HIV Vaccines

Submitted on Aug 23, 2024

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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 how to protect itself against disease-causing germs such as viruses or bacteria.

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

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There are two types of vaccines being studied for HIV: **preventive vaccines** and **therapeutic vaccines**. Preventive vaccines are designed to keep people from acquiring 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 for curing HIV.

In a best-case scenario, a preventive HIV vaccine would protect nearly everyone who receives it from acquiring 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 from acquiring HIV.

It is good to remember that none of the vaccines that are currently available (e.g., those for measles, polio, chickenpox) are 100 percent protective. Some vaccines work better in some people than in others; other vaccines only provide protection for a limited 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?

There is an urgent need for a variety of prevention options that women can choose without their partners' knowledge or consent. An effective HIV vaccine would give women this option.

Women still do not have many ways to protect themselves against HIV during sex that are private, woman-controlled, and independent of their partners' agreement. Pre-exposure prophylaxis (PrEP) — a daily prescription pill or an injection (every two months) that a woman takes before potentially coming into contact with HIV, to prevent herself from acquiring it — is a prevention method that can be controlled by the person taking it. But there is an urgent need for a variety of prevention options 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 that decision with her partner—or she might not. The choice would be hers.

It is important to have large numbers of women participate in HIV vaccine studies in order to find a vaccine that helps protect them. 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 participants in an HIV vaccine trial is a woman. As a result, scientists are concerned that study results will point us toward vaccines that may be more effective in men.

An effective HIV vaccine could also someday be given to infants born to birthing people living with HIV to provide them with additional protection from getting HIV through breast milk. This would be very useful in developing countries, where breastfeeding is considered the best option for birthing people living with HIV – but a baby staying HIV-negative depends on the birthing parent's viral load staying very low.

I Live With HIV - Why Do HIV Vaccines Matter to Me?

Right now, most of the potential vaccines that are being developed are designed to prevent HIV-negative people from acquiring HIV. These would benefit the sexual partners of people living with HIV. Additionally, there are research studies testing vaccines in people living with HIV. While these therapeutic vaccines will not cure HIV, they may help people living with HIV fight the virus. They would allow them to control the virus while taking fewer or no HIV drugs.

Can an HIV Vaccine Cause HIV?

No. Each vaccine being tested uses a slightly different design or strategy but none of them can actually transmit HIV. This is so because all potential vaccines only use small, synthetic (human-made) pieces of HIV. These pieces of HIV cannot cause a person to acquire HIV. 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. If you participate in an HIV vaccine trial, you may need to inform your medical and life insurance carriers that you may test positive for HIV using an antibody test (the standard test). To determine whether you have acquired HIV, a different test that looks for the actual virus, such as a viral load test, must be used. For more information, see the "Types of HIV Tests" section in our fact sheet on HIV Testing.

Is There an HIV Vaccine?

Not yet. Today there are no effective HIV vaccines.

Are There HIV Vaccine Studies Going on Now?

Yes. HIV-related vaccine clinical trials are being conducted around the world. This website from the US National Institutes of Health (NIH) is 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. Only vaccines that appear to be completely safe are considered for studies in larger groups of people; such studies test whether the vaccine works. HIV vaccines do not expose people to HIV.

Despite setbacks, the search for an HIV vaccine has not ended.

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 acquire 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 how many people in the group that was given the vaccine acquired HIV compared to people in the group that was given the placebo.

For example, if two out of 100 people who received the vaccine acquired HIV, and five out of 100

people who received the placebo acquired 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. Only after a vaccine successfully passes a Phase III trial can governmental agencies, such as 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.

Preventive Vaccine Research

Three large Phase III trials of preventive HIV vaccines have been completed. The first two involved a potential vaccine called AIDSVAX. 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 acquisition.

Two other trials were stopped early because the vaccines did not work. One, STEP, tested a vaccine manufactured by Merck. It was called off in 2007. Another, HVTN 505, tested a vaccine developed by the US National Institutes of Health Vaccine Research Center among over 2500 HIV-negative men. It was stopped in 2013.

In November 2016, a large-scale clinical trial of a preventive HIV vaccine (HVTN 702) was launched in South Africa. This trial tested the effectiveness of a vaccine regimen that was based on the one that was tested in Thailand in 2009 (RV 144). While no safety concerns were found in the study, the vaccine proved not to be effective in preventing HIV acquisition. This trial was stopped early, in February 2020.

Another large-scale clinical trial, called Mosaico, started in 2019 in Europe, North and South America. It was stopped in early 2023 because it was not effective in preventing HIV acquisition. While unsuccessful, it proved that this particular approach to an HIV vaccine does not work. Researchers are now developing a different approach based on broadly neutralizing antibodies (antibodies that attack HIV) (see Is HIV Vaccine Research Going Forward below), but it will likely take a few years before this approach is ready for large-scale trials. 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 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 shown that Vacc-4x can help reduce the viral load in people living with HIV, but not enough 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 HIV Cure-Related Research Strategies.

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 finding a vaccine that triggers the body to produce broadly neutralizing antibodies to HIV. Broadly neutralizing antibodies work against 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?

SARS-CoV-2, the virus that causes COVID-19, does not stay in the body's immune cells, as HIV does. This made the COVID-19 vaccine easier to manufacture and work against that virus.

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.

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 Acquiring 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, using clean injecting equipment, and in some cases taking pre-exposure prophylaxis.

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 acquiring HIV. All studies also provide free male condoms and counsel participants about other methods, such as internal (female) condoms or safe injection practices.

How Were Vaccines Developed So Quickly for COVID-19 When We Still Do Not Have an HIV Vaccine?

Beginning in early 2020, the novel coronavirus (COVID-19) pandemic swept the globe. However, several effective vaccines against COVID-19 had been developed and were starting to be used by the end of that same year.

One of the reasons why the COVID-19 vaccine could be developed so quickly is that SARS-CoV-2, the virus that causes COVID-19, does not stay in the body's immune cells, as HIV does. This made the COVID-19 vaccine easier to manufacture and work against that virus. The processes that led to COVID-19 vaccines included a massive amount of funding, as well as scientific innovations that will change other kinds of vaccine research going forward. HIV vaccines based on the technology developed for some of the COVID-19 vaccines are already in early testing.

As a result of advocacy by community members, people living with HIV were included in COVID-19 vaccine trials, and the vaccines appear to be **safe for people living with HIV**.

Taking Care of Yourself

Until there is an effective HIV vaccine, the best way to protect yourself and your loved ones from acquiring HIV is by taking HIV drugs or PrEP if appropriate, practicing safer sex and not sharing drug injection equipment.

Additional Resources

Select the links below for additional material related to HIV vaccines.

- 10 Reasons Why Women Need an HIV Vaccine - and Are Fighting To Create One (Buzz…
- Vaccines for Prevention (AVAC)
- HVTN 702 Clinical Trial of an HIV Vaccine Stopped (UNAIDS)
- Experimental HIV Vaccine Regimen Ineffective in Preventing HIV (US National Ins…
- Experimental Mosaico HIV Vaccine Safe but Ineffective; Phase 3 Study Stopped …
- Progress Toward an HIV Vaccine (U.S. National Institute of Allergy and Infectio…
- Progress Toward an HIV Vaccine (U.S. National Institute of Allergy and Infectio…
- The Search for an HIV Prevention Vaccine (aidsmap)
- HIV Vaccine Development (U.S. National Institute of Allergy and Infectious Dise…
- Inside the Fight to Include HIV-Positive People in Covid-19 Vaccine Trials (NBC…
- The Lightning-Fast Quest for COVID Vaccines — and What it Means for Other Disea…
- I Am Jealous of COVID-19 (TheBody)
- I'm Living with HIV and Have Had the COVID Vaccine (aidsmap)
- How'd We Get a COVID-19 Vaccine so Fast but None for HIV and Cancer? (POZ)
- International AIDS Vaccine Initiative (IAVI)
- U.S. HIV Vaccine Trials Network (HVTN)
- Global HIV Vaccine Enterprise
- NIH Launches Clinical Trial of Three mRNA HIV Vaccines (US National Institutes …
- HIV Vaccines (HIV.gov)
- What Is a Preventive HIV Vaccine? (HIVinfo)

- What Is a Therapeutic HIV Vaccine? (HIVinfo)