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# Fiscal Year 2025 NIH HIV/AIDS Professional Judgment Budget

**Accelerating Progress and Promise in HIV Research**





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## Director's Message

When the National Institutes of Health (NIH) Office of AIDS Research (OAR) was established in 1988, there was a limited understanding about human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), the disease caused by HIV. In the early days of the HIV/AIDS\* pandemic in the 1980s, few therapeutic options were available, and life expectancy for people with HIV was approximately three years after diagnosis. Over the past 35 years, incredible progress in HIV research has led to breakthroughs such as well-tolerated, long-acting antiretroviral therapy (ART) that can be used for treatment among people with HIV and for prevention of new HIV infections in those who may be at risk of HIV acquisition. These breakthroughs prevent perinatal HIV transmission, halt HIV disease progression, and protect sexual partners from HIV transmission. These and other scientific advances have resulted in an improved quality of life and a near-normal life expectancy for people with HIV who have access to treatment and services.



**Bill G. Kapogiannis, MD, FIDSA**  
*Acting Associate Director for AIDS Research and  
 Acting Director, Office of AIDS Research  
 National Institutes of Health*

Advanced HIV therapies, in conjunction with domestic and international initiatives developed with strong U.S. government support, have saved millions of lives since the beginning of the HIV/AIDS pandemic. However, global statistics indicate that the burden of HIV remains substantial, as these advances have not reached all those who may benefit from them.<sup>1</sup> Globally, new HIV infections and AIDS-related deaths have decreased in the past two decades, but not all populations have benefited equally. In 2021, more than 38 million people were living with HIV; over half of this population consisted of women and girls.<sup>2</sup> ART is highly effective, but the number of people on ART globally increased by only 1.5 million in 2021, a smaller increase than in previous years.<sup>3</sup>

In the United States, 2021 data on the HIV care continuum indicate that diagnosis and treatment gaps persist, as shown in the “Public Health Impact of HIV in the United States” snapshot on page 4. Despite availability of effective treatments, fewer than 60 percent of people with HIV, whether a diagnosis has been made or not, have achieved viral suppression, with disparities by age, race, and ethnicity.<sup>4</sup> Black/African American and Hispanic/Latino individuals, particularly those who report male-to-male sexual contact, are disproportionately affected by HIV.<sup>5</sup> Racial, ethnic, and gender disparities are compounded by other social determinants of health, such as income and geographic location, that limit access to HIV-related health services, contributing to health inequalities in the United States.

*\*Note the distinction between HIV and AIDS. AIDS is the late stage of HIV infection that occurs when the immune system is badly damaged because of the virus. Many people with HIV do not develop AIDS. People with HIV who take anti-HIV medications as prescribed and reach and maintain an undetectable viral load can live long and healthy lives and will not transmit HIV to their HIV-negative partners through sex. While HIV and AIDS are used throughout this document, “HIV/AIDS” is maintained in limited statements for necessary historical context.*

Over half of people with HIV in the United States are age 50 or older, and some projections estimate that nearly three-quarters of adults with HIV will be in this age group by 2030.<sup>6,7</sup> Individuals aging with HIV are more likely to experience the effects of accelerated aging, higher rates of neurocognitive and cardiovascular complications, some cancers, and metabolic and bone disorders.<sup>8,9</sup> These co-occurring conditions can complicate HIV treatment and care. In addition to experiencing higher levels of comorbidities compared to people of similar age without HIV, older people with HIV also face both age-related and HIV-related stigma.<sup>10</sup>

In response to the ongoing challenges posed by the HIV/AIDS pandemic, the NIH HIV research agenda has evolved continuously in the 35 years since Congress established OAR. Progress and growth are reflected in the [FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research](#)<sup>11</sup> (NIH HIV Strategic Plan) and in the [National HIV/AIDS Strategy](#)<sup>12</sup> (NHAS) and its companion document, the [NHAS Federal Implementation Plan](#).<sup>13</sup> These documents outline specific strategies to reduce new HIV infections, develop next-generation therapies, and discover approaches to cure HIV. In this context, the [Ending the HIV Epidemic in the U.S.](#) (EHE) initiative<sup>14</sup> supports equitable health access and community engagement across the United States. Together, these complementary frameworks guide biomedical, behavioral, clinical, and social sciences research priorities, as well as the implementation of evidence-based interventions and programs. Funds requested in the FY 2025 NIH HIV/AIDS Professional Judgment Budget will accelerate progress in key research goals identified in the NIH HIV Strategic Plan, NHAS, *NHAS Federal Implementation Plan*, and EHE initiative.

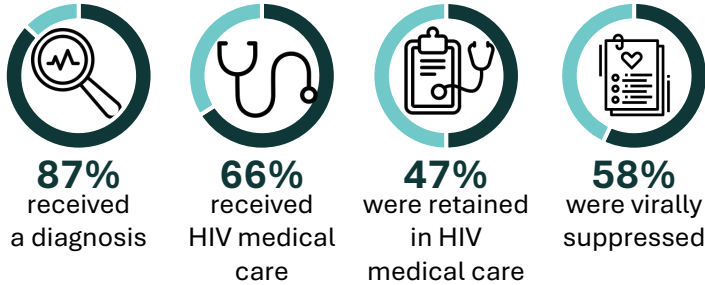
The NIH HIV and AIDS research agenda is intentionally shaped by the needs of the communities affected by HIV. Now, more than 40 years since the first cases of HIV were reported, community priorities continue to evolve, especially as people live longer and age with HIV. OAR-led listening sessions with community partners have provided insights on emerging challenges and concerns that are reflected in the NIH HIV and AIDS research agenda. Since 1988, OAR has coordinated HIV research across NIH, convening multiple partners to catalyze interdisciplinary efforts. Our goal remains the same: to end the HIV/AIDS pandemic and improve the health of people with HIV. We must take action to prevent, treat, and cure HIV, and to address its complications, including comorbidities and coinfections. These actions will require continued commitment, innovation, and creativity. To reduce any efforts now would inevitably lead to the resurgence of HIV worldwide, compromising global health in the 21<sup>st</sup> century.

We must remain flexible to respond to new challenges, leverage new and existing partnerships, and ensure all voices can contribute to HIV and AIDS research. We must build on our robust repertoire of prevention and treatment strategies. The FY 2025 NIH HIV/AIDS Professional Judgment Budget identifies key scientific investment opportunities to build on previous advances and respond to community insights, accelerating progress and promise in HIV and AIDS research. The scientific agenda will promote innovative research in pathobiology, immunology, virology, behavioral and social sciences, and implementation science.

# PUBLIC HEALTH IMPACT OF HIV IN THE UNITED STATES

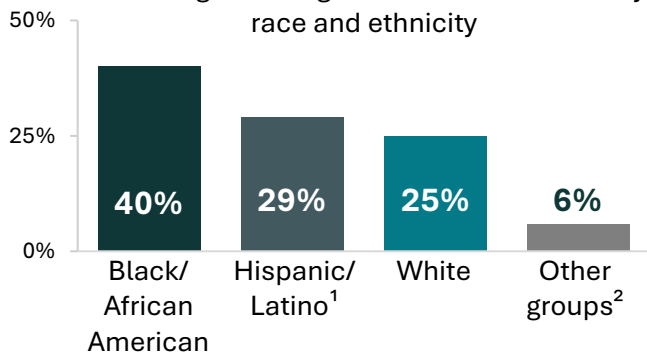
**Figure 1. HIV diagnosis and treatment gaps, 2021<sup>†</sup>**

Among the estimated 1.2 million<sup>‡</sup> people living with HIV in the United States:




**Figure 2. Disparities in HIV infection, 2021<sup>†</sup>**

Percentages of diagnoses of HIV infection by race and ethnicity

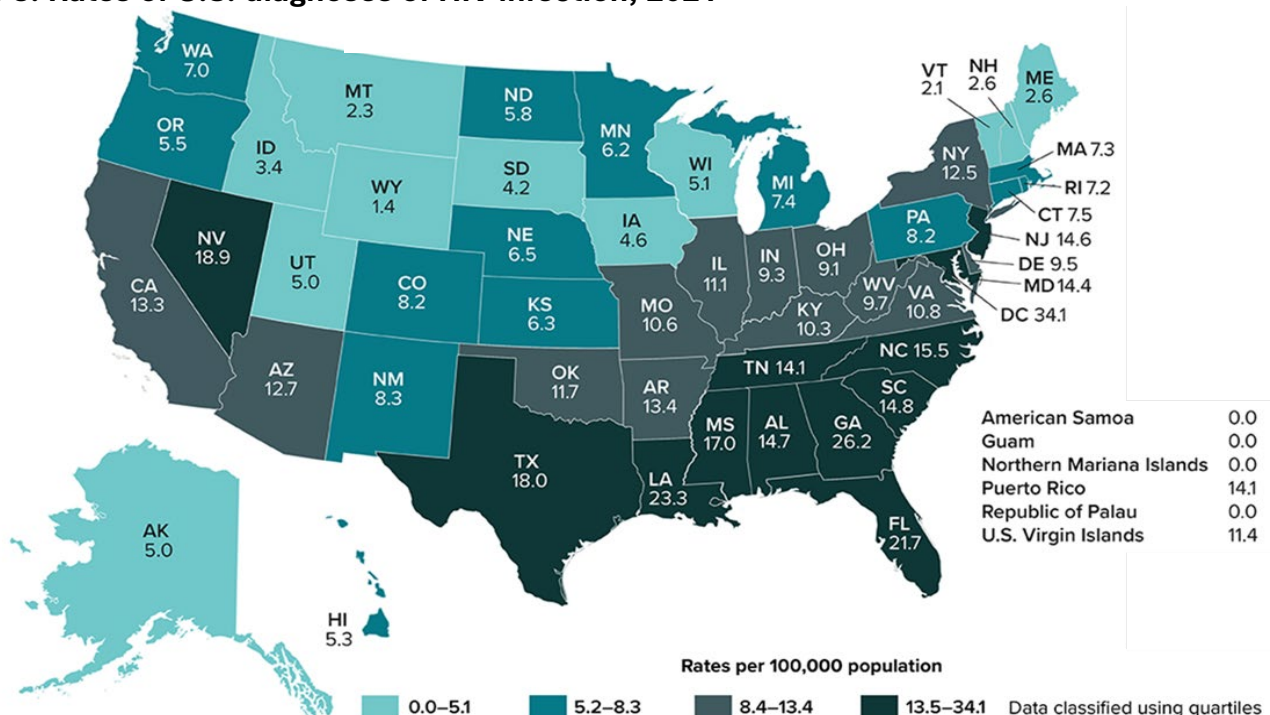


<sup>1</sup>Any race; <sup>2</sup>Includes Multi-racial, Asian, American Indian/Alaska Native, and Native Hawaiian/other Pacific Islander populations

## HIV/AIDS Public Health Milestones

- 1981** First report of the disease that will be named AIDS
- 1987** AZT is the first drug approved by the FDA for treatment of people with HIV
- 1988** Congress establishes OAR to coordinate HIV/AIDS research across NIH 
- 1996** Combinations of antiretroviral therapy become widely available
- 1997** CDC reports 47% decline in AIDS-related deaths in the U.S.
- 2003** U.S. government launches President's Emergency Plan for AIDS Relief (PEPFAR)
- 2012** FDA approves pre-exposure prophylaxis (PrEP) that prevents HIV transmission
- 2017** U = U (Undetectable = Untransmittable) Viral levels not detectable on tests = no risk of transmitting HIV
- 2021** FDA approves first long-acting HIV treatment and prevention options

**Figure 3. Rates of U.S. diagnoses of HIV infection, 2021<sup>†</sup>**



<sup>†</sup> Data source: [www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-28-no-4/](http://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-28-no-4/)

<sup>‡</sup> Data source: [www.cdc.gov/hiv/basics/statistics.html](http://www.cdc.gov/hiv/basics/statistics.html)

<sup>+</sup> Data source: [www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/](http://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/)

## Budget, Funding, and Resources Needed

OAR coordinates the scientific, budgetary, legislative, and policy elements of the NIH HIV and AIDS research program in the domestic and global fight against the HIV/AIDS pandemic. In this role, OAR continues to enhance HIV and AIDS research collaborations, minimize duplication, and ensure that NIH research funds are invested effectively and efficiently across the Institutes, Centers, and Offices (ICOs) conducting HIV and AIDS research.

The annual NIH HIV/AIDS Professional Judgment Budget builds on the justification to Congress for the President’s Budget, providing estimates of the funding needed to fully pursue highlighted scientific opportunities *“without regard to the probability that such amounts will be appropriated.”*<sup>15</sup>

In FY 2023, the congressional appropriation to NIH provided \$3.294 billion for NIH HIV and AIDS research, an increase of \$100 million or 3.1 percent above the FY 2022 enacted level and representing 15.6 percent of the \$639 million requested in the FY 2023 NIH HIV/AIDS Professional Judgment Budget. As shown in Table 1, the proposed FY 2025 NIH HIV/AIDS Professional Judgment Budget requests a \$659 million increase, for a total proposed budget of \$3.953 billion for FY 2025, an increase of 20 percent over the FY 2023 enacted budget.

**Table 1: FY 2025 NIH HIV/AIDS Professional Judgment Budget (Dollars in Millions)**

<b>FY 2023 Enacted Budget</b>	<b>\$3,294</b>	
<b>FY 2025 Proposed Increase by Overarching Research Priority</b>	<b>\$659</b>	<ul style="list-style-type: none"> <li>\$158 Reduce the Incidence of HIV</li> <li>\$62 Develop Next-Generation Therapies</li> <li>\$70 Research Toward a Cure</li> <li>\$119 Address HIV-Associated Comorbidities, Coinfections, and Complications</li> <li>\$250 Cross-Cutting Areas</li> </ul>
<b>FY 2025 Total Proposed Budget</b>	<b>\$3,953</b>	

*Note: Projected distribution of proposed increase shown across research priorities in the NIH HIV Strategic Plan. Cross-cutting areas include basic science, behavioral and social science, epidemiology, health disparities, implementation science, information dissemination, and research training.*

In FY 2025, the NIH HIV/AIDS Professional Judgment Budget emphasizes support for the multifaceted needs for HIV vaccines; uptake of current prevention options; and fundamental pathobiology, virology, and immunology research using the latest advances in technology. In recent years, the spending capacity of the HIV allocation has decreased when adjusted for inflation. Additional funding is needed to continue advancing research to end the HIV/AIDS pandemic. This budget highlights key scientific opportunities that address the strategic priorities outlined in the NIH HIV Strategic Plan and estimates the funding needed to accelerate progress in cutting-edge science, as well as strengthening research capacity and workforce development.

## Highlighted Scientific Opportunities

The FY 2025 NIH HIV/AIDS Professional Judgment Budget supports the NIH strategy to advance HIV science in prevention, treatment, and cure across the health research continuum: from foundational, basic science to translational, clinical, and intervention research to implementation science and dissemination. Research areas outlined in the budget will support studies on the individual-, community-, and population-level factors that influence HIV transmission and outcomes across the lifespan.

The FY 2025 NIH HIV/AIDS Professional Judgment Budget highlights key scientific investment opportunities across four areas:

### Basic research to promote discovery and advance HIV science

- › Advance HIV discoveries in pathobiology, immunology, and virology to address HIV and its complications, including new therapeutic and prevention product pipelines, as well as immune-mediated approaches for HIV prevention.
- › Accelerate development of novel drug combinations; dosing regimens; and delivery methods for treatment and cure modalities, including those that target the viral reservoir.
- › Develop innovative methods to detect, target, and destroy viral reservoirs in pursuit of a cure for HIV.
- › Investigate social determinants of health, including their interactive properties, that contribute to HIV health disparities.

### Development and assessment of novel interventions

- › Accelerate translation of promising vaccine and antibody-mediated protection strategies into clinical trials.
- › Advance multidisciplinary research to develop clinical, behavioral, and social interventions to effectively prevent and treat HIV and address comorbidities, coinfections, and complications of long-term HIV and its treatment across the lifespan.
- › Develop and evaluate the efficacy of integrated care models for management of HIV and co-occurring conditions.

### Translation, implementation, and dissemination of HIV research discoveries to optimize public health impact

- › Support implementation research to promote the systematic uptake of evidence-based HIV interventions and delivery approaches.
- › Improve community engagement and community-driven HIV research.
- › Support research on effective models of HIV-related science and public health communications that reflect community input and are culturally appropriate.

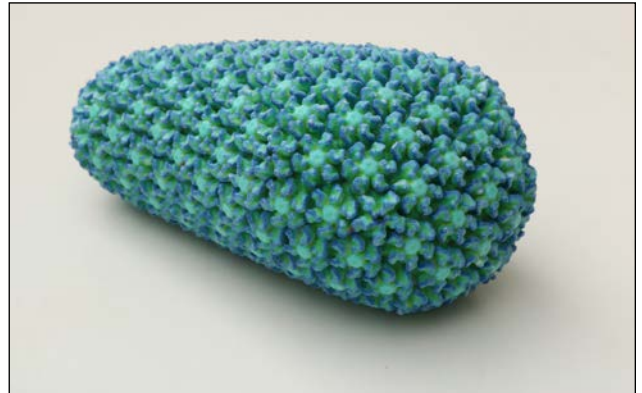
### Infrastructure and workforce development to enhance capacity and increase diversity

- › Develop and retain a skilled and diverse HIV research workforce.
- › Increase investment in facilities and resources to enhance research capacity in diverse settings and in institutions with limited resources.
- › Strengthen data infrastructure to enable effective data management, accessibility, and analysis.



## Basic Research to Promote Discovery and Advance HIV Science

Since the beginning of the HIV/AIDS pandemic, NIH has advanced understanding of disease mechanisms and pathways, supporting basic, foundational science to drive the discovery, development, and evaluation of novel HIV prevention and treatment strategies. Investment in basic biomedical, behavioral, and social sciences research has been a critical cornerstone for HIV science, enabling the scientific community to create an extensive array of safe and effective tools to treat and prevent HIV infection. Analysis of individual-, community-, and population-level factors in early stages of research is essential to inform community-appropriate, person-centered strategies to end the HIV/AIDS pandemic. These discoveries have also benefited other areas of science, including combatting the COVID-19 pandemic.



*3D-printed model of the HIV capsid, the protein shell that encloses the viral genetic material.*

*Credit: National Institute of Allergy and Infectious Diseases (NIAID)*

### Basic Biomedical Research

Basic biomedical research continues to pursue fundamental knowledge to inform development of strategies and drugs to both prevent and treat HIV and its complications. Research in pathobiology, virology and immunology aims to illuminate mechanisms of HIV immune response modulation and to discover novel drug targets for treatment and prevention of HIV and management of its associated comorbidities, coinfections, and complications. As an example, basic research on the structural biology of the HIV capsid protein core provided the foundation for development of lenacapavir, the first capsid inhibitor approved by the U.S. Food and Drug Administration (FDA) for treatment of HIV.<sup>16</sup>

Development of an HIV vaccine is particularly challenging but remains a high priority for HIV prevention research at NIH. As one of the fastest mutating viruses, HIV can replicate rapidly, produce millions of variants, evade the immune system, and create viral reservoirs in cells that allow the virus to go undetected. Despite these challenges, HIV vaccine research continues to progress and contribute to other research advances, including novel approaches to identify and sequence the genomes of viral pathogens and innovative technologies for vaccine delivery. For example, NIH scientists discovered that the structure of a protein on the surface of HIV facilitates viral entry into human cells, findings that contributed to the development of mRNA vaccines against SARS-CoV-2.<sup>17</sup> In 2022, NIH launched a clinical trial of three mRNA HIV vaccine candidates using technology from several approved COVID-19 vaccines.<sup>18,19</sup> In the wake of recent clinical trials demonstrating limited efficacy of HIV vaccine candidates that induce non-neutralizing antibodies, the need for alternative approaches for vaccine development is clear.<sup>20</sup> One approach under investigation in current vaccine research involves induction of broadly neutralizing antibodies (bNAbs) for protection against HIV strains. A recent Phase 1 clinical study found that a candidate HIV vaccine safely activated precursor bNAb-producing cells and demonstrated that a vaccine “boosting regimen” can elicit an immune response against multiple variants of HIV.<sup>21,22</sup> Current research is investigating vaccine adjuvants that optimally trigger and expand bNAb precursors, a strategy that holds potential to enhance the potency, efficacy, and persistence of HIV vaccine candidates.<sup>23</sup> Additional investments in basic biomedical research can address gaps in understanding bNAb-precursor cells and optimize use of adjuvants to revolutionize and accelerate the development of antibody-mediated approaches for HIV prevention.

Antiretroviral therapy (ART) was developed to treat HIV infection and slow disease progression by reducing viral replication and immune activation. ART was shown subsequently to prevent HIV infection when taken as pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP). When HIV infection does occur, ART can control virus replication effectively in people with HIV and inhibit transmission to others. Despite effective viral suppression with ART, the persistence of latent viral reservoirs in tissues and cells throughout the body requires lifelong use of these antiretrovirals. Long-acting ART can increase adherence, reduce infection in susceptible individuals, and slow disease progression in people with HIV. Additional resources can accelerate discoveries of novel drug targets and the development of optimal drug combinations, dosing regimens, and innovative delivery strategies to reduce the frequency of dosing, target viral reservoirs, and potentially eliminate HIV. Increased investment also can support efforts to leverage existing technologies, such as CRISPR-Cas9-powered nanobiosensors and microfluidics technologies, to advance portable HIV viral load detection for monitoring ART adherence and efficacy.<sup>24,25</sup>

Discovery of innovative strategies to detect, target, and destroy virus-infected cell reservoirs remains a primary goal in the search for a cure for HIV. Recent research using focused investigation of cells by nucleic acid detection and sequencing (FIND-Seq), a technology that characterizes latently infected cells, has revealed distinctive gene expression patterns of these rare cells that help explain the persistence of the virus even during effective ART.<sup>26</sup> This research provides a step toward identifying biomarkers of the latent reservoir and lays the foundation for a path towards new HIV cure strategies.

### Behavioral and Social Sciences Research

Basic behavioral and social sciences research (BSSR) provides a foundation for better understanding and mitigating the impact of individual, interpersonal, community, societal, and structural factors that contribute to HIV infection risk, as well as HIV prevention and treatment uptake and adherence. At the intersection of biomedical and BSSR research, syndemic (or synergistic epidemic) theory offers a framework to examine the relationships between social conditions, behavioral health, and physical health.<sup>27</sup> A syndemic occurs when two or more epidemics (e.g., HIV and substance use disorder) interact with social conditions (e.g., poverty), resulting in an exacerbation of health outcomes in a specific population. People with HIV commonly experience chronic HIV-associated comorbidities, coinfections, and complications, but the nonbiological factors that interact with disease clustering are often overlooked in comorbidities research. With additional resources, NIH will support critical interdisciplinary research to better understand the connections between social conditions and health problems associated with HIV in pursuit of evidence-based, holistic interventions to address them.



*Intersectional stigma and discrimination make people more vulnerable to HIV.*

*Credit: Yaw Niel/Shutterstock.com*

Social determinants of health (SDOH) reflect the conditions in which people are born, live, and work that influence health, well-being, and quality of life.<sup>28</sup> SDOH that often contribute to HIV health disparities and inequities include racism, discrimination, violence, housing instability, food insecurity, and unequal employment status. Populations disproportionately affected by HIV frequently experience stigma and discrimination due to their race or ethnicity, gender identity, and sexual orientation, among other identities and social positions. Intersectional stigma and discrimination represent a SDOH that can discourage HIV testing, reduce engagement and retention in HIV prevention and care services, and result in negative health outcomes.<sup>29</sup>

Advances in SDOH research will require integration of SDOH into existing HIV studies, as well as direct investigation of SDOH in communities affected by HIV. Consideration of these variables across the continuum of HIV-related research undertaken at and supported by NIH represents a key strategy to address inequities that drive health disparities. Increased investment in SDOH research will not only provide a foundation for development of more effective HIV prevention and treatment tools and approaches, but also will facilitate translation to practice, improve implementation, and inform effective public health policies.

To enable a comprehensive approach to ending the HIV/AIDS pandemic, additional investment is needed to support integrative, multidisciplinary research to address the complex interactions between the biological, behavioral, and social determinants that influence HIV risk, management, and care.

## Development and Assessment of Novel Interventions

Following the basic, discovery phase of research, the most promising products, tools, or strategies for prevention and treatment of HIV and management of its complications move into clinical trials or intervention studies to test their effectiveness in real-world community- or clinic-based settings. Rigorous randomized control trials test the biological outcomes (e.g., viral suppression or reduced mortality) and/or behavioral outcomes (e.g., increased uptake and adherence) of novel interventions. Other behavioral and social intervention studies may measure an intervention's feasibility, acceptability, and effectiveness, as well as potential barriers to its implementation.

### Clinical, Behavioral, and Social Intervention Research

To meet the needs of individuals and communities affected by HIV, interventions should be culturally appropriate, sustainable, and developed in consultation with members of the community. Inclusion of people with a variety of lived experiences and living conditions – as well as characteristics like race and ethnicity, age, sex, sexual orientation, and gender identity – is an essential strategy for HIV clinical trials and intervention studies to ensure that all communities benefit from scientific advances.

NIH supports HIV clinical trials networks that work in collaboration with one another, other research institutions, industry partners, and community organizations to conduct innovative intervention research focusing on key areas: HIV prevention; HIV vaccines; and HIV therapeutics for adults and for maternal, adolescent, and pediatric populations. Although these networks are a valuable global resource with unique cohorts and datasets, additional resources are needed to address emerging opportunities for HIV clinical research. For example, targeted investments to support clinical trials focused on older adults with HIV can help meet the needs of this increasing population. Increased funding to expand clinical investigation of multipurpose prevention technologies (e.g., PrEP combined with birth control) or other therapeutic modalities could lead to treatment and prevention options that enhance adherence.

Similarly, NIH supports the [Martin Delaney Collaboratories for HIV Cure Research](#), involving 10 groups working to foster multidisciplinary basic and intervention research toward an HIV cure. As promising methods emerge (e.g., gene editing and combined cord blood and stem cell transplants, among other possible approaches), additional resources are needed to test them in a range of populations and settings. Investigation of the dynamics of analytic treatment interruptions will be central to such intervention studies.

NIH also supports a large portfolio of HIV and AIDS research to develop and test behavioral, social, and combination interventions that are effectively integrated with biomedical approaches to significantly impact

the HIV/AIDS pandemic. The behavioral and social science agenda targets prevention of both transmission and acquisition of HIV, adherence to interventions to reduce the burden of disease, behavioral factors that influence participation in HIV cure trials, and studies that address the behavioral and social consequences of HIV infection and AIDS. Further intervention research is needed to examine the behavioral and social aspects related to the HIV continuum of care, including effective ways to increase access, initiation, and retention in care by individuals affected by HIV.

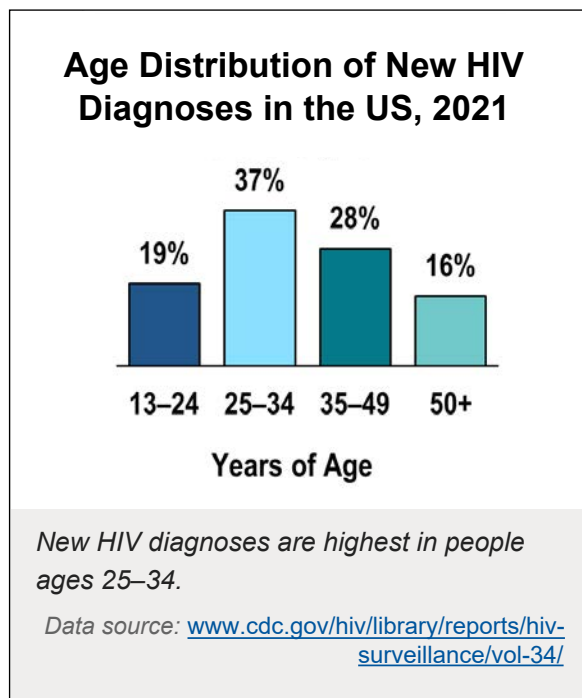
A key opportunity for further investment in intervention research is to develop and assess models of integrated care. Prevention and treatment for HIV often are delivered in specialized settings independent of other health care service components, such as care and management of co-occurring, chronic conditions, and noncommunicable diseases (e.g., hypertension and diabetes). This approach often leads to fragmented, uncoordinated care and contributes to suboptimal clinical outcomes. Evidence-based integrated models of care, in which HIV care is coordinated and integrated with primary care or behavioral health services (e.g., mental health and substance use screening and treatment) may have a positive impact on engagement and linkage to health care, adherence to ART, and viral load suppression.<sup>30</sup> In addition, integrated services can save resources and allow for a more person-centered approach to health care.

Additional funding is needed to leverage existing resources (e.g., clinical trials networks) to develop and test new methods and models to implement coordinated, integrated HIV and noncommunicable disease prevention and treatment services and to address delivery gaps to improve overall care for individuals at risk for and living with HIV.

### HIV Prevention and Treatment Across the Lifespan

Biological, behavioral, and social factors influence HIV risk, prevention, and treatment engagement across the lifespan. Research that addresses the unique needs of individuals at different times in their lives—from infants who acquire HIV perinatally to adolescents and young adults to older people with HIV—is necessary to inform the design and implementation of appropriate and effective HIV prevention, diagnosis, and care strategies.

NIH-supported research found that viral suppression through ART during pregnancy reduces the risk of HIV transmission through breastfeeding to less than 1 percent.<sup>31</sup> These findings were cited to support recent revisions to the U.S. clinical guidelines for infant feeding for people with HIV.<sup>32</sup> While a recent analysis from the Centers for Disease Control and Prevention (CDC) shows laudable accomplishments toward elimination of perinatal HIV transmission in the United States, more implementation science research is crucial to close the science-to-service gap and improve health outcomes for pregnant people with HIV and their infants.<sup>33,34</sup> Additional research is needed to determine how HIV and HIV treatment affect outcomes during pregnancy and in the postpartum period. Adherence to ART decreases during the postpartum period, indicating a need for behavioral interventions to support ART adherence during this timeframe.<sup>35,36</sup> For infants and children born with HIV, research is needed to characterize the impact of HIV therapies on development and to determine appropriate drug formulations and dosing regimens for this population.



In the United States, adolescents and young people ages 13–24 represent one-fifth of all new HIV infections and are the least likely of all age groups to be aware of their infection status, to enter and be retained in care, or to achieve viral suppression.<sup>37</sup> The transition from pediatric to adult health care often results in interruptions in HIV care and management. Adolescents with HIV may experience comorbid mental health conditions or substance use disorders that interfere with medication adherence. Despite success in research to test interventions aimed at preventing and treating HIV in resource-constrained settings, adolescents and young adults have been underrepresented in these studies, leading to gaps in understanding effective HIV prevention and treatment strategies for these populations.<sup>38</sup> With additional resources, research can evaluate HIV treatment and care models in age groups that experience a disproportionate risk of HIV infection.

More than half of all people with HIV living in the United States are age 50 or older, and about 16 percent of new infections annually occur in this population.<sup>39</sup> Older adults with HIV often have more complicated health care and support service needs as a result of age-related complications and multiple comorbidities. Specific concerns and challenges for older adults with HIV include frailty, polypharmacy and drug interactions, increased caregiver burden, and the need for HIV health services that address lived experiences (e.g., multilevel stigma or assisted living needs). Also, a number of cancers occur more frequently in people with HIV, and the risk of cancer is elevated in older people with HIV.<sup>40,41</sup> These challenges highlight the opportunities for research on integrated service delivery and other innovative strategies to improve HIV care and quality of life for the aging population.



*Research is needed to better understand the sex- and gender-specific needs for women with HIV across the lifespan.*

*Credit: Rawpixel.com/Shutterstock.com*

The intersection of aging with HIV and women's health represents another research area requiring increased attention. Women with HIV may experience menopause at a younger age, and with symptoms that are more severe compared to women who do not have HIV.<sup>42,43</sup> HIV diagnoses among U.S. women ages 55 and older have not decreased, suggesting a fundamental gap in understanding the sex- and gender-specific needs for HIV prevention in the aging population.<sup>44</sup>

Increased representation of women and meaningful inclusion of gender minorities in HIV research across the lifespan represents an important area of scientific opportunity. Although women comprise half of all people with HIV, they are still underrepresented in studies on treatment strategies. Gender minorities face unique challenges related to prevention,

including stigma and bias; lack of provider knowledge regarding transgender health and needs; and social and structural determinants of health, such as housing insecurity and economic instability. Transgender women and transgender men also have concerns related to health and HIV across the life course, such as exogenous hormone exposures, pregnancy, lactation, postpartum care, and menopause.

In the FY 2023 Consolidated Appropriations Act, Congress encouraged NIH to fund interdisciplinary research and training programs on HIV and aging. Additional investment can support much needed studies on the intersection of HIV infection, ART use, sex, gender, and the aging process to inform development of new treatment

formulations and determine optimal strategies to mitigate the severity of multiple comorbidities, coinfections, and complications among all people aging with HIV. Recently, the first large-scale clinical study to test a primary cardiovascular prevention strategy in people with HIV was stopped ahead of schedule after adequate evidence of efficacy: a daily statin medication was found to reduce the increased risk of cardiovascular disease in this population. A planned interim analysis showed that participants who took pitavastatin calcium lowered their risk of major adverse cardiovascular events by 35 percent compared with those who received a placebo.<sup>45</sup>

Coinfections—such as tuberculosis (TB), hepatitis, sexually transmitted infections, SARS-CoV-2, and mpox—affect the health and well-being of people with HIV of all ages. TB is the leading cause of death for people with HIV worldwide; hepatitis B and C progress faster and cause higher rates of mortality in people with HIV than in those without HIV; and both SARS-CoV-2 and mpox pose elevated risks for people with AIDS.<sup>46–52</sup> Intensification of research on diagnosis, prevention, and treatment of HIV-related coinfections is necessary.

Additional investments are needed to support research on clinical, behavioral, and social interventions that are responsive to the needs of all individuals with HIV across the lifespan, including models of integrated care for HIV and co-occurring health conditions.

## Translation, Implementation, and Dissemination of HIV Research Discoveries to Optimize Public Health Impact

To maximize public health impact, scientific findings from across the research spectrum must be translated to inform practice and connect with communities and the general public. Information-sharing through community partnerships, research collaborations, and dissemination activities can amplify the impact of research and promote health equity for all individuals, communities, and populations affected by HIV.

### Implementation Science and Community Engagement

HIV-related implementation research can identify the most effective strategies to facilitate the adaptation, uptake, integration, and scale-up of evidence-based HIV interventions and address the key barriers that interfere with their adoption across diverse communities and health care systems. With additional resources, NIH will expand innovative implementation science research to develop and optimize HIV testing, prevention, treatment, and care approaches in support of the domestic goals of the NHAS, the EHE initiative, and the global targets identified by [Joint United Nations Programme on HIV/AIDS](#) (UNAIDS).

Community input and partnerships are key to achieving successful and sustainable HIV and other health outcomes in real-life settings. A commitment to building strong relationships with communities through engagement, particularly with Black/African American and Hispanic/Latino communities, strengthened COVID-19 vaccine trials by ensuring those who were most impacted by HIV or SARS-CoV-2 were included in the clinical trials.<sup>53</sup> Similar engagement is necessary in studies examining the impact of other public health emergencies caused by natural disasters, economic disruptions, or political conflict on critical HIV services.

Further research is needed to identify factors that impede or facilitate effective engagement with communities in HIV research—from the development of research questions and protocols to the recruitment and enrollment of subjects, and interpretation and dissemination of study results back to the HIV community—in diverse global settings. Findings from such research will enhance research partnerships, optimize implementation of evidence-based strategies, and ensure that the benefits of research are shared by all.

## Information Dissemination and Health Communication

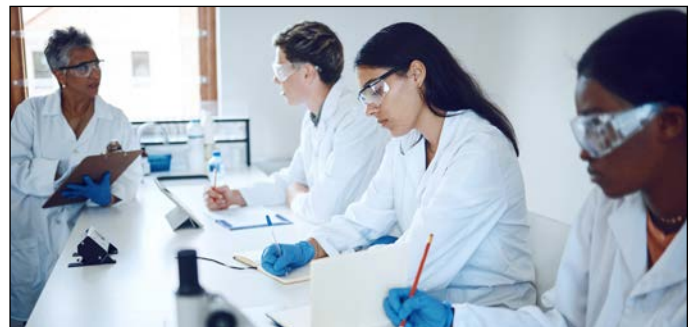
The widespread use of social media, app-based services, and other new communication technologies allows greater access to real-time health information but also has created challenges, such as the growing spread of misinformation that has resulted in health care distrust and negative public health impacts. In this evolving sociocultural landscape, there is a critical need for advanced health and science communications research to facilitate accurate translation of HIV research outcomes into evidence-based clinical practices, programs, and policies to optimize their public health impact. On a fundamental level, this means identifying better ways to measure exposure to and impact of both evidence-based health-related messages and those promoting misinformation and rejection of medical advice. On an intervention level, it means translating that basic knowledge into effective efforts to disseminate public health information.

NIH supports research to investigate health communication strategies designed to improve the introduction, explanation, and rollout of new HIV scientific discoveries and tools, such as promoting acceptance and uptake of PrEP, long-acting therapies for treatment and prevention, or a future HIV vaccine.<sup>54,55,56</sup> Additional investments are needed to develop relevant health communication strategies and innovative tools to disseminate information in appropriate context to diverse populations.

Additional resources to support community partnerships and information dissemination will enhance implementation of evidence-based practices and promote health equity.

## Infrastructure and Workforce Development to Enhance Capacity and Increase Diversity

To ensure continued progress in HIV science, investments must support research tools, computational resources, instrumentation, data and physical infrastructure, and workforce development. Efforts to enhance research capacity in diverse settings and in institutions with limited resources should also include building capacity in low- and middle-income countries with a high HIV burden. Increased support for institutions that serve underrepresented populations or are in states with historically low levels of NIH funding not only strengthen capacity, but also promote diversity and inclusion in the HIV research workforce.



*NIH is committed to developing, recruiting, and retaining a diverse, multidisciplinary HIV research workforce.*

*Credit: PeopleImages.com - Yuri A/ Shutterstock.com*

### HIV Research Workforce Development

NIH is committed to developing, recruiting, and retaining a diverse, multidisciplinary HIV research workforce. Listening sessions with researchers and community representatives, led by OAR, have highlighted the need to “address the ‘missing generation’ of junior and midcareer investigators, clinicians, and administrators... representative of communities most affected by HIV... to ensure a greater probability of retention and success.”<sup>57</sup> The OAR-led Early Career Investigator (ECI) initiative provides ongoing support and career development resources through outreach activities that target the next generation of HIV investigators. Particular emphasis is placed on reaching ECIs from underrepresented groups and under-resourced

institutions. In collaboration with NIH ICOs, OAR has hosted workshops to provide ECIs with information about HIV research across NIH, mentorship and networking opportunities, and HIV funding opportunities and the NIH grant application process.

As people with HIV live longer and experience more complex health care needs, a robust multidisciplinary workforce will be essential to advance research addressing HIV-related complications and multiple comorbidities. Additional resources are needed to expand NIH support for the HIV ECI initiative and foster more capacity to develop, replenish and sustain this mission-critical backbone of our HIV research infrastructure.

### Research Infrastructure

Cutting-edge science requires appropriate research resources and modern physical infrastructure to store specialized equipment and conduct experimental protocols. NIH funding supports alterations, renovation, equipment, and resources for such facilities. OAR collaborates with ICOs to offer funding opportunities for institutions to support development or renovation of HIV research facilities that serve underrepresented and underserved populations or are in states with historically low levels of NIH funding. These awards expand the diversity of researchers contributing to scientific discoveries and ensure significant long-term institution-wide support for HIV research, bringing HIV research capacity and capabilities to a new level. Additional funds will strengthen infrastructure and support training, capacity-building, and public-private partnerships to advance the mission of NIH HIV and AIDS research.



*Multidisciplinary training is essential to meet HIV research needs and foster diversity in the HIV research workforce.*

*Credit: Joseph Sohm/Shutterstock.com*

### Data Management and Accessibility

The increasing availability of large HIV datasets—including genomics data, clinical data, and electronic health records—highlights new opportunities for the field of HIV research. Enhanced infrastructure for data management and sharing allows for the combination of harmonized data into large, diverse, and interoperable datasets accessible to the research community for further analysis. Increased support for such activities will enhance the sharing, discovery, and use and reuse of NIH-funded HIV data. For example, additional resources can enable the migration, storage, and analysis of data in cloud-based storage, as well as the inclusion of those data in a registry of open HIV data. Accessibility of large datasets will also facilitate the integration of novel methodological and data science approaches across the HIV research continuum.

With additional investment, NIH will accelerate the development and expansion of novel programs for research resources, physical and data infrastructure, capacity-strengthening, and multidisciplinary training to meet HIV research needs and to foster diversity in the HIV research workforce.



## Conclusion

The additional resources estimated in the FY 2025 NIH HIV/AIDS Professional Judgment Budget would enable NIH to capitalize on scientific opportunities in pursuit of ending the HIV/AIDS pandemic as we:

- › Promote discovery and advance HIV science through fundamental research
- › Develop and assess novel interventions for HIV prevention, treatment, and cure
- › Optimize public health impact through implementation and dissemination of HIV research
- › Invest in infrastructure and workforce development to facilitate the advancement of HIV research

With increased investment, NIH can leverage the momentum of recent advances and accelerate progress and promise to end the pandemic and to improve the lives of individuals, communities, and populations affected by HIV.

Ending the HIV/AIDS pandemic is an ambitious but feasible goal.



## Acronyms and Abbreviations

<b>AIDS</b>	acquired immunodeficiency syndrome
<b>ART</b>	antiretroviral therapy
<b>bNAbs</b>	broadly neutralizing antibodies
<b>BSSR</b>	behavioral and social sciences research
<b>CDC</b>	U.S. Centers for Disease Control and Prevention
<b>COVID-19</b>	coronavirus disease
<b>CRISPR-Cas9</b>	clustered regularly interspaced short palindromic repeats and CRISPR-associated protein 9
<b>DNA</b>	deoxyribonucleic acid
<b>ECI</b>	early career investigator
<b>EHE</b>	<i>Ending the HIV Epidemic</i> in the U.S. initiative
<b>FDA</b>	U.S. Food and Drug Administration
<b>FIND-Seq</b>	focused interrogation of cells by nucleic acid detection and sequencing
<b>HIV</b>	human immunodeficiency virus
<b>ICOs</b>	NIH Institutes, Centers, and Offices
<b>mRNA</b>	messenger ribonucleic acid
<b>NHAS</b>	<i>National HIV/AIDS Strategy</i>
<b>NIH</b>	National Institutes of Health
<b>OAR</b>	Office of AIDS Research
<b>PEP</b>	post-exposure prophylaxis
<b>PrEP</b>	pre-exposure prophylaxis
<b>RNA</b>	ribonucleic acid
<b>SARS-CoV-2</b>	severe acute respiratory syndrome coronavirus 2
<b>SDOH</b>	social determinants of health
<b>TB</b>	tuberculosis
<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS

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