (FY 24) and FY 25 Professional Judgment Budgets to align with the U.S. government budget process. The FY 25 Professional Judgment Budget requests a $659 million increase, for a total proposed budget of $3.953 billion, an increase of 20 percent over the FY 23 enacted budget. The funding will be used to expand basic research to promote discovery and advance HIV science; develop and assess novel interventions; translate, implement, and disseminate HIV discoveries to optimize public health impact; and support infrastructure and workforce development to enhance research capacity and workforce diversity.

Dr. Kapogiannis highlighted three recent significant OAR engagements. On May 9, he represented NIH at an in-person briefing at the U.S. Capitol organized by the Research Working Group of the Federal AIDS Policy Partnership. OAR Deputy Director RDML Timothy Holtz represented NIH at a virtual briefing for House and Senate Appropriations staff on the Ending the HIV Epidemic in the U.S. (EHE) spending plan for FY 23. NIH received $26 million for EHE activities in FY 23; $5.6 million of this will support the final year of FY 22 EHE projects focused on health equity research, and the remaining $20.4 million will support new 2--year implementation research projects in the areas of syndemic approaches, leveraging of pharmacies, linkage to care after incarceration, and HIV cluster detection and response. The funding opportunities encourage applicants to partner with researchers from historically Black colleges and universities and minority-serving institutions. RDML Holtz also participated in the 76th meeting of the Presidential Advisory Council on HIV/AIDS (PACHA) in March and provided remarks on federal updates to EHE. OAR Senior Science Advisor CAPT Mary Glenshaw attended site visits in Washington, D.C.—including to two community clinics with NIH funding—with U.S. Department of Health and Human Services (HHS) Secretary ADM Rachel Levine and PACHA leadership.

OAR currently is executing the *FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research* and soon will begin formulating the next iteration of the strategic plan. The plan's strategic goals and scientific priorities are developed with input from multiple sources, and preparing the next plan provides opportunities to review HIV research priorities across NIH to ensure that resources are optimally aligned to needs. The NIH HIV research strategy informs the development and implementation of legislatively mandated documents, including the Professional Judgment Budget and the Congressional Budget Justification. OAR anticipates

establishing working groups later this year and including further discussion in future OARAC meetings.

OAR's Signature Programs, formed to coordinate NIH-wide initiatives in multidisciplinary and crosscutting areas, help guide OAR and NIH's current and future activities. This meeting includes a focus on the HIV and Women Signature Program, a partnership with the Office of Research on Women's Health (ORWH) that aims to promote the NIH vision for women's health—in which all women receive evidence-based, tailored HIV prevention, care, and treatment—and to support women in science careers. In 2021, 54 percent of all people with HIV worldwide were women and girls, and almost 50 percent of all new HIV infections were in women. An estimated 20 percent of transgender women were living with HIV in 2021, and transgender women were 14 times more likely than cisgender women to acquire HIV. Despite these disparities, only 15 to 19 percent of HIV funding in the past 5 years was coded as women's health. To identify gaps and priorities at the intersection of women's health and HIV, OAR and ORWH recently established an NIH HIV and Women Working Group, and the HIV and Women Signature Program webpage keeps the public informed of upcoming activities.

Dr. Kapogiannis outlined the day's agenda and noted that the next OARAC meeting, also planned as a hybrid meeting, is scheduled for Thursday, October 26. He reminded attendees that National HIV Testing Day is June 27 and added that OAR is planning a workshop on self-testing with the NIH HIV/AIDS Executive Committee in November.

## NIH ORWH: Intersecting Priorities

*Janine A. Clayton, M.D., Associate Director for Research on Women's Health, Director, ORWH, NIH*

Dr. Janine Clayton outlined how ORWH and OAR priorities intersect. Shared goals include promoting the inclusion of women, advancing partnerships, and addressing gaps in funding. ORWH was founded to advocate for better inclusion of women in NIH-supported clinical research and better application of the findings to women. Its current mission is to expand women's health research, ensure that women and minority groups are included in research, and advance women in science careers. ORWH seeks to incorporate sex and gender considerations across the research continuum to advance rigor, discovery, innovation, and equity.

Women face unique considerations in HIV research. ORWH uses a life course perspective, as demonstrated in the most recent Vivian Pinn Symposium, which was dedicated to menopause, a health inflection point. Women with HIV are more likely to experience depressive symptoms and have more frequent hot flashes, and distinguishing menopause symptoms from HIV symptoms can be difficult.

ORWH supports HIV research by studying the most affected populations, initiating research that incorporates sex as a biological variable from the study design stage, and supporting research that examines the intersection of sex and gender. The U3 (focusing on women from understudied, underrepresented, and underreported populations) interdisciplinary research program was created to draw attention to persistent disparities in women's health care and counter the historic exclusion from biomedical research of women from underrepresented groups. ORWH also recently issued R01 and R21 funding opportunities to support research on chronic conditions understudied in women, and the Specialized Centers of Research Excellence (known as SCORE) on Sex Differences program is an integral part of ORWH's

efforts to expand implementation of NIH's Sex as a Biological Variable policy. ORWH also supports an R01 on the Intersection of Sex and Gender Influences on Health and Disease.

To support careers in HIV research, ORWH has created an R25 focused on galvanizing health equity through novel and diverse educational resources. ORWH has a variety of other programs to help women receive the research support and training they need, including the signature Building Interdisciplinary Research Careers in Women's Health (known as BIRCWH) program. Dr. Clayton also co-chairs the NIH Working Group on Women in Biomedical Careers. She emphasized the importance of intersectionality on the health of women and noted an upcoming webinar on Diverse Voices in Intersectionality and the Health of Women.

**NIH HIV and Women Signature Program**

*Leslie Marshall, Ph.D., Health Scientist Administrator, Senior Science Advisor, OAR, NIH*
*Elizabeth Barr, Ph.D., Social and Behavioral Scientist Administrator, ORWH, NIH*

Dr. Leslie Marshall reiterated that OAR and ORWH have been actively engaged in research to support women with and affected by HIV. OAR and ORWH's partnership in the HIV and Women Signature Program creates opportunities for programmatic coordination and information dissemination by supporting joint promotion of initiatives and proactive collaboration among staff of both offices. Increasing information dissemination is one critical step to advance research at the intersection of HIV and women's health by improving the awareness of existing NIH initiatives among the HIV research community.

The foundation of the HIV and Women Signature Program is an intersectional, equity-informed, and data-driven approach to research on HIV and women. The program aims to promote health and well-being for all women—including transgender women, gender-diverse people, and individuals assigned female at birth—and ensure that they receive evidence-based, gender-affirming, tailored HIV prevention, care, and treatment. OAR and ORWH also use the HIV and Women Signature Program to support career development for women in HIV research.

The program was launched in February 2023 at the Women & HIV Symposium: Considerations from Across the Lifespan, which highlighted research from emerging investigators and reflections from the field's leaders. Input also was gathered from members of the community on the issues related to HIV and women's health that are important to them. One of the HIV and Women Signature Program's ongoing offerings is the HIV and Women webpage, which is designed to be a central resource for researchers, clinicians, and the community. The page is updated regularly with curated content and links to NIH and federal partner websites.

Dr. Elizabeth Barr outlined the organization of OAR and ORWH within the NIH Office of the Director. Both offices are tasked with coordinating research relevant to their missions, and each has an NIH-wide coordinating committee. In 2022, a joint working group of both coordinating committees was established to harmonize work related to HIV and women's health. The working group is charged with promoting health and well-being for all women with or affected by HIV—including cisgender and transgender women, gender-diverse people, and individuals assigned female at birth—and supporting career development for women in HIV research. The working group aims to maximize collaboration across NIH to promote meaningful research on HIV and women. The group meets monthly and receives regular updates on activities related to women and HIV.

Ongoing activities of the joint working group include conducting literature reviews and portfolio analyses and participating in workshops to review the state of the science on HIV and women, inform the NIH research agenda, and set priorities for future programmatic efforts. These activities will inform future plans, which may include identifying and responding to funding gaps and opportunities, hosting workshops, and ensuring that HIV and women's health topics are included in strategic plans.

## HIV in Women 2.0: Reflections From Observational Cohorts Over the Past Decade

*Seble G. Kassaye, M.D., M.S., Associate Professor of Medicine, Division of Infectious Diseases and Tropical Medicine, Georgetown University*

Dr. Seble Kassaye explained that more than half the people affected by HIV worldwide are women and that HIV in the Washington, D.C., region is heavily minoritized, disproportionately affecting women of color. Effective therapies have significantly improved mortality and reduced transmission, and surveillance data demonstrate improvements in diagnosis locally, nationally, and globally. Unmet needs remain in linkage to care and viral suppression. Effective antivirals have been key to preventing perinatal transmission, and efforts to eliminate pediatric HIV have provided notable successes, including for women.

Dr. Kassaye, who is the principal investigator of the Washington, DC branch of the national Women's Interagency HIV Study (WIHS) cohort, noted that observational cohorts have been important to elucidating the effects of HIV on women. WIHS, which began enrollment in 1994, is a multisite collaborative cohort designed to ensure that recruitment adequately represents the affected population. WIHS data have shown increasing viral suppression over time, with 60 percent of women virally suppressed most recently. Longitudinal analysis shows distinct patterns of viremia, and factors associated with high probability of viremia include African American race, younger age, lower education, moderate or higher alcohol use, depressive symptoms, drug use, and unstable housing. Dr. Kassaye pointed out the need to understand the unique factors associated with this group to achieve universal viral suppression.

The social cognitive theoretical framework was used to assess the social, behavioral, and biologic basis for viral suppression. The premise of this framework is that interactions between individual and interpersonal factors lead to manifested behaviors, influencing virologic outcomes. Key to the framework is a concept of self-efficacy shaped by social structures and environmental exposures—cognition and behavior can be influenced and changed, leading to improvements in self-efficacy and the desired behaviors and health outcomes. Higher treatment self-efficacy was found to be associated with viral suppression, and use of illicit drugs was associated with viremia. No association was found between viral suppression and social support or personalized stigma, which may be related to the high prevalence of HIV in the region or shifting societal concepts around stigma.

When data related to provider trust were assessed, high trust in providers was associated with greater adherence to antiretroviral therapy (ART) and lower distrust of health care services. The rates of trust in providers have changed over time, so further analysis is needed to understand the relationship between trust and the health care system. In a survey of provider knowledge and attitudes about HIV, gaps were identified related to comfort discussing HIV risk, drug use, and sexual practices. Lower HIV stigma was associated with greater HIV knowledge and comfort with counseling. These studies show a need for interventions to increase treatment self-efficacy, improve patient–provider interactions, and effectively address drug and alcohol use.

Additional studies are needed to determine which and what combination of such interventions will improve viral outcomes.

Dr. Kassaye also commented on the low rates of pre-exposure prophylaxis (PrEP) use in women, noting that although almost half of those who could benefit from PrEP in the United States are women, only 10 percent of the women who could benefit actually receive PrEP. Longitudinal data show that PrEP use among the 10 to 15 percent of eligible women is not consistent. Dr. Kassaye pointed out the need to understand the role of providers in this area, reiterating that most do not ask about sexual practices or drug use. She emphasized that observational cohorts provide opportunities to gain insights into both biology and implementation challenges, including relevant issues related to HIV and women, and these cohorts are an important platform for educating the next generation of researchers.

*Discussion Highlights*

Dr. Monica Gandhi commended the commitment to defining sex differences in HIV research and asked how interventional research could be added to the observational nature of the WIHS platform. Dr. Kassaye explained that numerous requests for applications leverage the cohort for interventions, but its status as a collection of population-level data is unique.

Dr. Montaner suggested improvements to reduce the recurring gap between the execution of research and recruitment of resources to include women in the field, such as specifically requesting information on recruiting women in the human subjects section of the application and on resources for recruiting diverse populations in the budget section. He pointed out that there are limited grant opportunities for women who have experienced interruptions in their career or have otherwise come from nontraditional career paths. Dr. Montaner noted that the R21 mechanism may be underutilized for this purpose, in part because R21 grants are often typically submitted with preliminary data, and because innovation is weighed heavily in review. Given that available small grants may limit research scope, other mechanisms with larger budgets could serve as a stimulus grants. He indicated that investing in these mechanisms could help women advance their research careers. Dr. Montaner also encouraged NIH to partner with the Federally Qualified Health Centers to incentivize access to PrEP and encourage investigators to develop collaborative research.

## Updates: Signature Programs

### HIV and Aging Signature Program

*Geetanjali Bansal, Ph.D. M.Sc., Health Scientist Administrator, Senior Science Advisor, OAR, NIH*

Dr. Geetanjali Bansal provided an update on the OAR HIV and Aging Signature Program, noting that although people with HIV who receive appropriate treatment now have a nearly normal life span, they face unique health challenges as they age. Aging with HIV is more complex, and this is a high-priority topic for NIH and HHS. The HIV & Aging Signature Program, launched in 2022, aims to catalyze collaborations to address research gaps and opportunities at the intersection of HIV and aging, with a focus on biomedical, behavioral, and social needs to promote healthy aging. The program engages in many current and future activities, including a working group with representation from 12 institutes and centers (ICs) and OAR. The working group is collating HIV and aging-related research resources and activities to determine how to leverage existing resources, identify new opportunities, and develop informational documents. The working group

discusses important research questions and has strongly recommended leveraging long-standing HIV cohorts.

An HIV and Aging workshop and Federal-community linkage session will occur in connection with the U.S. Conference on HIV/AIDS (USCHA) in September 2023. In addition to NIH staff, the planning group includes members of the community, as well as representatives of the Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA). The research workshop will be held virtually, and the linkage session will be a hybrid format. These events will center on four pillars: interdisciplinary research, integrated models of care, implementation research, and interagency efforts. Dr. Bansal reviewed the timeline of the HIV & Aging Signature Program and pointed out that the team is dynamic and growing as the program moves forward.

**Early Career Investigator Signature Program**

*Rahel Abebe, M.H.S., Public Health Analyst, OAR, NIH*

Ms. Rahel Abebe provided an update on the OAR Early Career Investigator Signature Program, which was created to provide resources and networking opportunities to HIV investigators within 10 years of their terminal degree who have not yet received an R01. The program aims to support early research independence and enhance workforce diversity. The HIV research workforce has been highlighted as a high-priority area in many HIV/AIDS planning efforts, including as one of the main strategy goals in the *NIH Strategic Plan for HIV and HIV-Related Research*, which notes that building the workforce will enhance the sustainability of HIV research, discovery, and implementation. The Early Career Investigator Signature Program aims to expand support for new HIV investigators, collaborate with institutes, centers, and offices (ICOs), promote networking and mentorship, and develop and diversify the HIV research workforce.

OAR convened a recent Workshop for Early Career Investigators in HIV to stimulate scientific exchange, networking, and collaboration; facilitate interactions; enhance skills in identifying funding opportunities; increase familiarity with the NIH review and funding process; and disseminate information about HIV-related activities and opportunities. The participants represented numerous disciplines within HIV research, and feedback from the previous year's workshop was incorporated to improve the conference. OAR also supports a pilot program to increase the early career HIV investigator workforce to 5 percent of the HIV research portfolio, which is similar to the percentage in other disciplines at NIH. Additional information is available on the OAR Early Career Investigator Resources website. Future plans include hosting summer coffee hours for early career HIV investigators to meet NIH staff, planning a 2024 workshop (tentatively planned for September), and continuing to monitor program support for early career investigators.

*Discussion Highlights*

Dr. Montaner suggested listing the Centers for AIDS Research (CFARs) core resources in a central location on OAR's Early Career Investigator Resources website, noting that these CFAR core resources are available to all investigators, including those who are not affiliated with institutions involved in the CFAR.

COL Julie Ake commented on the increasing importance of HIV and aging considerations in low- and middle-income countries. When asked about global considerations, Dr. Bansal noted the importance of global partnerships and that the group endeavors to have an international

speaker for the September meeting. Dr. Kapogiannis added that OAR has a number of long-standing relationships with global agencies.

Dr. Rohan Hazra pointed out that HIV funding can be used in unique ways to encourage early career investigators to enter the field; for example, investigators may pursue pediatric HIV in response to recent discoveries about infant immunity that can apply broadly to other conditions.

Dr. Anne Neilan recommended strong emphasis on Critical Event Supplemental Funding for career development awardees; Dr. Hazra suggested highlighting the NIH Loan Repayment Programs.

**NIH OAR Data Hub: Showcasing the NIH HIV/AIDS Research Portfolio**

*Robert Cregg, M.S., M.B.A., Supervisory Health Scientist, Senior Analytics Advisor, OAR, NIH*

Mr. Robert Cregg explained that the OAR Evaluation and Analytics Team uses analyses of the HIV research portfolio to better understand funding patterns in HIV research. The current NIH HIV research portfolio includes approximately 3,800 grants, intramural projects, and contracts and an annual budget of approximately $3.2 billion. The new NIH OAR Data Hub allows the public to view the portfolio through interactive dashboards in a way that is clear, comprehensive, and comprehensible, in line with OAR's legislative mandate to disseminate information about its portfolio to the public. The Data Hub also aligns with OAR's communications goals and NIH's efforts to disseminate information and promote scientific transparency and public accountability.

The OAR Data Hub is unique in its specific focus on the HIV research portfolio. It includes data on NIH HIV research priorities and objectives, with more detail and links to publicly available project data and offers the ability to visualize the HIV portfolio in the context of other topical areas of science. The dashboard visualizations are interactive and allow the user to narrow results to the information of interest. Every HIV-related project in the NIH portfolio is manually coded to one or more of OAR's 44 research objectives, allowing a granular breakdown of the supported research. These data also are mapped to one of the five research priorities in OAR's strategic plan.

Mr. Cregg provided a live demonstration of the Data Hub and how it can be used to view the portfolio in a variety of ways. He emphasized that the project currently is only in its first phase, but dashboards can be generated quickly, and many additional dashboards are anticipated in the future.

*Discussion Highlights*

Dr. Naghavi asked whether a dashboard specific to early career investigators would be added; Mr. Cregg explained that such a dashboard is a high priority as an upcoming addition to the Data Hub.

In response to a question about how the dashboard interacts with the NIH RePORTER, Mr. Cregg clarified that the OAR Data Hub uses only data specific to HIV and adds data only after the end of each fiscal year. Dr. Montaner recommended adding information about investigators and institutions.

Dr. Kapogiannis explained that the Data Hub can provide more detail than other methods about how well the OAR priorities and objectives are being fulfilled.

## Updates From the NIH Advisory Council Representatives

### AIDS Research Advisory Committee (ARAC)

*Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), NIH*

Dr. Carl Dieffenbach provided updates from the June 5, 2023, ARAC meeting, including remarks on the NIAID budget and paylines and staffing changes. He emphasized NIAID's commitment to diversity, equity, inclusion, and accessibility (DEIA) efforts and noted several relevant funding opportunities and DEIA activities, including a CFAR program that helps high school and college students become engaged in research. Research highlights include a clinical trial showing a larger than expected reduction in cardiac disease when a statin was added to an HIV drug regimen, a trial studying the effects of a COVID-19 vaccine in people with HIV in sub-Saharan Africa, and an mpox treatment trial that aims to enroll more than 500 participants globally, including remote enrollment options in certain sites. Dr. Dieffenbach reviewed new and renewal concepts and programs proposed for FY 25, including a concept on mechanisms of inducing HIV immunity in early life, the HIV Vaccine Research and Design program, the Simian Vaccine Evaluation Units program, and a program to advance therapeutics research by supporting investigators through difficult parts of the process. Future efforts include accelerated research on hepatitis B virus in people with HIV and novel HIV cure concepts, including biological products to eliminate HIV-infected cells, a pipeline of cell and gene therapies, and individually tailored HIV curative strategies.

### NIH HIV/AIDS Executive Committee

*Coretté Byrd, R.N., M.S., Health Science Policy Advisor, HIVinfo Program Manager, OAR, NIH*
*Dianne M. Rausch, Ph.D., Director, Office on AIDS, National Institute on Mental Health (NIMH), NIH*

Ms. Coretté Byrd and Dr. Dianne Rausch reviewed the 26 HIV-related concepts cleared by ICO advisory councils and published since the previous OARAC meeting. The 14 newly cleared concepts and 12 previously cleared concepts that were recently reissued were approved by the advisory councils of NIAID, NIMH, the National Cancer Institute, National Institute on Alcohol Abuse and Alcoholism, National Institute of Diabetes and Digestive and Kidney Diseases, Fogarty International Center, and Office of Research Infrastructure Programs.

*Discussion Highlights*

In response to a question about the development of HIV assays for international settings that involve clades other than clade B, COL Ake pointed out that such assays are in development, but the length of time required to start trials in these settings requires that trials begin before new assays become available.

Dr. Sleasman suggested further development of novel analytics.

In response to a question about reservoir identification, Dr. Dieffenbach pointed out that several major programs on reservoir tracking and neuroAIDS are in progress.

## HIV Clinical Guidelines Working Groups of OARAC Updates

### Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV

*Henry Masur, M.D., Senior Investigator, Critical Care Medicine Department, NIH*

Dr. Henry Masur provided updates on the Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. He emphasized that all guidelines remain widely used, suggesting they remain necessary. The Adult Opportunistic Infection (OI) Guidelines have 30 OI-specific groups that meet regularly and provide rolling updates as needed. The most recent major updates address the epidemiology of Chagas disease, as well as changes to the labeling and availability of nitrofurmox. Several other sections have recent or upcoming minor updates. The panel also has worked to streamline the update process. Currently, updates are published in about 16 weeks, but the panel recognizes that currency is one of the important features of the guidelines, and it will continue exploring ways to expedite the update process.

### Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection

*Rohan Hazra, M.D., Director, Division of Extramural Research,* Eunice Kennedy Shriver *National Institute of Child Health and Human Development*

Dr. Hazra presented updates on the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection, which are updated annually in the spring. Several sections are published jointly with the Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States, which were updated in full on January 31, 2023. Updates to the Pediatric Antiretroviral Guidelines include clarifications about rapid initiation of ART in response to particular OIs, the addition of a table on CD4 counts in healthy children that previously had been removed, and the addition of guidance on viral load monitoring for adolescents initiating long-acting cabotegravir and rilpivirine. The guidelines note special considerations for the use of ART in adolescents and recommend that providers caring for adolescents with HIV consider incorporating age-appropriate screening for suicidality—Dr. Hazra noted that the substantial increase in mental health issues in adolescents predated the COVID-19 pandemic and has continued. Several other sections were updated, and information about providing medications was clarified. Dr. Hazra also commented on new panel members and recognized the substantial impact of panel members who have recently resigned or retired, all of whom contributed to the efforts to eliminate pediatric HIV in the United States and allow infants with HIV to live normal lives.

### Guidelines for the Prevention and Treatment of Opportunistic Infections in Children with and Exposed to HIV

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

Dr. Kapogiannis presented on the Guidelines for the Prevention and Treatment of Opportunistic Infections in Children with and Exposed to HIV, which are updated on a rolling basis and harmonized with information in other guidelines. Since the last update, a rescoping effort has been ongoing and has included broad consultation with the community and led to a plan to better align the guidelines with current epidemiology and provider needs. One recommendation was to add more editors, so the panel has engaged a number of new members. Section updates are anticipated by the end of June 2023 and include new recommendations and harmonized guidance for testing of HIV exposed infants for and treatment of congenital

cytomegalovirus, updated references and recommendations for treatment of *Mycobacterium tuberculosis* and use of ART regimens in the context of tuberculosis, and updates to the introduction and several tables.

### Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV

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

Dr. Alice Pau outlined the updates to the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, which were published in March 2023. Major updates focused on lenacapavir, which was approved in December 2022 primarily for patients with virologic failure and multiple drug–resistant HIV-1 infection. A number of other sections were updated, and new panel members have been added. In September 2023, the panel will host its first in-person meeting since May 2019, and work is underway on a new section on HIV and transplant, as well as updates for other sections. The Guidance for COVID-19 and People with HIV is no longer being updated; users are now being referred to the Special Considerations in People with HIV section of the NIH COVID-19 Treatment Guidelines.

*Discussion Highlights*

In response to a question about January 2023 updates to the new section on breastfeeding, Dr. Hazra explained that the panels worked closely with HRSA, which is updating its training materials, and with CDC, which plans to update its website as well. The National Clinical Consultation Center's Perinatal HIV Consultation and Referral Services Hotline has been updated, and research proposals on monitoring have been proposed. Dr. Kapogiannis added that usage data from the hotline can be captured and analyzed. CAPT Glenshaw pointed out that OAR can develop some provider-facing resources in addition to the patient-facing materials.

### Public Comment

*CAPT Mary T. Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary and Supervisory Senior Science Advisor, OAR, NIH*

CAPT Glenshaw summarized a comment from Mr. David Kawana from the Ashowad Christian Charitable Organization for Vulnerable Groups of Children, Youth, Widows, and People Living with HIV in Uganda, who noted that access to ART is difficult in his community and that programs for young girls are needed, and a comment from Mr. Jules Levin of the National AIDS Treatment Advocacy Project, who emphasized the need for implementation research to provide better care to people aging with HIV. *[The full text of these public comments appears at the end of the document.]*

### Closing Remarks and Adjournment

*Bill G. Kapogiannis, M.D., OAR, NIH*
*Ivy E. Turnbull, D.L.P., Ed.M., M.A., The AIDS Institute*

Dr. Kapogiannis thanked the Council members and speakers. Dr. Turnbull added her thanks and adjourned the meeting at 4:42 p.m. EDT.

**Certification**

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

Ivy Turnbull

Ivy Turnbull, D.L.P., Ed.M., M.A.
Acting Chair, OARAC

9/18/2023
Date

Mary Glenshaw -S

Digitally signed by Mary Glenshaw -S
Date: 2023.09.13 16:32:46 -04'00'

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

9/13/23
Date

**Public comment received:** 2:40 pm on June 22, 2023
**Comment made by:** David Kawana, Ashowed Christian Charitable Organization for Vulnerable Groups of Children, Youth, Widows, and People Living with HIV in Uganda

Create awareness programs for young girls and adults in Uganda's Kassanda District, which are most vulnerable. Access to health services and facilities for people and those on ARV are real big problems in our community. Through your support and partnership we hope to create an impact.

Thanks

David Kawana

**Public comment received:** 2:41 pm on June 22, 2023
**Comment made by:** Jules Levin, National AIDS Treatment Advocacy Project

I am watching the very interesting and important discussions today. I want to thank the OAR and Bill and Geeta for pushing aging and HIV and thank the NIH's Women's Program for its needed initiatives. And thank Dr Kassaye as well for her commitment to WIHS.

Indeed many of us older and in particular elderly PLWH are suffering severe effects of aging with HIV including physical and mental impairment and disability. And it's painfully obvious many of us elderly and older PLWH are not getting our care needs met. Your recognition of this problem is important. Women do experience worse rates of comorbidities and physical decline as they age. I have suggested before that we need implantation research to help to provide better clinical care and I think Dr. Kassaye discussed that too. We could for one example provide a support project for women and men to provide better evaluation and monitoring and care for heart disease and bone disease as well. Plus the implementation studies of geriatric screenings and support in HIV clinics would be useful.

Thousands of PLWH are over 65 now and need immediate interventions they are not receiving so implementation research is a way to insert geriatric care and screenings in HIV clinics.

Thanks

Jules Levin