**U.S. Department of Health and Human Services (HHS)**
**National Institutes of Health (NIH)**
**Office of AIDS Research (OAR)**

**Office of AIDS Research Advisory Council (OARAC)**
**69th Meeting**
**September 18, 2025**

**Virtual (VideoCast Link)**

**Meeting Minutes**

**Council Members Present:**
Dr. Luis J. Montaner (Chairperson)
Dr. Courtney V. Fletcher
Dr. Sonia Castro Flores
Dr. Anne M. Neilan
Dr. Diane M. Santa Maria
Dr. Sara L. Sawyer

***Ex Officio* Members Present:**
COL Julie A. Ake
Dr. Carl W. Dieffenbach
CAPT Robyn Neblett Fanfair
Ms. Heather L. Hauck
Dr. Rohan Hazra

**Advisory Council Representative:**
Dr. Gregory Greenwood

**OAR Leadership:**
Dr. Geri R. Donenberg
Dr. Geetanjali Bansal
CAPT Mary Glenshaw
Dr. Leslie Marshall

**Invited Speakers and Guests:**
Dr. Roy "Trip" Gulick
Dr. Henry Masur
Dr. Alice Pau
Dr. Sandra A. Springer
Dr. Franklin Yates

## Welcome and Introductions

*CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Associate Director of External Engagement, OAR, NIH*
*Luis J. Montaner, D.V.M., D.Phil., M.Sc., OARAC Chairperson, Executive Vice President and Director, HIV Cure and Viral Diseases Center, The Wistar Institute*

CAPT Mary Glenshaw and Dr. Luis J. Montaner welcomed participants to the 69th meeting of the NIH OARAC. A quorum was present. Meeting materials provided to Council members included the agenda, a conflict-of-interest form, public comments received prior to the meeting, and minutes from the 68th OARAC meeting, which was held on June 26, 2025. Minutes from the 68th OARAC meeting were approved by notational vote by the Council in advance of the 69th OARAC meeting.

CAPT Glenshaw conducted roll call, and Dr. Montaner reviewed the agenda for the 69th meeting, noting the inclusion of time for public comments.

## Report: OAR Director

*Geri R. Donenberg, Ph.D., Associate Director for AIDS Research and Director, OAR, NIH*

Dr. Geri R. Donenberg began by acknowledging National HIV/AIDS and Aging Awareness Day, which raises awareness about the need for HIV prevention and treatment strategies for older

adults and long-term survivors with HIV and emphasizes the importance of research. She noted that OAR has a working group and a dedicated HIV and Aging Program to catalyze research at the intersection of HIV and aging. Dr. Donenberg also acknowledged the upcoming observance of National Gay Men's HIV/AIDS Awareness Day, which aims to increase awareness of the disproportionate impact of the HIV epidemic on gay and bisexual men in the United States and encourage HIV prevention and treatment services in this population. She also noted OAR staff changes, including CAPT Glenshaw's new position as OAR Associate Director of External Engagement, Dr. Leslie Marshall's role as OAR Acting Deputy Director, and Dr. Rachel Anderson's new role as OAR Chief of Staff.

Dr. Donenberg outlined OAR's efforts to advance HIV implementation science, explaining that effective HIV prevention and treatment tools are not reaching everyone, especially the communities most in need. The benefit from NIH research investments and innovations is not being fully realized. She noted that a comprehensive research program that includes collaboration with federal and community partners is needed to achieve these goals. NIH will catalyze implementation research to understand how best to reach all populations and study how to improve uptake, adoption, sustainability and scale-up of evidence-based strategies and tools. NIH will share these findings with our partners at other federal agencies and the community to strengthen the HIV response. OAR is approaching this effort in several ways. First, the office is establishing an internal working group to coordinate activities centered on an implementation research agenda and an NIH-wide task force consisting of experts in implementation science. The task force will bring their expertise to the discussion and consider how their learnings can apply to HIV research. Second, a preliminary analysis of the HIV research portfolio is planned, but some internal coding work is needed to capture the full landscape of HIV and implementation science grants. Third, OAR will catalyze new research in HIV and implementation science by expediting awards through challenge competitions and new funding opportunities.

Dr. Donenberg described several recent events that included OAR participation. She attended the International AIDS Society meeting in Kigali, Rwanda, where conversations focused on long-acting injectables, as well as challenges associated with recent funding reductions. Dr. Donenberg noted a recent OAR Director's Seminar titled "A New Era for HIV Persistence Research" and several NIH-led sessions and discussions at the U.S. Conference on HIV/AIDS. She highlighted the recent OAR Innovation in HIV Research Symposium, pointing out that OAR distributes innovation funds broadly across institutes. She reported on an upcoming workshop for early career investigators (ECIs) designed to provide updates about HIV priorities and NIH policies, guidance to prepare responsive grant applications, strategies for successful career transitions, and opportunities to connect with program staff across institutes, centers, and offices (ICOs). Dr. Donenberg added that this workshop was developed in response to six recent listening sessions in which ECIs detailed what they need for success. She noted the upcoming International Workshop on Aging and HIV, which will focus on mentorship for early stage investigators conducting implementation science in HIV and aging.

Dr. Donenberg then provided a brief update on the next iteration of the *NIH Strategic Plan for HIV and HIV-Related Research*, explaining that the plan is currently under review at NIH. The strategic plan has five goals: (1) fundamental research, (2) intervention research, (3) implementation research, (4) strengthening capacity, and (5) operational efficiency. Its foundational principles are comprehensive, multidisciplinary research; population-focused health; and multisectoral partnerships. She thanked those who were involved in the plan's development.

Dr. Donenberg informed attendees that the next OARAC meeting is scheduled for Wednesday, November 19, and is planned for as an in-person meeting.

*Discussion Highlights*

Dr. Montaner expressed excitement about the focus on implementation science and encouraged OAR to explore partnerships with Federally Qualified Health Centers, which could be effective test locations for implementation research, as well as strategies to interface with HRSA. Dr. Donenberg noted that the task force also suggested leveraging the Ryan White HIV/AIDS Program (RWHAP) networks to study prevention in addition to the networks' focus on treatment.

When asked what will happen to the HIV budget under a continuing resolution, Dr. Donenberg explained that she understood that a continuing resolution preserves the status quo. She expressed hope that the budget would continue at its current level at a minimum, and noted that the NIH Director's priority for ending the HIV epidemic suggests strong support.

In response to a question about the new coding that will be developed for the portfolio analysis, Dr. Donenberg pointed out that the NIH OAR Data Hub already is available to the public and includes codes for many categories of research; she encouraged interested parties to use the Data Hub to explore the many HIV grants funded by NIH. She also noted that the improvements in coding should allow more nuanced coding of implementation science.

Dr. Courtney V. Fletcher commented on the importance of community pharmacists in the implementation of pre-exposure prophylaxis (PrEP) and asked how pharmacists are involved in the implementation effort. Dr. Fletcher noted that there is no ICO that specifically focuses on pharmacy. Dr. Donenberg clarified that the internal implementation science task force will grow into a multidisciplinary working group and will include pharmacists. She pointed out that HIV and pharmacy is one of OAR's focus areas, and pharmacy-centric research is integral to ending the HIV epidemic, especially in terms of work related to delivering long-acting products. Dr. Fletcher requested more information on awards in response to the recent OAR-NIMH led HIV and Pharmacy RFAs and recommended a broader announcement when applicable.

Dr. Rohan Hazra noted that the NIH Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative operated a challenge program that successfully catalyzed the development of community partners and distributed funding quickly. He offered assistance from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development to learn from IMPROVE's successes.

**HIV Clinical Guidelines Optimization and Opportunities to Inform Implementation Science**

*Geri R. Donenberg, Ph.D., Director, OAR, and Associate Director for AIDS Research, NIH*

Dr. Donenberg provided an update on the federally approved Clinical Practice Guidelines for HIV/AIDS. She emphasized that OAR heard the feedback and public comments indicating the guidelines are important resources that should stay within NIH and OAR. The office is adjusting its plans to advocate to retain the guidelines at OAR. The OAR will focus on optimizing the production of the guidelines on the part of OAR, recognizing the extensive contributions of the volunteer panels. This effort aims to streamline production costs. OAR will also develop a research agenda related to the clinical practice to understand their reach, access, and dissemination.

OAR staff have spent the past several months discussing the guidelines' utility with the guidelines' panels, professional societies, service organizations, and other individuals, all of whom reaffirmed their importance. The next step is to assess the processes, including contract costs, and identify opportunities to improve efficiency. Dr. Donenberg asked OARAC members and guests to comment on how the guidelines can inform NIH's expanded view of implementation science and its HIV/AIDS research priorities, how OAR can evaluate the guidelines' impact rigorously, and how dissemination and adoption of the guidelines can be expanded.

*Discussion Highlights*

In response to a question about the intended audience for these efforts, Dr. Donenberg explained that OAR is aware of the guidelines' importance and would like to shift the conversation to understand who is using them, whether they reach everyone who could use them, and what aspects of the guidelines are used most. She noted that these implementation science questions can have bidirectional impacts.

OARAC members suggested studying how to inform basic scientists about the value of the guidelines and how they could be used in basic science.

Dr. Alice Pau noted that the panels have access to web analytics that show which sections of the guidelines are accessed most often. She suggested partnering with organizations that have large databases and assessing the outcomes of implementation efforts.

Dr. Roy "Trip" Gulick expressed appreciation for OAR's careful consideration of the guidelines' future. He asked for additional information on the guidelines' budget and on why efficiency is now a priority given the decades-long success of the guidelines. He also asked whether assessment of the guidelines and their importance is considered a new research area or a justification for the guidelines' continued existence. Dr. Donenberg responded that discussions about the details of the guidelines' cost are ongoing. Justification will likely be required in the future, and thorough knowledge of the guidelines' processes will help ensure they can remain at OAR; this effort also provides an opportunity to integrate the guidelines with the implementation science research agenda. Dr. Montaner suggested that an analysis of the total cost of guidelines, including estimated consultancies currently provided on a volunteer basis would likely demonstrate the efficiency of the current process.

Dr. Henry Masur pointed out that the 30-year history of the guidelines could be considered a "victory" for the importance of the federal government in ensuring this resource is trusted, credible, and used widely. He emphasized the guidelines' efficiency, and the importance of extensive volunteer efforts, as well as the contracted editors and administrative staff who assume much of the burden of producing the guidelines. He cautioned against creating new conflicts of interest with potential payment for expertise and noted most guidelines do not compensate subject matter contributors. Dr. Masur advocated for OAR's ability to take the lead in demonstrating to NIH and the federal government why this type of work is important.

Dr. Fletcher appreciated OAR's willingness to listen to feedback received and agreed that in-kind contributions should be considered in addition to OAR costs when quantifying the value of the guidelines. He noted that most universities encourage their faculty to participate in national panels and volunteer work to give back as members of public institutions. Regarding the guidelines' usefulness, he noted data availability at the clinic, institution, and insurance levels that could be leveraged to understand HIV regimens used, if these follow guidelines

recommendations, and the impact of regimes on viral load levels. He pointed out that OAR could encourage publication of these analyses.

Dr. Donenberg clarified that although OAR intends to continue its support for the guidelines, this plan is pending approval by the NIH Director.

Dr. Neilan recommended that research questions could include the flexibility many clinicians use in adhering to the guidelines' recommendations. She also noted that panels identify areas where more research is needed to address critical patient care questions; this information could be used by NIH in developing funding opportunities and help align guidelines work to the OAR and NIH mission. Dr. Santa Maria noted that the widespread commitment to maintaining OAR's support for the guidelines from leaders across the nation is itself invaluable.

**Driving Change Through Research: Overcoming Roadblocks to End HIV in the U.S.**

*Sandra A. Springer, M.D., Professor of Medicine, Yale School of Medicine, Section of Infectious Diseases, Yale AIDS Program*

Dr. Sandra A. Springer, a physician in infectious disease and addiction medicine who works with people with and at risk for HIV in both clinical and research settings, introduced her work focused on reducing barriers across disciplines and settings. She emphasized that social contexts and individual needs must be considered in HIV service delivery and shared decision-making and when tailoring intervention strategies that address whole-person health. No single solution will work for all people, and the complexity of real-world issues requires creative, multifaceted implementation strategies.

Dr. Springer pointed out the significant disparities in access to treatment and prevention across populations and noted that HIV outbreaks are increasing among people who use drugs in both Medicaid expansion states and non–Medicaid expansion states, showing that these groups are not accessing services regardless of whether they are available. Criminal justice–involved populations also show poor viral suppression after release, and although integration of HIV and medication treatment for substance use improves viral suppression, many people cannot access such services. Although the *Ending the HIV Epidemic in the U.S.* initiative is supported by many years of evidence-based science, including such strategies as offering syringe services, as well as either antiretroviral therapy (ART) or PrEP immediately after an HIV test, goals are not being met, and current progress is insufficient.

Dr. Springer explained that in the current health care system, people are expected to know where to go to access HIV testing and PrEP, but services are not integrated, and lack of access is rarely interrogated. She reviewed some of the many barriers people often experience and presented a study in which a mobile health clinic was used to overcome some of those barriers. Communities must be evaluated to determine how to increase uptake of evidence-based interventions in each case, and Dr. Springer emphasized that access to insurance and syringe services are significant barriers to address in ending the HIV epidemic. The mobile health clinic allowed her team to see a diverse group of participants, and the team was able to provide links to several kinds of services, including PrEP and substance use treatment, housing and transportation assistance, and access to clinicians and community health workers. She noted that asking participants whether they had ever used opioids or stimulants revealed a moderate to high level of substance use disorders among the population, suggesting the importance of asking participants about comorbidities that may affect prevention and treatment.

Dr. Springer emphasized that although clinicians assume people will accept treatments offered, understanding differing perceptions of risk is critical to ensuring uptake. She discussed national PrEP-to-need differentials, and shared data from a recent study that demonstrated low self-perception of HIV risk among participants with high levels of risk behavior (condomless sex, recent STI, and shared injection drug use equipment). This population had many needs that they prioritized higher than PrEP, for which they expressed low interest. These data demonstrate the need to consider individual choice and engage in shared decision-making with providers. Dr. Springer pointed out that although most participants in this cohort were not interested in PrEP, those who were interested expressed a preference for long-acting injectables; she added that matching what an individual wants makes them more likely to engage with and continue treatment.

Dr. Springer then outlined several barriers related to access to prescription treatments, such as the need for specialty pharmacies, the lack of pharmacies in neighborhoods where people receive services, and stigma- and privacy-related concerns. Her team created the first legal retail mobile pharmacy, which allows anyone to access pharmacy services, primary and specialty care, rapid testing, social services, and medication. She noted that state legislation to legalize mobile pharmacies was required before this project could be implemented. This service was able to reach a diverse population, increase access, and match patient preference better, extending whole-person care to underserved areas.

Dr. Springer commented on the future goals for her work, including collaborating with partners to create a learning health system that will better predict patient locations and desires. Implementation science and collaborations with patients can be used to continually evaluate and improve interventions which then can be used as models for other areas of the United States. She reiterated the need to understand and overcome barriers to access in order to end HIV, which requires aligning the needs of people at risk for and with HIV with effective evidence-based interventions. Dr. Springer emphasized the critical nature of translation and policy considerations and repeated that no single strategy will work for everyone.

*Discussion Highlights*

In response to a question from Dr. Montaner about federal partnership to address fundamental social and economic issues, Dr. Springer emphasized the need for federal partners such as the Centers for Disease Control and Prevention, Health Resources and Services Administration, and Substance Abuse and Mental Health Services Administration and partnering with pharmacy groups to enable access to services. She noted that this work is multi-sectoral and complex, and there is a need to align with existing partners and resources to enhance sustainability.

In response to how mobile services impact gaps in the care cascade, Dr. Springer shared that the mobile clinic was able to restart treatment for many people who had fallen out of care, and then provide a warm hand off to standard services. She noted, however, that many people are reluctant to return to a brick-and-mortar clinic, and the ability to start or restart ART the same day as well as address substance use and mental health-related comorbidities is critical.

When asked about awareness of the ongoing HIV epidemic among the general population, Dr. Springer reiterated that many people do not perceive themselves as being at risk, and most advertising related to HIV is focused on men who have sex with men, which leaves many populations unaware that they also could be affected. Additionally, many people in underserved populations have more pressing concerns (housing, food, transportation) than a potential future risk of HIV. Dr. Springer suggested that nuanced communication strategies may be needed.

In response to a question about how to export this strategy when Medicaid expansion varies by state, Dr. Springer emphasized the need to consider which policies or funding options could help individuals at risk for HIV in states without Medicaid expansion. Dr. Montaner pointed out that many organizations are increasing their case management services given the need to navigate increasing requirements. Dr. Springer added that community health workers are covered health services now, which suggests that innovative strategies could be considered.

When asked about tracking long-acting injectable use among populations using the mobile health clinic, Dr. Springer explained that many people remember when they received an injection, and some pharmacies keep records. Electronic health records and improved communications could help improve tracking, but increasing access to PrEP is a more pressing priority.

Dr. Fletcher commented on the increase in pharmacy deserts across the country, emphasizing the need to address barriers to access thoughtfully. Dr. Diane M. Santa Maria noted her work with young people experiencing homelessness and emphasized the importance of demonstrating that work with at-risk populations is important and effective.

## Update: NIH Advisory Council Representative

### National Advisory Mental Health Council (NAMHC)

*Gregory Greenwood, Ph.D., M.P.H., Deputy Director, Division of AIDS Research, National Institute of Mental Health, NIH*

Dr. Gregory Greenwood highlighted three current funding opportunities presented to the NAMHC; for all three, awards are pending following application receipt and review. The first supports an anti-stigma effort focused on communities disproportionately affected by HIV and will use RWHAP networks to adapt, implement, and test anti-stigma interventions. The second focuses on harnessing multimodal artificial intelligence to accelerate HIV clinical care by integrating diverse data sources for richer knowledge and more personalized care. The third opportunity will support studies on the role of T cells in HIV central nervous system reservoir seeding, persistence, and neuropathogenesis, which will aid in efforts to identify a functional cure for HIV. Dr. Greenwood also highlighted the National NeuroHIV Tissue Consortium, a critical research resource that provides high-quality biospecimens.

## Updates: HIV Clinical Guidelines Working Groups of OARAC

### 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, NIH*

Dr. Hazra commented that recent updates to the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection reflect an effective collaboration between this panel and the Perinatal Guidelines panel. The most recent Pediatric ARV Guidelines update should be available by the end of September; three of the sections shared with the Perinatal Guidelines were published at the end of December 2024, and the fourth was published in May 2025. Upcoming updates include routine edits to multiple sections, an emphasis on optimization to integrase strand transfer inhibitor–based regimens, the addition of Symtuza for adolescents weighing 40 kg or more, and updated drug sections for dolutegravir, rilpivirine tablets for oral suspension, and

Odefsey. Dr. Hazra noted that the recommendations for optimized care of adolescents were inspired by the work of OARAC member Dr. Anne M. Neilan, which showed that individuals with perinatally acquired HIV can expect to live an almost normal lifespan with optimal care.

### Antiretroviral Agents in Adults and Adolescents With HIV

*Alice K. Pau, Pharm.D., Staff Scientist/Clinical Pharmacist, National Institute of Allergy and Infectious Diseases, NIH*

Dr. Pau commented on two recent publications authored by the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV panel to disseminate information on statin therapy for individuals with HIV and publicize the discussion of the role of integrase resistance testing before starting ART. Dr. Pau noted the importance of disseminating information to the public on questions for which experts lack a clear answer, such as the role of resistance testing.

The update to the Adult ARV Guidelines is expected to be published on September 25. A new section focused on cardiovascular and metabolic complications of HIV includes five subsections and required the panel to recruit three new members with expertise in this area. Other major revisions include adjustments to recommendations for laboratory monitoring and initiation of ART in elite controllers, as well as new subsections on early and acute HIV and ART initiation during hospitalization. The section on suboptimal CD4 T lymphocyte recovery despite viral suppression has been separated from the inflammation section and expanded, and the cost considerations section has new subsections on health care coverage to maximize access to ART, long-acting injectables, and drug pricing programs. Dr. Pau thanked the many individuals who volunteer their time for this effort.

### Opportunistic Infections in Adults and Adolescents With HIV

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

Dr. Masur noted that many experts are eager to participate in the panels and reiterated the importance of the guidelines as an NIH effort. He explained that the Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV panel has 5 co-chairs, 31 chapters, 22 section group leads, and 150 panel members. Page view numbers are high and have remained steady over time, and the classic opportunistic infections are the most-visited pages, which Dr. Masur attributed to the fact that treatments are known but clinicians often need to review the most current recommendations. Sections are updated as often as the panel members deem appropriate to ensure recommendations are up to date; many chapters have been published recently, and many more are scheduled for update soon. Dr. Masur noted that although the guidelines are meant for a U.S. audience, they are accessed worldwide. He also commented that panel members recognize the guidelines are recommendations, not mandates; the guidelines also indicate when data are insufficient to provide recommendations.

### Public Comment

*CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Associate Director of External Engagement, OAR, NIH*

CAPT Glenshaw provided an update on the public comments received after the previous June meeting, explaining that the window was left open for 4 weeks. A total of 70 comments were

received, 68 of which expressed support for the guidelines. Four of these included other concerns, such as budget cuts and HIV and aging. CAPT Glenshaw summarized the two remaining comments. The first focused on the extreme disparities regarding new HIV diagnoses among Black women and girls and emphasized the need to focus on context when implementing community-driven interventions. The second noted disparities in care for the growing population of people aging with HIV and the need for the health care system to prepare for the increasing needs of this group.

CAPT Glenshaw summarized the four comments received for the current meeting. The first was a duplicate from last meeting, reiterating concerns about the population aging with HIV. The second expressed support for continuing the guidelines under OAR and noted that their adaptation for use in Australia and New Zealand prevents inconsistencies, reduces costs, and adds to their impact. The remaining two comments emphasized the critical role of the guidelines and NIH's support of them; the final comment particularly noted the need for implementation science to include clarity on core research questions, prioritize community and its involvement, and translate strategies to inform global efforts, which also can be translated to inform domestic efforts. It also emphasized the importance of maintaining a balanced research portfolio, including support for basic, pre-clinical, and clinical research.

Public comments received in advance of and during this OARAC meeting appear as an appendix to these meeting minutes.

## Closing Remarks and Adjournment

*CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Associate Director of External Engagement, OAR, NIH*
*Luis J. Montaner, D.V.M., D.Phil., M.Sc., OARAC Chairperson, Executive Vice President and Director, HIV Cure and Viral Diseases Center, The Wistar Institute*

CAPT Glenshaw reminded participants that the next meeting would be in person. Dr. Montaner adjourned the meeting at 3:45 p.m. EDT.

**Certification**

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

Luis J. Montaner

Digitally signed by Luis J. Montaner
Date: 2025.12.12 15:42:06 -05'00'

Luis J. Montaner, D.V.M., D.Phil., M.Sc.
Chairperson, OARAC

12/12/25
Date

Mary Glenshaw -S

Digitally signed by Mary Glenshaw -S
Date: 2025.12.12 09:11:23 -05'00'

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

12/12/25
Date

**U.S. Department of Health and Human Services (HHS)**
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**69th Meeting**
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**Public Comments Received through September 18, 2025**

# Table of Contents


PUBLIC COMMENT 1 ..... 2

Attachment for Public Comment 1 ..... 3

PUBLIC COMMENT 2 ..... 5

PUBLIC COMMENT 3 ..... 6

Attachment for Public Comment 3 ..... 6

PUBLIC COMMENT 4 ..... 9

Attachment for Public Comment 3 ..... 9

# PUBLIC COMMENT 1

**Public comment received:** 12:12 am on August 25, 2025

**Comment made by:** Alexis Apostolellis | CEO

**Affiliate:** ASHM (previously named the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine)

Dear Dr. Donenberg,

I am writing on behalf of ASHM (previously named Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine) regarding two critical developments that will significantly impact HIV care globally.

Please find attached a formal letter outlining our concerns about the announced discontinuation of NIH support for the U.S. federal HIV clinical practice guidelines and the removal of the Transgender People Living with HIV section.

As a longstanding partner that has adapted the DHHS guidelines for Australia and New Zealand since 2005, we respectfully urge your reconsideration of both decisions outlined in our attached letter.

Thank you for your time and consideration of our concerns.

Kind regards,

Alexis

## Attachment for Public Comment 1

**Dear Dr. Donenberg,**

ASHM (previously called the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine) writes to express our deep concern about two developments:

1) The announced discontinuation of NIH support for the U.S. federal HIV clinical practice guidelines by June 2026; and
2) The removal of the Transgender People Living with HIV section from the Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV.

The U.S. Department of Health and Human Services (DHHS) guidelines are recognised internationally as the gold standard for HIV care. They are an essential reference for the Australian and New Zealand healthcare workforce. Our recent comparative review of global HIV guidelines confirmed that the DHHS guidelines consistently demonstrate the highest quality and scientific rigour.

Since 2005, ASHM has partnered with DHHS to adapt these guidelines into the Australian Adult and Paediatric Antiretroviral Guidelines, which serve as the primary evidence base for treatment decisions made daily by thousands of clinicians, nurses, and pharmacists across our region. This partnership ensures that people living with HIV in Australia and New Zealand receive timely, evidence-based care aligned with the latest research—without the duplication of effort, cost, and potential inconsistencies that would arise if we were forced to develop equivalent guidelines independently.

Ending NIH support will have wide-reaching consequences:

- **For Australia and New Zealand,** it will create a significant evidence gap, delay the safe adoption of new antiretroviral therapies, risk inconsistencies in comorbidity management (including cardiovascular, metabolic, and mental health care), and reduce care quality for key populations.
- **Globally,** it will contribute to the fragmentation of HIV treatment standards, slow the uptake of new evidence, and place additional strain on already overburdened health systems.

The removal of the transgender care section is of equal concern and signals that the specific health needs of transgender and gender-diverse people living with HIV are not

being prioritised; it should be reinstated to maintain equity and clinical relevance. Transgender people are disproportionately affected by HIV, are over-represented in new diagnoses, and face intersecting—often socioeconomic—barriers to care. Removing dedicated guidance widens inequities, undermines decades of progress toward inclusive, evidence-based care, and contradicts international commitments, including WHO guidance, to meet the needs of key populations.

Our nearly two-decade partnership with the U.S. DHHS has been built on trust in the integrity, transparency, and excellence of your scientific work. It has been critical in ensuring that Australians and New Zealanders living with HIV receive world-class care informed by the best available evidence.

**We respectfully urge NIH and OAR to:**

1. Reconsider the decision to discontinue NIH stewardship of the DHHS HIV guidelines and maintain their production under NIH sponsorship.
2. Reinstate the Transgender People Living with HIV section and commit to preserving content for all special and priority populations.

Thank you for considering these concerns and your continued leadership in global HIV research. We look forward to your response.

Kind regards,

**Alexis Apostolellis**
Chief Executive Officer
ASHM

**Dr Rick Varma**
ASHM Chair, Adult Antiretroviral Guidelines Committee

**Dr Adam Bartlett**
ASHM Chair, Paediatric Antiretroviral Guidelines Committee

**ASHM Adult Antiretroviral Guidelines Committee — Members:**
Dr Andrew Grulich, HIV Epidemiologist
Arron Sparkes, Pharmacist
Brent Clifton, Community Representative
Danielle Collins, Nurse Practitioner
Dr David Griffin, Infectious Disease Physician

Dr David Nolan, Immunology Consultant
Helen Clancy, Community Representative
Dr Lewis Mackinnon, General Practitioner
Maggie Smith, Clinical Nurse Consultant
Dr Mark O'Reilly, General Practitioner
Dr Rupert Handy, Infectious Disease Physician

## PUBLIC COMMENT 2

**Public comment received:** 10:56 am on September 18, 2025

**Comment made by:** Jules Levin | Executive Director and Founder

**Affiliate:** National AIDS Treatment Advocacy Project (NATAP)

I would like to take this opportunity to remind you of the ongoing & worsening aging & HIV problem in the USA. I have spoken to the OARAC previously, since however care for older aging PWH has not gotten better but gotten mostly worse. In Ryan White & other HIV Clinics older PWH are not getting the care they require, their care needs remain unmet. They are not getting the recommended aging related screenings. Key HIV Guidelines recommend all PWH > 50 receive a bone mineral density test, a frailty screening, and a cognitive function screening & mental health evaluation for depression & anxiety, yet most older PWH are NOT receiving these screenings. A recent publication reported less than 15% nationally of HIV clinicians provide a bone mineral density screening, which is required to diagnose osteoporosis & to prescribe treatment, without which older PWH are at higher risk for fractures. Research clearly shows older PWH are at higher risk for & earlier onset for multiple comorbidities. It is predicted that by 2030, 70% or more will by over 50, that 50% will be over 60 & it's predicted that the number of PWH over 75 will increase 6-fold. It's estimated that by 2030, 80% of PWH over 70 will have 2 or more comorbidities. African-Americans, Latinos & women of color are disproportionately affected with higher rates & earlier onset for multiple comorbidities.

Our HIV healthcare system is unprepared to meet the needs of older PWH now & certainly even worse they are unprepared for the expected future.

HRSA implemented a 3-year pilot project of 10 aging clinics 3 years ago in 10 cities that provide geriatric care & services for older PWH but the project is ending now. This program of geriatric care & services needs to be broadly provided to all older PWH in the USA. There is a solution for our outdated care system, that was designed 20+ years

ago but it is not configured anymore to meet the needs of the vast majority of PWH – to update the RW Care system. Mortality rates are higher for PWH with multiple comorbidities. We need a change now before it's too late.

Jules Levin

## PUBLIC COMMENT 3

**Public comment received:** 2:37 pm on September 16, 2025

**Comment made by:** Andrea Weddle, MSC | Executive Director

**Affiliate:** HIV Medicine Association (HIVMA)

Greetings - I'm submitting the attached letter for the public record regarding the maintenance of the federal HIV guidelines at NIH on behalf of more than 30 organizations.

Please reach out to me with any questions.

Thanks,
Andrea

### Attachment for Public Comment 3

Dear Donenberg:

Thank you for your leadership of NIH's Office of AIDS Research. We are writing in response to the June 26 Office of AIDS Research Advisory Council (OARAC) meeting where the future of NIH's federal HIV treatment, care, and prevention guidelines was discussed. Our organizations represent people living with and affected by HIV and the diversity of health care professionals who care for people living with HIV across the lifespan. **We are writing to request a meeting to discuss the future of the federal HIV guidelines and potential strategies and opportunities for supporting their maintenance at NIH.**

We appreciate that you outlined a coordinated and transparent process during the June OARAC meeting for soliciting input on the future of the federal HIV guidelines and

indicated that a final decision on the fate of the guidelines had not yet been made. We would very much like to be a part of that process. As organizations representing individuals that interact with and are affected by the NIH HIV guidelines, we understand their importance and immense value to the care and treatment of people living with HIV and in supporting clinicians in providing the highest standard of treatment.

NIH demonstrated important foresight when the agency recognized it was uniquely positioned to rapidly translate the latest research to clinical practice by supporting the development of clinical practice guidelines. NIH also recognized the importance of responding to unique needs and HIV clinical issues during pregnancy and the postpartum period (including reducing perinatal transmission) for infants, children, adolescents and adults — with specific recommendations for the large and growing population of aging adults with HIV. The guidelines also provide highly specialized guidance for treating the rare but serious opportunistic infections that can occur in children, adolescents, and adults with HIV, particularly those who are not virally suppressed. As a result, people living with HIV in communities across the country, including in rural areas and others with limited infectious diseases or HIV expertise, have benefited from the remarkable HIV treatment advances led by the agency.

The availability, accessibility and timeliness of the HIV guidelines have saved countless lives, and decades later their utilization continues to increase because of the expertise and credibility that NIH brings to guideline development on complex HIV treatment and clinical issues. The rigorous process also advances NIH's priorities by identifying critical research gaps that inform NIH's research agenda and priority areas for implementation science.

We understand that NIH's proposal to transition away from maintaining the federal HIV guidelines is driven primarily by fiscal constraints. Given that there is not another federal agency with the expertise to maintain the guidelines, this short-term cost-saving measure could come at a high cost in the long term, if people living with HIV experience poorer health outcomes, which also will lead to more costly and intensive care and an increase in HIV transmissions. The potential transition of the guidelines also comes at a time when the HIV prevention and care infrastructure across the country faces unprecedented threats that will further strain an already insufficient HIV workforce – particularly in rural communities. This is especially concerning as the population of aging people with HIV continues to grow, bringing increased complexity in managing comorbidities, drug interactions and age-related conditions that require evidence-based guidance.

We would greatly appreciate the opportunity to meet with you to discuss these issues and how we may be able to partner with you to support the sustainability of the federal HIV guidelines at NIH. Please contact Andrea Weddle, executive director of the HIV Medicine Association, at aweddle@hivma.org to schedule a meeting.

Respectively submitted by the undersigned organizations:

AIDS Action Baltimore
AIDS United
American Academy of HIV Medicine
American Academy of Pediatrics
American College of Obstetricians and Gynecologists
Association of Departments of Family Medicine
Association of Nurses in AIDS Care
AVAC
Dandelions Inc.
Family Medicine Residency Directors
HIV Medicine Association
HIV+Hepatitis Policy Institute
Infectious Diseases Society of America
International Association of Physicians in AIDS Care
International Community of Women Living With HIV North America
NASTAD
North American Primary Care Research Group
PAC
Pediatric Infectious Diseases Society
Positive Women's Network - USA
Positively Trans
Ribbon – A Center of Excellence
San Francisco AIDS Foundation
SERO
SisterLove
Society for Maternal-Fetal Medicine
Society for Teachers in Family Medicine
Society of Infectious Diseases Pharmacists
Southern AIDS Coalition
The Reunion Project
The Well Project
Transgender Law Center
Treatment Action Group

# PUBLIC COMMENT 4

**Public comment received:** 1:38 pm on September 18, 2025

**Comment made by:** John Meade, Jr., MPH | Senior Program Manager - Policy

**Affiliate:** AVAC

Good morning,

I hope this email finds you well! I am emailing to submit public comment on behalf of AVAC for the 69th OARAC meeting.

Thank you

Kind Regards,

John Meade, Jr., MPH

## Attachment for Public Comment 3

Dear Dr. Donenberg,

My name is John Meade Jr., and I am writing on behalf of AVAC, where I serve as Senior Program Manager of Policy, as well as the co-chair of the Research Working Group (RWG) of the Federal AIDS Policy Partnership (FAPP). AVAC's mission is to accelerate the ethical development of HIV prevention options and ensure equitable access to these options as part of a comprehensive and integrated path to global health equity. We work to translate complex science and amplify community perspectives among civil society, researchers, funders, policymakers, and other key stakeholders. The RWG, as part of the FAPP, unites over 60 national and local HIV/AIDS researchers, and advocates to strengthen U.S. leadership in advancing HIV/AIDS and co-morbidity research through publicly funded institutions like NIH. Together, AVAC and the RWG are committed to driving progress in HIV/AIDS research, and advocate for adequate investment and evidence-based policymaking to realize a vision to end HIV/AIDS in the U.S. and globally. Together, AVAC and the RWG are committed to driving progress in HIV/AIDS research.

On behalf of these entities, I express deep concern for the future of HIV research investment, programmatic implementation and roll-out at NIH.

First, we are concerned with reported plans on diminishing NIH's vital role in the development of federal HIV treatment, care, and prevention guidelines. At the June 2025 OARAC meeting, you described a transparent process for gathering input on the future of the federal HIV Guidelines and confirmed that no final decision had been made on this matter. Earlier this month, more than 30 organizations, including AVAC, sent a letter to NIH OAR leadership underscoring why the Guidelines must remain under NIH's stewardship and offering the community perspective on their importance.

For decades, these guidelines have been the gold standard in HIV clinical decision-making—valued for their rigor, timeliness, and credibility, and uniquely positioned within NIH to translate research into practice while addressing the needs of infants, children, adolescents, pregnant people, and aging adults with HIV. Preserving NIH's leadership is essential to evidence-based guidance, strong patient outcomes, and U.S. leadership in HIV research. Shifting the Guidelines away from NIH for short-term savings would undermine progress, weaken the care infrastructure, and increase long-term costs at a moment of growing workforce strain and clinical complexity.

Secondly, we are concerned that overly ambitious intention of NIH to pursue an implementation science strategy at the expense of investments in basic, preclinical, and clinical HIV research.

A robust implementation science agenda is critical to the next phase of the HIV response, particularly with the advent of long-acting technologies for both treatment and prevention. AVAC has consistently urged NIH to increase investment in this area, recognizing that effective implementation of biomedical technologies in real-world settings is just as important as scientific breakthroughs. With the emergence of injectable lenacapavir for PrEP and other promising technologies in the pipeline, we agree that now is the moment to prioritize research that identifies and overcomes barriers to uptake, expands the power of choice in prevention, especially in Ending the HIV Epidemic (EHE) jurisdictions and across the U.S. South where disparities remain stark. As highlighted in Dr. Patrick Sullivan's recent JAMA article, the risks of backsliding on PrEP access are real; failing to act now would not only squander opportunities to expand long-acting innovations but could also reverse hard-won progress. The news of investment in implementation science is welcome, but also requires clarity on what the core research questions are, which communities will be prioritized, how community voices will be incorporated in shaping the implementation science strategy to ensure it meets real-world needs, and how this links with global efforts, including the recent

commitment from PEPFAR to expand access to LEN. A “whole of government”, global strategy is urgently needed.

It is also essential that the implementation science agenda includes broad stakeholder input – both domestic and global. We call on OARAC and the highest levels of NIH leadership to uphold and safeguard the core values of equity, evidence, and accountability that must remain central to our collective efforts.

While the current emphasis is on U.S. challenges, we cannot forget that research relationships developed globally through NIH have been historically core to advancements in HIV treatment and prevention, and important to bolster global health security for America. Any comprehensive implementation research agenda must also be comprehensive in its geographies. We urge NIH to heavily lean into the research and community partnerships that have been built over decades to inform the forthcoming implementation research agenda with a necessary depth of community engagement, expertise, and perspective for its success. Lessons learned from implementation science in the United States must be rapidly translated to inform global efforts, and vice versa. We gain an edge by engaging diverse geographies for implementation science in HIV, for instance, linkages with PEPFAR and global rollout programs of innovations like lenacapavir that can inform domestic initiatives. Limiting the scope to the U.S. alone would be a missed opportunity, when the realities of HIV demand integrated solutions that strengthen both domestic and global responses.

Finally, we urge NIH to ensure that increased investment in implementation science does not come at the expense of basic, preclinical, and clinical research, but rather is articulated within a balanced scientific portfolio that advances all stages of research and development. To truly end the epidemic, we must also support the 1.2 million people living with HIV in the US by sustaining research toward a cure. To achieve a durable end to the HIV epidemic, NIH should prioritize flexible mechanisms—particularly the P30 structure within the CFAR programs and UM1 of the Martin Delaney Collaboratories—that can support implementation science and basic research while also sustaining robust community engagement. We underscore that early-phase trials are the foundation upon which later-stage innovations are built. Without investment in basic science and exploratory research, the pipeline will stagnate. The bold decision in expanding implementation science offers a significant opportunity for NIH to rebalance its entire HIV research portfolio, and make sure that scientific progress against HIV on all fronts continue unbated and backed by a robust flow of resources. In a time of increased politicization of science and targeting of marginalized communities vulnerable to HIV, we strongly recommend that the NIH continue to follow the evidence and epidemiology of the HIV epidemic to drive its science, agenda-setting, and

policymaking. But even more crucially, following the evidence and epidemiology to meet the specific and unique prevention needs of these communities, and prioritize their meaningful involvement and inclusion in all aspects of NIH research.

AVAC and the Research Working Group urge the Office of AIDS Research and OARAC to work with community stakeholders to maintain the federal HIV guidelines within NIH, develop an implementation science strategy, and recommit to prioritizing basic, preclinical, and clinical HIV research.

We thank the OARAC committee for the opportunity to submit these comments and invite further dialogue on strategize on investments in HIV R&D and deepening community involvement in HIV research across NIH. Should you have any questions regarding this comment, please contact John Meade, AVAC's Senior Program Manager – Policy and co-chair of the RWG, at john@avac.org.

Respectfully submitted,

John Meade Jr., MPH
Senior Program Manager: Policy
AVAC