



COMMUNITY PARTICIPATION IN VACCINE RESEARCH

By raising awareness and encouraging study participation, individuals and communities can contribute to the successful development of HIV vaccines. Although tens of thousands of people have already volunteered to take part in HIV vaccine studies, many more will be needed. A large HIV vaccine trial will require thousands more participants of all race/ethnicities, genders and socioeconomic backgrounds to ensure that the vaccine works in all populations.

Therefore, community support is essential in efforts to break down stigma and myths about HIV vaccine research. Developing an effective HIV vaccine depends upon individuals and communities informing, educating and supporting others.

HOW TO HELP

- Let others know you support HIV vaccine research
- Educate others about the need for an HIV vaccine
- Support vaccine trial volunteers and/or volunteer yourself

The National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH), supports a comprehensive program of HIV vaccine research.

For more information about HIV vaccines, please visit:
www.niaid.nih.gov/daids/vaccine
www.vrc.nih.gov
www.hvtn.org
www.aidsinfo.nih.gov
or call 1-800-448-0440.

Para información en español sobre las vacunas contra el VIH, llame al: 1-800-448-0440.

WHAT IS AN HIV VACCINE?

A preventive HIV vaccine is a substance that teaches the body's immune system to recognize and protect itself against HIV, the virus that causes AIDS. HIV vaccines currently being tested in humans are made from man-made materials that **CANNOT** cause HIV infection.

Scientists believe that an effective HIV vaccine, given before exposure to HIV, could have a number of possible outcomes. These include:

- Preventing infection in most people
- Preventing infection in some people
- Preparing a person's immune system to block continued infection and eliminate the virus (vaccines against measles, mumps and polio work this way)
- Delaying or preventing the onset of illness or AIDS

The long-term goal is to develop a vaccine that is 100 percent effective and protects everyone from infection. However, even if a vaccine only protects some people, it could still have a major impact on controlling the epidemic. A partially effective vaccine could decrease the number of people who get infected with HIV; those people, in turn, would not pass the virus on to others. Even when an HIV vaccine is developed, education and other prevention efforts will be needed so that people continue to practice safe behaviors.

HISTORY OF VACCINES

The value of vaccines was recognized approximately 200 years ago, beginning with a vaccine against smallpox. The smallpox vaccine saved millions of lives, and its success helped people understand that introducing a vaccine into the body can actually trigger a protective immune response, and prevent disease.

Today, there are numerous safe and effective vaccines. Vaccines have been used successfully against many life threatening diseases, including measles, and polio in most of the world.



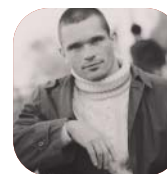
February 2004

NIH Publication No. 04-5279

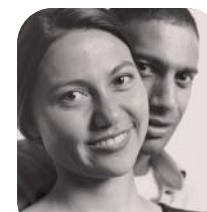


HIV VACCINES EXPLAINED

MAKING HIV
VACCINES
A REALITY



HIV VACCINE RESEARCH
Our best minds. Our best science. Our best hope.



THE NEED FOR AN HIV VACCINE

Despite the availability and success of HIV treatment drugs in the United States, the best long-term hope for controlling the AIDS epidemic worldwide is the development of safe, effective and affordable preventive HIV vaccines. Consider these facts:

HIV/AIDS IN THE UNITED STATES

- Nearly half a million Americans have died of AIDS since the epidemic began.
- The Centers for Disease Control and Prevention (CDC) estimate that as many as 950,000 Americans are living with HIV, and more than one-third of them do not know it.
- Each year, over 40,000 people become infected with HIV, a rate that has remained virtually unchanged in recent years. Seventy percent are men and 30 percent are women. Of these, half are younger than 25 years of age.
- Minority communities are disproportionately affected by the epidemic. More than half of all new HIV infections occur in African Americans, who make up 12 percent of the U.S. population. AIDS is the fifth leading cause of death of Americans aged 25-44, and is the number one cause of death in African American men of all ages. Nineteen percent of new HIV infections occur in Latinos, who make up 13 percent of the population.

HIV/AIDS AROUND THE WORLD

- To date, nearly 25 million men, women and children have died from AIDS worldwide.
- Currently, 40 million people are estimated to be living with HIV/AIDS and 14,000 new infections occur each day.
- Today, more than 13 million children under the age of 15 have lost one or both of their parents to AIDS, most in sub-Saharan Africa.



PREVENTIVE VERSUS THERAPEUTIC HIV VACCINES

Preventive HIV vaccines currently under development are given to HIV negative people and are designed to prevent infection and control the spread of HIV, not to cure AIDS.

Multiple HIV vaccines may be necessary to prevent infection or disease in the same way multiple drugs are needed to treat people already infected with HIV.

Researchers are also evaluating therapeutic vaccines to treat people with HIV infection or AIDS. While the same vaccine may be tested for both preventive and therapeutic effects, what works to prevent HIV infection may not necessarily work to treat people who are already infected with HIV.

IS AN HIV VACCINE AVAILABLE NOW?

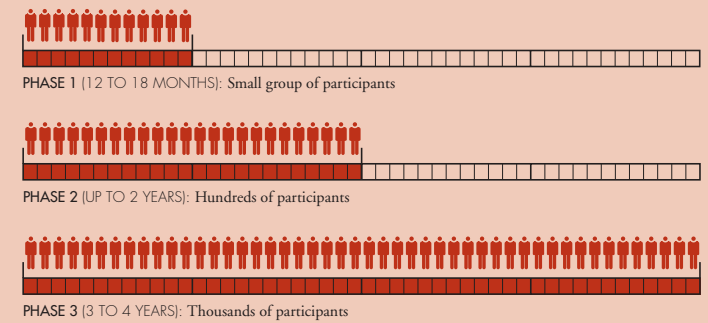
No! Scientists have been studying HIV for over two decades — and continue to make progress. Even when a promising vaccine is discovered, it will take time to test and evaluate its safety and effectiveness.

TESTING HIV VACCINES

Vaccine development requires several years of research in laboratories and animals before testing in humans can begin. A potential vaccine goes through three phases of testing in humans before the Food and Drug Administration (FDA) can consider licensing it for public use. The three phases of preventive HIV vaccine clinical trials are:

- **Phase I** — involves a small number of healthy volunteers (HIV-negative) to test the safety and various doses of the vaccine; usually lasts 12 to 18 months
- **Phase II** — involves hundreds of volunteers (HIV-negative) to test the safety and immune responses of the vaccine; can last up to 2 years
- **Phase III** — involves thousands of volunteers (HIV-negative) to test the safety and effectiveness of the vaccine; can last 3 to 4 years

Throughout all phases of human testing, independent reviewers regularly monitor the study to ensure the safety of the volunteers.



PROTECTING RESEARCH PARTICIPANTS

HIV vaccine clinical trials are voluntary. Researchers are required to obtain the informed consent of all participants to make sure they fully understand the purpose of the study, how the HIV vaccine will be tested, the number of clinical visits required and the possible risks and benefits associated with receiving the vaccine.

So far, few side effects have been associated with experimental HIV vaccines. Those that have occurred generally have been mild to moderate and similar to those of approved vaccines. The most common side effects are soreness at the site of the injection, a low-grade fever, and body aches, which readily disappear on their own. Throughout the study, volunteers are carefully examined to determine if there are any serious side effects associated with the vaccine.

After a volunteer receives an HIV vaccine, it is possible to test positive for HIV antibodies on a standard HIV test (i.e., ELISA) because the vaccine triggers the body to produce antibodies against HIV.

The HIV vaccines being tested in humans do not contain HIV; therefore, they cannot cause HIV infection. Other tests are available at the study sites to determine whether a volunteer is actually infected with HIV. If volunteers engage in behaviors that expose them to HIV, they may still become infected with HIV.

It is rare for volunteers to encounter problems as a result of testing positive for HIV antibodies. Testing antibody positive does not mean the person is infected. However, volunteers could potentially experience problems donating blood, getting insurance, traveling to other countries or getting employment.

All volunteers are offered an identification card to show they are part of the study, and research staff are available to help address any issues that may arise.