

AIDS vaccine research: FAQs



What is a vaccine?

A vaccine is a substance that is introduced into the body to protect a person from a particular infection or disease in the future. A vaccine prepares the body to defend itself against the pathogen (a disease-causing microorganism, such as a virus, bacteria or parasite) by creating an immune response.

In general, vaccines are given to healthy individuals who may be exposed to the pathogen in the future.

Currently available vaccines save millions of lives each year. A few examples are polio, tetanus, and measles vaccines, but there are many others. Many vaccines are designed for infants, but adults can also be vaccinated.

Does an AIDS vaccine exist?

At this time, no AIDS vaccine exists anywhere in the world. However, many possible vaccines (called “candidates”) are being studied by researchers and some are being tested in clinical trials throughout the world.

A preventive AIDS vaccine will be a substance given (most likely by injection) to people who are not infected with HIV, to prevent or reduce the chance of HIV infection if they are exposed to the virus in the future. There is a chance that a preventive AIDS vaccine could also delay development of AIDS in HIV-infected people.





What is a clinical AIDS vaccine trial?

Clinical trials are studies done in humans to find out if a candidate vaccine or drug will be safe and, in later-stage trials, effective. All vaccines and drugs must go through clinical trials to determine if they can be made available to the general public.

Each clinical trial has specific requirements for participation. Before joining a trial, potential volunteers receive counselling from trial staff to help them understand what the trial will involve. All trials require that volunteers give independent informed consent (written agreement) to the terms of the trial before they join.

In general, volunteering in an AIDS vaccine trial involves:

- **Visits to the trial site to receive medical check-ups.**
- **HIV testing and risk-reduction counselling.**
- **Laboratory tests on the volunteer's blood and urine.**
- **Injections of either the candidate vaccine or a placebo (an inactive substance used for comparison).**
- **Follow-up visits after all injections are complete.**

Who can participate in a clinical AIDS vaccine trial?

For any clinical trial, a volunteer must fully understand the key facts about the trial and independently give informed consent to participate.

In particular to AIDS vaccine trials, a volunteer must not be infected with HIV and should be generally healthy (specific requirements vary by trial). Women cannot be or become pregnant while participating. Volunteers must agree to receive HIV testing and counselling to reduce their risk of HIV infection throughout the trial.

Why is it necessary to test AIDS vaccines in developing countries?

The search for an AIDS vaccine is a global effort. Vaccine research must occur in both the industrialized and developing world, particularly in countries with high HIV prevalence. The best way to determine if a vaccine will be safe, effective, and accessible for a particular population is to include members of that population in vaccine trials.

Partnerships between countries are vital. In-country researchers often play a primary role in conducting trials. Partnering researchers, sponsors, and other groups, often from industrialized countries, look to resident researchers to ensure that studies are relevant to the region. Only through such partnerships can trials be conducted in a locally appropriate way.

In fact, trial communities often experience benefits from hosting trials. Communities may experience such benefits as improved health care, voluntary counselling and HIV testing (VCT) services, as well as increased knowledge about HIV/AIDS and vaccines.



How do we know that **AIDS** vaccine trials are ethical?

All medical research is governed by principles of ethics, and researchers design AIDS vaccine trials very carefully to uphold international ethical guidelines. Before trials begin, they must be approved by a number of local and national governing bodies, including those specifically focused on ethical standards.

Human rights and the well-being of volunteers are key concerns in AIDS vaccine trials. Obtaining volunteers' informed consent to participate in a trial is one important safeguard for volunteer protection. The process helps ensure that volunteers fully understand essential information about the trial and are not unfairly influenced to participate.

Can trial volunteers become infected by the candidate **AIDS** vaccine?

Candidate AIDS vaccines cannot cause HIV infection or transmission because they do not contain HIV. The vaccines contain only copies of small bits of genetic material from HIV. Science has shown that these small pieces cannot cause HIV infection. Additionally, volunteers are never intentionally exposed to HIV to see if the candidate vaccine prevents infection.

AIDS vaccine trial volunteers should **NOT** count on the trial vaccine to protect them against HIV, and they receive HIV-prevention counselling throughout the trial to practice risk-reduction behaviours. However, behavioural prevention is not perfect, and some volunteers may become infected through sexual transmission, contact with contaminated needles, or other means. A volunteer's risk of HIV infection if exposed through such means might be less, the same, or more than if the volunteer had not received the experimental vaccine. *See the next question for further information.*

In cases where a volunteer becomes HIV-infected, he or she will receive medical services or referrals to services as agreed with local and national stakeholders.

Do volunteers need to use condoms or other forms of HIV prevention while participating in an **AIDS** vaccine trial?

Yes, everyone should protect himself or herself against HIV and other sexually transmitted infections. People who join a clinical trial should **NOT** count on the trial vaccine to protect them against HIV infection! In fact, the purpose of the research is to find out whether the vaccine works.

When trials begin, researchers do not know for sure how a candidate vaccine might affect a volunteer's risk of HIV infection if exposed through such means as sexual transmission – the level of risk might be less, the same, or more than if the volunteer had not received the experimental vaccine.

Further, trials are designed to include a control group of volunteers for comparison to the vaccine group. Volunteers in the control group receive a placebo, which looks like the vaccine but is actually an inactive substance. Volunteers and study staff do not know who received the vaccine or the placebo until the trial has ended.

For these reasons, volunteers **MUST** continue safer sex practices, and they are counselled to use condoms and to continue other forms of HIV prevention.





Why is it taking so long to develop an **AIDS** vaccine?

Developing any vaccine takes a very long time. The polio vaccine, for example, took over 40 years to develop. AIDS vaccines are particularly hard for many reasons. The science involved in designing the vaccines is very complicated. Vaccine development strategies for diseases such as measles, which uses a weakened form of the virus, are not used for AIDS vaccines in order to avoid any risk of the vaccine causing HIV infection (see **Can trial volunteers become infected by the candidate AIDS vaccine?**).

Once scientists develop a possible vaccine, the process of testing it in animals and humans is very lengthy. Many candidate AIDS vaccines will need to be tested before one or more are proven to be effective; indeed, many candidates have already gone through various stages of testing in people. Although researchers are investigating promising vaccines, so far none have proven effective.

Despite the challenges, experts agree that development of an AIDS vaccine is possible.

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This fact sheet is a part of the AIDS Vaccine Literacy ("VaxLit") Toolkit which contains resources intended for training, mobilization, and advocacy purposes around AIDS vaccine research. To view the entire VaxLit Toolkit please visit <http://www.iavi.org/vaxlit> or contact IAVI at pubs@iavi.org to request print copies or CD-ROMs.