



R&D for HIV/AIDS

How new tools can transform the fight



Since emerging in the 1980s, the global HIV/AIDS epidemic has claimed the lives of more than 32 million people around the world—reversing gains in life expectancy and economic development in the world’s poorest places. The development of antiretroviral drugs (ARVs) has turned the trajectory of the epidemic, extending life expectancy of those living with HIV/AIDS and enabling the prevention of transmission between mothers and children and HIV-positive and negative partners.

Yet progress against the epidemic has slowed in recent years, and major gaps remain in our arsenal of treatment and prevention tools. We will not reach targets to end the HIV/AIDS epidemic without new and improved technologies.

37.9 million
people are living with HIV/AIDS globally

1.7 million
people became newly infected with HIV in 2018

300+ children
die every day from AIDS-related causes

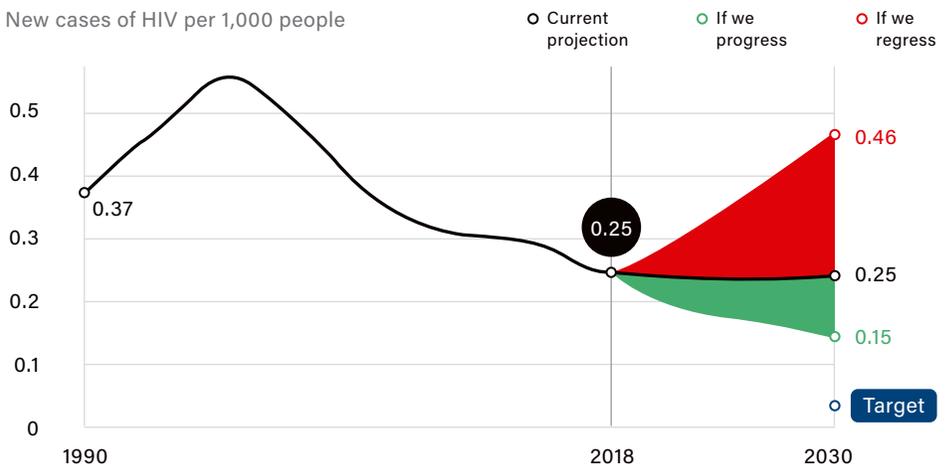
Research successes

Technologies have transformed the fight against HIV/AIDS:

- **ARVs**—developed with NIH support—are today used to treat 21.7 million people globally and have cumulatively averted more than 9.5 million AIDS-related deaths since 1995, with global economic benefits of US\$1.05 trillion.
- **Pre-exposure prophylaxis**, or PrEP—the use of ARVs to prevent infection—was shown to be effective through NIH, CDC, and USAID research and is today being introduced worldwide.
- Approaches to **prevent mother-to-child HIV transmission**—developed with NIH support—that involve treating women during pregnancy and their newborns with ARVs have contributed to a 41% decline in new infections in children since 2010.
- New **diagnostic innovations**, from rapid tests, to urine and oral tests, to home tests, have increased the percentage of people aware of their HIV status.
- **Recency tests**, which distinguish if an infection occurred in the last year or before, are enabling health programs to identify HIV transmission clusters and better target services.

Continued progress is possible, not inevitable

New cases of HIV per 1,000 people



Key missing tools

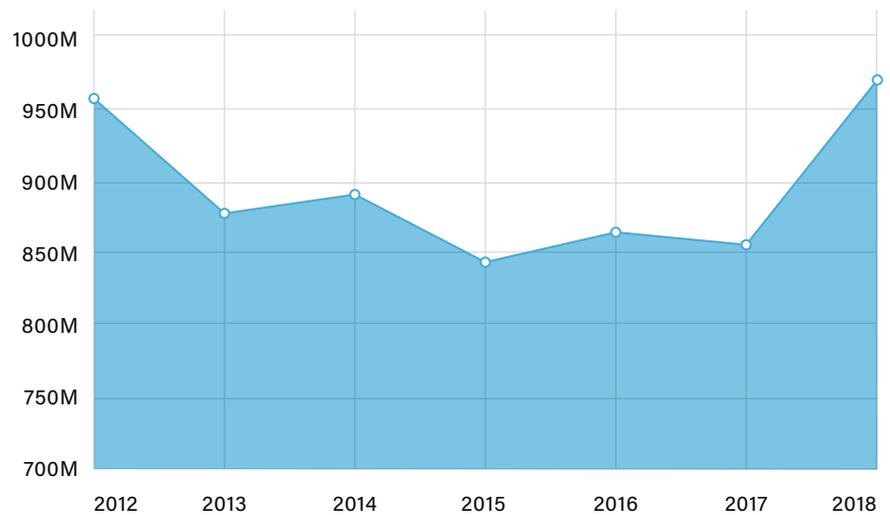
To end HIV/AIDS, we need new prevention and treatment tools including:

- **HIV/AIDS vaccines** to prevent and reduce new infections.
- **A cure** to control or eliminate infection from the body.
- **Microbicides** to prevent infections in women and men who have sex with men—populations disproportionately impacted by the epidemic.
- **Improved therapies for young children** that are safe, palatable, shorter course, and easier to administer.
- **New treatment and PrEP regimens** to help expand choice and improve adherence, such as long-acting injectable ARVs, fixed-dose combinations, and simplified treatments with fewer side effects.
- Additional **treatment options for those whose infection has become resistant** to existing treatments.

Breakthroughs on the brink

- A first-of-its-kind, monthly ARV-based **microbicide vaginal ring**, supported by NIH and USAID, is now under regulatory review and could expand prevention options for at-risk women.
- A promising “mosaic” vaccine designed to address several HIV strains at once is one of two **HIV vaccine candidates** now in late-stage clinical trials in sub-Saharan Africa. This and other scientific breakthroughs bring new hope to the quest for an HIV/AIDS vaccine, with around 40 vaccine candidates now in late-stage development.
- A 4-in-1 **child-friendly ARV regimen** for infants and young children that is palatable, easy-to-administer, and requires no refrigeration is now under regulatory review.
- Many clinical trials are underway to test **broadly neutralizing antibodies (bNabs)**—proteins shown to neutralize many different genetic variants of HIV—as treatment and preventions products, including late-stage clinical trials of a bNAb developed at NIH labs.
- **Long-acting injectable formulations of PrEP**, which could be administered monthly or every two months, are now in late-stage clinical trials and could soon offer a new option for patients.
- **Multipurpose prevention products**, including pills, injections, and a vaginal ring that combines ARVs with contraception, could expand HIV prevention options for women.
- A **second patient appears to be effectively cured of HIV** as of 2019, demonstrating that a cure for HIV infection, while difficult, is scientifically possible.

US government investment in HIV/AIDS R&D for low-resource settings
(in 2018) US\$ millions



US Government R&D efforts

The US government is leading efforts to advance research and development (R&D) to end the HIV/AIDS epidemic through a whole-of-government approach:

- **National Institutes of Health** conducts basic science and clinical research for new therapies, vaccines, microbicides, and a cure for HIV/AIDS, as well as research to improve use of existing interventions.
- **US Agency for International Development** advances R&D for HIV/AIDS technologies designed for low-resource settings, including research for a vaccine and microbicides, and helps accelerate introduction and access to new tools.
- **Department of State** oversees the President’s Emergency Plan for AIDS Relief (PEPFAR), which finances certain HIV/AIDS research programs.
- **Centers for Disease Control and Prevention** develops improved diagnostics and conducts research to inform use of existing tools and the risk factors influencing the spread of HIV/AIDS to better target interventions to those in need.
- **Department of Defense** undertakes research to protect US service members from HIV/AIDS, including vaccine research.
- **Food and Drug Administration** operates a tentative regulatory approval program to allow PEPFAR to distribute generic ARVs for use outside the United States.

