



Office of AIDS Research Advisory Council Meeting  
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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 with 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  
[titan@luriechildrens.org](mailto:titan@luriechildrens.org)

Colleen Kelley, MD, MPH  
[colleen.kelley@emory.edu](mailto:colleen.kelley@emory.edu)

Submitted by:

Andrea Weddle  
Executive Director, HIVMA  
[aweddle@HIVMA.org](mailto:aweddle@HIVMA.org)