Women

Answers about HIV vaccine research

How is HIV/AIDS affecting women?

Women are increasingly being affected by the HIV/AIDS epidemic. In 2001, HIV/AIDS was the sixth leading cause of death among all women ages 25 to 34 in the United States, and the fourth leading cause of death among all women ages 35 to 44. More than 84,000 women have already died with AIDS in the United States. Women now account for approximately 27% of the estimated 40,000 new HIV/AIDS diagnoses in the United States each year. African-American women comprise 67% of new AIDS diagnoses among women, while Hispanic women account for 15%. The majority of women acquire HIV through unprotected sex with HIV-infected men. Approximately 70% of women who acquired HIV in 2004 were infected by their male sexual partners, while approximately 28% acquired the virus through injection drug use.

HIV/AIDS disproportionately affects Women*

Women:
Represent nearly 1 in 3 newly reported cases of HIV infection in the United States

Women of color are increasingly affected by HIV/AIDS

African-American Women: In 2004, the AIDS case rate among African-American women was 23 times higher than among white women

White

African American

Hispanic/Latina Women: In 2004, the AIDS case rate among Hispanic/Latina women was 5 times higher than among white women

White

Hispanic/Latinas

*CDC Data

What is a vaccine?

A vaccine "teaches" the immune system to recognize and defend against a virus (such as HIV), bacteria or other disease-causing agent.

Why do we need a preventive HIV vaccine?

- There is NO cure for AIDS. While the availability of anti-retroviral therapy has had a dramatic impact by decreasing AIDS-related deaths in this country, these treatment regimens are complex, costly and can cause serious side effects. In addition, patients can develop drug resistance.
- Like smallpox and polio vaccines, a preventive HIV vaccine could help save millions of lives.
- Developing safe, effective and affordable vaccines that can prevent HIV infection in uninfected people is the best hope for controlling and/or ending the AIDS epidemic.
- The long-term goal is to develop a vaccine that is 100% effective and protects everyone from getting infected with HIV. However, even if a vaccine only protects some people, it could still have a major impact on the rates of transmission and help in controlling the epidemic. A partially effective vaccine could decrease the number of people who get infected with HIV, further reducing the number of people who can pass the virus on to others.
- An HIV vaccine may also be beneficial for HIV-infected individuals by helping to delay the onset of AIDS or slowing disease progression. These types of vaccines are referred to as "therapeutic" vaccines. It is not known if a preventive HIV vaccine will have a therapeutic benefit in HIV-infected individuals. This would require additional clinical trials in those populations.

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

What is happening in preventive HIV vaccine research?

- More vaccines are being tested than ever before.
- Since 1987, the National Institute of Allergy and Infectious Diseases (NIAID) has enrolled over 20,000 volunteers in 94 HIV vaccine clinical trials that have tested more than 56 different vaccine candidates.
- Despite these efforts, there is currently NO preventive HIV vaccine available.
- Scientists believe that an effective preventive HIV vaccine is possible and are working to speed up the research process.

How safe are the vaccines being tested in people?

- Preventive vaccines cannot cause HIV infection because they are made of man-made materials and do not contain the HIV virus.
- Few side effects have been associated with experimental HIV vaccines. The most common side effects are soreness at the site of injection, a low-grade fever and body aches. These responses normally disappear quickly on their own and are similar to those seen with licensed vaccines.
- Protecting the health and privacy of the volunteers is a high priority of HIV vaccine clinical trials. Prior to entering a trial, volunteers are fully informed of the processes, the vaccines being tested and possible outcomes. Volunteers who wish to participate are then required to sign an "informed consent" form to officially agree to take part in the trial. Once enrolled, a volunteer may leave the trial at any time.
- Throughout a vaccine clinical trial, volunteers are continually counseled on how to reduce behaviors that may put them at risk for HIV infection.

What can women do?

- **Let others know** you support HIV vaccine research.
- **Educate others** about the need for an HIV vaccine and the importance of trial participation of all races/ethnicities, genders and socioeconomic backgrounds.
- **Support vaccine volunteers** and/or volunteer yourself.
- **Get involved** by joining a Community Advisory Board.

How can I be sure the research is being done right?

- Safeguards and protections are built into HIV vaccine clinical trials to ensure that they meet the highest FDA standards to protect volunteers and assure the development of safe and effective vaccines.
- Clinical trials are monitored throughout the study to guarantee the safety of the participants and ensure that the trial can meet its objectives.
- Anyone who is interested can learn more about the NIAID clinical research process and get involved through participation in a Community Advisory Board (CAB). CABs are located in areas where NIAID-sponsored HIV vaccine trials are occurring. Through a CAB, members can provide input into study designs and local procedures and can help to prepare and educate the community about vaccine clinical trials. Participation in a CAB helps to ensure that a trial meets the needs of the community.

There is no preventive HIV vaccine available.

More vaccines are being tested than ever before. HIV vaccines do not contain any actual HIV, and therefore, cannot cause HIV infection.

Who is doing the research?

- Many public and private research organizations, both domestic and international, are working in collaboration to develop preventive HIV vaccines. These include leading universities, biotechnology companies, pharmaceutical firms and government agencies such as NIAID.
- NIAID conducts and supports research to understand, treat and ultimately prevent the diseases that threaten hundreds of millions of people worldwide. This includes a broad and diverse research and development program for HIV/AIDS prevention and treatment.

Where can I learn more?

For more information on preventive HIV vaccine research, go to: **www.bethegeneration.org**, or call 1-800-448-0440 (Bilingual English/Spanish).

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Division of AIDS

June 2006

NIH Publication No. 06-6072

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