



# AIDS Vaccines

This fact sheet provides basic information on AIDS vaccines, one of the options being tested now as part of the effort to identify additional tools to reduce the risk of HIV transmission.

## **What is an AIDS vaccine?**

An AIDS vaccine is an experimental strategy that aims to teach the body's immune system how to fight HIV to reduce the risk of infection or to reduce viral load in those who get the vaccine and go on to become infected. All of the candidates being studied are experimental; there are no effective AIDS vaccines available today.

## **Why are we looking at AIDS vaccines?**

Vaccines are one of the world's most effective public health tools. Effective vaccines against polio, measles, mumps, rubella, and other diseases have significantly reduced rates of these illnesses in many parts of the world. Today, many scientists, clinical trial teams, and communities are working together on the search for an AIDS vaccine.

AIDS vaccine scientists are testing two different vaccine approaches. In addition to research on AIDS vaccines that might prevent infection, researchers are studying AIDS vaccine candidates to see if it is possible to reduce viral load (amount of virus circulating in the body) in people who get the vaccine and go on to become infected with HIV. These vaccines would not provide complete protection against disease. It's hoped that these vaccines would help the immune system fight HIV and slow the rate at which HIV replicates (makes copies of itself). Slower replication could mean lower viral load. There is a general link between lower viral load and slower disease progression or time to treatment. A vaccine candidate that lowered viral load might slow disease progression or delay the need for antiretroviral treatment. It might also lead to the discovery of a vaccine that provides complete protection from infection.

*None of the vaccines being tested can cause HIV.*

## **How will we know if an AIDS vaccine works?**

Every HIV biomedical prevention candidate goes through an extensive series of evaluations, first in laboratory and animal studies and then in humans. The animal studies provide preliminary information about the safety and efficacy of the candidate. Only those candidates that appear safe in animals are considered for human testing. Efficacy data from animals can also be used to inform decisions about whether to test a candidate in humans. However, studies in animals cannot give a clear answer about whether a strategy will reduce HIV risk in humans. AIDS vaccine candidates that meet criteria in laboratory and animal studies are moved into small safety studies in humans (Phase I trials). Candidates that appear to be safe and meet certain criteria are then tested in expanded safety studies (Phase II trials). Some of the candidates that complete these stages with positive results are moved into large-scale efficacy or effectiveness trials, which may be called Phase III, Phase IIb, test-of-concept, or proof-of-concept trials. There are technical reasons why some trial designs are called efficacy and others are effectiveness studies. Both terms refer to trials that look at whether a candidate reduces the risk of HIV infection. For simplicity, the term efficacy is used below.

The details of these large-scale efficacy studies vary, but the design of vaccine efficacy trials is similar to that of most HIV prevention trials. These trials enroll healthy, HIV-negative people, most commonly in communities where researchers have conducted preparatory work to learn about the rates of risk behaviors and incidence. Each participant receives a basic prevention package including treatment for sexually transmitted infections,

condoms, and behavior change counseling. [Unfortunately, needle exchange is not provided in all of the efficacy trials involving injection drug users, and this area is receiving continued attention from advocates and activists.] Some of the participants are randomly assigned to receive the vaccine, while the other participants receive a placebo, a vaccine that has no effect on the body. No participant knows whether he or she is receiving the experimental vaccine or placebo. All participants are counseled at every study visit that they can't assume they will be protected by the vaccine and that they cannot know whether they have received the experimental vaccine or the placebo.

Over the course of the trial period, some participants get infected even though they are being counseled and receiving prevention services. This is consistent with what we know about the AIDS epidemic: even with information and services, not everyone can protect himself or herself all the time.

At the end of the trial, researchers compare the rates of new infections in the participants who received the vaccine and in those who received the placebo. They may also look at the viral load in participants who got infected, comparing vaccine and placebo groups. If there are significantly fewer new infections or lower viral load in the vaccine group, that is, if the difference is greater than that which can be attributed by chance, this suggests that the vaccine is beneficial.

### **Where are AIDS vaccine trials taking place?**

There are over 30 clinical trials of experimental vaccines currently underway in nearly 25 countries, enrolling thousands of participants. Visit [www.avac.org/globalmap](http://www.avac.org/globalmap) for a map of ongoing vaccine and other biomedical HIV prevention trials.

### **Who is participating in AIDS vaccine research?**

Like other HIV prevention strategies, AIDS vaccine trials are conducted among different populations, among them gay men and other men who have sex with men, injection-drug users, sex workers, and heterosexual men and women in sub-Saharan Africa.

### **When are results expected?**

There is currently no effective AIDS vaccine. Data from a large-scale vaccine trial in Thailand were released in September 2009. They showed that participants who got the vaccine regimen along with a standard prevention package were 31 percent less likely to become infected than those who received the placebo and a standard prevention package. (Visit [www.avac.org/thaitrial](http://www.avac.org/thaitrial) for in-depth coverage of the Thai trial result.) The largest ongoing AIDS vaccine trial is HVTN 505 (enrolling over 1,300 MSM in the US), which is designed to examine whether a prime-boost vaccine strategy lowers viral load and is safe in individuals who get the vaccine and go on to become HIV-infected. There are also a number of smaller trials testing a range of candidates. Visit [www.avac.org/trials](http://www.avac.org/trials) for more on ongoing and completed AIDS vaccine trials.

Visit the [www.avac.org/timeline](http://www.avac.org/timeline) and [www.avac.org/globalmap](http://www.avac.org/globalmap) for more on the full range of ongoing biomedical HIV prevention research trials.

*Founded in 1995, AVAC is an international, non-profit organization that uses education, policy analysis, advocacy and community mobilization to accelerate the ethical development and eventual global delivery of AIDS vaccines and other new HIV prevention options as part of a comprehensive response to the pandemic. For more information, visit **www.avac.org**.*