Health Care Professionals

Answers about HIV vaccine research

Why should health care professionals care about HIV vaccine research?

As more and more individuals consider participating in preventive HIV vaccine trials, it is increasingly important that health care professionals be well informed so they are able to answer questions accurately or make referrals to experts who can. Experience tells us that the most common questions include:

- **Will I get HIV from vaccines being tested? NO.** Participants cannot get HIV from vaccines being tested because they are man-made and do not contain the HIV virus.
- **Will an investigational vaccine make someone test positive for HIV antibodies, and what does that really mean?** Some investigational vaccines may be strong enough to cause an antibody response detectable on standard HIV tests. These tests measure the body's antibody response to HIV, and do not directly measure HIV itself. Therefore, having a false-positive antibody test for HIV after vaccination is not unexpected. It does not mean the participant is infected. Trial sites are able to perform specialized tests to prove that a person is not HIV infected.
- **How do I know if I am going to get a vaccine or a placebo?** Some volunteers are given a placebo (inactive substance) so that scientists can tell if there is a difference between those who get the study vaccine and those who do not. Neither the volunteers nor the doctors and scientists know who gets the study vaccine and who gets the placebo until after the trial is completed, which makes the trial 'double-blinded.'
- **Can I talk to my doctor or friends and family first, and what questions should I ask?** Prospective participants are encouraged to discuss their interest with family and friends, health care providers, and others whom they trust. With the individual's permission, trial site staff can also talk to these people to help answer their questions. People are encouraged to ask questions that help them to understand more clearly the risks and benefits of participation, and what their responsibilities as a trial participant will be.

According to a national survey conducted by the National Institute of Allergy and Infectious Diseases (NIAID), health care professionals are valued as trusted sources of information regarding HIV vaccine studies. African Americans, Hispanics and MSM ranked health care professionals third or higher as a trusted source of information about HIV vaccines.

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.

Health care professionals are often the first point of contact when it comes to someone learning about HIV vaccine trials. Their knowledge level and attitude can have a tremendous impact on whether individuals are supportive of HIV vaccine research and those who volunteer in vaccine trials.

Health care professionals are valuable assets in their respective communities, especially those health care providers who work with people who are most impacted by HIV: African Americans, Hispanics, Men who have Sex with Men (MSM), and women. The only way to know if a vaccine will work in all communities is to have all communities involved in the research. Health care professionals must take an active role in raising awareness about the hope and promise of HIV preventive vaccines across diverse communities and populations.

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.

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- 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.

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.

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
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