NIH HIV/AIDS Professional Judgment Budget

Catalyzing Partnerships for HIV Prevention

National Institutes of Health
Office of AIDS Research

OAR Mission

Ensure that NIH HIV/AIDS research funding is directed at the highest priority research areas and facilitate maximal return on the investment.

OAR Vision

Advance research to end the HIV pandemic and improve health outcomes for people with HIV.

Contents

The United Nations General Assembly declared the AIDS pandemic "a global emergency and one of the most formidable challenges to human life and dignity…which undermines social and economic development throughout the world and affects all levels of society."[1]

Catalyzing Partnerships for HIV Prevention

Since the start of the HIV pandemic, the National Institutes of Health (NIH) investment in HIV and AIDS research has produced critical advances leading to safe, effective antiretroviral medications that extend the lifespan of persons with HIV as well as effective interventions that prevent HIV transmission and acquisition. We have made remarkable progress, but HIV/AIDS remains a significant global health and economic challenge. Worldwide, approximately 37.9 million persons are living with HIV.[2] In America, an estimated 38,000 new HIV infections continue to occur each year.[3] While a toolbox of prevention modalities is available, durable prevention requires development of a safe, scalable, and effective vaccine.

The NIH Office of AIDS Research (OAR) works collaboratively with local, state, and federal agencies, as well as community and public health partners, to leverage scientific discovery to prevent HIV. OAR coordinates NIH research activities to fill gaps in the scientific understanding of the HIV pandemic and catalyzes partnerships to enhance the discovery and success of HIV prevention modalities. This prevention focus aligns with Ending the HIV Epidemic: A Plan for America (EHE), a national collaborative effort to reduce the total number of HIV infections by 90 percent within 10 years.[4]

The OAR is aligned with, and committed to, partners across the federal government in support of the strategies outlined in the National HIV/AIDS Strategy: Updated to 2020.

The OAR rapidly mobilizes and takes action to address emerging scientific and public health challenges; for example, the impact of coronavirus disease 2019 (COVID-19) on persons with HIV and on the overall NIH HIV research enterprise. The OAR Advisory Council (OARAC) approved in mid-March the Interim Guidance for COVID-19 and Persons with HIV[5] developed in partnership with scientific experts and government agencies. The unprecedented mitigation strategies, while essential to control the COVID-19 pandemic and save lives, are slowing scientific research, delaying discoveries, and stalling career development of the scientific workforce.

Guided in large part by the goals and strategies put forth in the NIH Strategic Plan for HIV and HIV-Related Research,[6] and as authorized by Congress in the NIH Revitalization Act of 1993,[7] the OAR develops the annual HIV/AIDS Professional Judgment Budget, which highlights the accomplishments and progress in HIV research during the prior year and identifies opportunities for additional investment to facilitate critical research. For fiscal year (FY) 2021, the HIV/AIDS Professional Judgment budget requests $769 million in additional funds, a 25-percent increase in the HIV/AIDS research investment. Funding at this level will expedite NIH efforts to pursue emerging areas of HIV science, explore vaccine and other prevention approaches, enhance partnerships and collaborations, and regain research momentum.

The NIH will continue to advance cutting-edge research and ensure that HIV/AIDS research funding is directed at the highest priority areas. The OAR remains ready and eager to continue building critically essential partnerships toward this end.

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Snapshot of the HIV Pandemic

Global

HIV is a persistent major global health issue, having claimed more than 32 million lives worldwide since the start of the pandemic.[8] Almost 38 million people were living with HIV in 2018 (including 1.7 million children); more than 20 percent were unaware of their HIV infection, and only 62 percent were receiving antiretroviral therapy (ART). An estimated 1.7 million new infections were diagnosed, and 770,000 HIV-related deaths occurred in 2018.[2] If this trend continues, the world will see a 10-percent increase in new infections every 4 years.

Although new HIV infections have been reduced by 40 percent since the peak in 1997, and AIDS-related deaths declined by more than 56 percent since peaking in 2004,[2] key populations and their sexual partners account for the majority of new infections globally. In some regions, the level of infection is catastrophic, with significant variability in treatment coverage:

- Sub-Saharan Africa accounts for nearly 68 percent of the global HIV burden and nearly 64 percent of all new infections. Significantly, four in five new infections among adolescents ages 15–19 years are in girls, while young women ages 15–24 years are twice as likely as men to be living with HIV.[2]
- Asia and the Pacific region are experiencing nearly 16 percent of the global HIV burden and 18 percent of new infections globally, but only 54 percent of people with HIV (PWH) are accessing ART. One of the most rapidly escalating HIV epidemics in the world is in the Philippines, where a 174-percent increase of the HIV incidence was observed between 2010 and 2017.[9]
- The Eastern Europe and Central Asia region has the fastest-growing HIV epidemic worldwide. The number of new HIV infections in this region increased by 29 percent between 2010 and 2018. Only 38 percent of PWH in Eastern Europe and Central Asia receive HIV treatment.[10]

Domestic

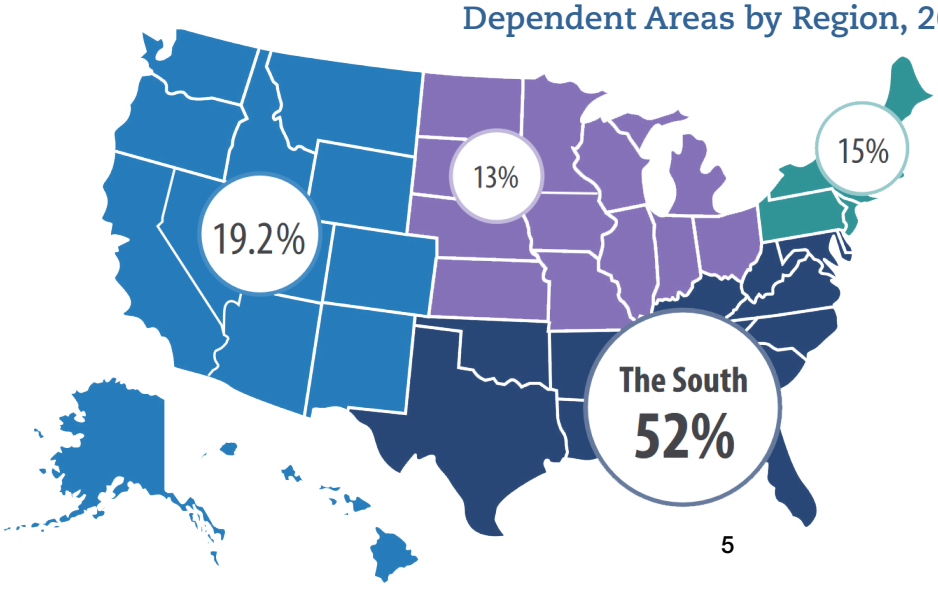
In the United States, HIV remains a significant public health challenge that continues to expand, particularly in parts of the country where health care resources are constrained. According to the most recent data from the Centers for Disease Control and Prevention—

- An estimated 1.1 million people in the United States are living with HIV; 14 percent (1 in 7) are unaware that they are living with HIV, and 37,832 received an HIV diagnosis in 2018.[11]
- Some populations have higher numbers of people newly diagnosed or living with HIV:
  - » Youth ages 13–24 years account for 21 percent of all new HIV diagnoses.[11]
  - » Approximately 17 percent of new HIV diagnoses are among people ages 50 years and older.[12]
  - » Gay, bisexual, and other men who have sex with men (MSM) account for 69 percent of all new HIV diagnoses. Black/African American and Latinx MSM are disproportionately affected by HIV.[11]
  - » Heterosexual women account for 16 percent of new HIV diagnoses.[13]
  - » Almost 20 percent of transgender women are living with HIV.[14]
  - » Approximately 7 percent of new HIV diagnoses involve injection drug use.[15]
  - » More than half of the new diagnoses (52%) occur in the U.S. South.[15]
  - » More than 50 percent of new HIV diagnoses occur in 57 jurisdictions: 48 counties; Washington, D.C.; San Juan, Puerto Rico; and seven states with substantial rural epidemics.[16]

The global and U.S. domestic epidemiological data clearly indicate that the HIV pandemic is not under control. Increased resources are essential to accelerate the discovery, development, and evaluation of technologies and tools that can play a role in decreasing HIV transmission, preventing new infections, improving the health of people with HIV, and ultimately ending the pandemic.

Based on global and U.S. domestic epidemiological data, the HIV pandemic is not under control.

Percentage of New HIV Diagnoses in the United States and Dependent Areas by Region, 2018



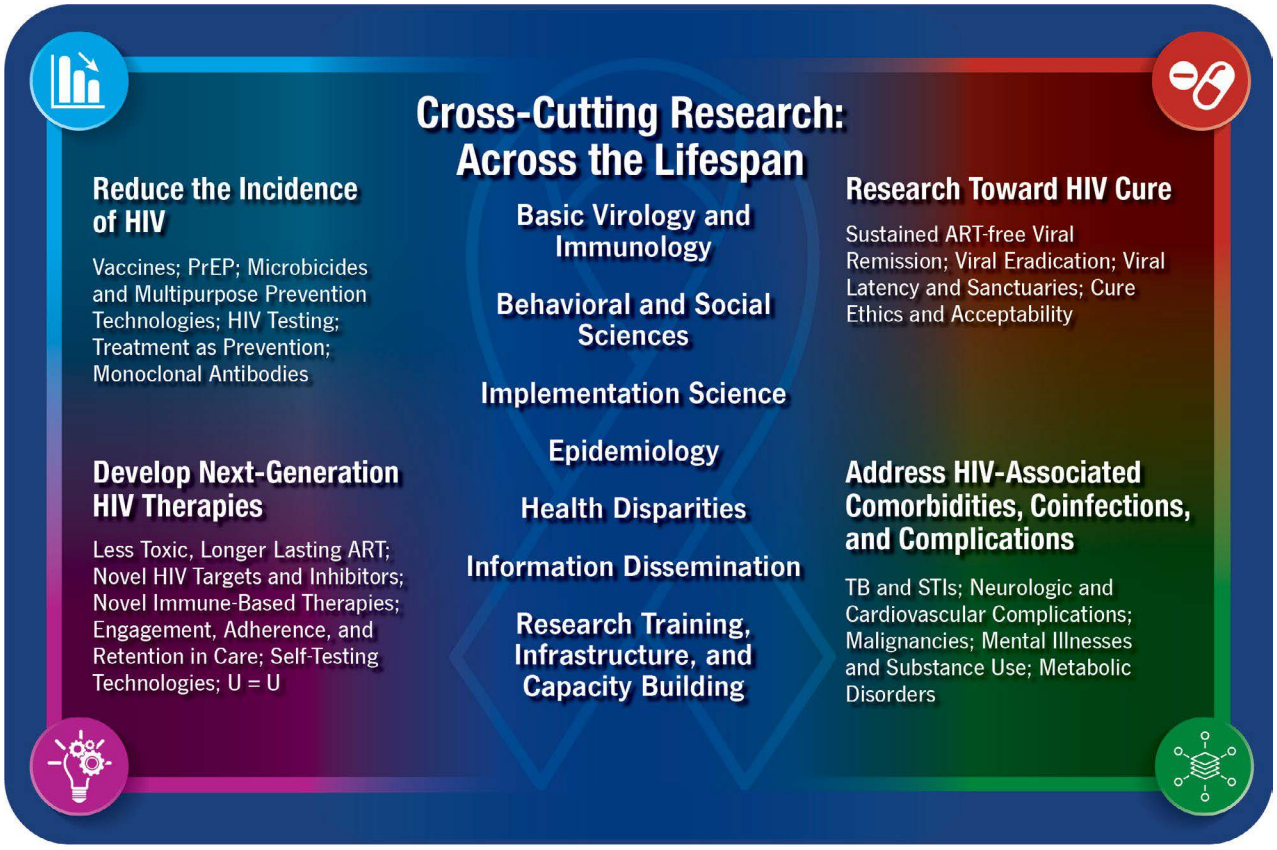
Source: Centers for Disease Control and Prevention. *Diagnoses of HIV Infection in the United States and Dependent Areas, 2018.* HIV Surveillance Report 2019;30.

NIH Priorities for HIV and HIV-Related Research

The NIH priorities for HIV and HIV-related research outline a broad HIV/AIDS research agenda, guide decision-making processes related to HIV funding, and inform the development of the NIH Strategic Plan for HIV and HIV-Related Research.[6] The OAR develops, coordinates, and manages NIH HIV-related research and ensures that research funds are invested in the areas of highest scientific priority.

The OAR works across the NIH and with partners and stakeholders—including the scientific community, people with HIV, and nongovernmental groups—to establish the NIH scientific research priorities for the global fight against HIV. The current research priorities, implemented in 2016 for 3–5 years, were based on data about the pandemic and the science to prevent, treat, and ultimately cure HIV. After careful review in FY 2019, stakeholders recommended continuing the priorities as the framework for the NIH HIV research agenda through FY 2025 (see NOT-OD-20-018).

NIH Priorities for HIV and HIV-Related Research



NIH Strategic Goals for HIV Research

The FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research[6] outlines a robust research agenda in prevention, treatment, and cure that extends across the lifespan and is inclusive of all persons with or at risk for HIV. Informed by the NIH priorities for HIV and HIV-related research, the Plan provides a framework for focusing investments and partnerships in novel ways to stimulate scientific discovery to develop new and more effective strategies, enhance existing approaches, and accelerate innovation for prevention and treatment.

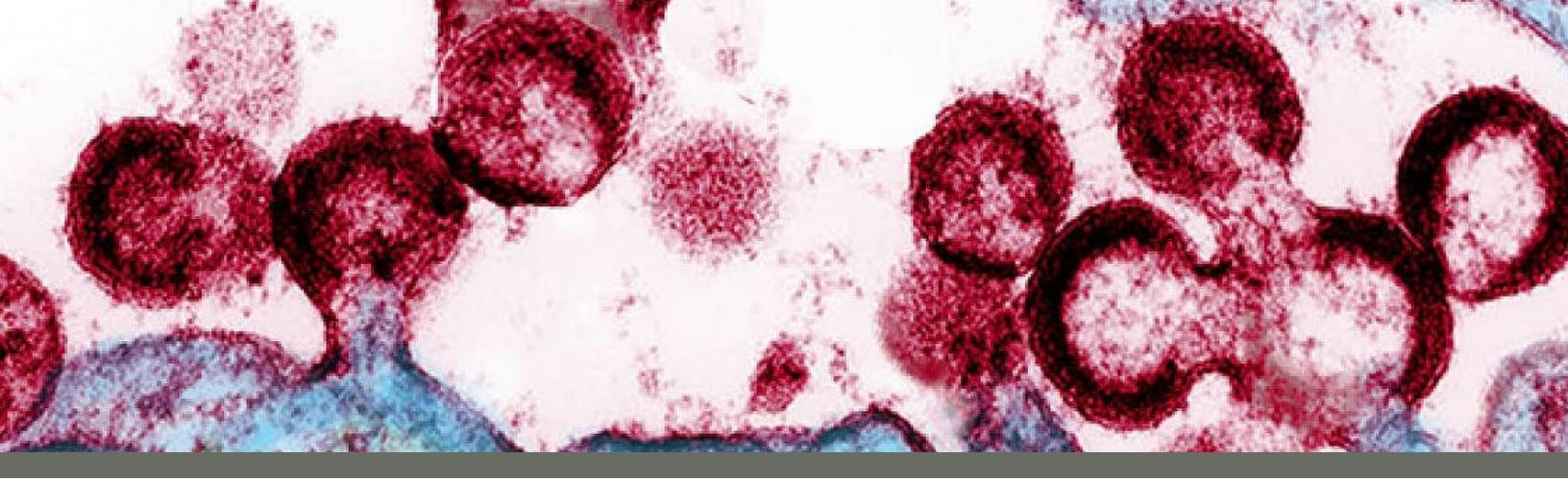
The integrated strategic approach in the Plan leverages partnerships to develop new and innovative research efforts that effectively address the challenges and move us closer to ending the HIV pandemic and improving health outcomes of all persons with or at risk for HIV. Based on the current state of the HIV pandemic and the global and national objectives, the Plan focuses on four strategic goals that emanate from the scientific priorities for FY 2021–2025:

Strategic Goal 1: Advance rigorous and innovative research to end the HIV pandemic and improve the health of people with, at risk for, or affected by HIV across the lifespan.

Strategic Goal 2: Ensure that the NIH HIV research portfolio remains flexible and responsive to emerging scientific opportunities and discoveries.

Strategic Goal 3: Promote dissemination and implementation of research discoveries for public health impact across agencies, departments, and stakeholders within the U.S. government and globally.

Strategic Goal 4: Build human resource and infrastructure capacity to enhance sustainability of HIV research discovery and the implementation of findings by a diverse and multidisciplinary workforce.



Scientific Advances

Since the discovery more than three decades ago that HIV was the virus causing AIDS, a devastating immune deficiency disease, HIV infection has been transformed from a rapidly fatal condition to a manageable chronic illness. Such a remarkable achievement is due in large part to the significant NIH investments in scientific research that continues to produce groundbreaking discoveries and advances in our understanding of HIV and has contributed to the prevention, diagnosis, and treatment of HIV.

Some Major Successes of NIH-Funded HIV Research Over the Years

- Basic science discoveries in virology, cell biology, and human immunology—coupled with major advances in protein structure, imaging, and modeling technologies—provide the framework for understanding the structure of HIV, how the virus replicates within cells, and the complexities of immune responses needed for novel vaccine and treatment strategies.
- Potent, broadly HIV-neutralizing antibodies target key binding sites of the HIV envelope protein, opening new avenues for prevention and treatment research.
- Triple-drug ART significantly prevents HIV transmission from mothers with HIV to their infants during pregnancy, labor and delivery, or breastfeeding, both in high-income countries like the United States and in low- and middle-income countries around the world.
- Combination ART regimens enable PWH to achieve undetectable viral loads, achieve longer lifespan, and prevent sexual transmission to their partners, firmly establishing that "Undetectable Equals Untransmittable" or U=U.

Long-acting ART offers the possibility of effective treatment without the need for daily medication.

- Pre-exposure prophylaxis (PrEP) for people at substantial risk for HIV infection is highly effective, with daily administration, at reducing the risk of HIV transmission.
- New diagnostic tools offer a high degree of specificity, sensitivity, and reproducibility to rapidly identify new infections and drug resistance in various settings.

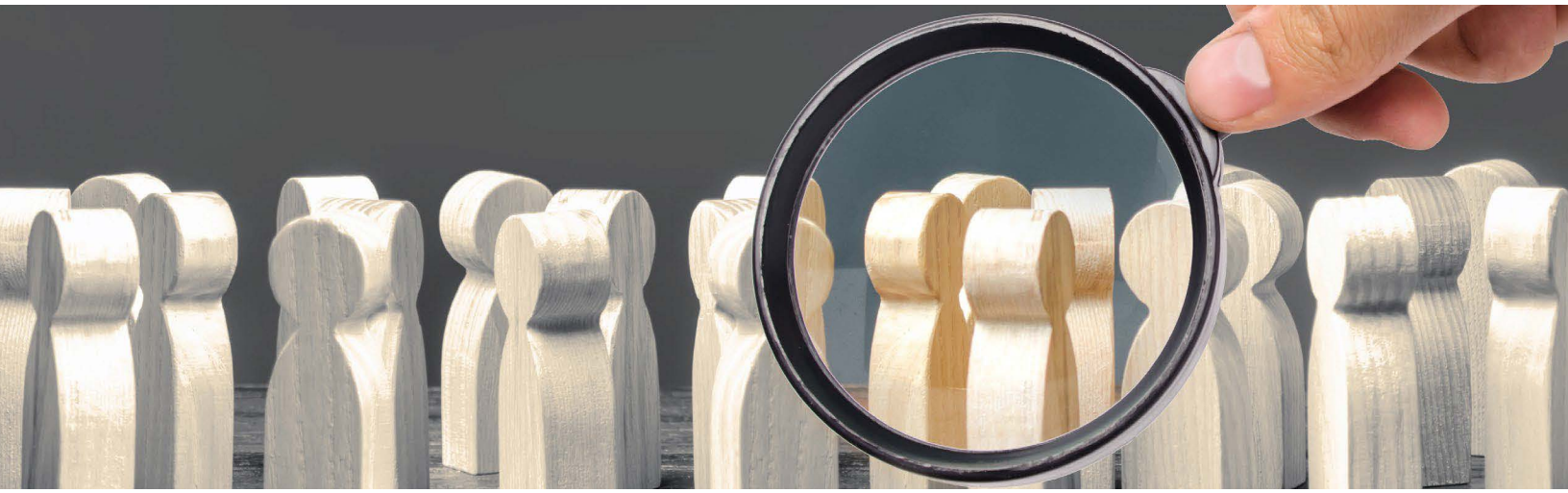
Innovative Cross-Cutting Research Is Underway

New Products for Prevention

Long-acting injectables show exciting promise for the prevention of HIV infection. For example, HIV Prevention Trial Network (HPTN) study, HPTN 083, just announced that the long-acting injectable Cabotegravir (CAB LA) is highly effective for the prevention of HIV infection in cisgender men and transgender women who have sex with men. A companion study, HPTN 084, is currently comparing the safety and efficacy of CAB LA to daily oral tenofovir/emticitabine for PrEP among women in sub-Saharan Africa.

Investigational broadly neutralizing antibodies (bNAbs) can recognize different strains of HIV and bind to a specific site on its surface, preventing viral entry into uninfected CD4-expressing immune system cells and halting HIV replication. The NIH is working with industry partners to identify and further engineer bNAbs that could serve as the next generation of HIV preventive options, as well as treatment regimens for PWH. Novel bNAb products developed by scientists at the NIH currently are being assessed for safety, tolerability, and efficacy in preventing HIV acquisition in MSM, transgender persons, women, and other individuals across the lifespan.

An intravaginal ring with the microbicide dapivirine was evaluated for HIV prevention in two recent studies among women in Africa. Results from the Dapivirine Ring Extended Access and Monitoring (DREAM) and HIV Open-Label Prevention (HOPE) studies suggest a reduced risk of acquiring HIV infection. The intravaginal ring currently is under regulatory review in Europe and, if approved, will be the first discreet, self-initiated, and long-acting HIV prevention option for women.



Care Cascade: Engaging and Retaining Key Populations in HIV Care

Elimination of implementation gaps is essential to ensure that all PWH are diagnosed and receive the treatment and care needed to achieve and maintain viral suppression to end the epidemic. Recently an NIH-supported clinical trial conducted in four U.S. cities with high HIV burdens (Atlanta, Baltimore, Birmingham, and Boston) showed that vulnerable populations—including gay, bisexual, other MSM, and transgender women with HIV who are not in care—can be engaged in care. These findings underscore the importance of developing and optimizing culturally appropriate implementation strategies to identify and connect PWH to HIV treatment services.

Next-Generation Therapies

International clinical trials among PWH indicate that monthly injectable ART is non-inferior to daily oral treatment. These long-acting treatment options represent the first steps toward making less-frequent dosing of ART a reality with significant implications for quality-of-life and cost.

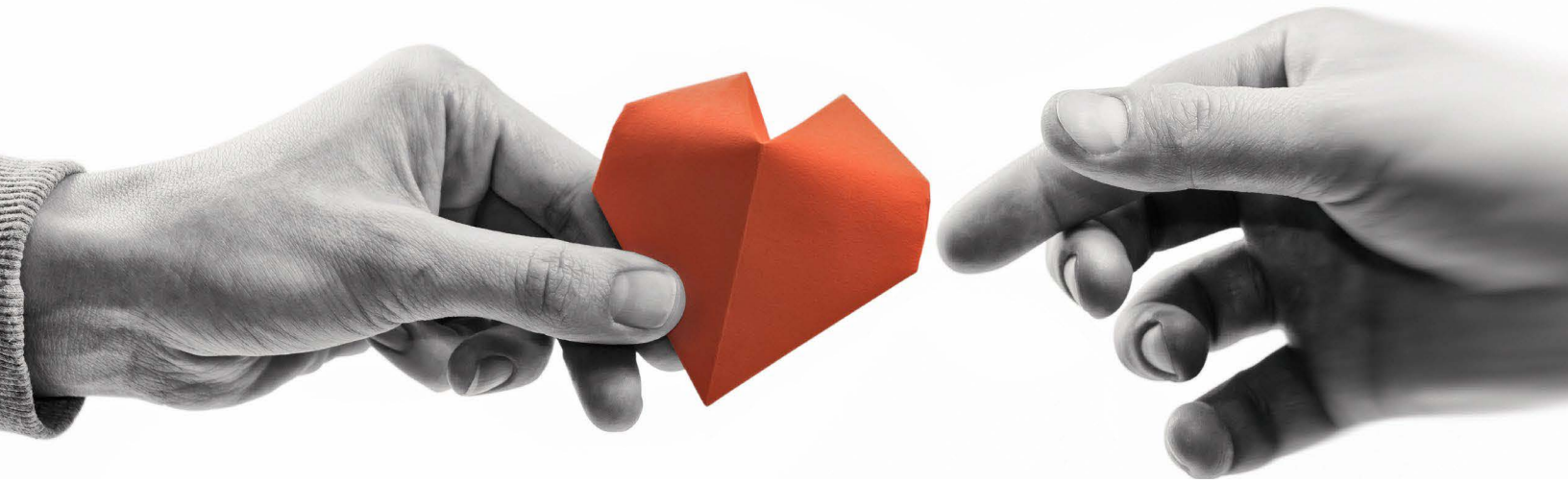
Novel Approaches to Predict and Respond to Co-Epidemic Outbreaks

NIH-supported studies are using an interdisciplinary approach combining epidemiology, statistics, operations research, and decision science by studying three interlocking epidemics—opioid use disorder, HIV, and hepatitis C virus—among people who use drugs. Researchers are examining how epidemics play out across time and across cities and towns to the level of census tracts and neighborhoods in the United States to provide a framework for predicting and quickly responding,

at the local level, to each of these epidemics alone and in combination. Results will translate into web applications and other support tools to guide decision-makers as they seek to respond more efficiently to the current public health crisis. These approaches and tools will be invaluable in applying to other co-occurring epidemics, such as the rapidly evolving COVID-19 pandemic.

Transplantation from HIV-Positive Donors to HIV-Positive Recipients

Passage of the 2013 HIV Organ Policy Equity Act (HOPE Act) legislation is an important milestone in HIV and solid organ transplantation research. Now, PWH who need a transplant may not wait as long if an organ from a donor with HIV becomes available. This also means that PWH may sign up to become organ donors and potentially give the gift of life when they pass away. The HOPE in Action Multicenter Liver Study was launched in 2019 as the first large-scale clinical trial to study liver transplantation between PWH.



HIV Cure Research

Using a combination of CRISPR gene-editing technology and sequential long-acting slow-effective release (LASER) ART therapeutic treatment, scientists have succeeded in erasing HIV DNA from cellular reservoirs of HIV in mice and are testing the CRISPR-LASER ART combination in nonhuman primates, The aim is to obtain U.S. Food and Drug Administration approval to conduct a phase 1 clinical trial in humans. Other gene therapies to delete or alter the HIV-specific CCR5 receptor on the cell surface are focused on rendering host cells less susceptible to infection by HIV reactivated from latency. Together, these advances mark progress toward finding an effective cure for HIV.

Next Frontier
Overcoming the Challenges

As the HIV pandemic continues to evolve, the NIH must continue to lead in basic, clinical, translational, behavioral, and social sciences research to address both current knowledge gaps and emerging opportunities in the scientific response to HIV. Until an HIV vaccine is available, other effective HIV prevention modalities must be implemented and optimized. Closing the pipeline of new infections is paramount to reverse the trajectory of the HIV pandemic globally. This will require expanding NIH investments and leveraging resources—through strengthening existing partnerships and building new ones—to advance scientific discoveries to prevent and treat HIV, improve health outcomes for PWH, and, ultimately, find a cure for HIV.

Vaccine Trials

An effective vaccine is essential for ending the HIV pandemic. However, multiple challenges unique to HIV, such as the virus's ability to mutate rapidly, the existence of multiple HIV subtypes requiring universal or different vaccines, and the need to determine the immune system markers of protection against HIV need to be addressed. The recent discontinuation of the HIV Vaccine Trials Network (HVTN) 702, or Uhambo, trial in South Africa due to a lack of efficacy illustrates the continued need for sustained novel research in this area. The NIH continues to test the efficacy of vaccine candidates, adjuvants, and delivery platforms in animal models and translate the most promising approaches into early-stage clinical trials. Additional investment is essential to expand preclinical discovery and development to maintain a robust pipeline of candidate vaccine products.

Basic Research

Support for basic research to elucidate the underlying mechanisms driving HIV acquisition, define the pathways preventing the immune clearance of the virus, and delineate how HIV infection subverts the immune system and causes immune system dysfunction must be increased. Emergence of viral resistance to ART is a persistent threat to pandemic control. Further study is essential to determine the structure and dynamics of HIV and host factors to understand the mechanisms of drug resistance and identify new therapeutic targets. Breakthroughs in cutting-edge structural biology approaches and 21st-century computational and imaging technologies are expected to provide powerful insights into the etiology, prevention, and treatment of HIV/AIDS.

Other Global Pandemics and HIV

COVID-19. Information and data on the coronavirus that causes COVID-19 are rapidly evolving. No evidence about whether PWH are at a greater risk of acquiring the novel virus or experiencing severe disease is available; consequently, research on the impact of COVID-19 on immunosuppressed populations, including PWH, is needed. The HIV Antiretroviral and Opportunistic Infections Guidelines Working Groups of OARAC are responsible for updating the U.S. Department of Health and Human Services (HHS) HIV/AIDS Treatment Guidelines and have issued an Interim Guidance for COVID-19 and Persons with HIV.[5] The outbreak of the COVID-19 pandemic presents an unexpected challenge, but it also provides opportunities for leveraging the NIH-supported HIV research platforms and the clinical trial networks in partnerships to tackle unanticipated research questions related to COVID-19, particularly in PWH.

Tuberculosis. Worldwide, tuberculosis (TB) ranks as the leading cause of human mortality among PWH, accounting for around 1 in 3 AIDS-related deaths.[2] In 2018, an estimated 10 million people developed TB disease; approximately 9 percent of these individuals were also living with HIV and an estimated 251,000 PWH co-infected with TB died.[17] In many regions, such as southern Africa, high rates of HIV infection are key drivers of the TB and drug-resistant TB epidemic, presenting unique challenges to public health efforts to battle the HIV/TB co-pandemics and highlighting the urgent need for improved diagnosis, optimized treatment, and prevention strategies suitable for these vulnerable populations. PWH but no active TB disease need TB preventative therapy, which lessens the risk of developing TB and reduces TB/HIV death rates by around 40%.[9] Research is needed to optimize the best regimens for TB preventive therapy to shorten the length of treatment time, reduce adverse events, and improve adherence.

HIV and Opioid Co-Epidemics

The growing epidemic of opioid misuse and addiction is a significant public health threat in the United States today that, along with injection drug use, continues to foster HIV transmission and create barriers to HIV prevention and ART adherence in PWH. Rural areas are particularly unprepared to deal with the opioid/HIV co-epidemics due to limited infrastructure and access to health care services, such as syringe services programs and sexually transmitted infection clinics. Another significant issue is that community re-entry from incarceration is a time of heightened risk for opioid use relapse, HIV risk behaviors, discontinuation of ART, increased transmission of the virus, and increased morbidity/mortality. Multidisciplinary research and partnerships across the NIH to enhance the treatment of mental and substance use disorders in these populations is needed to address these intersecting epidemics and improve health outcomes.

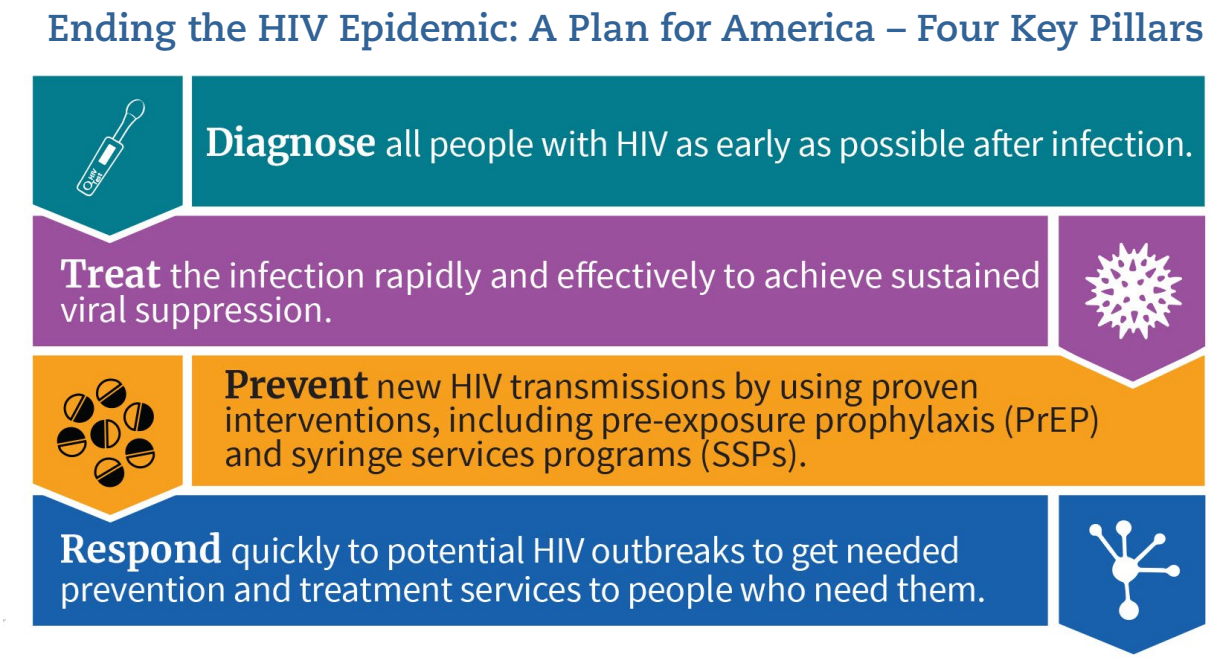
Ending the HIV Epidemic

As reflected in NIH's Strategic Goal 1 for HIV research, the ultimate and optimal prevention strategy is to end the HIV epidemic globally and to improve the health of persons with, at risk for, or affected by HIV across the lifespan. Significantly, this goal is linked to the strategic pillars of Ending the HIV Epidemic: A Plan for America (EHE), which is being implemented across the entire United States.

The OAR/NIH role in the EHE is to—

- Coordinate harmonized NIH-wide research activities to fill gaps and build on opportunities to leverage resources and knowledge;
- Track, monitor, and evaluate NIH research activities related to achieving the EHE goals; and
- Represent the NIH on the Operational Leadership Team of the Federal HHS EHE Agency Priority Goal Action Plan Working Group and on the Presidential Advisory Council on HIV/AIDS (PACHA).

To maximize effectiveness in achieving the EHE goals, the NIH will continue to promote targeted HIV implementation science research to assess approaches to translate, integrate, and disseminate evidence-based prevention and treatment interventions into culturally responsive clinical and community practice, with an emphasis on populations disproportionately affected by HIV. These efforts will support the National HIV/AIDS Strategy for the United States[18] and the Joint United Nations Programme on HIV and AIDS (UNAIDS) Fast-Track global targets.[19]



Coordinating with other Federal agency partners and building sustainable partnerships with local health authorities and communities most affected by the HIV epidemic will be critical in achieving these targets.

Integrate Biomedical with Behavioral and Social Sciences Research (BSSR) to Enhance HIV Prevention and Treatment Programs

Research is increasingly identifying and addressing behavioral, social, and structural factors that promote or impede the ability to prevent and treat HIV. These factors involve powerful dynamics that exist at the individual, community, and societal levels. Improved acceptability, coverage, uptake, and outcomes of new HIV technologies, interventions, and programs can be achieved when BSSR is integrated with biomedicine and public health planning, and communication campaigns are disseminated and resonate with diverse populations. To optimize impact and end the HIV pandemic, expanded implementation science approaches must be developed to address comorbidities, syndemics, and key sociocultural factors.

Novel Study Design and Modeling Approaches in Implementation Science

Alternative clinical trial designs and economic modeling can answer questions related to the impact of successful implementation of an HIV intervention, the best pathways to reach intervention goals, scale-up, and importantly, the appropriate

allocation of resources, thus expanding the value of NIH investments in HIV prevention research. These approaches may accelerate research, help address critical disparities in HIV health, and provide evidence to translate data into policy to improve public health impact.

Health Disparities and Stigma

Health disparities can be based on individual, community, and structural factors, such as gender, race/ethnicity, income, and geographic location. Emerging disparities in the distribution of new HIV diagnoses based on regional differences, such as a growing HIV burden in rural areas (particularly the U.S. South), are of great concern. At the same time, stigma remains one of the most critical barriers to the provision and utilization of HIV prevention and care services in key populations. More research is needed to—

- Enhance reach to populations disproportionately affected by HIV;
- Reduce barriers that affect people's willingness to access HIV testing, adopt prevention strategies, and seek care; and
- Identify and implement effective strategies to mitigate underlying health disparities.

HIV-Associated Comorbidities and Aging

With potent ART and simplified treatment regimens, HIV infection has become a manageable, chronic condition, and people with HIV are living longer and achieving near-normal lifespans. At the same time, aging in PWH presents unique challenges for the prevention and management of comorbidities, such as cancers, cardiovascular and lung diseases, and HIV-associated neurocognitive disorders. Research is needed to understand the common underlying etiologies and shared mechanisms that may drive chronic inflammation, immune dysfunction, and accentuated aging, which in turn affect multiple organ systems and result in concurrent comorbid conditions that may lead to decreased quality of life or lifespan in PWH, even in those individuals who have undetectable viral loads with ART.

Multidisciplinary and Diverse Workforce

The NIH is committed to promoting opportunities for new researchers and enhancing training and mentorship programs to encourage successful, independent careers for early stage investigators (ESIs) in a way that enhances workforce diversity. Over the last several years, the NIH has taken numerous steps to balance, strengthen, and stabilize the biomedical research workforce, but increased investments in supporting and expanding ESIs in the HIV field are needed. A priority for developing workforce diversity is to promote research on the engagement of community health

workers as integral members of a multidisciplinary health care team to improve HIV care engagement, antiretroviral adherence, viral suppression, and ultimately, health outcomes.

Critical Infrastructure Needs

Research to improve existing animal models or develop better models will help to advance our understanding of the underlying HIV/AIDS disease mechanisms and improve preventive and therapeutic interventions for HIV infection. At the same time, there is a need to develop and ensure adequate physical infrastructure to meet requirements for specialized environments, including germ-free or barrier facilities, to support specific pathogen–free animals. The construction and renovation of research facilities, good manufacturing practice–level laboratories, and manufacturing facilities will support the production of candidate HIV vaccines and therapeutics for research and development. Investment must be expanded to strengthen basic and clinical research infrastructure in under-resourced areas, which carry a significant burden of the HIV epidemic in the United States.

Augment the NIH commitment to the development of the next generation of HIV researchers, particularly those from underrepresented populations and institutions within the U.S. and globally, to enhance the pipeline of HIV researchers in multiple disciplines.[21]

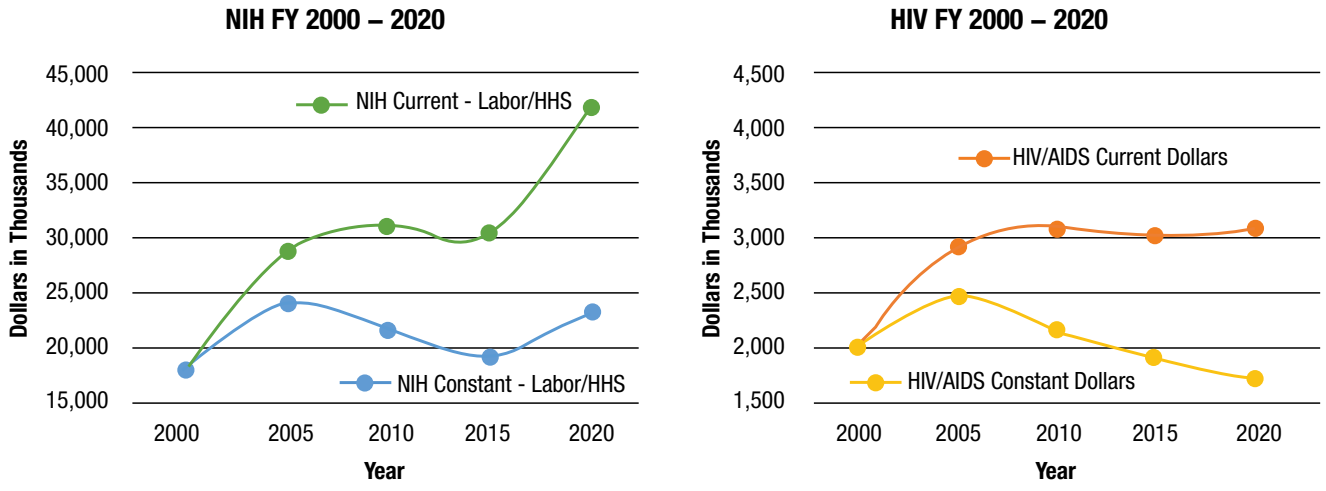
Innovative Technologies

Thoughtful investment is needed to apply the latest technological advances to HIV research, particularly to advance the development of rapid, point-of-care diagnostics and self-administered viral load testing. Promising tools—such as 3-D printing, artificial intelligence (including machine learning), advanced bioinformatics, genetics, big data mining, and geospatial modeling—are expected to simplify monitoring, improve ART adherence to achieve viral suppression, and, ultimately, enhance prevention of HIV transmission. The use of digital media, e/mHealth, social media, and influencers in designing effective HIV prevention and treatment interventions that focus on end users as well as health care providers offers a growing potential to improve access to care and health outcomes. Assessment of affordability, sustainability, and cost-effective implementation of each novel technology or intervention will play a key role in policy and funding decision-making related to HIV research investments.

Professional Judgment Budget

NIH HIV research funding has increased only modestly over the past 10 years and has lagged behind the increases in costs associated with conducting this critical research. As PWH are living longer and experience more comorbidities associated with HIV and ART, the overall cost of HIV management is projected to continue to increase.[21] Strengthening the HIV/AIDS research investment now to end the HIV pandemic will reap the benefit of controlling health care costs in the future.

Inflation Effect on Research Purchasing Power



Note: The above funding does not include COVID-19 appropriations.
Source: Biomedical Research and Development Price Index (BRDPI).

The OAR is legislatively mandated to develop an annual NIH-wide Full-Funding Budget Estimate or Professional Judgment Budget that advances the NIH-wide HIV/AIDS research agenda and to ensure investment of resources in the highest scientific priority areas. The budget estimate is based on current research opportunities and scientific gaps, as determined by internal and external stakeholders, and supports a comprehensive research program.

In response to the challenges and priorities associated with the NIH HIV research agenda, the FY 2021 NIH HIV/AIDS Professional Judgment Budget request—

- Aims to correct the increased loss of spending power;
- Encourages innovative technology approaches, including 3-D printing, artificial intelligence, advanced bioinformatics, genetics, big data mining, and geospatial modeling for advanced discovery;
- Addresses both intramural and extramural HIV/AIDS research, as well as funding for research facilities and infrastructure, research training, and program evaluation;
- Alleviates individual, community, and social-structural factors influencing (1) inequalities in HIV testing; (2) engagement, adherence, and persistence with prevention and care services; and (3) health outcomes in different settings;
- Focuses on the President's goal to reduce the number of new HIV infections in the United States by 90 percent within 10 years and provides for novel developments to EHE;
- Accommodates new research on the susceptibility of PWH to COVID-19 infection, disease sequelae, and recovery; and
- Invests in reactivation of the research enterprise disruption following mitigation strategies for the COVID-19 pandemic.

The FY 2021 Professional Judgment Budget estimate for the NIH-wide HIV/AIDS research program is $3,845 million, an increase of $769 million, or 25 percent, over the FY 2020 estimate (see Table 1). This budget estimates the resources needed to support the highest-priority HIV/AIDS research across the NIH in partnership with key partners and stakeholders, with an enhanced focus on prevention.

Table 1. FY 2021 HIV/AIDS Professional Judgment Budget Request (Dollars in Thousands)

Research Priority	FY 2019 Actual	FY 2020 Estimate	FY 2021 Professional Judgment	FY 2021 +/– FY 2020	Percent Change
Reduce the Incidence of HIV	$741,401	$737,348	$1,048,259	$310,911	42.2%
Develop Next-Generation Therapies	368,907	365,526	428,680	63,154	17.3%
Research Toward a Cure	187,776	197,637	215,775	18,138	9.2%
Address HIV-Associated Comorbidities, Coinfections, and Complications	531,442	543,531	619,902	76,371	14.1%
Cross-Cutting Areas†	1,207,767	1,232,019	1,532,460	300,441	24.4%
Total	**$3,037,293**	**$3,076,061**	**$3,845,076**	**$769,015**	**25.0%**

† Cross-cutting areas include basic sciences, behavioral and social sciences, epidemiology, health disparities, implementation science, information dissemination, and research training.

This increased investment provides essential resources to the NIH to address specific and critical scientific opportunities related to the HIV portfolio to—

- Develop safe, effective, practical, and affordable HIV vaccines and non-vaccine prevention strategies, such as antibody-mediated approaches;
- Evaluate community-level behavioral and social-structural approaches for HIV prevention and improve systematic uptake of evidence-based prevention and care interventions in diverse settings and populations, while identifying strategies for mitigating HIV-associated stigma;
- Study basic mechanisms of virus–host cell dynamics to support the development of innovative prevention, treatment, and cure strategies for HIV infection; and
- Develop alternative clinical trial designs and economic modeling to estimate and improve outcomes and public health impact to accelerate ending the HIV pandemic and enhance the health outcomes of people with HIV.

Looking Forward

Catalyzing Partnerships to Build Collaborations

NIH's investment in HIV/AIDS research continues to leverage partnerships and catalyze collaborations to produce significant scientific discoveries benefiting millions of people affected by, at risk of, or living with HIV. Advances resulting from NIH-funded research and collaborations promote the development of tools and effective interventions that bring us closer to achieving the ambitious goal of ending the HIV epidemic in the United States and globally. The NIH and OAR has developed and continues to expand a network of effective partnerships with—

- Nonprofit organizations and foundations, such as the AIDS Vaccine Advocacy Coalition and the Bill and Melinda Gates Foundation for Cure
- Industry partners, such as pharmaceutical companies, for development of vaccines and therapeutics

- Federal agency partners, including the Centers for Disease Control and Prevention, Health Resources and Services Administration, Indian Health Service, and the Substance Abuse and Mental Health Services Administration and their funded partners within the EHE initiative
- PACHA

The OAR works in close partnership with the NIH Institutes, Centers, and Offices (ICOs) through the NIH AIDS Executive Committee (NAEC), which is composed of representatives from all NIH ICOs that support HIV research, to identify NIH-wide HIV research priorities, scientific gaps, and opportunities in emerging areas of research. Through the NAEC, the OAR facilitates information exchange and supports scientific and funding collaborations among the ICOs.

A key partner is the OARAC, whose members are diverse subject-matter experts in a range of disciplines from across the country. Collaboration and bidirectional dialogue with the OARAC allow the OAR to exchange updates on late-breaking science from the HIV field, as well as obtain advice from external experts regarding potential directions for future NIH initiatives.

Just as important are the NIH and OAR partnerships with community and faith-based organizations, academic institutions, and public health departments to ensure dissemination of research and evidence-based strategies to be implemented in local settings and in diverse populations and to contribute to the EHE. By conducting community listening sessions across the United States with groups of stakeholders from research and HIV-affected communities, the OAR is well positioned to make informed decisions regarding the evolving NIH HIV/AIDS research agenda.

The OAR is confident that the FY 2021 Professional Judgment Budget request provides the framework needed to catalyze partnerships and collaborations to accelerate the groundbreaking research discoveries and implement the most effective interventions that will end the HIV/AIDS pandemic and improve the health of PWH. The HIV pandemic continues to evolve in an unpredictable environment that requires creative and flexible approaches to research. The requested FY 2021 Professional Judgement Budget will allow the NIH to amplify its leadership and accomplishments to accelerate approaches to eradicate HIV. We look forward to sharing scientific progress on HIV discoveries with stakeholders in research, medicine, policy, industry, and—most important—the people and communities living with and affected by HIV across the globe.

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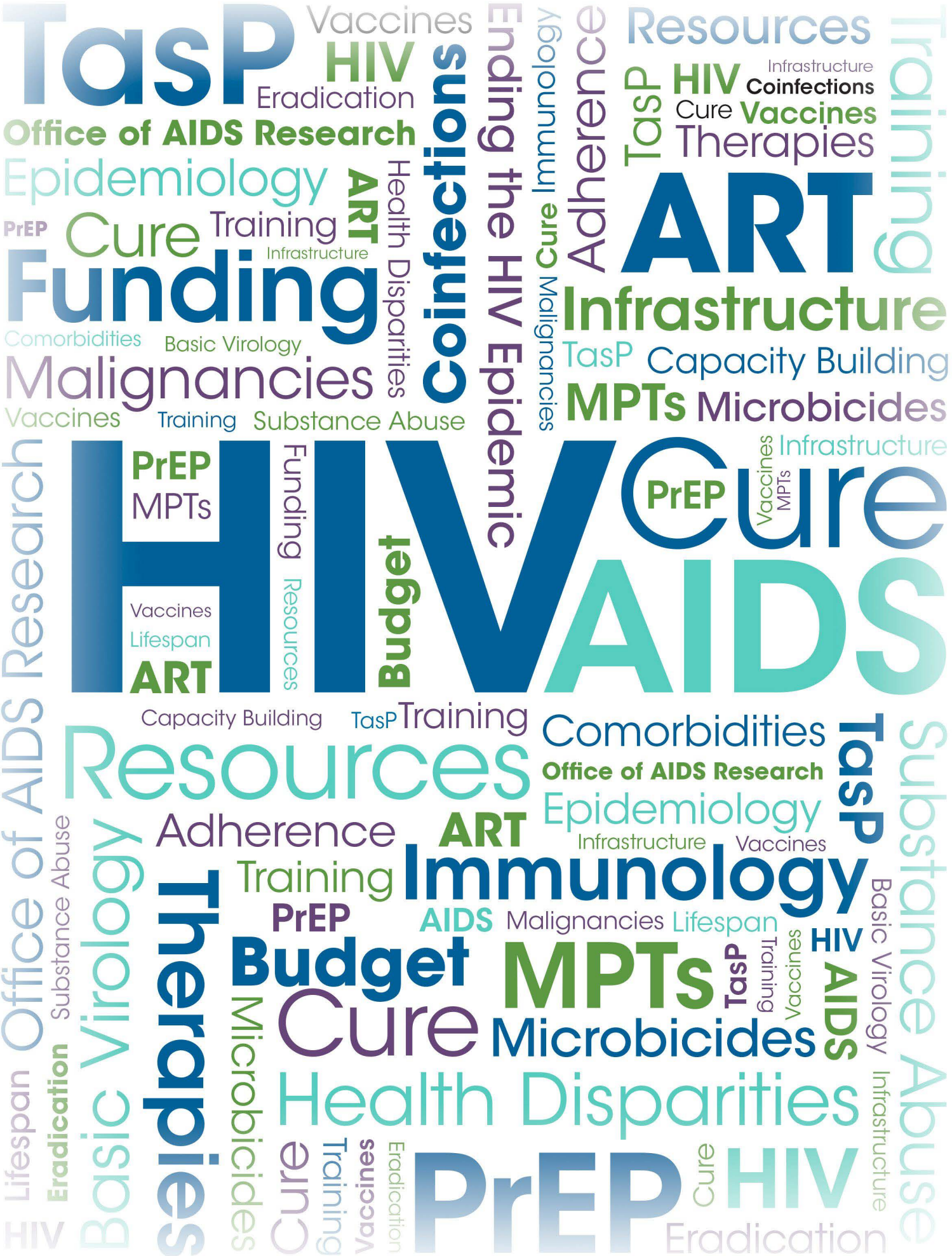
Acronyms/Abbreviations

AIDS	acquired immune deficiency syndrome
ART	antiretroviral therapy
BSSR	behavioral and social sciences research
bNAbs	broadly neutralizing antibodies
CAB LA	Cabotegravir (long-acting injectable)
COVID-19	coronavirus disease 2019
CRISPR	clustered regularly interspaced short palindromic repeats
DREAM	Dapivirine Ring Extended Access and Monitoring Study
EHE	*Ending the HIV Epidemic: A Plan for America* Initiative
ESI	early stage investigator
FY	fiscal year
HHS	U.S. Department of Health and Human Services
HIV	human immunodeficiency virus
HOPE	HIV Open-Label Prevention Study
HOPE Act	2013 HIV Organ Policy Equity Act
HPTN	HIV Prevention Trials Network
HVTN	HIV Vaccine Trials Network
ICOs	[NIH] Institutes, Centers, and OD Offices
LASER ART	long-acting slow-effective release antiviral therapy
MSM	men who have sex with men
NAEC	NIH AIDS Executive Committee
NIH	National Institutes of Health
OAR	Office of AIDS Research
OARAC	OAR Advisory Council
PACHA	Presidential Advisory Council on HIV/AIDS
PrEP	pre-exposure prophylaxis
PWH	people with HIV
TB	tuberculosis
U=U	undetectable equals untransmittable
UNAIDS	Joint United Nations Programme on HIV and AIDS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Epidemiology
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