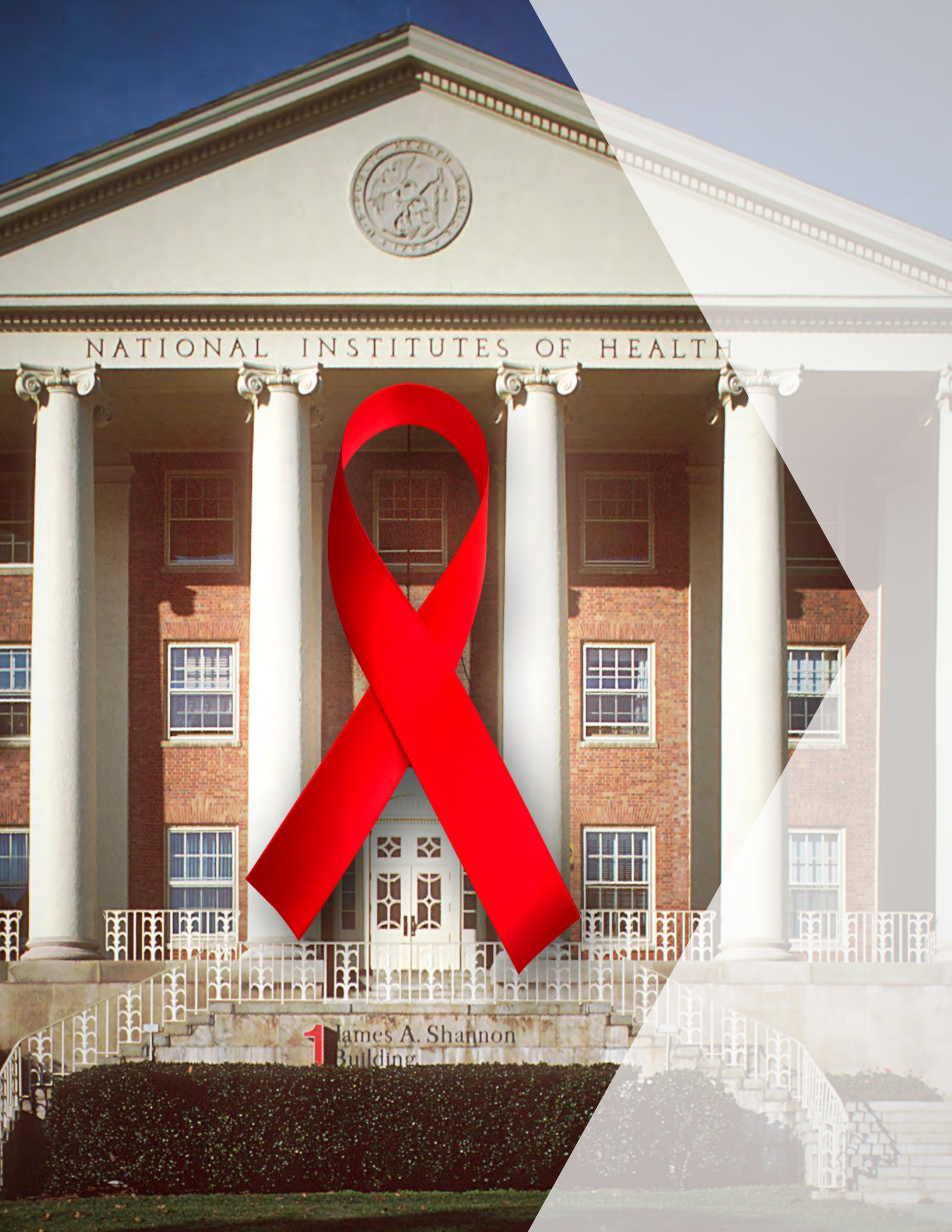


FY 2021-2025

NIH
Strategic
Plan
for
HIV and
HIV-Related
Research

Prepared by the
Office of AIDS Research





NATIONAL INSTITUTES OF HEALTH

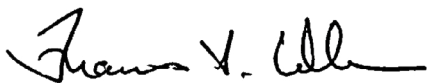
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Foreword

We are at a momentous time in the history of the HIV epidemic in the United States and around the world: highly effective tools now exist to prevent new HIV infections, treat the virus once it is acquired, mitigate the impact of HIV-associated comorbidities, and even imagine a cure. Much of this progress has emerged from research funded by the National Institutes of Health (NIH) and conducted over more than three decades. Unfortunately, this hope for a future free from HIV is not yet a reality to all, and we must continue our work to develop better tools, such as a vaccine.

In February 2019, President Trump announced “*Ending the HIV Epidemic: A Plan for America*,” which aims to reduce the number of new HIV infections in the United States by 75 percent within five years and by 90 percent within ten years through a coordinated inter-governmental strategy to reach those U.S. populations with the highest incidence of new HIV infections. NIH, in partnership with our sister agencies across the Federal Government, will continue to be a leader in advancing HIV research as a key component of the President’s strategy to help end HIV in America. We will strive towards the goals of: (1) diagnosing all people with HIV as early as possible; (2) treating HIV infection rapidly and effectively to achieve durable viral suppression; (3) protecting people at risk for HIV using proven prevention interventions; and (4) responding quickly to emerging outbreaks of HIV infection. NIH-sponsored research in pursuit of these goals also will be valuable to addressing HIV epidemics in other parts of the world.

The NIH Office of AIDS Research (OAR) continues to be the coordinating force behind a range of scientific and budgetary activities across NIH. By collaborating with all Institutes, Centers, and Offices across NIH, OAR continues to provide effective leadership in identifying scientific priorities, developing and evaluating programs, and allocating funding to ensure that NIH maintains a robust and multidisciplinary HIV portfolio. OAR seeks to address the most significant opportunities for new discovery and to help meet the needs of those at risk for or living with HIV. To further this effort, OAR has developed a 5-year strategic plan that I am confident will optimize the future investments in HIV research that span basic, clinical, translational, and implementation sciences; nurture the next generation of HIV investigators; and stimulate innovative discovery to prevent new HIV infections and improve the health of ALL people with HIV.



Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health



Progress Against HIV/AIDS

HIV/AIDS | HHS | HHS and HIV/AIDS

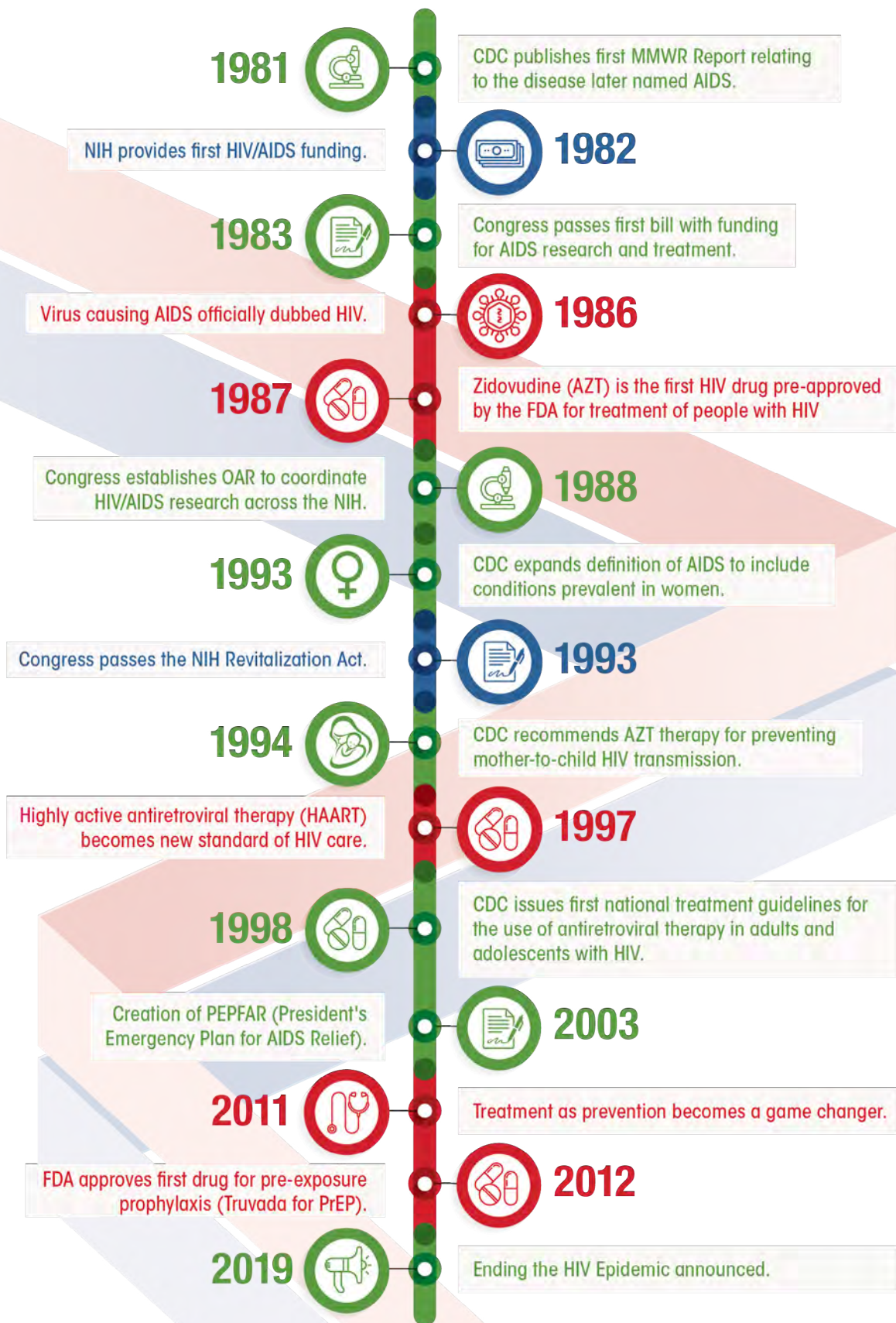


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Preface

The NIH Office of AIDS Research (OAR) presents the *NIH Strategic Plan for HIV and HIV-Related Research* (the Plan) for fiscal years (FY) 2021–2025. The Plan serves as the guiding framework for OAR to allocate funds to the NIH Institutes, Center’s and OD Offices (ICOs) that advance the NIH-wide HIV research agenda and ensure investment of resources in the highest priority areas of scientific opportunity.

With the FY 2021–2025 Plan, the NIH is transitioning from a long-standing practice of annual Strategic Plans for the HIV agenda to a 5-year Plan that recognizes the multiyear timelines associated with most NIH-supported basic, clinical, behavioral and social, translational, and implementation research projects. Additionally, the multiyear Plan harmonizes the cycle of priority-setting for the NIH HIV research agenda with the overarching *NIH-Wide Strategic Plan* and other U.S. Government plans for addressing HIV, including the *National HIV/AIDS Strategy for the United States, Ending the HIV Epidemic: A Plan for America*, and the *President’s Emergency Plan for AIDS Relief (PEPFAR)*, as well as the international *90-90-90* and *95-95-95* initiatives launched by the Joint United Nations Programme on HIV and AIDS (UNAIDS).

NIH investments in innovative HIV and AIDS research over more than three decades produced groundbreaking advances that enabled the development of safe, effective antiretroviral medications to extend the lifespan of people with HIV, and the design and implementation of effective interventions to prevent HIV transmission and acquisition. Nonetheless, globally and in the United States, new infections continue at rates that are incompatible with ending the pandemic. The NIH will continue to lead in basic, clinical, and translational research to develop cutting-edge solutions for the ongoing challenges of the HIV pandemic.

The Plan 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. 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.

With sincere appreciation,



Maureen M. Goodenow, Ph.D.

Associate Director for AIDS Research and
Director, Office of AIDS Research
National Institutes of Health



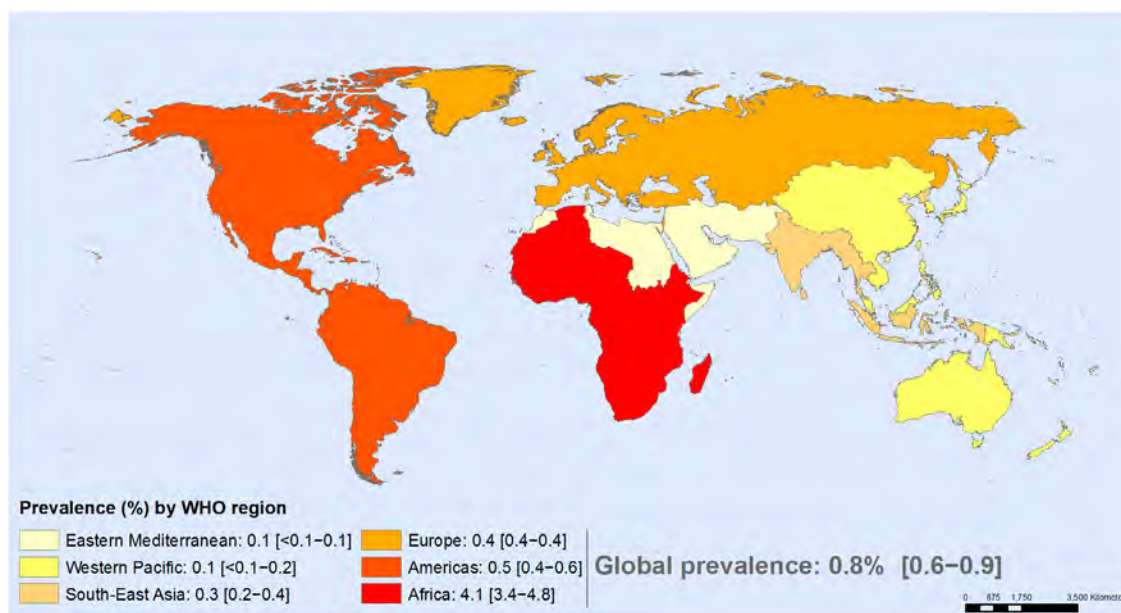
Overview: Putting the NIH HIV Research Agenda in Context



The Global HIV Pandemic

HIV persists as one of the world's most serious public health, development, and economic challenges. New infections continue to devastate communities and destabilize crucial socioeconomic infrastructure around the world. In 2018, an estimated 37.9 million people worldwide were living with HIV, an increase of more than 12 percent from 33.4 million people in 2010. HIV prevalence is distributed unequally around the world ([Figure 1](#)).

Figure 1. Prevalence of HIV Among Adults Aged 15 to 49, 2017, by WHO Region



Source: World Health Organization

Note: Recent data can be accessed from the Kaiser Family Foundation at [kff.org/global-health-policy/fact-sheet/the-global-hiv-aids-epidemic](https://www.kff.org/global-health-policy/fact-sheet/the-global-hiv-aids-epidemic)

HIV in the World

From 2010 to 2018, new HIV infections declined approximately 16 percent among adults and 41 percent among children.¹

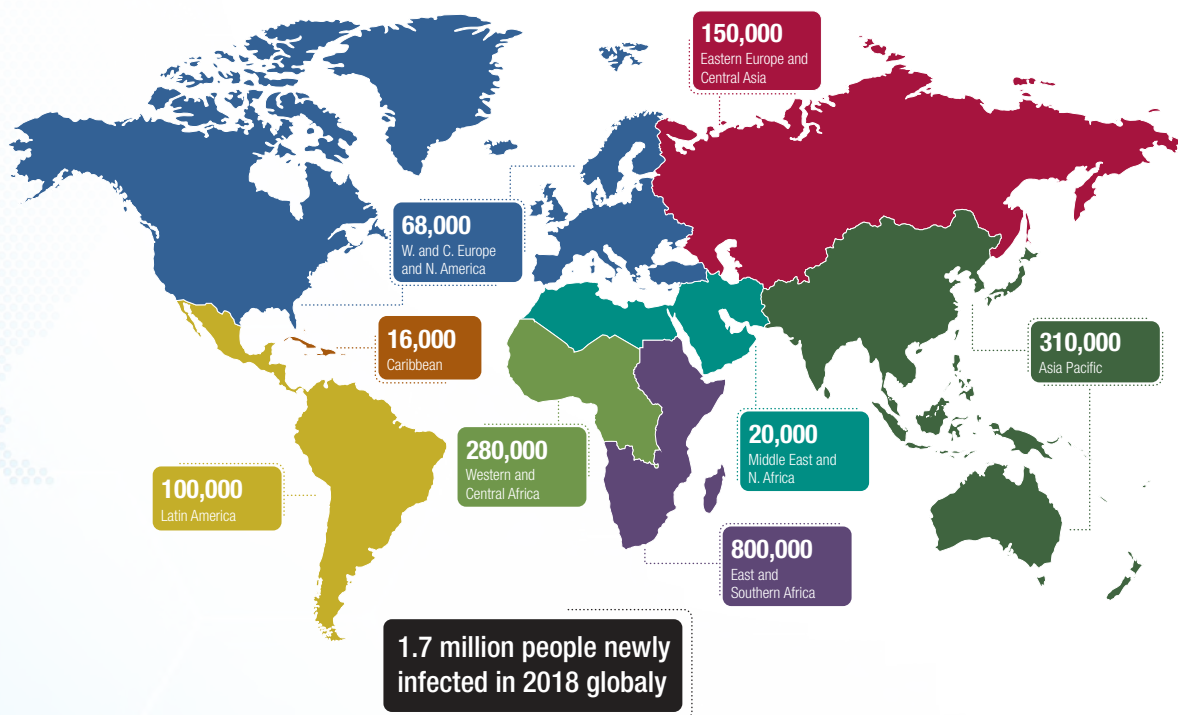
Nonetheless, about 1.7 million new infections occurred worldwide in 2018, including:

- Nearly two-thirds located in sub-Saharan Africa
- One-third among young people between the ages of 15 and 24 years
- Approximately 10 percent among children 14 years and younger mostly acquired during gestation, childbirth, or breastfeeding

While HIV testing capacity is increasing, an estimated one fifth of people with HIV worldwide are still unaware of their status.¹ This proportion is even higher in certain areas and among several populations.²

Although some regions and countries have declining or flat incidence, the global pandemic remains unstable as other countries and regions experience rising incidence ([Figure 2](#)). Continued HIV transmission underscores the growing, unmet needs for HIV prevention, treatment, and care services that are appropriate to the persons and communities most affected in particular areas.

Figure 2. Number of New HIV Infections in 2018



Source: 2018 UNAIDS data.

Key Populations

- › Women comprise about half of all adults living with HIV.
 - HIV and AIDS is a leading cause of death among women of reproductive age and the leading cause of death for women and adolescent girls aged 15–49 years globally.³

In many regions, men who have sex with men (MSM), people who inject drugs, sex workers, transgender individuals, and incarcerated persons are disproportionately affected and experience inequalities along the entire HIV prevention and care continua.²

- › Between 2000 and 2016 the proportion of people living with HIV who are aged 50 years or older increased from 8% to 16% and is estimated to reach 21% in 2020.⁴

Progress and **challenges** in the global efforts to address the pandemic:

- › In 2018, deaths from HIV/AIDS declined by 55 percent since peak numbers in 2004, and 33 percent since 2010, although **the current number of 770,000 annual deaths is deeply troubling.**¹

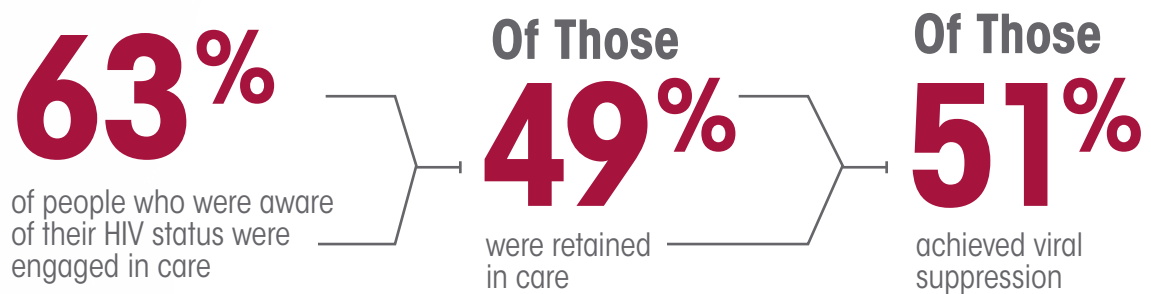
2018 Deaths
from HIV/AIDS
declined by **55%**

- › 62 percent of people with HIV were accessing antiretroviral treatment (ART) at the end of 2018, but **more than 40 percent, about 15 million individuals, still need access to ART.**¹

More than
40% **received**
ART

The HIV Epidemic in the United States

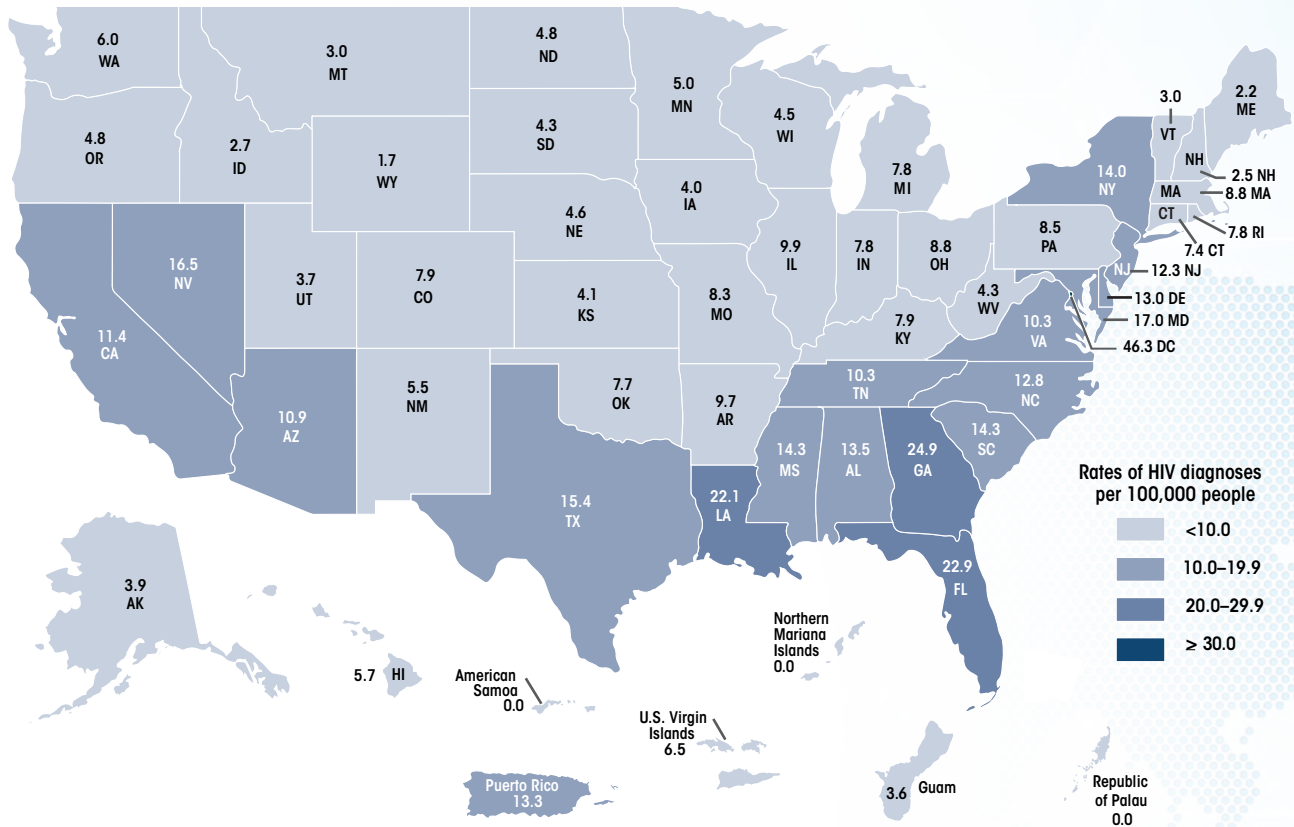
At the end of 2016, approximately 1.1 million adults and adolescents were living with HIV in the United States.⁵ About 15 percent of these were unaware of their HIV status. Of those who were aware of their HIV infection, only 63 percent were engaged in care, only 49 percent of those were retained in care, and only 51 percent of those in care achieved viral suppression.^{5,6} The low rates of treatment and viral suppression are alarming, especially given the overwhelming evidence from National Institutes of Health (NIH)-funded clinical trials in multiple settings that ART enhances health and quality of life and that durable viral suppression virtually eliminates the risk of sexual transmission of HIV.⁷



HIV in America

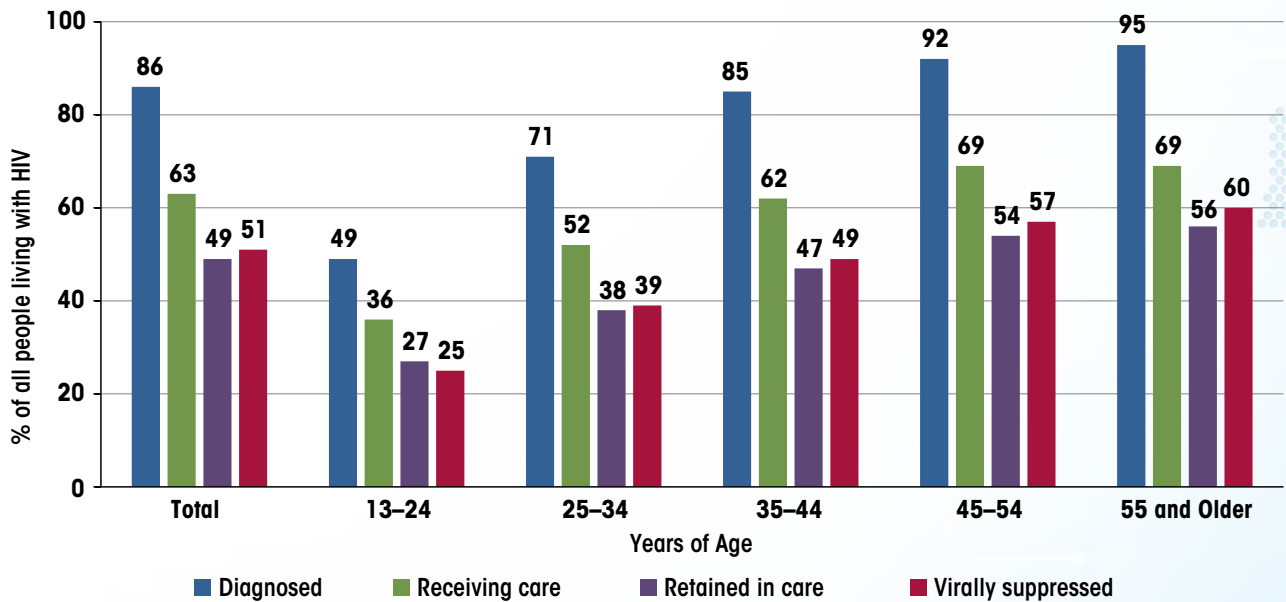
- HIV incidence has decreased overall in the United States from its peak in the mid-1980s, but new infections continue to occur in every state ([Figure 3](#)).
- In 2017, more than 38,000 people were diagnosed with HIV, similar to the numbers for the preceding 4 years.⁶
- The Southern region includes 38 percent of the U.S. population; but in 2017 more than 50 percent of new HIV diagnoses in the United States occurred in the South.⁸
- Blacks/African Americans and Hispanics/Latinx are disproportionately affected by HIV compared to other races and ethnicities, and account for approximately 43 percent and 26 percent of new HIV diagnoses, respectively.^{5,6}
- About 20 percent of new infections occur in people under the age of 24,⁹ about 17 percent occur in persons over 50 years of age,¹⁰ and trajectories along the HIV care continuum vary by age ([Figure 4](#)).

Figure 3. Rates of HIV Diagnoses in the United States, 2017



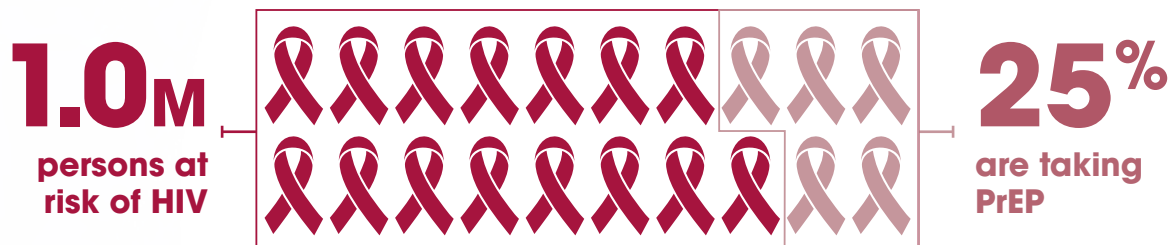
Source: CDC. *Diagnoses of HIV Infection in the United States and Dependent Areas, 2017* HIV Surveillance Report 2018;29.

Figure 4: HIV Care Continuum Across the Lifespan in the United States, 2015



Source: CDC 2015.

HIV prevention remains key to ending the epidemic, and highly effective prevention tools now exist. For example, new infections can be reduced substantially by the uptake and consistent use of pre-exposure prophylaxis (PrEP). However, among the one million people in the United States who are at highest risk for HIV, only about 25 percent are using PrEP.¹¹ Although both awareness and use of PrEP have increased, disparities for access exist by race, ethnicity, sex, gender, age, economic status, and region of residence. For example, Black and Latinx MSM have higher risk for acquiring HIV, but lower rates of both awareness and uptake of PrEP, than their White counterparts.¹² Females, youth aged 24 years or younger, and people residing in the South have lower levels of PrEP use relative to need than males, people aged 24 to 55 years, or people residing in other regions of the country.¹³



To address some of these issues in HIV diagnosis, prevention, and care, in February 2019, President Trump announced a new domestic initiative, called *Ending the HIV Epidemic: A Plan for America* (EHE).¹⁴ This multi-agency initiative aims to reduce the number of new HIV infections by 75 percent within 5 years and by 90 percent within 10 years. The effort focuses on four key strategies: diagnose all individuals with HIV as early as possible; treat people with HIV rapidly and effectively to reach sustained viral suppression; prevent new HIV transmissions by using proven interventions, including PrEP and syringe services programs; and respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

NIH is part of the EHE initiative, and the *FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research* outlines scientific priorities, and activities that will contribute to its success. (See page 20 for details about NIH’s role in EHE.)

NIH HIV Research Priorities



Role of the Office of AIDS Research

In 1988, Section 2353 of the Public Health Service Act established the NIH Office of AIDS Research (OAR) in the Office of the NIH Director (OD) to coordinate the scientific, budgetary, and policy elements of a diverse HIV research program across the NIH. Over the past three decades, OAR has coordinated the expansion of NIH-supported HIV research into a robust, multidisciplinary program with a substantial research pipeline, from basic science to public health and policy ([Figure 5](#)). In FY 2019, more than \$3 billion of HIV/AIDS funds was distributed across NIH Institutes, Centers, and Offices (ICOs), representing the largest public investment in HIV/AIDS research globally ([Figure 6](#)).

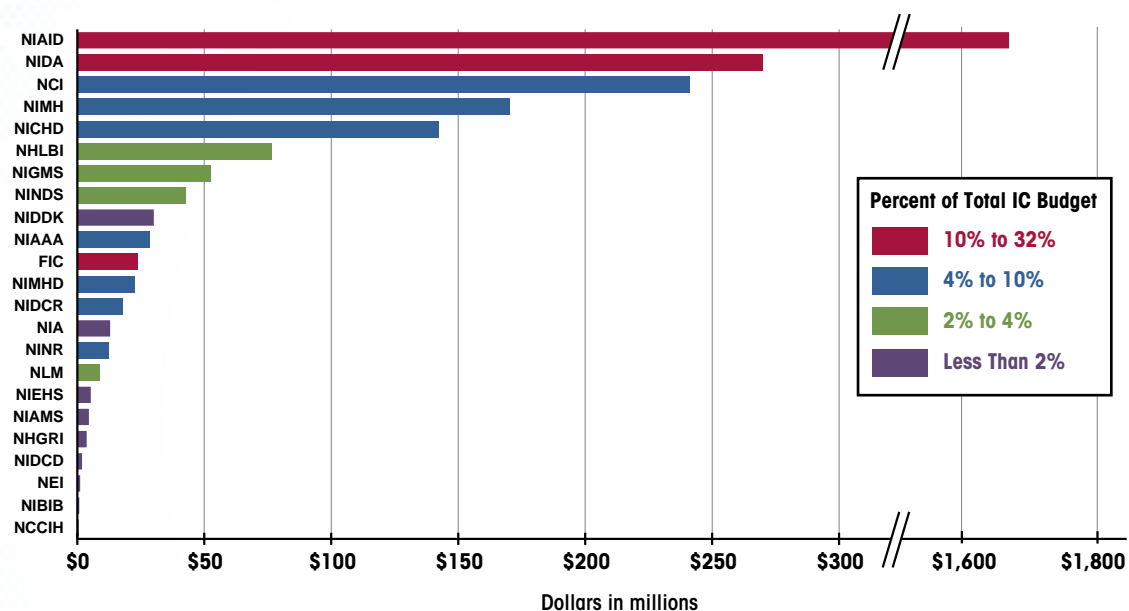
Figure 5. Research Pipeline



The NIH Vision and OAR Mission

The NIH vision is to end the HIV/AIDS pandemic and improve health outcomes for people living with, at risk of, or affected by HIV. The OAR mission is to ensure that NIH HIV research funding is directed at the highest priority research areas and to facilitate maximum return on the investment.

Figure 6: NIH Institutes and Centers HIV Funding Distribution, FY 2018



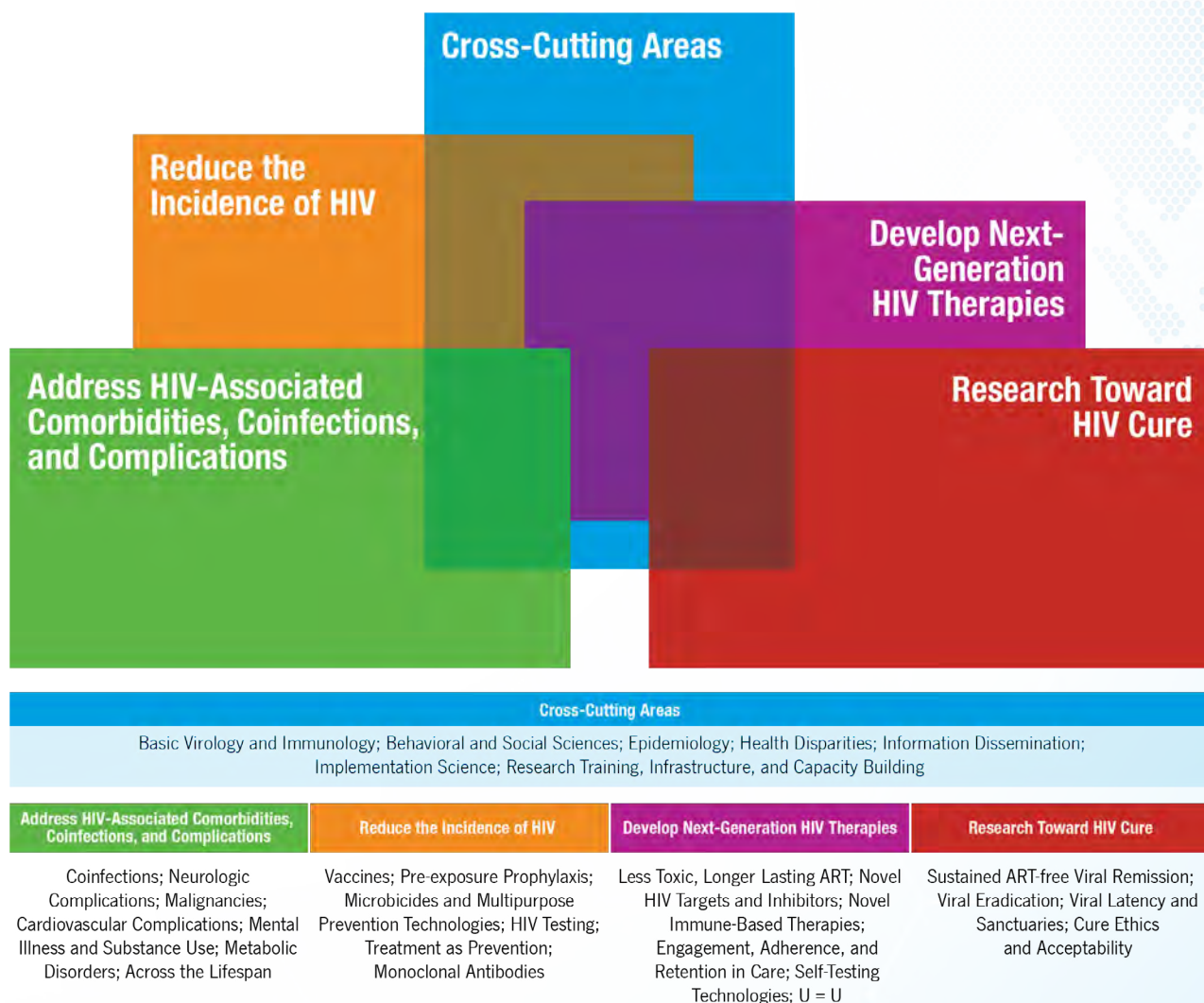
OAR's role is accomplished in partnership within the NIH with the ICOs that plan and implement specific HIV programs or projects, the NIH HIV/AIDS Executive Committee (NAEC), and the OAR Advisory Council (OARAC), as well as with federal agencies across the U.S. Government. OAR receives input from stakeholders in academia, the community, advocacy, and organizations engaged in policy and program implementation. (More details about the role and mandate of OAR are provided in [Appendix 2](#).)

To optimize the vision of the NIH HIV research agenda and the mission of OAR, a streamlined set of priorities for the NIH HIV research agenda was announced in FY 2015 and implemented in FY 2016 for a maximum period of five years (through FY 2020). Input from a broad array of NIH HIV research stakeholders (described in [Appendix 2](#)) confirms that these priorities continue to provide a comprehensive, yet flexible, research approach for HIV prevention, treatment,

cure, and comorbidities. Consequently, these priorities will continue as the framework for the NIH HIV research agenda from FY 2021 to FY 2025. (See NOT-OD-20-018 and [Appendix 3](#) for more details about the priorities.)

The priorities are represented by overlapping boxes to illustrate the interwoven, multidisciplinary nature of the science, as the strategies for HIV prevention, treatment, cure, and comorbidities increasingly converge ([Figure 7](#)). For example, antiretroviral treatment also can prevent HIV transmission; sustained viral suppression may lead to remission; and vaccine discovery and the development of broadly neutralizing monoclonal antibodies (bNAbs) and their derivatives have led to new immune-based candidate products for HIV prevention, treatment, or cure.

Figure 7. NIH Priorities for HIV and HIV-Related Research, FY 2015–2020 and FY 2021–2025





MISSION

NIH HIV Research Program Strategic Goals



Based on the current state of the HIV pandemic and the global and national objectives, the *FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research* 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.

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.

- › Foster basic science to discover fundamental knowledge that will facilitate advances in prevention, treatment, or cure of HIV.
- › Catalyze multidisciplinary research to prevent new infections through a combination of strategies that will lead to significant and sustainable reduction in the spread of HIV.
- › Discover novel approaches to treat and cure HIV in diverse populations across the lifespan.
- › Develop tools and strategies to prevent HIV-associated coinfections and reduce comorbidities, co-infections, and complications (CCCs) that greatly affect people with HIV.
- › Advance innovative research to identify and implement effective strategies to mitigate underlying HIV-associated medical and social inequalities that diminish the health and well-being of persons living with or at risk for HIV.
- › Pursue development of novel research methods and innovative technologies to accelerate advances across the research agenda and to improve the translation of research findings into clinical and community practice.

Strategic Goal 2



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

- › Enhance monitoring, review, and analysis of the NIH HIV research portfolio to optimize alignment with current NIH research priorities, address emergent opportunities, reduce unnecessary duplication, promote cross-ICO collaborations, and facilitate the budget allocation processes.
- › Facilitate the timely application of important study outcomes to ensure that the NIH HIV research portfolio is nimble and responsive to pivotal research findings.

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.

- ▶ Promote nimble implementation science research to assess best approaches to integrate evidence-based health interventions and strategies into culturally responsive clinical and community practice for maximum effectiveness in achieving the goals of the *National HIV/AIDS Strategy for the United States*,¹⁵ *Ending the HIV Epidemic: A Plan for America*,¹⁴ and the Joint United Nations Programme on HIV/AIDS (UNAIDS) global 95-95-95 targets.¹⁶
- ▶ Support development of robust information dissemination strategies to ensure timely and broad availability of HIV and HIV-related information—including updated U.S. Government guidelines for prevention, care, and treatment—and to promote its application in evidence-based and culturally responsive public health practice.

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 multi-disciplinary workforce.

- › Augment the NIH commitment to the development of the next generation of HIV researchers, particularly women and those from underrepresented populations and institutions within the United States and globally, to enhance the pipeline of HIV researchers in multiple disciplines.¹⁷
- › Ensure that researchers have access to important scientific resources and adequate research infrastructure.

Key NIH HIV Research Areas FY 2021–2025

- ✓ Effective HIV vaccines and antibody mediated protection strategies
- ✓ Basic mechanisms of virus/host cell dynamics to support development of innovative cure and treatment strategies
- ✓ New methods and delivery of pre-exposure and post-exposure prophylaxis, multi-purpose prevention technologies, and community-level behavioral and social-structural interventions
- ✓ Novel diagnostics and novel treatment strategies to enhance viral suppression
- ✓ Strategies for achieving sustained ART-free viral remission
- ✓ HIV-associated coinfections, prevalent chronic conditions, and syndemics
- ✓ Complications from virus exposure, long-term HIV disease, immune dysfunction, and/or ART for treatment or prevention related to aging and to development in infants, children and youth
- ✓ Individual, interpersonal, community, and social-structural factors influencing inequalities in HIV testing, engagement and persistence with prevention and care services, and health outcomes in different settings
- ✓ Strategies for mitigating HIV-associated stigma and discrimination
- ✓ Implementation strategies to improve systematic uptake of evidence-based prevention, care, and treatment interventions in diverse settings and populations
- ✓ Novel design approaches, such as mixed methods, alternative clinical trial designs, and economic modeling, to estimate and improve outcomes and public health impact
- ✓ Innovative technology approaches including 3-D printing, artificial intelligence (including machine learning), advanced bioinformatics, genetics, sequencing, omics, big data mining, phylodynamics, and geospatial modeling for advanced discovery

Optimizing the NIH HIV Research Investment



To ensure that HIV research continues to have the greatest public health impact, OAR will work collaboratively with the NIH ICOs and in partnership with all stakeholders to manage dedicated HIV/AIDS resources efficiently and to harness emerging scientific findings.

Collaborations and Partnerships

OAR sets the direction of HIV research through NIH-wide collaborations and strategic partnerships among stakeholders. OAR works in partnership with the ICOs through the 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. OAR facilitates scientific and funding collaborations between ICOs, such as the recently merged Multi-Center AIDS Cohort Study (MACS) and Women's Interagency HIV Study (WIHS).

To encourage multi-disciplinary approaches to emerging scientific topics relevant to NIH HIV research goals, OAR is continuing implementation of a cost-sharing approach in close collaboration with the ICOs. Cost sharing provides flexibility for an ICO to combine non-HIV/AIDS funds with HIV/AIDS funds to support research on an intersectional area of science where anticipated results have the potential to inform both HIV and non-HIV research priorities. This approach encourages new investments in emerging areas of science that will contribute to progress in HIV prevention, treatment, and cure, while also addressing co-occurring health conditions.

OAR also partners with community-based organizations and public health departments to ensure that research-based strategies are relevant, responsive, and appropriately implemented in local settings and in diverse populations.

NIH as a whole continues to meet new and complex challenges by enhancing strategic partnerships among stakeholders from government, academia, communities, and the private sector to advance HIV research.

Responding to Emerging Scientific Developments

In the next few years, a number of NIH-supported studies will yield important findings in HIV prevention, treatment, and cure. These clinical trials are translating basic science developments into potentially effective interventions that will be significant for ending the epidemic in the United States and for achieving the global 95-95-95 targets. The expected timeframe for results from these and other studies helped to inform OAR's decision to move to a 5-year Strategic Plan with more frequent program reviews to allow for course correction and nimble incorporation of new discoveries that will lead to next-generation studies.

Linking HIV Research Activities with Broader U.S. Government Initiatives



Alignment with NIH Strategic Priorities and Policies of Inclusion

In addition to advancing high priority HIV-focused research, OAR ensures that the NIH HIV/AIDS research program addresses broader, Institute-wide themes and priorities established by the NIH Director. For example, the scope of the Plan includes the mandate of the 21st Century Cures Act (<https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.xml>), which provides the NIH with critical tools and resources to advance biomedical research across the spectrum, from foundational basic research studies to advanced clinical trials of promising new therapies.

The Plan aligns HIV and related research with broad NIH research policies related to the inclusion of women and minorities (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html>) and people across the lifespan (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>) in clinical research. Attention to sex, gender, age, and other social and demographic factors is essential to achieving the goals of the *NIH Strategic Plan for HIV and HIV-Related Research*.

The National HIV/AIDS Strategy and The President's Advisory Council on HIV/AIDS

The strategic goals of the Plan closely align with the four goals of the current *National HIV/AIDS Strategy for the United States (NHAS): Updated to 2020*

(<https://www.hiv.gov/federal-response/national-hiv-aids-strategy/nhas-update>): reduce new HIV infections; increase access to care and improve health outcomes for people with HIV; reduce HIV-related health inequities; and achieve a more coordinated national response to the HIV epidemic. OAR is actively engaged with the Department of Health and Human Services (HHS) Steering Committee that is developing the next 5-year (FY 2021–2025) NHAS. The OAR Director is the NIH representative on the Presidential Advisory Council on HIV/AIDS (PACHA), which provides the HHS Secretary with recommendations on implementation of the NHAS.

Ending the HIV Epidemic: A Plan for America

Ending the HIV Epidemic: A Plan for America (<https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>), announced in the 2019 State of the Union Address, is a bold domestic initiative to reduce the number of new HIV infections by 75 percent within 5 years and by 90 percent within 10 years through a coordinated, interagency strategy led by HHS. The approach involves leveraging important scientific advances in HIV prevention, diagnosis, and treatment—chiefly made by researchers supported by the NIH over the years—with successful programs in outreach and service delivery supported by other agencies. Initially, efforts are being focused on geographic and demographic hotspots in the United States where the majority of new HIV infections are reported, and revolve around: diagnosing all people with HIV as early as possible after infection; treating HIV infection rapidly and effectively to achieve sustained viral suppression; providing people at highest risk of HIV acquisition with effective, evidence-based interventions; and responding rapidly to emerging clusters and outbreaks of HIV infection.

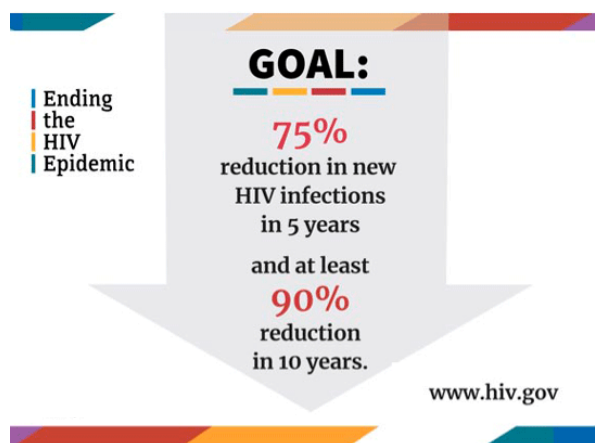
The Strategic Goals in the *FY 2021–2025 NIH Strategic Plan for HIV and HIV-Related Research* are aligned with the strategic activities outlined in the President’s initiative. NIH-supported basic, clinical, behavioral, and social science research on preventing new infections, developing optimal treatments, addressing comorbidities, and tackling health inequalities will continue to lead to the development of effective and culturally responsive interventions whose implementation will be essential to achieving the goals of the *Ending the HIV Epidemic* initiative.

Conclusion



The FY 2021–2025 Plan outlines critical, strategic goals and priorities that will continue to produce significant scientific discoveries benefiting millions of people living with, at risk for, or affected by HIV. The strong and sustained U.S. commitment to HIV research continues to position NIH as the global leader in the HIV/AIDS research response. That commitment strengthens the ability of NIH to capitalize on recent research accomplishments, further advance multidisciplinary science, meet the goals of EHE (Figure 8), and facilitate the implementation of novel and effective strategies to prevent, treat, manage, and eventually cure HIV for all people everywhere.

Figure 8. Ending the HIV Epidemic: A Plan for America Goal



“Ending the HIV pandemic is more than an aspirational goal. We can make it a reality if we harness the opportunities afforded by continued advances in scientific discovery and fully implement what we know works.”

— Maureen M. Goodenow, Ph.D.,
Associate Director for AIDS Research and Director, Office of AIDS Research, NIH

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Appendix 1

Acronyms/Abbreviations

AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral treatment
bNAbs	Broadly neutralizing antibodies
CCCs	Comorbidities, coinfections, and complications
CDC	Centers for Disease Control and Prevention
EHE	<i>Ending the HIV Epidemic: A Plan for America</i>
FDA	U.S. Food and Drug Administration
FIC	Fogarty International Center
FY	Fiscal year
HAART	Highly active antiretroviral therapy
HHS	U.S. Department of Health and Human Services
HIV	Human immunodeficiency virus
ICOs	Institutes, Centers, and OD Offices
MMWR	<i>Morbidity and Mortality Weekly Report</i>
MSM	Men who have sex with men
NAEC	NIH AIDS Executive Committee
NCCIH	National Center for Complementary and Integrative Health
NCI	National Cancer Institute
NEI	National Eye Institute
NHAS	<i>National HIV/AIDS Strategy for the United States</i>
NHGRI	National Human Genome Research Institute
NHLBI	National Heart, Lung and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Disease
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development
NIDA	National Institute on Drug Abuse
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NIMHD	National Institute on Minority Health and Health Disparities
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
OAR	Office of AIDS Research
OARAC	OAR Advisory Council
OD	Office of the Director, NIH
PACHA	Presidential Advisory Council on HIV/AIDS
PEPFAR	President's Emergency Plan for AIDS Relief
the Plan	NIH Strategic Plan for HIV and HIV-Related Research
PrEP	Pre-exposure prophylaxis
RFI	Request for Information
STIs	Sexually transmitted infections
UNAIDS	Joint United Nations Programme on HIV and AIDS

Appendix 2

Role and Mandate of the OAR

Development of the NIH Strategic Plan for HIV and HIV-Related Research

The *NIH Strategic Plan for HIV and HIV-Related Research* (the Plan) provides information about the NIH HIV research agenda to the general public, scientific community, Congress, and HIV-affected communities. Development of the Plan involves a comprehensive and unique process that begins with the formulation of overarching research priorities, followed by solicitation of input from HIV and related scientific experts across the NIH to further refine key priorities for the next 3- to 5-year period. NIH scientific input for the Plan is provided through the NAEC, consisting of representatives from the NIH ICOs with an HIV research agenda. During the planning process, critical public health needs are assessed, and new scientific opportunities are identified.

External advice for the Plan was sought through a Public Notice Request for Information (RFI) designed to solicit input from other government agencies, nongovernmental experts, affected communities, and other stakeholders. The RFI for the current Plan included five questions related to respondents' perceptions of emerging areas of HIV science, developments, gaps and opportunities in research, and critical needs in training and capacity-building. OAR received more than 500 responses to these questions from more than 170 individuals representing a wide range of HIV research and community stakeholders. Respondents' input is reflected in the narrative sections of the Plan. Additional input from NIH HIV research stakeholders was obtained through a series of Listening Sessions convened around the country by the OAR Director, as well as through engagement with topic-focused OAR Working Groups, and at regular OARAC meetings.

The process allows for the development of a 5-year Strategic Plan that encompasses a longer-term vision of research than an annual or biennial Plan, while still allowing for a dynamic review of progress and emerging opportunities.

NIH HIV Budget Development

The Plan provides the framework for developing, in partnership with the ICOs, the annual HIV research budget for the NIH. Each ICO submits requests to OAR for proposed new, expanded, or re-competing HIV-related research program initiatives that support the specific priorities of the Plan. OAR allocates funding to each ICO, based on scientific opportunities and the ICO's capacity to support and manage the most meritorious HIV science. This process reduces unnecessary duplication, promotes harmonization of effort, and ensures cross-ICO collaborations. At the time of the HIV funding appropriation, OAR informs each ICO of its HIV-related budget allocation, specifying amounts for each approved initiative. The ICOs develop the funding announcements, facilitate peer review, and award funds for each project determined by OAR to be aligned with current HIV research priorities.

Review and Analysis of the HIV Portfolio

A critical element of the annual planning process is a multi-tiered NIH-wide review of all grants and contracts supported with HIV-designated funds across the ICOs that are due to expire or re-compete in the coming fiscal year. Each project is reviewed by a team of OAR and ICO staff for alignment with current HIV priorities. At the end of the review, OAR informs ICOs of projects that are unaligned with the current priorities and that should not be funded with HIV-designated dollars if they successfully re-compete for ICO funding. This review ensures that the HIV research budget is used to support evolving scientific priorities, taking into account the changing needs of the HIV epidemic.

In addition, OAR regularly undertakes an analysis of the NIH-wide HIV portfolio to determine the level of investment relative to topical areas across the ICOs. This analysis provides a picture of the distribution of research topics across the NIH to ensure that overall investment is balanced and aligned with the highest priority research in order to identify opportunities for collaboration and cost-sharing across the NIH.

These portfolio reviews and analyses are integral components of OAR's strategic planning and budget-development processes.

Appendix 3

NIH HIV Research Priorities

OAR allocates funds to the ICOs to advance the NIH-wide HIV research agenda and ensures that funds are aligned with the HIV research priorities outlined in NOT-OD-15-137 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html>), NOT-OD-19-078 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-078.html>), and NOT-OD-20-018 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-018.html>). These priorities are described below.

Reduce the Incidence of HIV

Preventing new HIV infections remains the fundamental way to end AIDS. Because HIV is a transmissible disease, and infection occurs in the course of human relationships, it is essential to focus on both transmission and acquisition and the biological, behavioral, and social contexts in which these occur. Research will be supported to develop effective vaccines and antibody mediated protection strategies, new formulations and methods of pre-exposure and post-exposure prophylaxis, and behavioral and social-structural interventions.

Develop Next-Generation HIV Therapies

Over the past two decades, there have been remarkable advances in treatment for people with HIV that provide the foundation and set the stage for how to further improve current HIV therapy; optimally assess, manage, and prevent coinfections and comorbidities; and extend the benefits of treatment to all groups equitably. Continued research will be supported to produce next-generation therapies that are more effective in suppressing viral replication, formulated and dosed for increased convenience, and less toxic than those currently available.

Research Toward HIV Cure

Significant challenges to cure HIV continue because of the persistence of integrated HIV DNA in latently infected cells and other reservoirs. To date, only

one individual has been cured of HIV through a complex and costly bone marrow transplant procedure. While this suggests that cure of HIV ultimately may be achievable, focus now is on achieving long-term HIV remission as a vital step towards cure. Further research will be supported to better characterize, measure, eliminate or control the reservoir and to test the efficacy of novel cure strategies in appropriate animal models and human clinical trials.

Address HIV-Associated Comorbidities, Coinfections, and Complications (CCCs)

HIV infection affects and is affected by co-occurring infections, conditions, and non-communicable diseases. Among people with HIV, tuberculosis, viral hepatitis, and cancer are among the greatest causes of mortality, and the risk for comorbidities such as cardiovascular disease, some cancers, bone fractures/osteoporosis, liver disease, kidney disease, cognitive decline, and aging-related frailty is higher than among those without HIV. Additionally, treatment of cancer and other comorbidities can be complicated by co-existing HIV infection. Similarly, HIV often occurs concomitantly with other sexually transmitted infections and/or in association with alcohol, tobacco, and drug misuse, violence and trauma, and mental illness. Further research will be supported to better understand and address all of these co-occurring conditions.

Basic Science

Basic biomedical research has generated fundamental knowledge to improve understanding of HIV virology, immunology and pathogenesis that can inform the development of effective prevention, treatment, and cure strategies. Nonetheless, significant gaps remain in areas that could lead to innovations in vaccine development, better therapies, and cure approaches. Further research will be supported to enhance understanding of fundamental aspects of innate immunity, B and T cell immunology, virology, and interplay between the virus and host, and basic mechanisms involved in host cellular interactions with HIV. Systems biology approaches to examine HIV risk, immunity, treatment response, and disease progression in diverse populations will provide additional scientific value.

Behavioral and Social Science

Insights about human behavior, social networks, community institutions, and social forces that influence the emergence and spread of HIV epidemics have contributed to the development of important HIV prevention, care, and social-structural interventions. Further research will be supported to better understand and address key individual, relational, community, and social-structural dynamics—including the role of stigma and discrimination—that fuel or mitigate HIV epidemics in diverse populations and settings.

Epidemiology

Epidemiologic methods provide accurate, real-time information to better understand the global HIV/AIDS pandemic and its associated CCCs, inform prevention and treatment approaches, and determine where research should be conducted. The use of surveillance, big data science, machine learning, modeling, registries, phylodynamics, and other epidemiologic approaches will contribute to improved outcomes across the HIV prevention and care continua.

Health Disparities

HIV epidemics often result from and provide a lens on social inequalities and health disparities among population groups that are based on such things as sex, gender, race, ethnicity, socioeconomic status, age, sexual orientation and behavior, substance use behavior, and geographic location. Research to better understand and address such disparities and inequalities—including through community-based participatory research methods—will be supported to improve HIV testing and engagement and retention in prevention and care services, and to enhance the health and well-being of persons living with and at risk for HIV in underserved and marginalized communities.

Implementation Science

To have the greatest impact on domestic and global HIV programs and policies and help move from efficacy to effectiveness, the NIH will support implementation science to promote and improve the systematic uptake of evidence-based

HIV prevention, care, and treatment interventions in diverse settings. Further understanding of the processes and factors that influence scale-up and sustainability of effective strategies will help achieve the goals of the *National HIV/AIDS Strategy for the United States, Ending the HIV Epidemic: A Plan for America*, and the UNAIDS global 95-95-95 targets.

Information Dissemination

A critical component of the NIH HIV research program is ensuring that research findings are shared with diverse communities and stakeholders, including patients, clinicians, researchers, public health practitioners, policy-makers, and the general public. Efforts also must focus on utilizing emerging technologies and venues to develop accurate, timely, and culturally responsive communication approaches that target underserved populations.

Training, Infrastructure, and Capacity Building

To ensure that the priority areas of HIV science are addressed with novel, innovative, and culturally responsive approaches, the NIH will augment its commitment to the development of the next generation of HIV researchers, particularly women and those from underrepresented populations and institutions. This includes providing both human resources (e.g., mentoring) and support for infrastructure (e.g., laboratories).



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