WOMEN:

ANSWERS ABOUT HIV VACCINE RESEARCH

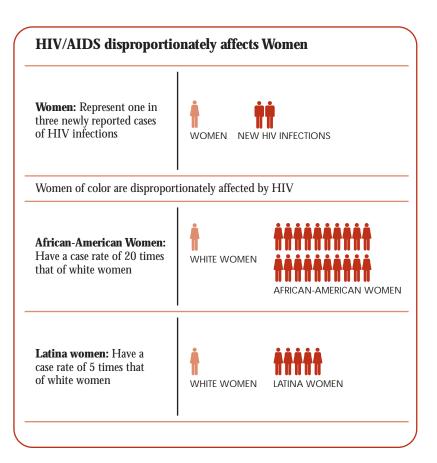






HOW IS HIV/AIDS AFFECTING WOMEN?

Women are increasingly being affected by the HIV/AIDS epidemic. HIV/AIDS is now the third leading cause of death among women ages 25 to 44 and over 75,000 women have already died of AIDS in the United States. Women now account for an estimated 30% of the over 40,000 new HIV infections occurring in the United States each year. Within minority communities African-American women comprise nearly 64% of new HIV infection cases while Latino women account for 18%. In the United States, the majority of women become infected with HIV during sex with an HIV-infected man or while using HIV-contaminated syringes for the injection of drugs such as heroin, cocaine, and amphetamines. Women are particularly vulnerable to heterosexual transmission of HIV due to substantial exposure to seminal fluids, the high prevalence of non-consensual sex, sex without condom use, and the high-risk behaviors of their partners. Of the new HIV infections among women in the United States, CDC reports 75% were attributed to heterosexual contact and 25% to injection drug use.



WHAT IS A VACCINE?

A vaccine is a substance that when introduced into the body, "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 currently available treatments have had a dramatic impact on decreasing AIDS-related deaths in this country, these treatment regimens are complex, costly and in many cases can cause serious side effects. In addition, the development of drug resistance is common.
- 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 percent 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.
- Like smallpox and polio vaccines, a preventive HIV vaccine could help save millions of lives as well as millions of dollars in health care costs.
- 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.

WHAT IS HAPPENING IN PREVENTIVE HIV VACCINE RESEARCH?

- Scientists believe that an effective preventive HIV vaccine is possible and are working to speed up the research process.
- More vaccines are being tested than ever before, and the number of HIV vaccine trial sites is expanding worldwide.
- Since 1987, the National Institute of Allergy and Infectious Diseases (NIAID) has enrolled over 4,700 volunteers in 73 HIV vaccine clinical trials which have tested more than 41 different vaccine candidates.
- Despite these advances, there is currently **NO** preventive HIV vaccine available.

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 HIV.
- 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 preventive 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 quit the trial at **any time**.
- Throughout a vaccine clinical trial, volunteers are continually counseled on how to reduce behaviors which may put them at risk for HIV infection.

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 to ensure that the trial can meet its objectives. Monitors can recommend that a trial be stopped if the data show that it is appropriate to do so.
- Anyone who is interested can learn more about the NIAID clinical research process and can 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, 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.

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 volunteers of all race/ethnicities, genders and socioeconomic backgrounds participating in clinical trials.
- Support vaccine volunteers and/or volunteer yourself.
- Get involved. Join a Community Advisory Board.

CURRENTLY, THERE IS NO PREVENTIVE HIV VACCINE AVAILABLE.

More vaccines than ever before are being tested. In addition, it is important to know that HIV vaccines do not contain any actual HIV, and therefore, cannot cause HIV infection.

WHO IS DOING THE RESEARCH?

- Scientists around the globe are working on HIV vaccine research.
- Many public and private research organizations worldwide are working in collaboration to develop preventive HIV vaccines. This includes leading universities, biotechnology companies, pharmaceutical firms, and government agencies such as NIAID.
- NIAID conducts and supports research to understand, treat, and ultimately prevent the infectious, immunologic, and allergic 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.



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



National Institutes of Health National Institute of Allergy and Infectious Diseases Division of AIDS

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