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HIV Vaccines [1]

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What is a vaccine?

A vaccine is a treatment that prevents us from getting a disease. It works by teaching our immune system [2] how to protect itself against disease-causing germs like viruses or bacteria.

Vaccines are one of the world's most effective tools for preventing diseases. Serious illnesses like polio, smallpox, measles, and mumps have been nearly eliminated from many countries because of vaccines.

There are two types of vaccines being studied for HIV: preventive vaccines and therapeutic vaccines. Preventive vaccines are designed to keep people from getting HIV. Therapeutic vaccines would allow those already living with HIV to control the virus without needing to take HIV drugs. Therapeutic vaccines are being considered as one of several strategies to cure HIV.

In a best-case situation, a preventive HIV vaccine would protect nearly everyone who receives it from getting HIV. But many scientists think that the first-generation HIV vaccines will provide more limited forms of protection, in which some, but not all of the people who receive the vaccine are protected against becoming infected.

It is good to remember that none of the vaccines that are currently available (e.g., those for measles, polio, chicken pox) are 100 percent protective in 100 percent of the people who receive them. Some vaccines work better in some people than in others; other vaccines only provide protection for a limited amount of time. Yet these vaccines have been very effective and are now considered 'tried and true' public health tools. Therefore, even a partially protective HIV vaccine could be a very important tool for slowing the spread of HIV. It would also help scientists develop more effective vaccines over time.

Why do HIV vaccines matter to women?

Over 30 years into the epidemic, we still do not have ways to protect ourselves against HIV during sex that are private, woman-controlled, and independent of our partners' agreement.

There is an urgent need for prevention methods that women can choose without their partners' knowledge or consent. An effective HIV vaccine would give women this option. A woman could decide to be vaccinated against HIV. Later on she might decide to talk about the decision with her partner?or she might not. The choice would be hers.

It is important for women to participate in large numbers in HIV vaccine studies in order to find an HIV vaccine that helps protect us. This is the only way that researchers will be able to find out whether a particular vaccine works equally well in women and men. In Africa, where women bear a larger burden of the HIV epidemic than men, only about one in five HIV vaccine trial participants is a woman. As a result, scientists are concerned that study results will point us toward vaccines that may only be effective in men.

An effective HIV vaccine could also someday be given to infants born to women living with HIV to help protect the infants from getting HIV through breast milk. This would be very useful in developing countries where feeding with formula is not possible for many women living with HIV.

I have HIV - why do HIV vaccines matter to me?

Right now, most of the potential vaccines that are being developed are designed to prevent HIV infection in HIV-negative people. However, there are also research studies testing vaccines in people living with HIV (HIV+). While these therapeutic vaccines will not cure HIV, they may help people living with HIV fight the virus. They would allow people living with HIV to control the virus while taking fewer or no HIV drugs.

Can an HIV vaccine cause HIV infection?

No. Each vaccine being tested uses a slightly different design or strategy but none of them can actually cause HIV infection. This is because all the potential vaccines only use small, synthetic (human-made) pieces of HIV. These pieces of HIV cannot cause HIV infection. However, they often cause the body to make antibodies. Antibodies are proteins that the body makes to mark HIV-infected cells for destruction. As a result, HIV-negative people who have been vaccinated against HIV need to use HIV tests that look for the actual HIV virus and not for antibodies to HIV in the bloodstream. For more information, see the "Types of HIV Tests" section in our fact sheet on HIV Testing [3].

Is there an HIV vaccine?

Not yet. Today there are no effective HIV vaccines.

Are there HIV vaccine studies going on now?

Yes. As of December 1, 2016, there were over 100 ongoing clinical trials [4] of vaccines being conducted in more than 20 countries around the world. Go to this website [5] provided by the US National Institutes of Health (NIH) to find a searchable database of publicly and privately funded clinical trials across the globe, including those for HIV vaccines.

How are HIV vaccines tested?

Like all experimental medical treatments, potential HIV vaccines go through a series of safety tests?first in animals and then in small groups of people. These small studies help determine whether or not the vaccine causes any serious side effects [6]. Only vaccines that appear to be completely safe are considered for studies in larger groups of people that test whether the vaccine works. HIV vaccines are not tested by exposing people to HIV on purpose.

Before a research study on the effectiveness of a preventive vaccine begins, scientists usually spend two or more years looking at communities where studies may take place. They gather many types of information, including how many people get HIV each year.

Once these numbers have been collected, people from the community are asked to enroll in the preventive vaccine study. People in the study are randomly assigned to receive either the vaccine or a placebo (an inactive substance). Neither the researchers nor the study participants know who has received the vaccine and who has received the placebo.

The people in the study are followed for a long time?usually two to three years. At the end of the study, the researchers look to see whether fewer people got HIV who were in the group of people given the vaccine, as compared to in the group of people given the placebo.

For example, if two out of 100 people who received the vaccine got HIV, and five out of 100 people who received the placebo got HIV, that might mean that the vaccine was protecting some people against HIV.

What results have been seen in HIV vaccine research?

The search for an HIV vaccine has not been easy. A number of potential vaccines have been studied since the mid-1980s, but few have made it to Phase III trials. Phase III trials test a product's effectiveness and safety in very large groups of people over several years. It is only after a vaccine successfully passes a Phase III trial can governmental agencies like the US Food and Drug Administration (FDA), European Medicines Agency (EMA), or Medicines and Healthcare products Regulatory Agency (MHRA in the UK) approve the vaccine for public use. For more information about all phases of clinical trials, see our fact sheet on Understanding Clinical Trials [4].

Preventive Vaccine Research

There have been three large Phase III trials of preventive HIV vaccines. The first two involved a potential vaccine called AIDSVAX [7]. They were completed in 2003 and did not show any evidence that the vaccine worked.

The third trial (RV144) took place in Thailand and enrolled 16,000 people, making it the largest HIV vaccine study ever. It tested AIDSVAX with another vaccine called ALVAC. In 2009, after much debate over the results, researchers concluded that the vaccine only had a modest effect in preventing HIV infection.

There had been high hopes for a fourth trial called STEP [8], which was a smaller study of a vaccine manufactured by Merck. In 2007, the STEP study and another study of the same

vaccine in South Africa were called off early due to results that showed the vaccine did not work.

Another potential vaccine was developed by the National Institutes of Health (NIH) Vaccine Research Center (VRC). In 2013, a trial named HVTN 505 [9], which tested the VRC's vaccine among over 2500 HIV-negative men, was stopped because the vaccine neither prevented HIV infection nor reduced viral load in those who became infected with HIV.

In November 2016, an exciting new large-scale clinical trial of a preventive HIV vaccine (HVTN 702) was launched in South Africa. This trial will test the effectiveness of a vaccine regimen that is based on the one that was tested in Thailand in 2009 (RV 144). To learn more about progress in finding a preventive HIV vaccine, watch this video from the US National Institute of Allergy and Infectious Diseases (NIAID).

Therapeutic Vaccine Research

In 2012, a therapeutic vaccine called Vacc-4x [10] showed that it may be possible to teach the immune system to control HIV reproduction in some people living with HIV and reduce their viral load. Further testing has showed that Vacc-4x can help reduce the viral load in people living with HIV, but not enough to for them to stop taking their HIV drugs. A Phase I trial (first time in humans) of a therapeutic vaccine called Vacc-5C showed that Vacc-5C was safe and well tolerated, generated an immune response, and may improve some people?s response to vaccination with Vacc-4x.

Researchers continue to test new models for what is now being referred to as HIV remission or a functional cure (keeping viral load suppressed without antiretroviral medications). A combination of a vaccine and an immune stimulant recently showed promise when tested in monkeys. This combination is designed to awaken the dormant or hidden HIV then attack it with the vaccine-induced immune response. For more information on functional cure strategies, see our fact sheet on Finding a Cure for HIV [11].

Is HIV vaccine research going forward?

Yes. Despite setbacks, the search for an HIV vaccine has not ended. The disappointing STEP study results and the controversy over the results of the Thai study caused a lot of debate among researchers and advocates about what to do next. However, research is still moving forward. The focus is on answering basic scientific questions that can help guide vaccine development, while continuing to learn valuable information from previous studies and mapping out future ones.

A number of potential vaccines remain in development and evidence from different studies suggests that an effective HIV vaccine is still possible. In fact, scientists continue to discover new potential ways to stop HIV, including the finding of a vaccine that triggers the body to produce broadly neutralizing antibodies to HIV. Broadly neutralizing antibodies are antibodies that are effective at neutralizing several strains of HIV. Because HIV mutates, or changes, so quickly, it is important for a potential vaccine to trigger an immune response against several strains of HIV.

Scientists have discovered ways to make some of these broadly neutralizing antibodies in the lab. These pre-made antibodies can then be given to people directly in a process known as 'passive immunization' (active immunization refers to the natural process in which your body?s immune system makes antibodies itself). Recent research in monkeys has shown that broadly neutralizing antibodies have the potential to protect against infection and to reduce the amount of HIV in the body of those already living with HIV.

How long will it take to find an HIV vaccine that works?

The honest answer is that we do not know. It takes several years to study whether a potential vaccine is safe and effective. This first-generation vaccine is not likely to provide complete protection against HIV infection.

Although this sounds discouraging, it is important to remember that vaccine research takes a long time. It has taken decades, with more setbacks than advances, to discover other vaccines. Because effective vaccines have ended many epidemics in modern times, it is important to keep moving ahead with HIV vaccine research.

Do vaccine trials do anything to help lower the participant's risk of becoming infected with HIV?

Yes. Vaccine trials provide a lot of information to people who are thinking about volunteering to be in the study and to people who decide to join the study. One of the key messages is that there is no way of knowing whether the vaccine is effective before the study ends. That makes it important for everyone who joins to continue protecting themselves by enjoying safer sex [12] and using clean injecting equipment [13].

This message is repeated to participants every time they come for a study visit. By educating people in the study, it is possible that the research study reduces the participants' risk for getting HIV. All studies also provide free male condoms and counsel participants about other methods like the female condom or safe injection practices.

Taking care of yourself

Until there is an effective HIV vaccine, the best way to protect yourself and your loved ones from HIV is by practicing safer sex [12] and not sharing drug injection equipment [13].

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Additional Resources

Select the links below for additional material related to AIDS vaccines.
First New Vaccine Efficacy Study in Seven Years Has Begun (NIH) [28]
South Africa Launches HIV Vaccine Trial (DW) [29]
Why Women and Girls Need an AIDS Vaccine (IAVI) [30]
Questions and Answers: The HVTN 702 HIV Vaccine Study (NIAID) [31]
Progress Toward an HIV Vaccine (YouTube video; NIAID) [32]
Progress Toward an HIV Vaccine (pdf; NIAID) [33]
HIV Vaccine Research: An Update (AVAC) [34]
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New Therapeutic Vaccine Approach Holds Promise for HIV Remission (Science Daily) [36]
The International AIDS Vaccine Initiative (IAVI) [37]
The U.S. HIV Vaccine Trials Network (HVTN) [38]
Global HIV Vaccine Enterprise [39]
Video: Introduction to AIDS Vaccines (AVAC) [40]
Two Women Unlock Possible Key to HIV Vaccine (IRIN) [41]
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How Vaccines Work (video by IAVI) [43]

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[29] http://www.dw.com/en/south-africa-launches-hiv-vaccine-trial/a-36586779
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[42] http://www.aidsmap.com/Vaccines/page/1065617/

[43] http://www.iavi.org/how-to-help/learn/how-vaccines-work