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)
68th Meeting
June 26, 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. Dianne M. Rausch

OAR Leadership:
Dr. Geri R. Donenberg (OAR Director)
Dr. Geetanjali Bansal
CAPT Mary Glenshaw (OARAC Executive Secretary)

Invited Speakers and Guests:
Dr. Lisa Abuogi
Dr. Julio Aliberti
Dr. Constance Benson
Dr. John Brooks
Dr. David Chang
Dr. Nahida Chakhtoura
Dr. Andrea Ciaranello
Dr. Roy "Trip" Gulick
Dr. Henry Masur
Dr. Shawn Mulvaney
Dr. Alice Pau
Dr. Carina Rodriguez
Dr. Rodney Wright
Dr. Franklin Yates

Welcome and Introductions

CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Acting Deputy Director, 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, Herbert Kean, M.D., Family Professor, The Wistar Institute

CAPT Mary Glenshaw and Dr. Luis J. Montaner welcomed participants to the 68th 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 67th OARAC meeting, which was held on October 24, 2024. Minutes from the 67th OARAC meeting were approved by notational vote by the Council in advance of the 68th OARAC meeting.

CAPT Glenshaw welcomed attendees and conducted roll call. Dr. Montaner reviewed the agenda for the 68th 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 noting that this meeting occurred the day before National HIV Testing Day, which encourages people to get tested, know their status, and connect to care and treatment. She acknowledged the delays and disruptions that have posed challenges within the research community and thanked NIH staff and grantees for their dedication. Dr. Donenberg noted that during the OARAC meeting, OAR could not comment on specific individual grants, applications, institutions, or investigators; pending or ongoing litigation; internal guidance developed to ensure alignment with current priorities and executive orders; or whether opportunities will be reopened or reissued in the future. Dr. Donenberg directed attendees to review publicly available resources, such as the NIH Grants and Funding Information Status webpage.

Dr. Donenberg welcomed Dr. Montaner as the new OARAC Chairperson and thanked Dr. Ivy Turnbull for her leadership as previous OARAC Chairperson. Dr. Donenberg also welcomed two new *ex officio* members: CAPT Robyn Neblett Fanfair representing the Centers for Disease Control and Prevention, and Heather Hauck, representing the Health Resources and Services Administration. Dr. Donenberg briefly noted several leadership transitions within NIH institutes, centers, and offices (ICOs). She pointed out that the President's Budget for fiscal year 2026 (FY26) proposes reducing the NIH budget from $48 billion (B) to $27 B and consolidating 19 existing NIH institutes into eight. OAR's FY26 Congressional Budget Justification is now available and organized according to the proposed new structure. Under this budget, NIH HIV funding would be reduced by nearly $1.4 B, or 42 percent. Dr. Donenberg emphasized that this budget is a proposal; Congress will determine the final budget.

The priorities of the new NIH Director, Dr. Jay Bhattacharya, are to improve population health, ensure reliable results, make big advances, maintain safety and transparency, and encourage academic freedom. Dr. Donenberg emphasized that OAR is well positioned to continue managing and coordinating the NIH HIV research portfolio within this framework while working to identify new opportunities, address challenges, increase efficiency, promote innovation, facilitate collaborative science, and ensure rigor and reproducibility.

OAR also plans to work with partners at all levels to scale and sustain existing evidence-based interventions and promote the utilization of implementation science to close the gap between innovative discoveries and real-world applications. Dr. Donenberg emphasized that rigorous implementation science approaches at multiple levels are needed to understand how to improve uptake and adoption of evidence-based interventions. OAR is engaging with ICOs to discuss opportunities to expand HIV-related implementation science. OAR will work with ICOs to strengthen their existing programs while developing new cross-ICO collaborations. The goal is to create inclusive funding opportunities across institutes and centers (ICs) to foster implementation science and end the HIV epidemic.

OAR's NIH-wide initiatives in HIV and aging, HIV and women, early career investigators (ECIs), advancing technology, and leveraging pharmacies are designed to catalyze science to meet the needs of people with and affected by HIV. Dr. Donenberg also noted that OAR promotes transparency through a robust analytics platform available to the public called the NIH OAR Data Hub, which synthesizes NIH portfolio data and enables researchers to identify HIV-related awards relevant to their specific interests. The Data Hub aims to enhance understanding of NIH HIV research, improve transparency, and disseminate HIV research information.

Dr. Donenberg provided an update on lenacapavir, a remarkably effective HIV prevention antiretroviral drug supported by decades of investment in NIH research. Recent clinical trials on lenacapavir showed that more than 99.9 percent of participants were protected from HIV acquisition following two injections annually; the drug was recently approved by the U.S. Food and Drug Administration (FDA). Dr. Donenberg emphasized that if its use is implemented properly, lenacapavir could change the course of the epidemic.

The *FY 2026–2030 NIH Strategic Plan for HIV and HIV-Related Research*, which is nearing publication, highlights HIV-related opportunities across the research continuum and emphasizes capacity building at each level. OAR developed the plan based on feedback from multiple internal and external sources, discussion by expert task forces, and recommendations from OARAC and NIH ICOs. The plan is currently undergoing internal NIH review and clearance and will be sent to OARAC for a notational vote before public release later this year.

In closing, Dr. Donenberg remarked on the OAR-led NIH observance of World AIDS Day, held on December 4, 2024, and noted several upcoming meetings. The 13th International AIDS Society Conference on HIV Science will be held in Kigali, Rwanda, and will feature both research-based presentations and discussion of the current political and funding issues affecting the HIV response, including global implications, particularly in sub-Saharan Africa. The upcoming 2025 U.S. Conference on HIV/AIDS (USCHA) in Washington, DC will focus on aging with HIV and include three interactive OAR sessions in partnership with NIH ICs and HIV community leaders. These sessions will focus on comorbidities, menopause and women with HIV, and viral load monitoring. Dr. Donenberg noted that the next OARAC meeting will be held on September 18.

Discussion Highlights

Dr. Donenberg clarified that in planning for the proposed FY 2026 budget, each IC was asked to estimate how they would proportion a 40 percent cut, and all ICs that currently support HIV research retained a strong commitment to the field.

When asked about the threat that frozen research funding poses to the biomedical research workforce, Dr. Donenberg explained that she cannot comment on these issues but many NIH meetings offer opportunities to express concern about how current issues affect the future of science and investigators.

In response to a question about how international research aligns with OAR's current and future priorities, Dr. Donenberg stated that discussions are ongoing about how foreign subawards and activities may be funded or integrated into the NIH system. She pointed out that a statement on the value of global health research has been released but that she has not been provided with additional information. Dr. Donenberg added that OAR has had internal opportunities to comment on what the office considers to be important.

Advanced Platforms for HIV Viral Load Monitoring at the Point-of-Care

Shawn Mulvaney, Ph.D., Health Science Administrator, Division of Health Informatics Technologies (Informatics), National Institute of Biomedical Imaging and Bioengineering, NIH

Dr. Shawn Mulvaney presented an overview of the Rapid Acceleration of Diagnostics (RADx®) initiative and its current efforts to accelerate point-of-care products for HIV viral load monitoring. Under typical circumstances, diagnostic tests require 3 to 5 years of research and development, followed by regulatory tests before reaching the market. RADx was started during the COVID-19 pandemic to accelerate this timeline, and it designed a funnel structure integrating best practices from industry, academia, and government to de-risk each project as quickly as possible. A subset of respondents to a call for proposals participate in interviews with RADx scientists, who consider the technology and organization, infrastructure, and critical elements required for project success. During this process, RADx determines the likely barriers to success and whether they can be overcome. The success of this approach to bring over-the-counter COVID-19 tests to the general public shifted testing away from central laboratories and dramatically reduced the time to market. One advantage in this process was the Point of Care Technology Research Network (POCTRN), a U54 program launched in 2007 that RADx could leverage and expand.

RADx was able to offer customized support and accelerate multiple parallel pathways to reach a common endpoint. Each innovator was paired with a RADx team that collected significant experience and facilitated a close working relationship, which fueled intensive risk assessment. RADx also established a group of subject-matter experts who could be consulted to strategically de-risk projects. Milestone-based contracts and schedules provided key success criteria at each step; these contracting mechanisms were flexible enough to apply across many technologies and respond to an evolving pandemic and all its translational needs. Dr. Mulvaney noted that codifying organizational structures through a coordination center, a commercialization center, and a validation center was critical to sustaining ongoing RADx efforts.

RADx's process can apply to many areas beyond COVID-19 because each project can be tailored in size and scope to address available opportunities. The Advanced Platforms for HIV Viral Load Monitoring at the Point-of-Care program is working to accelerate and de-risk the technology-to-design path for point-of-care HIV viral load tests and ready projects for clinical trials. Currently, no products in this space have been approved by the FDA for the domestic market. Market analysis and meetings with community members revealed that sensitivity is the attribute most valued in such a product, with price and time having significance in each scenario. The target product profile (TPP) is a test that uses whole blood, requires minimal sample handling, and has a total time of less than an hour. The tests also should be both quantitative and very sensitive, which is a significant challenge, but parts of the requirement have been solved in other areas.

Three teams were selected to develop projects with RADx support. The first company, Cepheid, currently offers 35 tests for its GeneXpert® platform, including a hepatitis C test developed in collaboration with RADx. Cepheid has an HIV viral load test available on the global market, but it requires a venous blood draw and access to a certified laboratory. The proposed solution includes capillary blood filtered in the testing cartridge and aims for detection limits of 200 copies/mL, which has been demonstrated in bench settings. Cepheid is using lessons learned in developing its hepatitis C test to balance sample collection, filtration efficiency, and detection goal challenges.

The Finder platform developed by Baebies, Inc., is a digital fluidic platform envisioned as a single system with a menu of tests. Baebies currently has an FDA-approved test for anemia that is routinely used for infants, and the company is working to determine how to apply sample collection, sample volume, and workflow concerns to the design of its HIV viral load test. The total volume to be used will increase the complexity of the digital microfluidics technology, but the assay shows promising applicability across many HIV clades.

The third company, Prompt Diagnostics, has magnetofluidic sampling expertise and a demonstrated ability to work in complex real-world matrices toward translation of its technology. Prompt Diagnostics participated in a RADx minifunnel program to develop a compact, portable instrument and disposable cartridge, and these will be adapted to meet the specifications of the new TPP. Tradeoffs in sensitivity, time, and instrument and cartridge design will be necessary to be able to use a lower volume of blood, and Prompt has engaged design partners to envision a new configuration of its instrument.

Dr. Mulvaney reiterated that RADx's innovation funnel was pressure tested during the COVID-19 pandemic as a model for technology acceleration and that the team has a demonstrable track record of success. The in-kind services RADx provides can offer more value to projects than funding alone. Expert guidance and mentorship can help teams avoid costly mistakes, and validation support can provide a difficult-to-access resource that de-risks decision making and provides credibility when innovators seek funding. RADx's significant flexibility and partnerships have been key to building sustainable infrastructure and expanding scope, and RADx accelerators are in place for usability, analytical, and preclinical evaluations.

Discussion Highlights

Dr. Mulvaney clarified that all three product development teams currently are separating whole blood to plasma, which guides their current volume choices. Dr. Montaner pointed out that some studies have shown detectable viral load in whole blood when plasma levels are undetectable and encouraged the teams to try using whole blood.

When asked about cost, Dr. Mulvaney explained that no constraints were implemented given that the market currently has no options in this space. The program is designed to accelerate the technology to the regulatory testing stage, and market forces will drive the eventual price. Dr. Mulvaney acknowledged concerns about access but reiterated that options must be developed before they can become accessible.

In response to a question about contracting, Dr. Mulvaney clarified that the value of the contracts is their flexibility to accelerate technologies and provide the underlying structure to support additional achievement.

When asked about options for home testing in more accessible biofluids, Dr. Mulvaney pointed out that the current lower limit of quantitation is unknown and that this program focuses on point-of-care rather than home testing. Developing a home test would require discussions with innovators and the mapping of potential regulatory pathways.

In response to a question about complementary tests for medication adherence, Dr. Mulvaney explained that experts at POCTRN are developing use case settings for different device configurations, as appropriate.

HIV Clinical Practice Guidelines: Strategy Update

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

Dr. Donenberg explained that OARAC coordinates five expert working groups to develop and update the federally approved HIV Clinical Practice Guidelines, which are recommended for use by U.S. health care practitioners and inform the work of practitioners around the world for people with and affected by HIV. The guidelines panels became working groups of OARAC in 2005, with management, publication, and dissemination support provided by NIH's National Library of Medicine until OAR assumed these responsibilities in 2020. Dr. Donenberg emphasized that it has been an honor for OAR to contribute to the health of people affected by HIV. She expressed gratitude for the substantial and dedicated work of the volunteer experts who contribute to the guidelines. OAR is aware of the life-sustaining value of the guidelines and is eager to ensure that they continue to do so.

Amid recent efforts to streamline federal coordination and reduce spending, OAR successfully fought to secure funding to support the guidelines for the next 12 months. After that time, a more limited OAR budget may force OAR to reallocate resources from guidelines management and support to activities more directly related to the office's primary mission of coordinating NIH's HIV research program. Dr. Donenberg characterized the next year as a critical opportunity to proactively plan for a potential transition. OAR initially intended this OARAC meeting to include a broader discussion on this topic; however, after initial outreach to guideline panels, the office received swift and passionate responses expressing concern about plans for the potential transition of guidelines support. Dr. Donenberg noted that OAR deeply appreciates all of the feedback it received—this feedback prompted OAR to change its approach so that public input is obtained in a more coordinated way.

In consultation with the guideline Executive Secretaries and their respective leadership groups, OAR will be creating additional opportunities for input and more in-depth discussions. Dr. Donenberg explained next steps, which are designed to ensure that any transition is informed by federal partners, guideline panel members, and the broader community. First, small-group discussions involving each of the guideline panels will be convened to explore ways to improve the guidelines and gather input about areas of the guidelines to maintain, change, or initiate to ensure relevance across settings. Second, OAR will seek to identify opportunities to enhance the role of the community in the process and streamline and improve the guidelines management and production. OAR is particularly interested in feedback regarding process enhancements. Third, OAR will seek input on the transition of OAR's role in managing and producing the guidelines. Public input may be submitted to OARACinfo@nih.gov. And finally, OAR will discuss the future of the guidelines with HHS and other federal partners and will report back publicly at future OARAC and other federal meetings.

In closing Dr. Donenberg emphasized that OAR's intent is not—and has never been—to eliminate the guidelines. She then invited a discussion on next steps.

Discussion Highlights

Dr. Montaner expressed support for OAR's plans to convene small-group meetings to further discuss these issues, noting that there are significant implications associated with potentially transitioning the guidelines away from OAR. OARAC members emphasized that the guidelines are central to OAR's implementation science goals and the mission of coordinating the NIH HIV research program because the panels translate NIH discoveries into recommendations for use.

OARAC member Dr. Courtney Fletcher expressed concern about the sentiment that the guidelines are not central to coordination of the NIH HIV research program, noting that part of NIH's mission is to foster fundamental discoveries and their applications. Dr. Fletcher indicated that from his perspective, this is exactly what the guidelines do. As a member of one of the panels from 2001 through 2013, he has first-hand experience in a panel taking NIH discoveries and translating them into practice. Dr. Donenberg responded that she understands his perspective and emphasized that the OAR will continue its efforts to ensure that the guidelines are sustained.

Dr. Lisa Abuogi, Co-Chair of the Pediatric ARV Panel, agreed with the importance of soliciting feedback from the larger community regarding a potential transition. She echoed Dr. Fletcher's comments regarding the guidelines being central to OAR's mission. She noted that the guidelines are an example of the implementation of science, and that there may be opportunities to enhance efficiency and reduce cost. She also noted that it would be extremely difficult to find a good fit for the guidelines outside of HHS that could maintain the rigorousness, timeliness, accessibility, trust, and reputation associated with OAR's support. Dr. Abuogi commented that moving the guidelines outside of HHS would de-emphasize the importance of HIV in the United States—moving the guidelines to a smaller organization that does not have the reputation or the ability to provide broad access, it further sends a message that HIV is no longer important in this country. Dr. Donenberg responded that there is no intent to send a message indicating that HIV is not important.

Dr. Roy "Trip" Gulick, academic Co-Chair of the Adult ARV Panel, reminded the group that the guidelines have been in place for several decades and provide important information and guidance for both U.S.-based providers as well as providers around the world. He noted that at international HIV conferences, the guidelines are often referred to as the standard of care for the world and asked for additional information regarding the rationale for OAR's future plans regarding the guidelines. Dr. Donenberg reiterated that proposed budget cuts will likely force OAR to reallocate guidelines resources to activities tied more directly related to OAR's coordinating role. Dr. Gulick followed up by noting that there is a significant volunteer effort that contributes to the guidelines' development, maintenance, and timeliness. He added that in his view, the guidelines are remarkably streamlined and cost effective. He suggested that if cost is a motivating factor, OAR should examine the cost of supporting the guidelines relative to the effectiveness and impact of the guidelines. If there is a perceived disconnect between the guidelines and OAR's mission, Dr. Gulick commented that much of the guidelines work is mission driven. Dr. Donenberg agreed on the importance of distinguishing between cost- and mission-related considerations and recognized the volunteer efforts associated with the guidelines.

Dr. Montaner indicated that future discussions should clarify whether the guidelines could still fit within OAR's limited budget or whether a determination has been made that the guidelines must be transitioned out from the office. He noted that OARAC feedback indicates that there are benefits to retaining the guidelines within OAR that should be considered relative to how they would be maintained elsewhere. Dr. Donenberg reiterated that no final decision has been made about the future home of the guidelines. She added that OAR has laid out the next steps she described earlier in part to determine, from a cost standpoint, whether the guidelines can be more efficiently managed, produced, and disseminated. In response to a follow-up question from Dr. Montaner, Dr. Donenberg acknowledged that it is possible that the guidelines could remain under OAR's purview.

Dr. Abuogi commented in order for future discussions related to enhancing efficiency to take place, transparency is needed regarding the cost for producing and maintaining the guidelines. Dr. Donenberg noted that she agrees with this perspective.

Dr. Montaner concluded this discussion by thanking OAR, guidelines panel leaders, and OARAC members for their commitment to both the field and to those who benefit from the guidelines. He acknowledged the need to preserve that benefit within the current environment and commented that he looks forward to the subsequent discussions as a productive approach for finding a path forward that maintains the guidelines and the important role they play for people living with HIV.

OAR Updates

OAR Innovation Program Symposium

Julio Aliberti, Ph.D., Health Scientist Administrator, OAR, NIH

Dr. Julio Aliberti outlined OAR's Innovation Program, which provides 1 year of funding for meritorious projects that use innovative approaches to address high-priority scientific opportunities in NIH-sponsored HIV/AIDS research. Dr. Aliberti focused on intramural projects, noting that the Innovation Program has awarded 19 to 25 intramural projects each year since FY22, with total funding of $11 million to $14 million. He noted that because tracking is more difficult for intramural than extramural projects, OAR created an Innovation Symposium at which the scientific progress of Innovation Award research is presented. The symposium is also an opportunity for investigators to discuss their research and connect with new collaborators.

Dr. Aliberti pointed out the broad range of topics covered during each Innovation Symposium and noted that the upcoming event, scheduled for September 10, 2025 aligns with the upcoming NIH Research Festival. He requested OARAC members' input on metrics to evaluate long-term impact; ways to support cross-disciplinary teams and whole-person research approaches; strategies to enhance visibility, collaboration, or policy impact; and emerging scientific or policy trends for which OAR should prepare.

Early Career Investigator Engagement Activities

David Chang, Ph.D., Health Scientist Administrator, OAR, NIH

Dr. David Chang outlined OAR's multi-faceted efforts to support early career scientists in HIV research through its Early Career Investigators (ECI) Signature Program. OAR uses the term ECI, to describe researchers either currently pursuing their first substantial NIH independent research award, such as an R01 or DP2, or within the first 2 years after receipt of their first independent award. This term includes but is broader than the NIH's definition of early stage investigators (ESIs), which includes researchers pursuing their first substantial NIH independent research award and within 10 years of completion of their terminal research degree or clinical training. By focusing on ECIs, OAR aims to ensure that the future of HIV research remains innovative and sustainable across multiple disciplines. This priority is embedded in the current NIH Strategic Plan for HIV and HIV-Related Research and will continue in the upcoming plan, which emphasizes building and strengthening NIH's capacity to develop the next generation of HIV researchers. Informed in part by listening sessions, OAR is analyzing ECI awards and trajectories, engaging with the NIH HIV/AIDS Executive Committee's ECI Working Group, organizing an annual ECI workshop, integrating partner feedback to enhance ECI support, and

maintaining partnerships with ICOs. Dr. Chang noted that over the past seven years, an average of about 57 R01 and R01-equivalent awards per year are for ESIs in HIV research.

Dr. Chang described OAR's recent and ongoing initiatives in this area, including annual ECI workshops that have significantly expanded since their launch in 2022, with over 1,100 registrants in 2024. The 2024 workshop featured 18 participating NIH ICOs, breakout sessions with over 40 NIH staff, and presentations from investigators across disciplines and career stages. OAR also organizes listening sessions to directly hear from ECIs about challenges and opportunities, and these insights help inform programmatic planning and resource development. In 2024, OAR prioritized ECI visibility at conferences, such as hosting a spotlight symposium on HIV and aging research at the International Workshop on Aging & HIV. Additional outreach included the development of ICO-specific infographic guides to help ECIs navigate NIH's HIV research ecosystem. Dr. Chang also highlighted a 2024 OAR Director's Seminar that showcased the research trajectory of Dr. Sara Gianella Weibel, an ECI whose success during the COVID-19 pandemic illustrates the potential impact of sustained NIH support. Planning for the 2025 ECI Workshop, scheduled for September 26, has been shaped by real-time feedback from new listening sessions recently held with ECI in HIV research. Despite recent disruptions in NIH-wide communications, OAR remains committed to engaging ECIs through both virtual and in-person strategies, particularly reaching those outside traditional research hubs.

Discussion Highlights

When asked how to proceed with existing pipeline programs amid the current uncertainties, Dr. Chang responded that the listening sessions focus on ECIs because this group has expressed particular concern about their ability to remain in the field. The listening sessions aim to gather a real-time snapshot of the challenges ECIs are facing, which will be summarized and analyzed from multiple perspectives to inform OAR's next steps and shape recommendations to NIH. While these sessions are part of broader efforts to emphasize the need for sustained support and resources, Dr. Chang recommended that investigators speak directly with their NIH program officers to identify feasible strategies for continuing training or applying to alternative funding mechanisms during this challenging time.

In response to a request for input on expanding outreach, attendees suggested targeting medical school research days to engage future physician-scientists early in their training, particularly in light of concerns that interest in infectious diseases is declining among medical trainees. This highlights the need to address pipeline limitations earlier than the ESI stage. Dr. Chang shared that OAR is expanding its presence to non-HIV-specific conferences to reach investigators from diverse disciplines and to encourage fresh perspectives and new ideas in HIV research. Additional outreach opportunities suggested by attendees included collaborations with professional organizations such as the HIV Medicine Association, the Infectious Diseases Society of America, the Association of Nurses in HIV Care, as well as university research offices and biomedical libraries. Previous conference attendees could also be invited to help disseminate information about future opportunities within their networks.

In response to Dr. Aliberti's presentation, OARAC members suggested using metrics that measure output, such as K award applications or membership in honor societies, noting that immediacy of impact is a frequent metric but may be less useful for innovation. Considering the intended purpose of the Innovation Program—to seed high-risk, high-reward research and expand ideas during the funding period—may reveal metrics that are more relevant for this program.

National Advisory Mental Health Council (NAMHC)

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

Dr. Dianne M. Rausch outlined an initiative presented at the September NAMHC meeting to identify treatment strategies for central nervous system (CNS) complications in people with HIV. HIV enters the CNS within eight days of initial infection and causes many complications; antiretroviral therapy reduces the severity, but problems persist, and treatment options are limited. This initiative aims to identify modifiable targets to address CNS complications in people with HIV and employ an approach using personalized, treatable traits to design comprehensive and validated treatment strategies that will improve symptoms and quality of life.

Public Comment

CAPT Mary Glenshaw, Ph.D., M.P.H., OARAC Executive Secretary, Acting Deputy Director, OAR, NIH

CAPT Glenshaw summarized and read 35 public comments received during or in advance of the meeting; most public comments related to the guidelines. In response to the significant volume of public comments received, the comment period remained open for four weeks following the meeting (July 24, 2025). A total of 70 comments received in advance of, during, and after the 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, Acting Deputy Director, 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, Herbert Kean, M.D., Family Professor, The Wistar Institute

Dr. Donenberg thanked those who submitted public comments emphasizing the importance of the guidelines. Dr. Montaner adjourned the meeting at 4:16 p.m. EDT.

Certification

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

Luis Montaner

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

Sept 9, 2025

Date

Mary Glenshaw -S

Digitally signed by Mary Glenshaw -S
Date: 2025.09.09 11:47:20 -04'00'

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

Date

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

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Public Comments Received through July 24, 2025

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PUBLIC COMMENTS READ AT THE MEETING

The following comments were read during the 68th OARAC Meeting.

PUBLIC COMMENT 1

Public comment received: 12:20 pm on June 24, 2025

Comment made by: Lynne Mofenson MD | Former Branch Chief, Maternal and Pediatric Infectious Disease Branch, NICHD (retired 2014) | Senior HIV Technical Advisor

Affiliate, Elizabeth Glaser Pediatric AIDS Foundation

To Director, OARAC,

As the former NIH Panel Chair for the Pediatric, Perinatal and Pediatric Opportunistic Infections (OI) Guidelines Panel when I worked at NICHD, I can testify as to the importance of these guidelines both in the US as well as internationally. For historical background, I am attaching a word document I wrote in 2017 for Henry Masur regarding the history of all three pediatric/perinatal guidelines.

I was chair of the 1994 Public Health Service Task Force on perinatal HIV transmission following February 18,1994 announcement of the PACTG 076 trial results showing that AZT reduced perinatal transmission by 67%. The Task Force included obstetricians, pediatricians, women's health and internal medicine experts in HIV as well as representatives from major HHS agencies (CDC, NIH, HRSA, FDA). Initial guidance was rapidly published in the MMWR on April 29, 1994, and then a more detailed publication on August 4, 1994, following a public meeting in June. These guidelines were critical in providing guidance to clinicians caring for women with HIV, to the FDA, who approved AZT for this indication on August 8, 1994, and to HRSA/ Medicaid, with Medicaid coverage of AZT required in all states on December 5, 1994. Within 3 years, the US had a 65% reduction in new perinatal infections. This Task Force became the Perinatal Panel, meeting monthly since 1998 to develop guidelines updates. By 2013, the US had a 97% reduction in new perinatal infections. In 1994, one in every four mothers with HIV transmitted HIV to their infant; thanks to these guidelines, current transmission rates in the US are <1%. The guidelines are a critical source to clinicians on the most effective and safe antiretroviral drugs for pregnant women with HIV and have had rapid updates within weeks of new data becoming available.

The Pediatric Antiretroviral Therapy Guidelines Panel was initially going to be combined

with the Adult Guidelines Panel, but in recognition of the differences between pediatric and adult HIV infection and the complexities of pediatric drug formulations and dosing, a separate Panel was established in 1998 with expertise in pediatrics, neonatology, adolescent medicine, and pharmacokinetics. Like the Perinatal Panel, it meets monthly to update guidance on pediatric treatment, including importantly on pediatric antiretroviral drug dosing, which varies significantly between newborns, infants, children and adolescents. In 1989, 50% of children with HIV in the US died by age 2 years; thanks to these guidelines providing clinical guidance to clinicians, today children with perinatal HIV infection are young adults, some having uninfected children of their own. The Panel includes pediatric representatives from Canada and Australia, who adapt the US guidelines to their country.

The Pediatric OI Guidelines Panel was initially combined with adult OI guidelines, but recognition of significant differences in OI types and treatment between children and adults, a separate panel was developed, including pediatric infectious disease experts and representatives from DHHS agencies such as CDC, and professional organization such as American Academy of Pediatrics and Pediatric Infectious Disease Society of America.

The unique facets of all of these guidelines Panels include membership of specific experts in the field, members of multiple DHHS agencies, in some cases, representatives from other countries, as well as members of the community affected by HIV to ensure that the guidelines are understandable to the community as well as clinicians - all of who donate their time to provide the best guidance for treatment of children and pregnant women. The imprimatur of the DHHS allows the guidelines to be used by pediatric and obstetric specialty organizations and for reimbursement determination by Medicaid and HRSA. Monthly meetings allow for rapid development of guidance when new data becomes available. These guidelines have made major contributions to the health and lives of persons with HIV in the United States and need to be continued as new therapies are becoming available. Ideally, this would be within the US government to ensure consistency across agencies (NIH, CDC, HRSA, etc) and would include current guidelines group members who understand the history and mechanisms by which the guidelines are developed – members serve 3-year terms and the mechanisms for rotation are such that expertise is maintained year to year.

Thanks for allowing me to comment on the importance of these Panels and their contribution to the health of persons in the US.

Lynne Mofenson, MD

Attachment for Public Comment 1

History of Perinatal, Pediatric and Pediatric OI Guidelines – Lynne Mofenson MD (11/17/2017)

Note on review process:

The review process for the Perinatal and Pediatric guidelines initially was through approval of NIH (NICHD and NIAID) and when published through the MMWR, approval by CDC since MMWR is under CDC leadership. When the Perinatal and Pediatric guidelines panels came under OAR sponsorship and the guidelines moved to electronic publication in the early 2000's, approved rested with the OAR, with NICHD and NIAID staff represented on the Panel (from the NIH approval point of view). CDC is represented on both Perinatal and Pediatric Panels, but official CDC approval was not required for these guidelines, nor was any approval from professional organizations; while membership of these organizations are represented on the Panel, there is no official co-sponsorship of the guidelines from the American Academy of Pediatrics or American College of Obstetricians and Gynecologists. Neither CDC, NIH or any other organization is listed on the title of the guidelines as "sponsor".

The Pediatric OI guidelines are different – they were developed as an outgrowth from the adult OI guidelines, which had developed an official approval/sign-off process through NIH, CDC, and Infectious Disease Society of America (IDSA), all of which are listed as co-sponsors on the title of the guidance. Hence the approval process for the Pediatric OI guidelines is more time consuming, making the guidelines somewhat less timely (there have been delays as long as 12 months for CDC approval). The Pediatric OI guidelines are also officially sponsored by IDSA, the Pediatric Infectious Disease Society and American Academy of Pediatrics; hence review and approval by these organizations has also been required.

There has generally been less urgency with development of updates to the OI guidelines, but the antiretroviral guidelines require flexibility and the ability to rapidly update as new information comes in. Hence, the differences in approval processes has been beneficial to allow timely and needed antiretroviral guidelines updates.

After release of an update on AIDSInfo website, the public is given a 2-week period to submit comments to the relevant Panel, which are reviewed by the Panel to determine if changes are needed and response is sent to the commenter. The public can also comment at any time to AIDSInfo.

PUBLIC COMMENT 2

Public comment received: 6:25 pm on June 24, 2025

Comment made by: Andrew Trotter MD, MPH, FIDSA, FACP | Associate Professor of Clinical Medicine | Medical Director, UI Health Community Clinic Network (UCCN)

Affiliate, University of Illinois College of Medicine/UI Health, Chicago, IL

Dear Office of AIDS Research Advisory Council,

I am writing to you to provide comments regarding the planned transition of the federal HIV guidelines from the NIH to another HHS agency. First, I would like to provide information about my background. I am a HIV clinician with over 15 years of clinical experience taking care of people living with HIV, an Associate Professor of Clinical Medicine in the Division of Infectious Disease in the University of Illinois College of Medicine, medical director of our Ryan White Program (the UI Health Community Clinic Network) and steering committee member of the Ryan White Medical Providers Coalition at the HIV Medicine Association.

The federal HIV treatment guidelines are a critical resource for anyone taking care of people living with HIV in the United States. I personally utilize them for clinical care or refer to them in educational activities almost every day. They serve as the most comprehensive, up-to-date and evidence-based guidelines on treatment of HIV, management of opportunistic infections and perinatal HIV care available in the United States. They are also used as a standard of care for financial and insurance reimbursement considerations, ensuring that people living with HIV will be covered for the cost of appropriate medical care. Finally, they are easily accessible at the point of care.

Though I can understand budgetary and financial constraints, these guidelines must be maintained as a national standard of care for people living with HIV. If the guidelines need to be shifted to another agency in the HHS, it must be done in a way that the guideline review and revision process and administrative and technologic support would be maintained. HIV care is rapidly changing, and the federal HIV guidelines are the most up-to-date resource with readily available updates of the most recent scientific and clinical developments in care. This must be maintained so that people living with HIV in our communities and country have access to the most up-to-date and evidence based care available.

My comments are my own, provided as an experienced HIV provider, educator and

member of HIVMA and not on behalf of my institution.

Please contact me if I can provide any additional information that would be helpful

Best Regards,
Andrew Trotter, MD, MPH

PUBLIC COMMENT 3

Public comment received: 1:42 pm on June 26, 2025

Comment made by: Scott D Bertani, MNM, PgMP | Director of Advocacy

Affiliate, HealthHIV

Given the June 2025 OARAC agenda and the very recent news that NIH will phase out support for the HIV clinical practice guidelines by June 2026, there's growing disquiet about how this transition will be managed—and, importantly, what it may signal more broadly. While there's a dedicated session on guidelines sustainability, the agenda doesn't provide public-facing details about how OAR plans to preserve the rigor and independence of our essential HIV care and prevention data and resources. To us, these aren't just technical documents; rather, they anchor prescribing practices, shape policies under Ryan White, Medicaid Title XIX TCM, CMS, and CMMI, and influence standards of care nationwide and across healthcare systems.

In the current climate—amid federal cuts, rescission and budget reconciliation, workforce losses, and undoing of coordinated HIV infrastructure—shifting oversight without transparency raises important questions for the field. Questions remain whether the guidelines' scope, frequency of updates, and language—particularly as it relates to Black, Brown, Transgender, and other disproportionately affected populations—will remain protected. We look forward to OARAC affirming its commitment to community-informed, evidence-based guidelines and outlining how stakeholder voices will be meaningfully included in the transition.

Sincerely,
Scott D Bertani

PUBLIC COMMENT 4

Public comment received: 12:30 am on June 26, 2025

Comment made by: William J. Connors, MD MPH FRCPC FIDSA | Clinical Associate Professor, UBC, Infectious Diseases, Tuberculosis Medicine, St. Paul's Hospital

Affiliate, St. Paul's Hospital, BC Centre for Disease Control TB Services, New Westminster, BC

OAR,

I wish to express my deep concern about recent reports of ending OAR support of the HIV Clinical Practice Guidelines.

As an HIV care provider and educator I routinely use these exceptional 'evergreen', practical, and evidence based guidelines to inform care and educate students and colleagues. I can think of no other clinical resource I hold is such high regard as these guidelines. I strongly believe that any disruption to the updating process for these guidelines and loss of the high evidence-based standards and exceptional quality of them will be at incalculable cost to patients, providers, and learners both in the US and globally.

Sincerely,
Will Connors

PUBLIC COMMENT 5

Public comment received: 11:45 pm on June 25, 2025

Comment made by: Francesca Torriani, MD, FIDSA, AAHIVS | Program Director of Infection Prevention and Clinical Epidemiology and Tuberculosis Control | Professor of Clinical Medicine

Affiliate, UC San Diego Health, San Diego, CA

Dear OARAC Team,

I am writing to express deep concern and dismay over the reported decision to cut the Department of Health and Human Services (DHHS) Antiretroviral Guidelines Panel.

This decision is troubling because it goes against the core principles of the practice of Medicine, it does not support continued quality improvement and education of the medical profession and is counterproductive to public health. The Panel has been a cornerstone in ensuring that clinicians, researchers, and community stakeholders across the United States and beyond have access to clear, evidence-based, and up-to-

date treatment guidelines for HIV care. These guidelines are consulted by thousands of practitioners and institutions and are regarded globally as a gold standard.

Panel members serve voluntarily, donating their time and expertise without compensation to provide clinicians with the most updated and best quality of care to their patients. To eliminate such a high-impact and low-cost initiative sends the wrong message at a time when consistency, clarity, and trust in public health leadership are more vital than ever.

Disbanding the Panel will hurt the quality of care unnecessarily. It will create confusion in clinical practice, widen gaps in care, and undermine decades of progress in HIV treatment and management. We urge you to reconsider this decision and to reaffirm the federal government's commitment to evidence-based guidelines and expert-led processes in HIV care.

Thank you for your attention and for all that you do to support people living with HIV and the professionals who serve them.

Francesca Torriani, MD, FIDSA, AAHIVS

PUBLIC COMMENT 6

Public comment received: 9:20 pm on June 25, 2025

Comment made by: Sara Gianella Weibel, M.D. | Professor of Medicine | Director of Mentorship and HOPE T32 Training Program | CFAR, Translational Virology Core, Director | ACTG, San Diego Virology Specialty Lab, Director | Last Gift Program, Co-Director

Affiliate, University of California San Diego, La Jolla CA

Dear OARAC Team,

I am writing to express deep concern over the reported decision to cut the Department of Health and Human Services (DHHS) Antiretroviral Guidelines Panel.

This decision is not only short-sighted, it's also counterproductive to public health. The Panel has been a cornerstone in ensuring that clinicians, researchers, and community stakeholders across the United States and beyond have access to clear, evidence-based, and up-to-date treatment guidelines for HIV care. These guidelines are consulted by thousands of practitioners and institutions and are regarded globally as a gold standard.

What makes this decision even more difficult to understand is that Panel members serve mostly voluntarily, donating their time and expertise without compensation. To eliminate such a high-impact, low-cost initiative sends the wrong message at a time when consistency, clarity, and trust in public health leadership are more vital than ever.

Disbanding the Panel will hurt the quality of care unnecessarily. It will create confusion in clinical practice, widen gaps in care, and undermine decades of progress in HIV treatment and management.

We urge you to reconsider this decision and to reaffirm the federal government's commitment to evidence-based guidelines and expert-led processes in HIV care.

Thank you for your attention and for all that you do to support people living with HIV and the professionals who serve them.

Sincerely,

Sara Gianella

PUBLIC COMMENT 7

Public comment received: 2:24 am on June 22, 2025

Comment made by: Peter McKellar, MD

I have been a teacher and clinician in internal medicine and infectious diseases for the past 50 years. The Federal HIV Guidelines are essential to the teaching and practice of HIV medicine. For our government to suddenly curtail their production and use is unconscionable.

I ask that you promptly reconsider that reckless decision.

There are approximately 1.2 million Americans living with HIV. Half the folks living with HIV are over the age of 51 years. There are about 32,000 new HIV diagnoses each year in the USA.

Please reconsider the discontinuance of the Federal HIV guidelines.

Peter McKellar, MD
Phoenix, AZ

PUBLIC COMMENT 8

Public comment received: 1:16 pm on June 21, 2025

Comment made by: Philip Bolduc, MD | HIV Program Director | Associate Professor of Family Medicine and Community Health | Principal Investigator | Vice Chair,

Affiliate, Family Health Center of Worcester, MA | UMass Chan Medical School | New England AIDS Education and Training Center | HIV Medicine Association

Dear Office of AIDS Research,

As someone who has spent their career promoting HIV care in primary care settings, I am deeply alarmed by this week's announcement indicating NIH's decision to step away from producing the DHHS HIV Guidelines. This resource is absolutely essential for people like myself who are on the ground delivering care and educating colleagues, trainees and students in standards of HIV care. Along with the National HIV Curriculum and the National Clinician Consultation Center, the DHHS HIV Guidelines form an indispensable trifecta ensuring that persons with HIV receive not only appropriate, but cost-effective care. I strongly urge you to actively work on finding an alternative division and funding for continued production of the Guidelines within DHHS, perhaps within the HIV/AIDS Bureau. Especially with the proposed cuts to Part F of the Ryan White Program, which would eliminate the AIDS Education and Training Centers, preservation of this these three key national HIV resources is absolutely essential.

Philip Bolduc, MD

PUBLIC COMMENT 9

Public comment received: 8:23 pm on June 23, 2025

Comment made by: David R Boulware MD, MPH, CTropMed, FIDSA | McKnight Distinguished Professor

Affiliate, Infectious Disease & International Medicine, Department of Medicine | University of Minnesota, Minneapolis, MN

Dear Sir/Madam,

The HIV guidelines are a valuable resource for the HIV community in the United States and globally.

The stated rationale for discontinuing guidelines is based on finances. This seems rather remarkable as the vast majority of guidelines panel members are all unpaid volunteers and meetings are via Zoom (or Teams) calls. Volunteers write the guidelines.

Increased transparency would be ideal to share what is the budget for the HIV guidelines? Re-evaluating the costs would be the first step, instead of ending all support.

David

PUBLIC COMMENT 10

Public comment received: 10:14 pm on June 25, 2025

Comment made by: Hayden Andrews, M.D.

Dear NIH OAR,

I am a physician caring for people with HIV in Dallas, TX and use the DHHS ART, OI, and perinatal guidelines at least once per week to help with challenging cases. I have come to trust them as the authoritative source of information given the rigorous vetting of science and carefully selected members of the panels. They are updated frequently allowing them to serve as a living document.

I am quite distressed to learn of the plan to phase out the guidelines. It's hard to imagine another body being able to take this effort on in a similarly effective way. Moreover other guideline statements from professional organizations like IDSA are often updated every 5-10 years. Which is a major problem for them to stay current.

I urge the NIH and OAR leadership to reconsider this approach and continue the panels in their current form.

Sincerely,
Hayden Andrews, M.D.

PUBLIC COMMENT 11

Public comment received: 6:46 pm on June 25, 2025

Comment made by: Peter Solberg M.D. | Staff Physician | Associate Professor of Medicine, Infectious Disease Section

Affiliate, Dartmouth, Hanover NH

I’m writing, in light of your upcoming meeting on 6/26, to register my strong support of the utility of the Treatment Guidelines and my hope that NIH will reconsider any thought that they should not be a top funding priority under NIH’s specific high-quality supervision. As an HIV clinician in relatively rural New Hampshire, I cannot understate how much the guidelines provide the key role of disseminating best practice throughout the country, not only to clinicians in the big population centers. More and more, as we rely on a relatively inexperienced workforce often supported by associate providers, there is no substitute for the clear, evidence-based, super-practical strategies the guidelines have always offered. I would hope we could help recast to senior HHS leadership this notion that the Guidelines are in fact cost-effective and the BEST use of limited taxpayer dollars, rather than something the country can afford to deprioritize.

Thank you for your consideration.

Peter Solberg MD

PUBLIC COMMENT 12

Public comment received: 9:59 pm on June 25, 2025

Comment made by: Lynda Dee | Executive Director

Affiliate, AIDS Action Baltimore

Attached please find a letter to OARAC on the HIV Guidelines submitted for the record.

Thank you for your attention to this matter.

Lynda Dee

Attachment for Public Comment 12

Thank you for the opportunity to submit comments regarding the future of the National Institute of Health’s HIV guidelines. I am very disappointed that the discussion scheduled for today’s public session was essentially removed from the OARAC’s meeting agenda. I respectively urge NIH to ensure that the decisions regarding the HIV guidelines are made in a public and transparent manner with the opportunity for input from the HIV community, particularly individuals whose lives are directly impacted by their availability.

I strongly urge the NIH not to abandon its support for the five clinical guidelines that have set the standard for HIV care for more than three decades. The guidelines have

improved the lives of countless people with HIV and through an inclusive and community-driven process are a model for guideline development and community engagement.

While I recognize NIH is not in the business of guideline development, the institution took a bold and lifesaving step when it decided to develop guidelines that would better ensure the rapid advances in the HIV field were reaching those who need them and were not just being presented at conferences or published in esteemed medical journals. This was particularly important to ensure that people with HIV living outside of areas with HIV and ID experts, which are many, could benefit from the highly effective HIV treatment developed with support from NIH. The guidelines helped, and continue to help, to erode the stigma and discrimination that people with HIV face in finding and accessing treatment due to provider resistance and insecurity.

NIH's decision to discontinue support for the NIH guidelines could not be more ill-timed, and I fear is part of a broader strategy to abandon the HIV community and our country's efforts to end the HIV epidemic. The health and public health programs that people with HIV and their providers count on all are all under attack. The loss of the expert, unbiased and reliable HIV clinical guidelines that we have counted on to set a gold standard for HIV treatment across the life span will be a major blow and put the lives of Americans at risk.

I strongly urge NIH to reconsider this decision and instead work with the NIH guideline working group leaders and the HIV community to develop a strategy for reducing the budgetary costs of maintaining the guidelines without compromising their accessibility, timeliness and scientific rigor. Your consideration is greatly appreciated.

Very truly yours,
Lynda Dee, Executive Director

PUBLIC COMMENT 13

Public comment received: 1:57 pm on June 24, 2025

Comment made by: Sara Hurtado Bares, MD | Associate Professor, Division of Infectious Diseases

Affiliate, University of Nebraska Medical Center

Dear Office of AIDS Research,

I am writing to express my strong concern about the proposed phase-out of NIH support for the federal HIV clinical practice guidelines. As a clinician and HIV researcher, I have relied on these guidelines throughout my career to provide high-quality, evidence-based care to people living with HIV. Their potential discontinuation represents a significant threat to both providers and patients nationwide.

These guidelines have long served as the gold standard for HIV care in the United States. They are distinguished by their scientific rigor, clinical relevance, and timely responsiveness to emerging evidence. From the first prophylaxis recommendation for opportunistic infections to the most recent updates in antiretroviral therapy and perinatal care, the guidelines have consistently delivered high-impact, practical guidance that has improved care outcomes and saved lives.

The collaborative, multidisciplinary process that drives these guidelines — led by expert volunteer panels and supported by highly skilled NIH staff — is unmatched in both integrity and scope. This model has not only enhanced the credibility and adoption of the guidelines across clinical settings, but also contributed to equitable and standardized care nationwide.

The suggestion that another agency within HHS might assume responsibility for these guidelines is deeply concerning. No other agency has the infrastructure, clinical expertise, or established process to maintain the same level of quality and timeliness. Without continued NIH support, I fear the guidelines will become static, fragmented, or altogether inaccessible — all of which would be profoundly detrimental to patient care.

At a time when we are striving to end the HIV epidemic, this is not the moment to weaken one of our most effective and trusted tools. I urge the Office of AIDS Research and NIH leadership to reconsider this decision, and to continue providing the necessary resources to support the ongoing development and dissemination of the federal HIV clinical guidelines.

Thank you for your attention and for your continued commitment to improving the lives of people living with and at risk for HIV.

Sara Hurtado Bares, MD

PUBLIC COMMENT 14

Public comment received: 10:12 pm on June 25, 2025

Comment made by: Pablo Tebas, M.D. | Professor of Medicine

Affiliate, University of Pennsylvania, Philadelphia, PA

I would like to express my strong support for the continued development and maintenance of the NIH Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV and other NIH HIV associated guidelines

For more than 25 years, these guidelines have been an indispensable resource, offering timely, evidence-based, and practical recommendations that have directly improved clinical outcomes for people living with HIV. They have served as a model for how to translate clinical research into meaningful, real-world impact—a principle that aligns directly with the increasing emphasis on implementation science.

These guidelines have consistently enabled the rapid adoption of more effective and less toxic antiretroviral regimens, guided by clinical expertise and consensus rather than bureaucratic inertia. Their frequent updates, responsiveness to emerging data, and clear, actionable guidance have distinguished them from traditional society guidelines, which are often less nimble and more consumed by process than by patient-centered utility.

The leadership of Dr. Cliff Lane and Alice Pau has been instrumental in ensuring the integrity, scientific rigor, and independence of this effort. The process has been transparent, conflict-of-interest has been carefully managed, and most importantly, the guidelines have remained independent from industry influence—a feature that has given them unmatched credibility.

Globally, these guidelines have served as a model for HIV treatment policy, referenced widely and adapted internationally. The modest investment required to sustain them is negligible compared to the lives saved and the improved quality of care they enable.

I urge OARAC and NIH leadership to preserve this guideline program in its current form and continue to support it as a vital public health tool.

Thank you for the opportunity to comment.

Sincerely,
Pablo Tebas, M.D.

PUBLIC COMMENT 15

Public comment received: 6:06 pm on June 25, 2025

Comment made by: Terri Christene Phillips, DM | Executive Director

Affiliate, Pediatric Infectious Diseases Society, PIDS Foundation, Arlington, VA

Dear Mary,

Thank you again for providing submission guidance. Attached are the comments from the Pediatric Infectious Diseases Society for your consideration during tomorrow's OARAC meeting.

Please let me know if you have any questions.

Attachment for Public Comment 15

Dear OARAC members:

On behalf of the Pediatric Infectious Diseases Society (PIDS), we are writing to express our deep concern regarding the National Institutes of Health (NIH) decision to phase out support for the federal HIV clinical practice guidelines by June 2026. As a professional society representing pediatric infectious diseases specialists and researchers, many of whom are directly involved in the care of infants, children, and adolescents with HIV infection or at risk, we urge the Council to reconsider this decision and to advocate for continued federal leadership in the development and dissemination of these essential guidelines.

The current HIV clinical practice guidelines, developed and regularly updated by expert working groups under the auspices of the NIH Office of AIDS Research (OAR) and OARAC, are foundational to the delivery of high-quality, evidence-based care for over one million individuals living with HIV in the United States. These guidelines provide critical guidance for clinicians caring for all populations, including adolescents, children, and pregnant women. For pediatric patients, the guidelines are especially vital, as they address unique challenges such as early infant diagnosis and treatment, prevention of perinatal transmission, and the management and prevention of opportunistic infections in children.

It is important to reflect on the significant value these guidelines have provided in shaping an informed, evidence-based standard for HIV care in the United States. From their inception, they have marked critical milestones such as the first recommendation for trimethoprim-sulfamethoxazole (TMP/SMX) prophylaxis to prevent Pneumocystis pneumonia (PCP) in infants. This recommendation led to a 21.5% annual decrease in

PCP incidence from 1996 to 1998 and the near elimination of PCP as a cause of pediatric AIDS mortality by the early 2000s. Similarly, the initial perinatal guidelines, informed by the landmark ACTG 076 trial, resulted in a dramatic reduction in infant HIV acquisition: from 25% in the early 1990s to less than 1% by 2017, virtually eliminating perinatal HIV transmission in the United States.

Over the years, the guidelines have continued to evolve, consistently incorporating findings from practice-changing studies. Their status as a “living document,” with timely and regular updates, has enabled a level of responsiveness that traditional medical journals cannot match.

The federal guidelines serve as a key resource for clinicians, ensuring that all patients regardless of age or circumstance, receive care informed by the latest scientific evidence and best practices. They also play a significant role in shaping insurance coverage decisions and federal health policies, directly impacting access to life-saving diagnostics, treatments, and prevention services.

The loss or diminishment of these guidelines would create uncertainty for clinicians and patients alike, potentially leading to fragmented care and widening health disparities.

We urge the NIH and OARAC to maintain federal support for the HIV clinical practice guidelines and to ensure that their management remains under the stewardship of a body with the expertise and resources necessary to sustain their rigor, independence, and relevance. Rather than discarding decades of federal investment in HIV care guidelines, the NIH should collaborate with the federal guideline panels to prioritize key elements, streamline processes, and reduce costs. Public input from guideline users and the broader HIV community should also be solicited. Sustaining these evidence-based guidelines is especially critical amid ongoing workforce shortages and the erosion of our public health infrastructure.

The Pediatric Infectious Diseases Society stands ready to collaborate in any transition planning and to provide ongoing input to safeguard the health and well-being of children and adolescents affected by HIV.

Thank you for your consideration. Feel free to contact Christy Phillips, PIDS Executive Director, via email (cphillips@idsociety.org) should you have any questions.

PUBLIC COMMENT 16

Public comment received: 1:51 pm on June 24, 2025

Comment made by: Lisa Kanengiser M.D.

I am a practicing HIV provider at an NYC public hospital. I have been practicing HIV care for over 30 years. I have referred to these guidelines on a weekly basis to treat my patients. They have guided me in treated ill patients, treatment of pregnant HIV + women to prevent transmission to their babies, treat and prevent opportunistic infections. These continually updated guidelines are indispensable in the practice and care of HIV. I implore you to keep these guidelines.

Lisa Kanengiser MD

PUBLIC COMMENT 17

Public comment received: 1:51 pm on June 24, 2025

Comment made by: Jose M. Miro, MD PhD FESCMID/FIDSA | Senior Consultant, Infectious Diseases Service | Professor of Medicine

Affiliate, University of Barcelona, Barcelona, Spain

To whom it may concern,

As an international member of the expert panel for these guidelines for more than 20 years, I want to let you know that the guidelines on opportunistic infections are a global benchmark, are perfectly up-to-date, and are helping physicians around the world properly prevent and treat HIV-infected patients with opportunistic infections. These guides are saving lives! Their educational and healthcare work is invaluable, and I certainly believe their role should not be changed in the future. If anything, it should be strengthened.

I remain at your disposal for any clarification or questions.

Sincerely yours,
JMM

PUBLIC COMMENT 18

Public comment received: 3:50 pm on June 25, 2025

Comment made by: Kirk Fetters, MD | Division of Infectious Diseases

Affiliate, University of Colorado, Boulder CO

Dear Dr. Donenberg and other members of the OARAC,

I recently learned of the plan to remove OAR support for the NIH HIV/AIDS treatment guidelines. I strongly disapprove of this plan. The HIV treatment guidelines and clinicalinfo.hiv.gov are essential resources for both physicians and patients. The adult, pediatric, and perinatal HIV treatment guidelines, adult and pediatric guidelines for opportunistic infections, and other resources available on clinicalinfo.hiv.gov are invaluable for treatment of HIV or sequelae of HIV in uncommon scenarios that many clinicians, even infectious diseases specialists, may not have much experience treating. The hard work put into these guidelines by many talented clinicians and researchers over the years have improved and standardized HIV care around the country. While alternative guidelines exist at IAS, these treatment guidelines are not as tailored to the lived reality of clinicians and our patients here in the United States.

I also do not support transitioning these guidelines to another agency/entity within HHS. OAR has developed relationships and expertise with the guideline contributors that is unmatched in the rest of the Department.

This proposed change also comes in context of the unprecedented removal of CDC sexually transmitted infections guidelines, national HIV datasets, and all current ACIP members, plus the vaccine skepticism at FDA and cancellation of many HIV-related NIH research grants creates the appearance that the Department of Health and Human Services no longer supports research in or clinical care of infectious diseases. If true, this is a short-sighted policy goal that will result in many more people dying of preventable or treatable diseases.

Kirk Fetters, MD

PUBLIC COMMENT 19

Public comment received: 11:20 pm on June 25, 2025

Comment made by: Thomas Martin | UCSD ID physician

Affiliate, VA San Diego, San Diego CA

Dear OARAC Team,

I am writing to express deep concern over the reported decision to cut the Department of Health and Human Services (DHHS) Antiretroviral Guidelines Panel.

I am an HIV provider and am astonished that this invaluable committee is being disbanded. Thousands of providers like myself in the US, and others all around the world, depend on this guidance for expert and up to date recommendations regarding the optimal treatment of HIV.

To believe that individual providers have the time to review the extended literature, make complex cost efficacy analyses, and evaluate complex drug-drug interaction including pharmacokinetic evaluation is ridiculous and dangerous to patient care.

If you have interest in improving the cost effectiveness of HIV care I would be more than happy to discuss directly with anyone who cares to contact me. There are millions and millions of dollars in healthcare savings to be made that don't require thoughtless cutting of volunteer academics.

Yours sincerely,

Thomas Martin (he/him/his)

PUBLIC COMMENT 20

Public comment received: 3:34 pm on June 25, 2025

Comment made by: Susana Williams Keeshin, MD, AAHIVS | Associate Professor of Pediatrics and Internal Medicine

Affiliate, Division of Infectious Disease, University of Utah Health, Salt Lake City, UT

Hello,

I am an adult and pediatric ID/HIV physician who works in a relatively low HIV incident state, Utah. The Adult, Pediatric and Perinatal Guidelines are the most important HIV guidelines for my fellow colleagues in Family Practice, Pediatrics and Internal Medicine in the US. Below is a brief list of why they need to be continued under DHHS and their importance.

1. As a rural state the Perinatal Guidelines offer on demand support 24h for woman and infants living or affected by HIV in the Intermountain West. There is only one Pediatric ID group that serves all of UT, ID, parts of NV, ID, MT and western CO and it is nearly impossible for us to take consults even by phone and telemedicine for all infants born to a mother with HIV.

2. Not only do guidelines help working physicians and APC's it also serves as a tool for medical students, residents and fellows which are evidence based and updated regularly.
3. HIV changes rapidly with each year new medications and 1,000's of studies published yearly. The guidelines offer a place that no other source consolidates and review pertinent information yearly.
4. People living with HIV have an active role on each guideline committee which allows one of the few cases to have their important voice heard to help shape the guidelines towards a more patient centered approach.
5. The guidelines improve patient outcomes by recommending the most effective treatment, reducing morbidity and mortality and preventing opportunistic infections.
6. The guidelines identify areas of research that need further investigation, thus driving innovation in HIV diagnosis, treatment and prevention.
7. The guidelines are the source that guides public and private insurance coverage in a timely manner for those living or affected by HIV.
8. The guidelines include highly respected and leaders in HIV researchers, clinicians and the community across the US which gives validity unmatched any other guidelines.

Sincerely,

Susana Williams Keeshin, MD, AAHIVS

PUBLIC COMMENT 21

Public comment received: 1:42 pm on June 26, 2025

Comment made by: Brian Epling, MD, MHS | Staff Clinician

Affiliate, Division of Intramural Research/NIAID, National Institutes of Health

Good morning,

As both an HIV provider and researcher here at the NIH, I have turned to the OI Guidelines countless times. The Guidelines are an immense source of information and are an excellent synthesis of a vast field of research. Furthermore, the Guidelines

identify gaps in knowledge where further research is needed. This has served as an invaluable way to generate ideas and discussion.

In an environment where the care of people with HIV worldwide has been curtailed and HIV research has come under threat, it should be OAR's duty to continue to be an advocate for HIV research and care. By no longer supporting the Guidelines, OAR would be sending a message to the entire HIV community - including patients, providers, and researchers - that it does not consider the knowledge that the field has generated, and continues to generate, to be worth preserving and advancing. I sincerely hope that OAR reconsiders this decision.

Sincerely,
Brian Epling

PUBLIC COMMENT 22

Public comment received: 11:55 am on June 26, 2025

Comment made by: Elizabeth Laidlaw PA-C

Affiliate, National Institutes of Health

My name is Elizabeth Laidlaw, I'm a Physician Assistant (PA-C) and work at the National Institutes of Health (NIH) in infectious disease clinical research. I’m emailing to voice my support for the need to continue the federal HIV guidelines. I reference these guidelines frequently in order to ensure I’m providing the best medical care for my patients. I know they provide reliable, up to date information that I can reference quickly or can read more in depth as needed. I have also referred many PA and medical students over the years to these guidelines as they are an educational and highly practical source of information that I know they can continue to use to manage the medical care of patients living with HIV.

Thank you for your time.

Elizabeth Laidlaw PA-C

PUBLIC COMMENT 23

Public comment received: 6:06 pm on June 26, 2025

Comment made by: Eileen Scully MD, PhD

Affiliate, *(no information provided with public comment)*

Dear all – I am writing to express my concern about the ending of support for the ART Guidelines. As an HIV care provider for close to 20 years and a member of the panel over the last 3 years, I think that the guidelines are definitive of the public service that the DHHS should be supporting. The panel's many expert providers carefully review and debate the data, summarize it clearly and transparently report the findings for the use of care providers across the country and the world. The volume of data reviewed and synthesized in these guidelines is immense and it is a resource for both quick decision making and also for deeper consideration of the evidence base when unusual cases arise.

The guidelines are a clear public service that cannot be replaced or supported in their full scope and to phase out support is to lose a tremendous amount of investment. Please reconsider this decision and take a closer look at the incredible level of efficiency, the scope of voluntary time and effort from experts in the field, and the tremendous impact for providers that these guidelines have. I feel confident that you will continue to support this public good which has direct benefits to the American people.

Sincerely,

Eileen Scully MD, PhD

PUBLIC COMMENT 24

Public comment received: 3:17 pm on June 26, 2025

Comment made by: Alison C. Roxby, MD, MSc | Associate Professor, Departments of Medicine and Global Health

Affiliate, University of Washington, Seattle, WA

As a practicing HIV clinician, the DHHS guidelines are invaluable. I reference them all the time and they help me to perform the highest quality care for my patients. I hope that the guidelines can continue as a trusted source of information. There really is no other easily accessible resource that can be used for this purpose.

Sincerely, Alison Roxby

PUBLIC COMMENT 25

Public comment received: 3:01 pm on June 26, 2025

Comment made by: Christine Jamjian, Pharm.D., AAHIVP, BCPS

Affiliate, *(no information provided with public comment)*

I am writing to ask that you keep the DHHS HIV guidelines. Those guidelines allow us to provide the best up to date care possible to our patients. Throughout my 30 years career in taking care of this patient population I have relied heavily on those guidelines. In my teaching career I also have used the guidelines as a very valuable resource to teach the next generation of pharmacists. I also believe these guidelines to be the best guidelines available to us to take care of a disease.

Christine Jamjian, Pharm.D., AAHIVP, BCPS

PUBLIC COMMENT 26

Public comment received: 3:52 pm on June 26, 2025

Comment made by: Athe Tsibris, MD, MS | Associate Professor of Medicine

Affiliate, Brigham and Women's Hospital, Cambridge, MA

Dear OARAC,

I write to express my strong feelings that the DHHS HIV Guidelines, in all their forms, should be maintained and supported by the Federal Government. This is the single most important source of clinical information that we use at the point of care. These guidelines are mission-critical and a very worthy government function that contributes to making America great.

These guidelines define HIV care for the world – we are leaders in this space – and provide such a value to the community and to Americans across our great Nation.

Please make America great and retain these important guidelines and the work of the volunteers across academia who make these critical efforts possible.

Athe

PUBLIC COMMENT 27

Public comment received: 5:15 pm on June 26, 2025

Comment made by: Jennifer Janelle, M.D.

Affiliate, *(no information provided with public comment)*

To Whom It May Concern:

I was dismayed and concerned to learn of plans to end OAR support for federal HIV guidelines. I am an HIV care provider and educator both locally at a medical school and regionally through a federally funded training center. I use these guidelines nearly daily in providing care and in teaching and believe the loss of these unbiased and carefully considered guidelines will result in significant reductions in people providing optimal care to those with or at risk for HIV. Providers rely on these guidelines to help quickly make care decisions in real time. These decisions can mean the difference between life and death.

For many years, there have been efforts to expand the HIV workforce outside of infectious disease providers. Primary care providers have been willing to care for patients, particularly in underserved parts of our nation because they don't have to filter through numerous papers but can rely in carefully vetted studies with outcomes clearly summarized in these guidelines. Without this unbiased and carefully considered information, I believe we will lose providers who lack focused HIV expertise but are willing to provide care with the support of these guidelines.

Combined with the proposed changes with these guidelines has been substantial cuts to Part F Ryan White HIV/AIDS programs which have for years helped develop and disseminate research and education to organizations and providers caring for those with HIV. These compounding losses, if not stemmed, will result in loss of knowledge and expertise that will set back the progress we have made in ending the HIV epidemic in our own country.

Without these guidelines, providers will likely rely on biased information from the pharmaceutical industry that may not be in the best interests of public health, the health of individuals, or the financial health of our healthcare system.

Please take steps to ensure the ongoing support for the national HIV guidelines to continue to be updated as living documents by unbiased experts in the field of HIV treatment and prevention as they are currently.

Thank you for your consideration.

Jennifer Janelle, MD
Gainesville, FL

PUBLIC COMMENT 28

Public comment received: 7:57 pm on June 19, 2025

Comment made by: Sarah McBeth, MD MPH

Affiliate, *(no information provided with public comment)*

Hello,

I am an Infectious Disease physician and HIV specialist in Pittsburgh, PA. I frequently use the HIV Clinical Practice Guidelines currently available at https://clinicalinfo.hiv.gov/en/guidelines

These are an important source of up to date information regarding the nuances of caring with people for HIV. I've found these guidelines especially critical in the care of people with infrequently seen opportunistics infections. They are also a critical tool for teaching our future HIV care providers.

I urge you to maintain these guidelines online, accessible to all, and as a living document updated with expert input.

Thank you,

Sarah McBeth, MD MPH

PUBLIC COMMENT 29

Public comment received: 4:36 pm on June 26, 2025

Comment made by: Nicola Dee, PA

Affiliate, *(no information provided with public comment)*

I have read with surprise that there are plans to discontinue federal funding for the HIV guidelines. As you know, these guidelines are continuously updated by the world's leading HIV experts at NIH. The panel includes physicians, scientists and pharmacists whose life work has been the advancement of HIV care, based on the most recent and exhaustive peer reviewed research. Those taking care of patients living with HIV rely on these expansive guidelines as a roadmap to provide the correct antiretroviral medications, recommendations regarding reducing transmission and the treatment of opportunistic infections.

If I may speak personally, as a clinician at the NIH (now retired), I referred to these guidelines on a very regular basis, confident in knowing that they had been made by an

extraordinarily dedicated panel of experts who created these documents after intense focus and attention to detail and laborious discussion to reach concensus.

Nicola Dee, PA (retired).

PUBLIC COMMENT 30

Public comment received: 12:39 pm on June 26, 2025

Comment made by: Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA)

Affiliate, Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA)

Office of AIDS Research Advisory Council Meeting
June 26, 2025
Statement for the Record
Tina Q. Tan, MD, FIDSA, FPIDS, FAAP, President, Infectious Diseases Society of America
Colleen Kelley, MD, MPH, FIDSA, Chair, HIV Medicine Association

Thank you for the opportunity to offer comments on behalf of the Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) regarding the National Institute of Health's decision to stop supporting its five federal HIV Clinical Guidelines that have set the standard for HIV treatment in the United States for more than three decades. IDSA is a community of 13,000 clinicians, scientists and public health experts working together to solve humanity's smallest and greatest challenges, from tiny microbes to global outbreaks. Within IDSA, HIVMA is a community of more than 6,000 physicians and other health care professionals who work on the frontlines of the HIV epidemic in communities across the country.

We write to urge NIH to reconsider the decision to discontinue support for the guidelines given their immense value to HIV clinical care and their critical role in promoting an effective response to the HIV epidemic in the U.S. We also respectfully urge for all discussions regarding the future of the NIH guidelines to be public and transparent so that the large community of infectious diseases and HIV clinicians, general pediatricians and clinicians and people with HIV who count on the guidelines can follow and inform the process.

Implementation Science, Improving Patient Care and Strengthening Public Health
We are deeply concerned about the impact of NIH's decision to terminate the HIV

guidelines on people with HIV and on efforts to dramatically reduce HIV transmission in the United States. Decades of groundbreaking NIH-supported HIV research resulted in the medical advances that transformed HIV from a near certain fatal disease to a complex chronic condition for people with access to appropriate HIV care and treatment.

We commend NIH for recognizing early in the HIV epidemic the importance of ensuring that the latest scientific discoveries were rapidly translated into clinical care and easily accessible to clinicians caring for people with HIV. In doing so – NIH has saved lives and made it possible for people with HIV in communities across the country to benefit from the HIV treatment developed with federal funding. These guidelines are especially important to care providers in rural or other areas that lack access to HIV experts. Guidelines allow these providers to implement the most recent research findings and to deliver state-of-the art patient care. The maintenance of the guidelines as living documents that clinicians can count on for the latest and best medical evidence has been a critical factor in their success in informing and improving patient care. The NIH guidelines also have played an important role in informing coverage and services provided by federal health programs and health insurers.

The HIV antiretroviral treatment guidelines for adults and adolescents and for children are rapidly updated to incorporate peer-reviewed research on newly approved and emerging antiretroviral agents, including when and what to start, drug-drug interactions, laboratory monitoring and use in special populations such as those with kidney disease or concurrent infections such as hepatitis B and C. The perinatal HIV guidelines are critical to ensuring infants and their parents stay healthy during pregnancy and following delivery. The opportunistic infections guidelines are critical to prevent severe adverse health consequences in children and adults and adolescents with weakened immune systems if they do not receive timely and effective diagnosis and treatment. They address nearly 30 infections that take advantage of people with weakened immune systems, such as community-acquired pneumonia, tuberculosis and toxoplasmosis.

Health Outcome and Health Care Cost Impacts

We are concerned that NIH is moving away from federal HIV guidelines as a short-term cost saving measure without consideration of the impact on patient outcomes or the increased health care expenditures for patients whose clinicians no longer have access to guidance to appropriately manage their treatment. It is well documented that people with HIV who are prescribed the most effective HIV treatment for them soon after diagnosis will have better health outcomes and have lower health care costs due to the need for less intensive care and treatment. The prevention of vertical transmission is one of the most cost-effective interventions in HIV care, saving money

and averting costly pediatric HIV infections. The intervention provides a substantial benefit and very good economic value to maternal health.

In addition, with the federal retreat on HIV prevention infrastructure and services, ensuring people with HIV are effectively treated will be essential for their health and for preventing HIV transmissions. The NIH guidelines level the playing field by ensuring that clinicians without HIV expertise can quickly and effectively go to a reliable source to provide evidence-based and accurate care.

Increased Demand for HIV Clinical Guidance

As reported at the October 2024 OARAC meeting – utilization across all five of NIH's federal HIV guidelines is high and continues to increase demonstrating the ongoing importance and need for the guidelines. As an example, from 2021 to 2024– page views for the Adult HIV antiretroviral guidelines increased by 22% from 574,463 to 701,894.

In addition to infectious diseases and HIV specialists relying on NIH's guidelines to stay up-to-date on the most optimal HIV treatment recommendations, the guidelines are a lifeline for primary care providers, pediatricians and obstetrician-gynecologists who play an important role in caring for people with HIV but manage fewer patients or provide episodic HIV care. The NIHinfo.gov online platform has been essential to ensuring the guidance is widely accessible to non-HIV specialists in a format that is available at any time at the point of care site.

The guidelines play a pivotal role in the training of doctors, nurses, pharmacists, and other members of the care team. The need for up-to-date HIV treatment guidelines will continue to grow as the ID and HIV clinical workforce faces unprecedented threats and constraints due to cuts and delays in funding for federal HIV programs, including the AIDS Education and Training Centers. Prior to a decline in federal support for ID and HIV programs and research, nearly 80% of U.S. counties did not have a single ID physician with rural counties being less likely to have ID experts. A study conducted in 14 Southern states with some of the highest rates of new HIV transmissions found that 80% did not have access to a single experienced HIV clinician with once again the disparities being greatest in rural areas.

NIH's Unique Role in Federal HIV Guidelines

The NIH HIV guidelines are used widely in practice because of the expertise, rigor and credibility that NIH brings to guideline development on complex highly specialized HIV treatment and clinical issues. In addition, the guidelines often highlight research gaps that provide valuable feedback to NIH for its research agenda planning process and are important to inform priority areas for implementation science. The unbiased scientific

expertise and approach that NIH has brought to the guidelines has ensured that major breakthroughs in NIH-supported research could be rapidly implemented to benefit patient care, such as AIDS Clinical Trials Group Protocol 076 that demonstrated the effectiveness of zidovudine at preventing perinatal transmission, a transformative intervention with a dramatic impact on patient care. We are concerned that transferring the guidelines within HHS without the NIH's scientific expertise, resources and the infrastructure that has been developed over decades will compromise the integrity of the guidelines and ultimately put at risk the health and lives of millions of people with HIV.

Evolving the Guidelines at NIH
We appreciate the pressures to lower budgetary costs in the current environment. As an alternative to abandoning the decades of federal investments in the guidelines, we urge NIH to meet with the leadership of the five federal guideline panels to identify key elements of the guidelines to prioritize for maintenance, strategies for streamlining the process and other recommendations for lowering the cost associated with maintaining the guidelines. We also strongly recommend soliciting public comments from the users of the guidelines and the HIV community.

Evidence-based HIV care and treatment allows people with HIV to stay healthy while also stopping HIV transmission and lowering health care costs. ID and HIV workforce shortages and the erosion of our country's public health infrastructure heighten the importance of sustaining NIH's federal HIV guidelines as the gold standard for HIV treatment.

In closing, we are grateful for NIH's leadership in developing and maintaining clinical guidelines that have been influential in changing the trajectory of the HIV epidemic in the U.S.

Thank you for considering our comments and recommendations.

Contact Information: Tina Q. Tan, MD
Colleen Kelley, MD, MPH titan@luriechildrens.org colleen.kelley@emory.edu

PUBLIC COMMENT 31

Public comment received: 3:38 pm on June 26, 2025

Comment made by: Jenna Januszka Secretary/Treasurer on behalf of the American College of Clinical Pharmacy's HIV Practice and Research Network.

Affiliate, American College of Clinical Pharmacy's HIV Practice and Research Network.

Attn.: Dr. Donenberg, Associate Director for AIDS Research and Director, Office of AIDS Research, NIH
Subject: Urgent Request to Maintain NIH Support for Federal HIV Clinical Practice Guidelines

Dear Dr. Donenberg,

On behalf of the American College of Clinical Pharmacy's HIV Practice and Research Network (ACCP HIV PRN), we write to express our profound concern regarding the recent announcement that the National Institutes of Health (NIH) will remove support for the federal HIV clinical practice guidelines by June 2026.

Since our establishment in 2014, the ACCP HIV PRN has comprised pharmacists from the United States, Canada, and Saudi Arabia, all committed to advancing the care, outcomes, and research of people living with or at risk for HIV. Our membership relies extensively on the U.S. Department of Health and Human Services (HHS) HIV clinical guidelines as guidance to provide evidence-based care and recommendations to promote consistent and lifesaving care equitably to all in need. Ongoing access to these high-quality guidelines is imperative; their absence could lead to preventable loss of life.

These guidelines represent the global resource for the prevention and treatment of HIV and HIV associated opportunistic infections across the lifespan. Maintained through NIH, this document allows for adoption of peer-reviewed, scientific evidence and expert consensus into clinical practice. The impact of these guidelines extends far beyond U.S. borders, as reflected in their adoption and application by clinicians worldwide, including within our international membership.

The planned discontinuation of NIH support threatens the integrity, reliability, and availability of this vital resource. We are particularly concerned about the implications of transferring responsibility without a clear and transparent plan to preserve the rigorous standards, regular updates, and global reach that have long defined the HHS guidelines. Such a move risks undermining decades of progress in HIV care and could hinder ongoing efforts to end the HIV epidemic.

We respectfully and urgently urge the NIH and the Office of AIDS Research to reevaluate and reverse this decision. Continued NIH support is essential to safeguard the integrity, authority, and global utility of these guidelines, which remain an irreplaceable cornerstone of HIV clinical practice. Thank you for your attention to this critical matter.

Sincerely,
Jenna Januszka
Secretary/Treasurer

PUBLIC COMMENT 32

Public comment received: 4:39 pm on June 25, 2025

Comment made by: Erin Ready, BSc(Pharm), ACPR, MPH, AAHIVP | 2025-2026 Chair, Canadian HIV and Viral Hepatitis Pharmacists Network (CHAP) | Clinical Pharmacy Specialist, St. Paul's Hospital Ambulatory Pharmacy | Clinical Assistant Professor, Faculty of Pharmaceutical Sciences, The University of British Columbia

Affiliate, Canadian HIV & Viral Hepatitis Pharmacists Network (CHAP)

Dear Dr. Donenberg,

Please find attached a letter from the Canadian HIV & Viral Hepatitis Pharmacists Network (CHAP) executive expressing our strong support for the continued NIH sponsorship of the federal HIV clinical practice guidelines. These guidelines are essential to ensuring consistent, evidence-based care for people living with HIV in the USA, across Canada, and abroad.

Thank you for your attention to this matter and we appreciate your ongoing commitment to public health and HIV care.

Sincerely,
Erin
Erin Ready, BSc(Pharm), ACPR, MPH, AAHIVP (she/her)

Attachment for Public Comment 32

Subject: Letter of Support for Continued NIH Sponsorship of the Federal HIV Guidelines

Dear Dr. Donenberg,

On behalf of the Canadian HIV & Viral Hepatitis Pharmacists Network (CHAP), we are writing to express our deep concern regarding the recent announcement that the National Institutes of Health (NIH) will phase out support for the federal HIV clinical practice guidelines by June 2026.

CHAP is a national network of pharmacists across Canada dedicated to optimizing care

for individuals living with HIV and/or viral hepatitis. Since our formation in 1997, we have collaborated on clinical practice, research, and education to improve patient outcomes for those with HIV and those at risk of acquiring HIV (eg. prevention of HIV). Our members rely heavily on the HHS HIV guidelines as a trusted, evidence-based resource that informs our clinical decisions and ensures consistency in care across diverse healthcare settings.

The HHS HIV guidelines have long served as a gold standard in HIV treatment, offering timely, rigorously reviewed, and accessible recommendations that are invaluable to clinicians worldwide. These guidelines also provide critical recommendations that reduce the risk of HIV transmission to unborn children and guide management of children with HIV. Their living-document format allows for rapid integration of emerging evidence, which is critical in a field where treatment paradigms evolve quickly. The guidelines' influence extends far beyond U.S. borders — they are a cornerstone in global HIV care, including here in Canada.

We are deeply concerned that discontinuing NIH support will jeopardize the quality, credibility, and accessibility of these guidelines. The proposed transfer of responsibility to another to-be-determined agency raises serious questions about feasibility, continuity, and the preservation of the guidelines' high standards. The loss of NIH stewardship would be a significant setback for clinicians and patients alike.

We urge the NIH and the Office of AIDS Research to reconsider this decision and to recognize the irreplaceable value these guidelines provide to the global HIV community. Continued NIH support is essential to maintaining the integrity and utility of this critical resource. Thank you for your attention to this matter and for your ongoing commitment to improving the lives of people living with HIV.

Sincerely,
Erin Ready
Chair, Canadian HIV and Viral Hepatitis Pharmacists Network (CHAP) on behalf of the CHAP Executive Committee

PUBLIC COMMENT 33

Public comment received: 4:48 pm on June 26, 2025

Comment made by: Treatment Action Group

Affiliate, Treatment Action Group

Treatment Action Group Comments for the Office of AIDS Research Advisory Council (OARAC) Meeting, June 26, 2025

Treatment Action Group appreciates the opportunity to submit public comments to the Office of AIDS Research Advisory Council (OARAC) Meeting of June 26, 2025.

TAG writes to advocate for the unconditional reversal of the decision to end NIH's commitment to producing HIV treatment guidelines. This guidance for multiple populations — including transgender people — serves a vital role in keeping clinicians, caregivers, people with HIV, and advocates up to date on the latest developments as new interventions are approved and/or important new data becomes available.

As with other significant changes being rushed through by the current administration, there's no evidence that any analysis was conducted to justify the decision to end NIH's support for the guidelines, and suggestions that the work could be facilitated elsewhere are vague and unconvincing.

We completely oppose the decimation of grant awards on multiple important topics that address realities that the current administration finds unpalatable for political reasons, and prefers to deny. As reported in an analysis by the scientific journal *Nature*,[1] preferentially targeted grants were HIV/AIDS and transgender health related awards. Around half the grants on LGBTQI+ topics have been cut compared to 2024.

A broad spectrum of other peer-reviewed NIH funding commitments for work involving topics claimed to be related to diversity, equity, inclusion, and accessibility (DEIA) have also been revoked, without any clarity over how the current administration defines these terms or what they believe them to mean. Homogeneity, inequity, exclusion and inaccessibility are all clearly anathema to the NIH's mission to support scientific research. These cuts have now been ruled illegal and discriminatory by Judge William G. Young of the Federal District Court for the District of Massachusetts, a Reagan appointee with 40 years of experience. Young stated: "This represents racial discrimination and discrimination against America's LGBTQ community, that's what this is."[2]

The recent termination of a peer-reviewed NIH funding commitment to an HIV vaccine development consortia that was making crucial progress toward the induction of broadly

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[1] Kozlov M, Ryan C. How Trump 2.0 is slashing NIH-backed research — in charts. Nature. 2025 April 10.

[2] Montague Z. Trump's Cuts to N.I.H. Grants Focused on Minority Groups Are Illegal, Judge Rules. New York Times. 2025 June 16.

neutralizing antibodies (bNAbs) egregiously undermines the award process. OARAC should question how this termination occurred and why required procedures weren't followed.

We urge OARAC members to pay attention to the plight of the HIV trial networks who, after playing a vital emergency role in the development of COVID-19 vaccines, are being rewarded with withheld funding and terminations of grants to institutions at which key data collection and analysis centers reside. The networks have also been roiled by the unjustifiable decision to prevent funding to South Africa and the subsequent "pause" on funding for all international subawardees, including clinical trial units. The NIH has a legal obligation to ensure appropriate care and safety monitoring for clinical trial participants.

The recent approvals of injectable cabotegravir and twice-yearly lenacapavir for pre-exposure prophylaxis (PrEP) — widely hailed as breakthroughs — would not have been possible without international research sites. In addition, clinical trials over the past two decades which have advanced tuberculosis (TB) care and prevention in adults and children — many co-infected with HIV — would not have been possible without international sites. Finally, better treatment regimens for HIV and cure-related research among infants, children, adolescents, and around pregnancy also requires the participation of international sites.

# # #

About TAG: Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and hepatitis C virus. TAG works to ensure that all people with HIV, TB, and HCV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions.

PUBLIC COMMENT 34

Public comment received: 4:44 pm on June 16, 2025

Comment made by: Loren Klein | Director of Health & Wellness

Affiliate, Phyllis B. Frank Pride Center of Rockland County, Nyack, NY

To whom it may concern,

Cutting funding for HIV research is extremely short sighted and politically motivated.

The world is on the brink of being able to prevent HIV via vaccine and to cure HIV through globally coordinated research. Multiple candidate vaccines move through the testing pipeline each year. It will only take one to succeed. Each year, more people are functionally cured of HIV via stem cell transplants. While these transplants are only indicated for use in people with advanced cancers, each case teaches scientists more about the biological mechanisms at play. Thus, getting closer to a functional cure for the general population.

Pretending that the “NIH expects to be shifting its focus towards using currently available approaches to eliminate HIV/AIDS" means that the NIH is content to have Americans continue to contract HIV, become sick, and die. The current approaches to preventing HIV are not perfect. They are made less effective when the federal government cuts funding to support them. It is also made less effective when there is a Supreme Court case to ban the ACA from covering PrEP because it "promotes homosexual behavior." In context, it is clear that the NIH does not actually expect the "currently available approaches" to in fact "eliminate HIV/AIDS." Perhaps it expects undesirable Americans to die of AIDS.

The decision to cut NIH funding for HIV research is short sighted and politically motivated. This decision is not popular with the American people. It is not ethical or in line with Christian values.

Sincerely,
Loren Klein

PUBLIC COMMENT 35

Public comment received: 6:41 pm on June 25, 2025

Comment made by: John Meade Jr., MPH | Co-Chair

Affiliate, Federal AIDS Policy Partnership

Good afternoon,
Please see attached Public Comment for the 68Th OARAC meeting on behalf of the Federal AIDS Policy Partnership (FAPP) Research Working Group. If it’s possible to give remarks verbally, please let us know.

Please reach out to myself or Kendall if you have any questions.

Attachment for Public Comment 35

Dear Dr. Donenberg,

On behalf of the Federal AIDS Policy Partnership's Research Working Group, we thank the National Institutes of Health (NIH) Office of the Director for the opportunity to provide public comment for the 68th Meeting of the NIH Office of AIDS Research Advisory Council (OARAC).

The Research Working Group (RWG) of the Federal AIDS Policy Partnership (FAPP) is a coalition of national and local HIV/AIDS research advocates, patients, clinicians and scientists from across the country. Our goal is to advance and support U.S. leadership to accelerate progress in the field of HIV/AIDS research and related comorbidities across our government's publicly funded research institutions. As the FAPP RWG, we submit these comments to OARAC:

My name is John Meade Jr., and I serve as Co-Chair of the FAPP Research Working Group and as a Senior Program Manager of Policy at AVAC. I also had the honor of serving as a community representative on the NIH OAR HIV Strategic Plan Behavioral and Social Sciences Research Task Force.

Today, I rise with deep concern about the future of our HIV research infrastructure and a call to action for this body to safeguard the values of equity, evidence, and accountability that must guide our work.

The FY26 President's Budget proposes a disastrous 36.4 percent cut to NIAID and a 41.9 percent cut to the Office of AIDS Research (OAR). These are not just budget line items— and if passed these cuts represent a significant setback for thousands of researchers, providers, and, most importantly, the communities who rely on NIH supported science to stay alive. Jeopardizing the U.S. standing as a scientific superpower, in which its publicly funded research has been a core diplomatic and peace building strategy by improving the lives of millions of people worldwide and in the U.S. that suffer from health conditions like HIV/AIDS, tuberculosis, hepatitis, STIs, and other infectious diseases.

These cuts would halt promising research on long-acting PrEP, HIV cure strategies, and comorbid conditions such as cancer, mental health, and substance use—all of which disproportionately impact Black, Brown, and LGBTQ+ communities here and abroad. They also threaten to erase the hard-won gains in building community trust and

participation in research, especially among populations historically excluded from clinical trials. Their participation and leadership in clinical research have been critical to informing and implementing the next generation of prevention and therapeutics that are tailored to community needs, bridging the gap between R&D and programmatic implementation.

As someone who has contributed to the development of the OAR Strategic Plan with a focus on behavioral and social sciences, I know firsthand the importance of not just biomedical innovation but equitable implementation. Simply put: we need more funding for research that examines how to build trust, address stigma, and overcome systemic barriers to access—not less.

We urge OARAC to:

- Publicly oppose these proposed cuts in the FY26 budget proposal and defend OAR's coordinating role across NIH.
- Advocate for at least $3.953 billion for NIH HIV and AIDS research, as identified in the Professional Judgment Budget.
- Reinforce the importance of community led research and investments in implementation science and equity frameworks like the People's Research Agenda1.
- Push for transparency and accountability regarding how NIH grant terminations are being handled under the current administration.

Federally funded science in HIV has brought us extraordinary prevention breakthroughs—from daily PrEP to a just recently approved twice yearly injectable — but it is equitable access, community engagement, and sustained federal investment that will determine whether we end the epidemic or allow it to regress. Scaling up these interventions and investing in new technologies is required to achieve sustainability in the domestic and global epidemics and bring us closer to an end to HIV/AIDS everywhere.

We welcome the opportunity to continue working with OARAC and NIH leadership to ensure that HIV research is community centered, scientifically sound, and adequately resourced. For any questions regarding this comment, please contact the co-chairs of the FAPP Research Working Group: John Meade at john@avac.org and Kendall Martinez-Wright at kendall.martinez.wright@treatmentactiongroup.org.

Thank you for your time and for your leadership. We look forward to hearing from you and for further action from the NIH to address these urgent issues of racial equity in HIV-related research.

Sincerely,

John Meade and Kendall Martinez-Wright, on behalf of the FAPP RWG

END OF PUBLIC COMMENTS READ AT THE MEETING

PUBLIC COMMENTS NOT READ AT THE MEETING

The following comments were received, but not read during the meeting due to incorrectly routed or late submission. They are included below for the record.

PUBLIC COMMENT 36

Public comment received: 6:54 pm on June 26, 2025

Comment made by: Jill Blumenthal, MD MAS | Professor of Medicine

Affiliate University of California, San Diego,

Dear OARAC Team,

I am writing to express my concern over the reported decision to cut the Department of Health and Human Services (DHHS) Antiretroviral Guidelines Panel.

This decision is both short-sighted and counterproductive to public health. The Panel has been a cornerstone in ensuring that clinicians, researchers, and community stakeholders across the US and beyond have access to clear, evidence-based, and current treatment guidelines for HIV care. These guidelines are consulted by thousands of practitioners and institutions and are regarded globally as a gold standard.

What makes this decision even more difficult to understand is that Panel members serve voluntarily, donating their time and expertise without compensation. To eliminate such a high-impact, low-cost initiative sends the wrong message at a time when consistency, clarity, and trust in public health leadership are more vital than ever.

Disbanding the Panel will hurt quality of care unnecessarily, and it will create confusion in clinical practice, widen gaps in care, and undermine decades of progress in HIV management. We urge you to reconsider this decision and to reaffirm the federal

government’s commitment to evidence-based guidelines and expert-led processes in HIV care.

Thank you for your attention and for all that you do to support people living with HIV and the professionals who serve them.

Sincerely,

Jill Blumenthal, MD MAS

PUBLIC COMMENT 37

Public comment received: 7:58 pm on June 27, 2025

Comment made by: Rachel Husmann, M.D.

Affiliate *(no information provided with public comment)*

Dear colleagues,

As an HIV clinician, I am devastated to hear that the Office of AIDS Research Advisory Council intends to phase out support for the US DHHS HIV Related Guidelines. These guidelines have supported the clinical work we do and have informed our clinicians and learners since their inception in the 1990's, based on rigorous science and expert opinion where the data are lacking. Moving the guidelines away from OARAC working groups could destabilize the objective non-government input from voluntary panel members, and decrease the trust that clinicians currently place in the guidelines.

We routinely reference these guidelines in clinic to advise patients, make decisions based on best practice and evidence-based medicine and teach our future generations of clinicians. The potential loss of these guidelines will be palpable and will directly and deeply impact the quality of care we are able to provide and the quality of medical education for future generations to come. I sincerely encourage you to reconsider this loss of investment for our nation and medical field, which has the potential to lead to the preventable deaths and to put persons in all communities throughout the United States at risk for HIV without guidance on best practices from our nation's experts.

As clinicians for persons living with HIV, we rely on our colleagues and their expertise to help elevate and continually inform our medical practice to be optimally up-to-date, and to scrutinize and condense the available evidence to allow us to most efficiently and effectively elevate the care we provide to our patients. The US DHHS HIV Related Guidelines committee helps to maintain an updated document that allows every HIV

clinician to reference this in order to deliver the highest quality of care possible in day-to-day clinical practice through the time, dedication and expertise of those who have invested their lives in research in this field and who are best equipped to analyze and summarize the available literature. Without a doubt, HIV care delivery and our patients living with HIV in this country will suffer from the loss of these guidelines.

I strongly urge you to reconsider this ill-informed decision. The health of our society and all people in this country will be at risk with the loss of these guidelines.

Sincerely,

Rachel Husmann, MD

PUBLIC COMMENT 38

Public comment received: 6:32 pm on June 27, 2025

Comment made by: Keith Henry, M.D., | Professor of Medicine University of Minnesota Medical School Positive Care Clinic | Director-St Paul Department of Public Health STD/HIV Clinic

Affiliate, University of Minnesota Medical School; Hennepin County Medical Center

Dear Colleagues,

As an HIV clinician and researcher, I am very upset to hear that the Office of AIDS Research Advisory Council intends to phase out support for the US DHHS HIV related Guidelines. I started the first HIV clinic in Minnesota in 1985 and served on the guidelines panel for years. These guidelines have supported the clinical work we do and have informed our clinicians and learners since their inception in the 1990's, based on rigorous science and expert opinion where the data are lacking. Moving the guidelines away from OARAC working groups could destabilize the objective non-government input from voluntary panel members, and decrease the trust that clinicians currently place in the guidelines.

We routinely reference these guidelines in clinic to advise patients, make decisions based on best practice and evidence-based medicine and teach our future generations of clinicians. The potential loss of these guidelines will be palpable and will directly and deeply impact the quality of care we are able to provide and the quality of medical education for future generations to come. I sincerely encourage you to reconsider this loss of investment for our nation and medical field, which has the potential to lead to the

preventable deaths and to put persons in all communities throughout the United States at risk for HIV without guidance on best practices from our nation's experts.

As clinicians for persons living with HIV, we rely on our colleagues and their expertise to help elevate and continually inform our medical practice to be optimally up-to-date, and to scrutinize and condense the available evidence to allow us to elevate the care most efficiently and effectively we provide to our patients. The US DHHS HIV related Guidelines committee helps to maintain an updated document that allows every HIV clinician to reference this to deliver the highest quality of care possible in day-to-day clinical practice through the time, dedication, and expertise of those who have invested their lives in research in this field and who are best equipped to analyze and summarize the available literature. Without a doubt, HIV care delivery and our patients living with HIV in this country will suffer from the loss of these guidelines.

I strongly urge you to reconsider this ill-informed decision. The health of our society and all people in this country will be at risk with the loss of these guidelines.

Sincerely,

Keith Henry, MD

PUBLIC COMMENT 39

Public comment received: 12:19 pm on June 27, 2025

Comment made by: Constance Laflamme

Affiliate *(no information provided with public comment)*

Dear OARAC Leadership,

I am writing to express deep concern over the decision to phase out NIH support for the federal HIV clinical practice guidelines by June 2026.

I support you and the work you do, knowing that these guidelines are not just documents — they are the backbone of standardized, evidence-based HIV care in the United States. Clinicians across the country rely on them daily to make informed treatment decisions, respond to emerging research, and improve patient outcomes. The rigor, responsiveness, and collaborative structure of the NIH-led panels have made these guidelines a gold standard.

What’s especially troubling is how **cost-effective** this initiative is. The entire program costs NIH an estimated **$1.2 to $2.2 million annually** — a rounding error in the

agency’s nearly $50 billion budget. Panelists volunteer their time. There are no stipends, and the infrastructure already exists. Yet eliminating this effort shifts a vastly greater burden — in both **time and dollars** — to clinicians and health systems nationwide.

Without these federal guidelines:

- Clinicians will need to navigate and reconcile **multiple fragmented or conflicting protocols**, costing an estimated 5–10 hours per month per provider.
- Institutions may face **increased administrative, legal, and compliance risks**.
- Professional organizations will be forced to duplicate what NIH already does with rigor and integrity.
- Most importantly, **patients will suffer** from inconsistent care and avoidable delays.

In short, cutting the guidelines doesn't save money — it **redistributes cost and chaos** onto those already delivering care in a strained system. Tell me who else I can write to to express my concern! I have written NIH, and my senators. Thank you for the work you do.

This is not the time to eliminate a program that works. I urge HHS to reconsider this decision, or at the very least, ensure a transparent and workable transition plan that preserves the quality, independence, and accessibility of these national standards.

Sincerely,

Constance Laflamme

PUBLIC COMMENT 40

Public comment received: 4:28 pm on June 27, 2025

Comment made by: Amanda Noska, M.D., M.P.H. | Medical Director, Positive Care Center | Assistant Professor of Medicine

Affiliate, University of Minnesota; Hennepin Healthcare

Dear Colleagues,

As a clinician and Medical Director of a RWCA funded clinic that provides care to over 3,000 persons with HIV, the largest HIV clinic in Minnesota, I am devastated to hear that the Office of AIDS Research Advisory Council intends to phase out support for the US

DHHS HIV related Guidelines. These guidelines have supported the clinical work we do and have informed our clinicians and learners since their inception in the 1990's, based on rigorous science and expert opinion where the data are lacking. Moving the guidelines away from OARAC working groups could destabilize the objective non-government input from voluntary panel members, and decrease the trust that clinicians currently place in the guidelines.

We routinely reference these guidelines in clinic to advise patients, make decisions based on best practice and evidence-based medicine and teach our future generations of clinicians. The potential loss of these guidelines will be palpable and will directly and deeply impact the quality of care we are able to provide and the quality of medical education for future generations to come. I sincerely encourage you to reconsider this loss of investment for our nation and medical field, which has the potential to lead to the preventable deaths and to put persons in all communities throughout the United States at risk for HIV without guidance on best practices from our nation's experts.

As clinicians for persons living with HIV, we rely on our colleagues and their expertise to help elevate and continually inform our medical practice to be optimally up-to-date, and to scrutinize and condense the available evidence to allow us to most efficiently and effectively elevate the care we provide to our patients. The US DHHS HIV related Guidelines committee helps to maintain an updated document that allows every HIV clinician to reference this in order to deliver the highest quality of care possible in day-to-day clinical practice through the time, dedication and expertise of those who have invested their lives in research in this field and who are best equipped to analyze and summarize the available literature. Without a doubt, HIV care delivery and our patients living with HIV in this country will suffer from the loss of these guidelines.

I strongly urge you to reconsider this ill-informed decision. The health of our society and all people in this country will be at risk with the loss of these guidelines.

Sincerely,

Amanda Noska

PUBLIC COMMENT 41

Public comment received: 2:53 am on June 30, 2025

Comment made by: Megan K. Shaughnessy, M.D., M.S. | Infectious Disease Staff Physician | Associate Professor of Medicine | Medical Director of the International Travel

Medicine clinic | Director of the Global Health Pathway | Co-course Director of the University of Minnesota Global Health Course

Affiliate, Hennepin Healthcare; University of Minnesota

Dear Colleagues,

As an ID physician, I am devastated to hear that the Office of AIDS Research Advisory Council intends to phase out support for the US DHHS HIV related Guidelines. These guidelines have supported the clinical work we do and have informed our clinicians and learners since their inception in the 1990's, based on rigorous science and expert opinion where the data are lacking. Moving the guidelines away from OARAC working groups could destabilize the objective non-government input from voluntary panel members, and decrease the trust that clinicians currently place in the guidelines.

We routinely reference these guidelines in clinic to advise patients, make decisions based on best practice and evidence-based medicine and teach our future generations of clinicians. The potential loss of these guidelines will be palpable and will directly and deeply impact the quality of care we are able to provide and the quality of medical education for future generations to come. I sincerely encourage you to reconsider this loss of investment for our nation and medical field, which has the potential to lead to the preventable deaths and to put persons in all communities throughout the United States at risk for HIV without guidance on best practices from our nation's experts.

As clinicians for persons living with HIV, we rely on our colleagues and their expertise to help elevate and continually inform our medical practice to be optimally up-to-date, and to scrutinize and condense the available evidence to allow us to most efficiently and effectively elevate the care we provide to our patients. The US DHHS HIV related Guidelines committee helps to maintain an updated document that allows every HIV clinician to reference this in order to deliver the highest quality of care possible in day-to-day clinical practice through the time, dedication and expertise of those who have invested their lives in research in this field and who are best equipped to analyze and summarize the available literature. Without a doubt, HIV care delivery and our patients living with HIV in this country will suffer from the loss of these guidelines.

I strongly urge you to reconsider this ill-informed decision. The health of our society and all people in this country will be at risk with the loss of these guidelines.

Sincerely,
Megan K. Shaughnessy, MD MS

PUBLIC COMMENT 42

Public comment received: 11:43 am on June 22, 2025
**OARACinfo mailbox experienced a technical issue and this message was not received until after the meeting.*

Comment made by: Kathy Thompson, M.D.

Affiliate, *(no information provided with public comment)*

Dear Friends,

I have been a physician caring for HIV-infected patients since 2007. The federal HIV guidelines have been invaluable to providing care and information for these patients.

As I join the wave of retiring physicians who have the experience of providing medically necessary to HIV-infected patients, I worry that the care these patients received will be impacted by a lack of experienced HIV doctors and crucial information such as the federal HIV guidelines.

To say that this will cut costs and save money is folly. If HIV infections are not treated adequately the medical costs of caring for the HIV infections and the consequent opportunistic infections will be staggering.

Please do not let this happen.

Sincerely,
Kathy Thompson, MD

PUBLIC COMMENT 43

Public comment received: 2:59 am on June 24, 2025
**OARACinfo mailbox experienced a technical issue and this message was not received until after the meeting.*

Comment made by: David M. Allen, M.D.

Affiliate, *(no information provided with public comment)*

Dear Colleagues

Writing as a tax-payer and an Infectious Diseases physician, please undertake and share transparently a non-partisan 20 year cost-benefit economic analysis of the proposed change.

Sincerely yours,
David M. Allen, MD

PUBLIC COMMENT 44

Public comment received: 7:44 pm on June 24, 2025
**OARACinfo mailbox experienced a technical issue and this message was not received until after the meeting.*

Comment made by: Nichole Regan, RN, BSN, MSN, APRN-NP-C

Affiliate, *(no information provided with public comment)*

Good afternoon. I am writing as a specialty HIV nurse practitioner, and a concerned citizen and taxpayer.

I am aware that the Office for AIDS Research committee is meeting on June 26 to consider a phase out of NIH support of the HIV treatment guidelines in the coming year. Please be aware that these guidelines are referenced by me, my colleagues, educators, those being educated--including Frontline primary and acute care providers, students, researchers, and even consumers of HIV care to assure the most up-to-date knowledge and expertise is applied in daily clinical practice. I strongly urge you to reconsider the NIH support phase out. Passing the responsibility to HHS is not an acceptable alternative at this time.

Best,
Nikki Regan, RN, BSN, MSN, APRN-NP-C

PUBLIC COMMENT 45

Public comment received: 11:05 pm on June 24, 2025
**OARACinfo mailbox experienced a technical issue and this message was not received until after the meeting.*

Comment made by: Kaitlyn Rivard on behalf of the Society of Infectious Diseases Pharmacists

Affiliate, the Society of Infectious Diseases Pharmacists

To the Office of AIDS Research Advisory Council,

The attached comments are respectfully submitted on behalf of the Society of Infectious Diseases Pharmacists regarding the upcoming OARAC meeting to discuss withdrawal of funding for the HIV Clinical Practice Guidelines.

Thank you,
Kaitlyn Rivard
Vice Chair, Policy & Government Affairs Committee
SIDP

Attachment for Public Comment 45

Comment from the Society of Infectious Diseases Pharmacists

As a federal advisory committee under the National Institutes of Health (NIH), the role of The Office of AIDS Research Advisory Council (OARAC) is to "advise the Director of the NIH's Office of AIDS Research (OAR) on planning, coordinating, and evaluating HIV/AIDS research activities across NIH and to provide guidance on the NIH Strategic Plan for HIV and HIV-Related Research, as well as on policy and program updates in HIV science."

In light of NIH's announcement that support of the guidelines will phase out by June 2026, the Society of Infectious Diseases Pharmacists (SIDP) is concerned that we will lose this critical resource for up-to-date HIV/AIDS management.

We strongly advise a reconsideration of this move and continued funding of these guidelines for the following reasons:

1. Progress in combating the HIV Epidemic in the US is nothing short of a miracle.

2. The HIV Clinical Practice Guidelines, funded by the Office of AIDS Research and the NIH, are an essential resource to healthcare providers to effectively:
    - Treat the 1.2 million Americans (children, adolescents, and adults) living with HIV
    - Prevent and treat opportunistic infections, in both patients with HIV and with other immunocompromising conditions such as cancer
    - Prevent mother-to-child transmission of HIV

3. Straightforward, evidence-based guidelines for the use of simplified, safe, and effective antiretroviral therapy (ART) needs continued support because it:

- Transforms HIV infection from a death knell into a manageable chronic condition
- Extends life expectancy to that of people without HIV
- Prevents transmission of HIV in people with undetectable viral loads, including that of a mother to an infant

4. It is important to have one body that oversees the development of HIV/AIDS research activities and government funding to protect the lives of the American people.

The HIV Clinical Practice guidelines are truly an indispensable resource for US healthcare providers.

- Timely: The NIH manages the largest portfolio of HIV/AIDS related research activities in the US and across the globe. HIV Clinical Practice Guidelines are updated frequently to incorporate the cutting-edge, robust clinical trial data that results from these NIH-funded studies.
    - All guidelines have been updated within the past year.

- Relevant: Recommendations for safe and effective therapy are crafted to be relevant to the needs of the United States population.
    - The timeliness and practicality of updates in including the most up-to-date clinical trial data makes them a go-to document for front-line clinicians, including those who are not infectious diseases specialist practitioners.
    - The guidelines are designed to improve the quality of life of people living with HIV by recommending a switch to better tolerated, simplified regimens as they become available.

- Accessible: Easily accessible to frontline healthcare providers
    - The guidelines are organized and outlined in a clear manner making it is easy for users to find the information they readily need for in the moment patient care.
    - They are essential for caring for people living with HIV in rural or other medically underserved areas that have limited access to infectious diseases specialists.

- Impactful: Opportunistic infections secondary to HIV-related immunodeficiency have significantly decreased in the age of effective ART.
    - Guidelines are critical to manage OIs when they do occur among those with uncontrolled or undiagnosed HIV infection
    - Scientific basis for treatment and prevention in other vulnerable populations, such as solid organ and bone marrow transplant recipients, and those on other immunosuppressive therapies

For these reasons, we ask the committee to please continue to fund and support this critical work. The health and safety of people living with HIV across the United States depends on it.

PUBLIC COMMENT 46

Public comment received: 2:19 pm on June 25, 2025
**OARACinfo mailbox experienced a technical issue and this message was not received until after the meeting.*

Comment made by: Marin Babb

Affiliate, *(no information provided with public comment)*

Dear NIH,
It has come to my attention that you are considering withdrawing your support for federal HIV guidelines. I am adding my voice to those of many concerned citizens.

The federal guidelines are a critical resource for people living with HIV, and to medical professionals working to treat and prevent the virus. These evidence-based guidelines are essential. Volunteer support allows them to remain up to date at a minimal cost compared to the value they provide. These volunteers make the guidelines a living document, factoring in ever-evolving research and data. We need you to stand with the medical professionals who collaborate with you to make this resource available.

Thanks to tireless, heartbreaking work by medical practitioners spanning decades, we have an opportunity to end HIV and AIDS in the modern world. Government funding and support has already been cut from this area. This is bafflingly short-sighted in a moment where we could be eradicating this illness. Withdrawing support now risks a backslide in years of progress--to the detriment of us all.

I ask you to continue your support of these guidelines.

Marin Babb

PUBLIC COMMENT 47

Public comment received: 1:42 pm on June 26, 2025
**OARACinfo mailbox experienced a technical issue and this message was not received until after the meeting.*

Comment made by: Susan E. Hoover, MD, PhD, FIDSA

Affiliate, *(no information provided with public comment)*

Dear Council members,

I just became aware of the plan to end NIH support for the HIV clinical practice guidelines. I am an infectious disease physician and I use those guidelines at least weekly in my care for people with HIV. They are current, carefully reviewed, evidence based, and contain the input of experts in the field in a variety of disciplines.

It would be very wasteful to start over with a different group, different agency, different structure. The guidelines are truly an example of valuable government work and the implementation of decades of American scientific research. Maintaining and updating them should be a budget priority.

Thank you,
Susan E. Hoover, MD, PhD, FIDSA
Seattle, WA

PUBLIC COMMENT 48

Public comment received: 2:31pm on July 7, 2025

Comment made by: Jessica Oswald, DO | Infectious Diseases Physician
Associate Program Director, Internal Medicine Residency | Assistant Professor of Medicine
Affiliate, University of Minnesota; Hennepin Healthcare, Minneapolis, MN

Dear Colleagues,

As an HIV clinician and clinician-educator to medical students, residents, and fellows, I am devastated to hear that the Office of AIDS Research Advisory Council intends to phase out support for the US DHHS HIV related guidelines. These guidelines have supported the clinical work we do and have informed our clinicians and learners since their inception in the 1990's. Moving the guidelines away from OARAC working groups could destabilize the objective, non-government input from voluntary panel members and decrease the trust that clinicians currently have in the guidelines.

We routinely reference these guidelines in clinic to advise patients, make decisions based on best practice and evidence-based medicine, and to teach the future generations of clinicians. The potential loss of these guidelines will be palpable and will directly and deeply impact the quality of care we are able to provide and the quality of medical education for future generations to come. I sincerely encourage you to

reconsider this loss of investment for our nation and medical field, which has the potential to lead to preventable deaths and to put persons in all communities throughout the United States at risk for HIV without guidance on best practices.

As a clinician caring for persons living with HIV, I rely on my colleagues and their expertise to help elevate and continually inform our medical practice to be optimally up-to-date, and to scrutinize and condense the available evidence to allow us to most efficiently and effectively elevate the care we provide to our patients. The US DHHS HIV related guidelines committee helps to maintain an updated document that allows every HIV clinician to reference this in order to deliver the highest quality of care possible in day-to-day clinical practice through the time, dedication and expertise of those who have invested their lives in research in this field and who are best equipped to analyze and summarize the available literature. Without a doubt, HIV care delivery and our patients living with HIV in this country will suffer from the loss of these guidelines.

I strongly urge you to reconsider this ill-informed decision. The health of our society and all people in this country will be at risk with the loss of these guidelines.

Sincerely,
Jessica Oswald, DO

PUBLIC COMMENT 49

Public comment received: 8:02 pm on July 9, 2025

Comment made by: Sylvia LaCourse MD, MPH
Affiliate, *(no information provided with public comment)*

I am writing to express my strong support for the HIV Clinical Care Guidelines. As an HIV clinician, I rely on these guidelines regularly—both in the clinic and while on hospital service—to efficiently access accurate, up-to-date information for patient care. They are also an invaluable resource in educating the next generation of healthcare providers, offering content that is expertly prepared and rigorously vetted.

As the primary reference for HIV treatment and prevention in the US in both adults and children, the guidelines offer clear, evidence-based recommendations for diagnosing, managing, and preventing opportunistic infections. Importantly, they also include critical guidance on the management of HIV during pregnancy, supporting the health of both mothers and infants.

Their accessibility and reliability make them an essential tool for delivering high-quality HIV care.

Sylvia LaCourse MD, MPH

PUBLIC COMMENT 50

Public comment received: 9:51 pm on July 10, 2025

Comment made by: Megan Duffey, MD
Affiliate, Baylor College of Medicine

To whom it may concern:

I am an infectious diseases specialist at Baylor College of Medicine. I transitioned from trainee to faculty about a year ago, and the past year has been very challenging as I take the next step in being the final decision-maker in caring for my patients. The HIV guidelines have been integral to this process for me, as I refer to these guidelines on a weekly basis to make sure I am making the right decisions for my patients. These guidelines are essential for anyone who provides care to patients with HIV, and they need to continue so that we can continue practicing evidence-based medicine.

Please don’t hesitate to reach out with any further questions.

Sincerely,
Megan Duffey, MD

PUBLIC COMMENT 51

Public comment received: 7:40 pm on July 11, 2025

Comment made by: Matthew M. Hamill MBChB, PhD, MPH | Associate Professor | Division of Infectious Diseases
Affiliate, Johns Hopkins School of Medicine, Baltimore MD

Dear Office of AIDS Research Advisory Council,

I wish to express my gratitude to the current and past HIV and OI treatment guidelines. These documents have doubtless improved medical care and clinical outcomes and saved inappropriate and potential harmful treatment for thousands upon thousands of people living with HIV.

I am in a fortunate position; I work in an institution that has access to some world leaders in HIV care. When I have a complicated question, I can call a colleague.

Not all providers — nor, more importantly, the patients we serve — have this luxury. Many healthcare providers rely completely on these guidelines to provide up-to-date management for people with HIV.

Many of these providers are not specialists in infectious disease but specialists in primary care or other areas of healthcare. They do not have the ability to 'phone a friend', particularly if they are in rural America and may be the only provider for miles.

These guidelines act as a community; they allow providers all over the US to connect. There is a clear chain here, dismantling any part of it reduces excellence for all. Our patients rely on us for our expertise — we rely on guidelines to provide that expertise — our patients trust us to know we are taking the best care of them possible.

Taking these excellent guidelines away diminishes the quality of care that we provide to our patients. It also takes away an incredible resource; a resource I learn from every time I read it — even after providing care for people with HIV for a quarter century.

These documents and the expertise that goes into them are an essential not a luxury.

I sincerely hope that the US HHS can continue to lead the world through this example of excellence.

Sincerely,
Matthew Hamill

PUBLIC COMMENT 52

Public comment received: 11:30 pm on July 10, 2025

Comment made by: Ganesh Krishnamurthi, MD
Affiliate, *(no information provided with public comment)*

Hello!

I'm an infectious diseases fellow currently at Baylor College of Medicine. The HIV infectious diseases guidelines have been crucial in my education and my clinical practice. I use them all the time when I treat people living with HIV. I ardently support

the continuation of these guidelines. Thank you for your time!

Best,
Ganesh Krishnamurthi, MD

PUBLIC COMMENT 53

Public comment received: 8:34 pm on July 9, 2025

Comment made by: Chloe L Thio, MD | Professor of Medicine | SOM DOM Division of Infectious Diseases
Affiliate, Johns Hopkins School of Medicine, Baltimore MD

Dear Office of AIDS Research Advisory Council,

I am a Lead of the hepatitis B section for the DHHS Guidelines on the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. I am writing to explain the importance of these guidelines in clinical practice and the thoughtful work that goes into making the best recommendations for clinicians all over the country and the world.

Caring for people with HIV is complex because of the effects HIV has on the immune system and inflammatory response as well as the opportunistic infections that are possible. The guidelines are an invaluable resource for the most up-to-date information for caring for people with HIV. These guidelines are developed and written by experts in each field who volunteer their time. It is impossible to be up-to-date on all topics in these guidelines; thus to give my patients the best care, I personally use the guidelines on a regular basis. I also use and refer trainees to these guidelines for teaching purposes when I am the attending on the inpatient service or in clinic. These guidelines are also impactful for clinicians who are not near large hospitals that have experts in HIV care since this is the source they use. I have been told by numerous clinicians in rural areas of the country how useful the guidelines are to them.

As a lead for the hepatitis B section, I can attest that our group updates the guidelines at least annually and then whenever new information comes out that affects the prevention and treatment of hepatitis B. We carefully review and discuss the literature to make evidence-based recommendations that can be implemented in any setting. Our recommendations then undergo further review by a panel of clinicians who use the guidelines to make sure they are clear and concise. Thus, this is an evergreen source of the best practice for people with HIV. A loss of these guidelines will undoubtedly lead to suboptimal care and more money spent on treating adverse outcomes of HIV.

Sincerely,
Chloe L Thio, MD

PUBLIC COMMENT 54

Public comment received: 1:10 pm on July 11, 2025

Comment made by: Anna Durbin, M.D. | Professor, International Health | Director, Center for Immunization Research
Affiliate, Johns Hopkins Bloomberg School of Public Health

I understand that the government is thinking of removing the HIV guidelines from the website and disbanding the working groups. I use these guidelines all the time. It is incredibly important to have experts develop and review guidelines for the management of HIV and this should be supported by the government. It would be a travesty to disband this working group and remove the guidelines. They are a resource for clinicians.

Anna Durbin, M.D.

PUBLIC COMMENT 55

Public comment received: 3:46 pm on July 14, 2025

Comment made by: Annukka (Annie) Antar, MD, PhD | Assistant Professor of Medicine | Division of Infectious Diseases
Affiliate, Johns Hopkins School of Medicine, Baltimore MD

Hi there,

I'd like to add a public comment here. I heard that OAR may end support for the DHHS HIV and OI guidelines, which would be a real loss for healthcare providers in our country. I am an infectious diseases physician, practicing at Johns Hopkins. I use those DHHS guidelines often throughout the year to help me make clinical decisions for my HIV patients. In fact, when I attend on the HIV inpatient service at the Johns Hopkins Hospital, I spend time teaching the internal medicine residents about these guidelines, and we look them up on the web together with the cases we have on service so they can use the guidelines to enhance their clinical decision making now and in their practice after residency. I trust these guidelines and use them regularly, both in practice and in teaching. Please don't end support for these.

Best,
Annie

PUBLIC COMMENT 56

Public comment received: 3:48 pm on July 14, 2025

Comment made by: Gail Berkenblit
Affiliate, *(no information provided with public comment)*

The DHHS guidelines are critical to management of HIV by internists such as myself. We rely on these guidelines to provide care. Cutting support for them will undoubtedly result in more costly care to Medicare and Medicaid through increased hospital admissions etc.

Do the right thing and continue supporting the DHHS guidelines,

Gail Berkenblit

PUBLIC COMMENT 57

Public comment received: 3:44 pm on July 14, 2025

Comment made by: Joel Blankson MD, PhD | Professor of Medicine | Director, Inpatient HIV Service
Affiliate, Johns Hopkins School of Medicine, Baltimore MD

Dear Directors,

I recently heard that there is a plan to end support for the DHHS guidelines.

As someone who has been caring for People Living with HIV for more than 30 years, I think this would be a big mistake and would adversely impact patients and professionals alike.

Antiretroviral regimens are complicated and there is a lot of nuance that goes into selecting a regimen.

I still consult the guidelines regularly especially when it comes to teaching housestaff,

infectious diseases fellows and medical students.

Clinicians strive to practice evidence-based medicine, and there is no easier way to review the evidence behind different regimens than going to the guidelines which are available to everyone.

Providers who practice in rural areas and those who don't have easy access to colleagues who have expertise in this area will definitely be severely impacted if the DHHS guidelines were not available.

I urge you to reconsider ending support for this crucial and potentially life saving resource.

Respectfully,
Joel Blankson MD, PhD

PUBLIC COMMENT 58

Public comment received: 4:24 pm on July 14, 2025

Comment made by: Mohammad M. Sajadi, MD | Professor of Medicine, Institute of Human Virology
Affiliate, University of Maryland School of Medicine

Dear Director,

The DHHS guidelines for HIV and zoos have been standards in the field for as long as I have been practicing (mid 1990’s). These have helped me in the management of thousands of American patients under my care through the years, as well as train hundreds of American doctors. I hope you will reconsider the decision to cancel these guidelines.

Mohammad M. Sajadi, MD

PUBLIC COMMENT 59

Public comment received: 4:51 pm on July 14, 2025

Comment made by: Jason E. Farley, PhD, MPH, ANP-BC | Associate Dean, Community Programs and Initiatives | Endowed Professor, Nursing Leadership and

Innovation | Director, Center for Infectious Disease and Nursing Innovation | Director, Regional Partner Site, MidAtlantic AIDS Education and Training Center (AETC) | Co-Director, Clinical Core, JHU Center for AIDS Research (CFAR) | Co-Director, Development Core, JHU TB Research Advancement Center (TRAC) | Adult Nurse Practitioner, Infectious Diseases, Johns Hopkins Medicine
Affiliate, Johns Hopkins University School of Nursing | Johns Hopkins School of Medicine, Baltimore MD

To whom in may concern,

The HIV treatment guidelines are an essential part of the clinical and public health response to HIV. These guidelines are evidence-based and provide clinicians with essential updates on the treatment of people with HIV. Please maintain this important resource!

Jason E. Farley, PhD, MPH, ANP-BC

PUBLIC COMMENT 60

Public comment received: 12:15 am on July 15, 2025

Comment made by: Gregory M. Lucas, MD PhD | Professor of Medicine
Affiliate, Johns Hopkins School of Medicine, Baltimore MD

The management of any disease evolves and (ideally for the better) over time, and this is certainly the case for the medical management of people living with HIV. Having cared for PWH for 25 years, I can attest that the DHHS guidelines for HIV treatment have played a vital role in my career. However, to stay relevant the guidelines must be a living document where the benefits and risks of new therapies are summarized by experts. Whatever it costs to update and maintain these guidelines is well worth it.

Sincerely,

Gregory M. Lucas, MD PhD

PUBLIC COMMENT 61

Public comment received: 7:51 pm on July 14, 2025

Comment made by: Tyler Gray | Senior medical director of community sites
Affiliate, Healthcare for the Homeless

as a family physician who works at an FQHC focused on people experiencing homelessness, I use the DHHS HIV treatment guidelines regularly. Last time I used the guildelines was to review recommended treatment options for a pregnant patient newly diagnosed with HIV. The guidelines gave me the confidence to get her quickly started on antiretroviral medication. I strongly support the continued support of these guidelines. Thank you.

PUBLIC COMMENT 62

Public comment received: 12:15 am on July 15, 2025

Comment made by: Stephen A Berry, MD | HIV provider | Associate Professor
Affiliate, Johns Hopkins School of Medicine, Baltimore MD

Dear Office of AIDS Research Director,

Please preserve the DHHS HIV and OI guidelines. The guidelines are an invaluable compilation of the distilled wisdom of scores of clinical trials and observational studies.

I routinely use them to ensure best care of persons with HIV, including teaching about these guidelines to medical students and residents 5-10 times per year.

Stephen A Berry, MD

PUBLIC COMMENT 63

Public comment received: 4:52 pm on July 15, 2025

Comment made by: Ank Nijhawan, MD,MPH, MSCS
Affiliate, *(no information provided with public comment)*

To whom it may concern

I understand that there is consideration of moving or discontinuing the DHHS guidelines for HIV and opportunistic infections.

I would like to emphasize what an incredibly useful tool these guidelines are for not only

providing up-to-date and evidence-based care to patients, but they are invaluable for teaching the next generation of HIV providers.

With this email, I am voicing my strong recommendation to maintain these important guidelines.

Sincerely,
Ank Nijhawan, MD,MPH, MSCS

PUBLIC COMMENT 64

Public comment received: 4:04 pm on July 15, 2025

Comment made by: Ellen Kitchell, MD
Affiliate, *(no information provided with public comment)*

Dear Members of OARAC,

I am writing to express my deep concern regarding the recent announcement that NIH support for the HIV clinical practice guidelines will be phased out by June 2026.

These guidelines are a critical resource for clinicians across the United States, providing timely, evidence-based, and unbiased recommendations that directly impact the care of people living with HIV. Their dynamic nature, updated constantly in response to emerging data, sets them apart as a gold standard that ensures consistent, high-quality care regardless of practice setting. HIV is a field that moves very rapidly, and it can be difficult to keep track of all the information without a centralized source. I tell young providers that the DHHS HIV guidelines are the "Bible of HIV care" because it is such a reliable source of information.

There is currently no other organization, whether academic, private, or advocacy-based, with the infrastructure, neutrality, and scientific rigor to take on this role without risk of bias and delay. The potential consequences of losing this resource are profound: patients may receive suboptimal or inconsistent care, and clinicians will be left without trusted guidance in a rapidly evolving therapeutic landscape.

Beyond the human cost, this move could also result in significant financial inefficiency. Without centralized, evidence-based guidance, providers will turn to more expensive, less effective, or duplicative treatment strategies, driving up healthcare costs in already strained systems—especially in federally funded programs like Medicare, Medicaid, and the Ryan White Program.

I urge OARAC to advocate for continued NIH leadership in maintaining these guidelines. The stakes for patient outcomes, clinical integrity, and national health system costs are too high to risk transferring this responsibility without a clear and equally capable successor.

Sincerely,
Ellen Kitchell, MD

PUBLIC COMMENT 65

Public comment received: 1:27 pm on July 21, 2025

Comment made by: Joyce Jones, M.D., M.S.
Affiliate, *(no information provided with public comment)*

Dear Office of AIDS Research,

I am emailing to express my appreciation for the DHHS Clinical HIV Guidelines (https://clinicalinfo.hiv.gov/en/guidelines) that present comprehensive and easy to use guidance on treatment of people with HIV. I am an HIV primary care physician, a Medical Director of an HIV clinic and teach medical students, medical residents and other physicians about HIV clinical care. I also teach other medical staff including nurses, medical assistants, case managers, social workers, patient navigators about HIV. I use these guidelines every day in my clinical practice and in all of my teaching to these groups. I urge the Office of AIDS Research to continue to support these guidelines as they are an opportunity for US clinical care providers to get up-to-date, evidence-based, expert guidance on the appropriate treatment for people with HIV. Please do not end this critical resource for clinical HIV care. Without these guidelines, the quality of HIV clinical care will suffer as will the education of future medical providers.

Thank you,
Joyce Jones, MD, MS

PUBLIC COMMENT 66

Public comment received: 3:24 pm on July 18, 2025

Comment made by: Gregory H Taylor, M.D. | Professor of Family and Community Medicine

Affiliate, University of Maryland School of Medicine

I am writing in support of the DHHS HIV and OI guidelines to highlight how valuable they are to support evidence-based care of patients with HIV. I utilize them on a regular basis to guide treatment of people living with HIV and also to educate medical students and residents . The loss of this valuable asset would hinder both care and education

Gregory H Taylor MD

PUBLIC COMMENT 67

Public comment received: 1:33 pm on July 24, 2025

Comment made by: Kaitlin Poole, MSN, CRNP
Affiliate, Johns Hopkins University School of Medicine

Hello,

I have recently been informed that there are efforts to end the support of the DHHS HIV and OI guidelines. I am a nurse practitioner who specializes in HIV care and I use these guidelines regularly to provide care to people living with HIV. These guidelines are crucial in allowing healthcare providers to provide evidence based, up to date care. Having easily accessible guidelines allows for patients to receive equitable, high quality care regardless of where they are receiving medical care. Just this week, I referenced the guidelines to find an antiretroviral treatment regimen for someone with impaired renal function. The guidelines gave me a quick, evidenced based answer.

There is strong evidence that people with HIV should be started on ART as soon as possible upon diagnosis. These guidelines assist primary care providers and non-HIV specialists to initiate appropriate ART in a timely manner while the patient is waiting to establish care with an HIV specialist. Without these guidelines, I worry that ART initiation will be delayed, contributing to poor clinical outcomes and an increased community viral load.

I urge you to continue support for these important guidelines.

Thank you for your consideration,
Kaitlin Poole, CRNP

PUBLIC COMMENT 68

Public comment received: 3:16 pm on July 24, 2025

Comment made by: Jesse Vasques Mesenburg, CRNP, MS | Medical Director, **Affiliate,** SPARC Center for Women**,** Johns Hopkins University School of Medicine

Hello,

I have recently been informed that there are efforts to end the support of the DHHS HIV and OI guidelines. I am a nurse practitioner who specializes in HIV care and I use these guidelines regularly to provide care to people living with HIV. These guidelines are crucial in allowing healthcare providers to provide evidence-based care. Having easily accessible guidelines allows for patients to receive equitable, high-quality care regardless of where they are receiving medical care. Just last week, I referenced the guidelines to find an antiretroviral treatment regimen for someone with impaired renal function. The guidelines gave me a quick, evidenced based answer.

There is strong evidence that people with HIV should be started on ART as soon as possible upon diagnosis. These guidelines assist primary care providers and non-HIV specialists to initiate appropriate ART in a timely manner while the patient is waiting to establish care with an HIV specialist. Without these guidelines, I worry that ART initiation will be delayed, contributing to poor clinical outcomes and an increased community viral load.

I urge you to continue support for these important guidelines.

Thank you for your consideration,

Jesse Mesenburg, CRNP

PUBLIC COMMENT 69

Public comment received: 11:03 pm on June 26, 2025
**OARACinfo mailbox experienced a technical issue and this message was not received until after the meeting.*

Comment made by: National Black Women's HIV/AIDS Network

Affiliate, National Black Women's HIV/AIDS Network

Dear Members of the Office of AIDS Research Advisory Council (OARAC),

We are writing to express deep concern about the proposed budget cuts to NIH funding and the far-reaching consequences this poses—especially for Black women and girls, who continue to bear a disproportionate burden of the HIV epidemic in the United States.

Although Black women represent only about 13% of the female population, they account for over half of new HIV diagnoses among women. This disparity is not just a matter of biology or behavior, it is a direct reflection of systemic inequities that have historically shaped access to care, prevention, education, and research investment.

NIH has long served as a critical engine for both scientific discovery and equity. Its support has enabled groundbreaking research, community-driven interventions, and—importantly—implementation science. This last area is particularly vital. Implementation science helps bridge the gap between research and real-world impact by ensuring that evidence-based interventions are adapted, scaled, and sustained in communities where they are needed most.

The proposed budget cuts to NIH funding threatens this essential work. Programs rooted in implementation science are especially effective for Black women and girls because they focus on context: the cultural, structural, and social factors that often make or break health outcomes. Without continued investment in implementation science, promising interventions risk remaining trapped in academic literature, never reaching the communities they were designed to serve.

We invite OARAC to prioritize the needs of Black women and girls in your guidance to NIH leadership. This includes advocating for the restoration and protection of funding streams that support community-engaged research, culturally responsive interventions, and implementation science frameworks that operationalize equity— not just as a principle, but as a practice. The future of the HIV response depends on sustained, evidence-based, and equity-centered investment.

Thank you for your ongoing commitment to public health and research excellence. We value the longstanding commitment of the Office of AIDS Research to advancing innovative, inclusive, and community-informed research. We urge continued and expanded investment in research that reflects the diverse lived experiences of all those impacted by HIV — especially Black women and girls. We cannot allow proposed funding losses to undo decades of progress.

Sincerely,
The National Black Women's HIV/AIDS Network, Inc

PUBLIC COMMENT 70

Public comment received: 10:04 am on June 27, 2025
**OARACinfo mailbox experienced a technical issue and this message was not received until after the meeting.*

Comment made by: Jules Levin | Executive Director, founder

Affiliate, National AIDS Treatment Advocacy Project

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 & its predicted that the number of PWH over 75 will increase 6-fold. Its 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. Mortality rates are higher for PWH with multiple comorbidities. We need a change now before its too late.

Jules Levin