

NIH Highlights HIV Research and Response on World AIDS Day

The HIV response is a shared global commitment to equitable health outcomes.

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On this 35th World AIDS Day, the National Institutes of Health (NIH) joins its partners in honoring the lives lost due to the HIV pandemic. For decades, this virus has exacted a tragic toll, affecting people, families, and communities worldwide, threatening social and economic development, and exacerbating stigma, often toward people who already experience discrimination and health disparities. We pay tribute to the loved ones and leaders taken by AIDS-related illness, and to the companions and service organizations who have provided compassionate and respectful care for people with HIV in communities around the world.

The U.S. government's theme for this year's World AIDS Day is "Remember and Commit." In addition to commemorating devastating losses, we must commit to applying the lessons learned from the HIV pandemic to improve the lives of people who continue to be affected by HIV today. HIV has already transformed public health. From prompting more transparent and inclusive dialogue on sexual health, to confronting racism, homophobia and transphobia, to demanding a research and public health infrastructure capable of person-centered service and innovation, the HIV response is a shared global commitment to equitable health outcomes. On this day, NIH reaffirms the importance of leadership from the HIV community that continues to guide our work, and reflects on the pivotal role publicly funded U.S. government institutions perform in supporting HIV research and implementation worldwide.

Over the past 35 years, HIV researchers have made tremendous strides toward ending the HIV pandemic. Antiretroviral therapy (ART) has evolved from limited, complicated, and poorly tolerated regimens to once-daily fixed-dose combination drugs that suppress HIV to undetectable levels. Multiple, highly effective biomedical HIV prevention methods now offer people choices that best suit their needs. Long-acting antiretroviral drugs (ARVs) for prevention and treatment are available, and ART for the prevention of perinatal HIV transmission has been widely adopted, substantially reducing the number of infants born with HIV. The global HIV community takes pride in our collective progress and highlights the urgent work that remains to end HIV and AIDS for all.

We pledge to prioritize access and tools for people who historically have benefited less from HIV research advances, such as gay, bisexual, and other men who have sex with men; transgender women; people who use drugs; and members of the Black and Latina/e/o/x communities.

In 2022, an estimated 1.3 million people were newly diagnosed with HIV, and 630,000 people died of AIDS-related illness, according to the Joint United Nations Programme on HIV/AIDS. More than 38 million people are living with HIV worldwide, including 1.2 million in the U.S., but fewer than 30 million people are on lifesaving ART. These statistics point to the need for expanded access and user choice among existing prevention, testing, and treatment methods, as well as the imperative to find more durable and convenient options like an HIV vaccine and a scalable HIV cure. They also underscore the necessity for research and implementation strategies to address the intersectional nature of health disparities, including social determinants of health.

NIH works with government, civil society, and advocacy partners in a whole-of-society HIV response. Our institutes, centers, and offices pursue basic, preclinical, and clinical research to discover biomedical technology and design evidence-based implementation approaches, including interventions to mitigate stigma and enhance prevention and treatment uptake. We coordinate closely with colleagues and partners to translate HIV research findings into policy changes and implementation at scale, namely through the <u>U.S. National HIV/AIDS Strategy</u> and, in prioritized foreign countries, the <u>U.S. President's Emergency Plan for AIDS Relief</u>. These two initiatives are vital for increasing equitable access to HIV interventions and serve as a blueprint for the cooperation needed to respond to other health threats. Combined, these programs have served hundreds of millions of people affected by HIV and helped national and local governments reach underserved communities worldwide with standardized, evidence-based health care.

NIH continues to support groundbreaking research to expand the frontiers of HIV testing, prevention, treatment, and cure. The <u>NIH Office of AIDS Research</u>, which coordinates the NIH HIV research program, supports four signature programs to advance highly significant but underresourced research and infrastructure priorities. These research programs focus on women and HIV, aging with HIV across the lifespan, advancing the development of HIV diagnostic and care technologies, and replenishing the HIV research workforce by supporting early-career investigators. These areas of focus have been identified through scientific input, community feedback—including contributions from OAR listening sessions—and in-depth analysis of the existing HIV research portfolio.

Over the last year, HIV prevention research has led to increased understanding of the acceptability and accessibility of injectable, topical intravaginal, and oral pre-exposure prophylaxis (PrEP) formulations. NIH continues to draw lessons from pivotal studies of long-acting cabotegravir (<u>HPTN</u> <u>083</u> and <u>HPTN 084</u>) and the monthly dapivirine vaginal ring (<u>MTN 034</u>), conducted by the HIV Prevention Trials Network and Microbicides Trials Network, supported through grants from the NIH National Institute of Allergy and Infectious Diseases (NIAID) with co-funding from other NIH institutes.

Mathematical modeling from the NIH Eunice Kennedy Shriver National Institute of Child Health and

Human Development (NICHD) elucidated the potential health and economic <u>benefits</u> of oral PrEP use by young gay, bisexual, and other men who have sex with men, and the NIH National Institute of Mental Health (NIMH) supported research to examine <u>factors</u> associated with oral PrEP use among women who were likely to benefit from its availability in Kenya. NIH soon will launch <u>HPTN</u> <u>102</u> and <u>HPTN 103</u>, two phase 2 U.S.-based clinical studies of a long-acting ARV called lenacapavir for HIV PrEP among women and people who inject drugs, respectively. These studies are intended to provide population-specific insights to complement larger efficacy studies. Preclinical work is also exploring new platforms for ARV-based HIV prevention including dissolvable vaginal film, rectal douche, and multipurpose technology that would pair PrEP with a contraceptive.

NIH HIV treatment research focuses on improving the health and quality of the life of people living with HIV through simpler, more tolerable ART regimens and by identifying strategies to prevent or manage HIV-related complications. Together with the NIH National Heart Lung and Blood Institute, NIAID supported the international REPRIEVE trial (short for Randomized Trial to Prevent Vascular Events in HIV) that found a daily statin reduced the risk of major adverse cardiovascular events by <u>more than one third</u>.

A demonstration study supported by NIAID, NIMH, and the NIH National Institute on Drug Abuse found long-acting ART given every 4-8 weeks with comprehensive support services <u>suppressed</u> <u>HIV</u> in people who were previously not virologically suppressed and concurrently experienced unstable housing, mental illness, and/or substance use. Additional research from NICHD and NIMH highlighted the importance of supporting ART <u>before</u> and <u>during</u> pregnancy and approaches to addressing barriers to ART <u>access</u>.

Thanks to effective treatment options, people with HIV are living longer; accordingly, NIH supports <u>research</u> to facilitate healthy aging over the lifespan for this population. As advances continue contributing to increasing cohorts of people aging with HIV, the NIH OAR is committed to engaging with the community while working to coordinate and advance all aspects of NIH HIV research to close the science-to-service gap for this growing population.

NIAID continues to leverage its robust HIV clinical trials networks to address other infections that share health determinants with HIV as part of the Institute's comprehensive research portfolios on <u>tuberculosis</u>, <u>viral hepatitis</u>, other <u>sexually transmitted infections</u> (STIs). Of note, Advancing Clinical Therapeutics Globally for HIV/AIDS and Other Infections (formerly called the AIDS Clinical Trials Group) is conducting the <u>STOMP trial</u> trial of the antiviral tecovirimat as treatment for mpox, and NIAID funded the pivotal <u>study</u> showing doxyPEP—use of the oral antibiotic doxycycline to prevent STIs after sex—reduced STI acquisition by two-thirds among transgender women and gay, bisexual, and other men who have sex with men.

NIH continues to prioritize discovery and development of a vaccine to prevent HIV, with strategies that activate cellular immunity—including a <u>T-cell based vaccine</u> trial being implemented by the NIAID HIV Vaccine Trials Network—as well as those that stimulate humoral immune processes to generate broadly neutralizing antibodies (bNAbs) that could work against a wide variety of HIV strains. bNAb science is evolving rapidly with the application of germline targeting—a technique

that closely guides naïve (new) B cells to develop into mature B cells that can produce bNAbs—and a vaccine concept using an <u>mRNA</u> platform to instruct the body to manufacture proteins that would teach the immune system to make bNAb-producing B cells in a similar fashion.

NIH cure research also examines the potential of bNAbs, among other cure strategies. The NIAIDfunded Phase 1/2 Tatelo study in Botswana, implemented through the International Maternal Pediatric Adolescent AIDS Clinical Trials network, found administering the two bNAbs—VRC01LS, developed by the <u>Vaccine Research Center</u>, and another called 10-1074—maintained HIV suppression in children for 24 weeks without ART. Additional bNAb studies are underway and planned. Meanwhile, <u>long-term results</u> were released from the case report of a woman who received a stem cell transplant from banked umbilical cord blood and was still free of HIV more than 5 years after the transplant. These findings will help inform future cure approaches. As part of its cure agenda, NIAID supports research in Southern Africa and other high burden settings, which contributes to local scientific leadership in regions with the largest populations of people living with HIV in the world.

HIV clinical research builds upon basic science discoveries, preclinical studies, and consultations with communities affected by HIV. Further, clinical research relies on the dedication of study participants and the people who support them. We express our deep gratitude to all who contribute to advancing HIV research.

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