Antibodies for HIV prevention

Translating **science** into **global** health impact

IAVI's broadly neutralizing antibodies (bnAbs) against HIV could offer a breakthrough in preventing HIV acquisition by infants.

We need new options for HIV prevention

Worldwide, 40.9 million people were living with HIV, and 570,000 people died from AIDS-related causes in 2025. Despite advances in treatment and prevention, notably through the broad availability of antiretroviral (ARV) drugs, about 1.2 million people contracted HIV in 2025. We need additional tools that can work for people unable to benefit from today's interventions. That's why IAVI is committed to developing vaccines and antibodies as options for HIV prevention.

Too many infants are acquiring HIV

Progress toward reducing HIV transmission to infants and young children has largely stalled in recent years. Data from UNAIDS shows that in 2025, 93,000 children acquired HIV, in large part due to exposure during breastfeeding. About 360 children die every day from HIV.

The standard of care for infants who are breastfed by mothers living with HIV includes daily ARV prophylaxis for the infant, alongside ongoing HIV treatment for the mother. While effective, these regimens can be challenging for new mothers to manage, and interruptions in regimens can increase the risk of HIV transmission to the infant. Infants may also be exposed to HIV if their mothers acquire HIV during the breastfeeding period. To better protect newborns, mothers need safe, effective, and convenient biomedical prevention options designed specifically for the unique needs of their newborns.

The basics of HIV bnAbs

- bnAbs are HIV antibodies that may develop naturally in some people after many years of living with HIV.
- bnAbs are classified based on their unique abilities to neutralize a vast range of variants of HIV, based on laboratory data.
- In the Antibody-Mediated Prevention (AMP) trials, bnAbs were shown to be efficacious at blocking HIV transmission in people when the bnAbs were well-matched to the HIV strain and at a high enough concentration in the body.
- IAVI scientists are optimizing HIV bnAbs in the lab to extend how long they last and make them more potent, and thus better able to block HIV transmission.

The potential of bnAbs to prevent HIV in infants

- A combination of bnAbs could block enough distinct strains of HIV to be effective for prevention.
- They have been shown to have an acceptable safety profile and to be well tolerated in infants.[1]
- They could be given in a small, simple, discreet injection.
- The bnAbs we have currently could prevent HIV acquisition for up to three months per dose.
- Infants are vulnerable to HIV acquisition during the time that they are breastfeeding. Just a few doses are likely to be needed to cover this window.

HIV/AIDS and bnAbs by the numbers[2]

40.9 million
people are living with HIV

200+
broadly neutralizing HIV antibodies discovered

1.2 million
people contracted HIV in 2025

3 months
of protection likely with 1 dose of bnAbs

93,000
children acquired HIV in 2025

2 clinical trials
evaluating IAVI HIV bnAbs ongoing

Partnerships drive discovery and development

IAVI scientists have identified more than 80 bnAbs from our HIV epidemiology studies and have developed powerful tools for antibody optimization. Our scientific collaborators that helped advance this work have included partner clinical research centers across Africa; Scripps Research; the U.S. National Institutes of Health (NIH) Vaccine Research Center (VRC) and Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID); the University of Maryland, Baltimore; the University of Oslo; and the Translational Health Science and Technology Institute in Gurugram, India.

Wellcome and Merck have supported IAVI authorship of two reports to stimulate global calls-to-action to accelerate the development of affordable and accessible antibody products. Additionally, IAVI and the World Health Organization have published guidelines for eventual regulatory approval of an HIV antibody-based intervention.

Clinical trials of IAVI's ebnAbs

Two Phase 1 clinical trials are evaluating IAVI's engineered bnAb (ebnAb) ePGT121v1-LS. HVTN 141/HPTN 105 is assessing the antibody in adults and will generate safety data to support future pediatric studies. PedMAb1-Ex is evaluating ePGT121v1-LS in adults and infants.

Partners in clinical evaluation of antibodies include the South African Medical Research Council (SAMRC); the Unit of Viral Evolution and Transmission at IRCCS Ospedale San Raffaele; the HIV Vaccine Trials Network (HVTN) and the HIV Prevention Trials Network (HPTN) of the NIAID. IAVI is also a member of the Global Health EDCTP3-funded ENABLE consortium, which brings together 21 leading research institutions for a future clinical trial examining ePGT121v1-LS in combination with ARVs for viral suppression in infants.

Ongoing clinical trials	
Clinical trials	**Partners**
HVTN 141/HPTN 105 (Phase 1) *bnAb: ePGT121v1-LS*	DAIDS, HVTN, HPTN
PedMAb1-Ex (Phase 1) *bnAb: ePGT121v1-LS*	SAMRC, Ospedale San Raffaele

Ensuring bnAbs are globally accessible and affordable

IAVI and partners are working across the continuum of product development to ensure that bnAbs, once shown to be efficacious, will be promptly, globally, and affordably accessible. The partners are accomplishing this by:

- Building user preferences and local community needs into product development plans from the very beginning of the process.
- Working with low-cost manufacturers and supporting innovations in production and delivery.
- Collaborating with regulatory bodies and policy makers to ensure pathways exist for rapid registration, adoption, and distribution of bnAbs.
- Expanding public-private partnerships to develop and commercialize affordable antibodies for global and sustainable access.

[1] Cunningham CK, et al. Safety, tolerability, and pharmacokinetics of long-acting broadly neutralizing HIV-1 monoclonal antibody VRC07–523LS in newborn infants exposed to HIV-1. JPIDS. 2025 Feb;14(2):piaf002.

[2] HIV/AIDS statistics from: Global AIDS brief: United to end AIDS. Geneva: Joint United Nations Programme on HIV/AIDS; 2026.

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