# WHAT CAN I DO TO HELP?

1. Learn the facts about HIV vaccine research at www.bethegeneration.nih.gov.
2. Let others know you are supportive of HIV vaccine research.
3. Talk to friends and family about the need for an HIV vaccine and the importance of trial participation by people of all races and ethnicities, sexes, and socioeconomic backgrounds.
4. Encourage vaccine participants and/or become one yourself.
5. Join a community advisory board, or CAB. A CAB is made up of people from a community where HIV vaccine trials are taking place. CAB members give input about study decisions and local context. They also educate and prepare the community for vaccine clinical trials. A CAB helps ensure that a trial meets the needs of a community.

For more information, email **bethegeneration@nih.gov** or go to: **www.bethegeneration.nih.gov**

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# BE THE GENERATION

## TO FIND A VACCINE TO PREVENT HIV

The HIV/AIDS crisis is not over.

**More than 33 MILLION people WORLDWIDE are living with HIV.[1]**

**More than 20 MILLION LIVES have been lost due to HIV/AIDS-related illness.[1]**

[1] *Source: http://data.unaids.org/pub/GlobalReport/2008/JC1511_GR08_ExecutiveSummary_en.pdf*

The need for an HIV vaccine remains urgent. Once infected, most people will eventually need to stay on treatment for the rest of their lives. But treatment just slows disease—there is no cure. We cannot stop the HIV/AIDS epidemic with care and treatment alone.

Prevention is essential.

Learn more at **bethegeneration.nih.gov**.

## Why do we need a preventive HIV vaccine?

- There is NO cure for AIDS.
- A preventive HIV vaccine could help save millions of lives and billions of dollars each year in treatment costs.
- Safe, effective, and affordable vaccines that can prevent HIV are the best hope for controlling and/or ending the AIDS epidemic.

**WHAT IS A VACCINE?**

**A vaccine helps your body learn how to fight off a virus, such as HIV. A preventive HIV vaccine would protect HIV-negative people from being infected with or getting sick from HIV.**

## What is the difference between a preventive HIV vaccine and a cure for AIDS?

A preventive HIV vaccine would prevent infection in a person who does not already have HIV. A cure for AIDS would remove the virus from the body of a person who is already infected.

The long-term goal is to develop a vaccine that protects everyone from getting infected with HIV. But even a vaccine that protects only some people would still be very helpful. Such a vaccine could decrease the number of people who are infected with HIV, which would reduce the number of people who can pass the virus on to others.

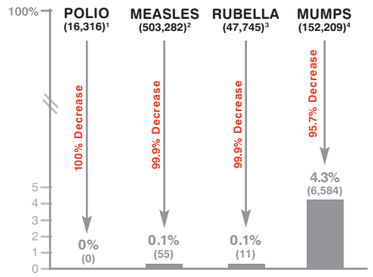
Right now, people infected with HIV can take antiretroviral therapy to help control the virus and prevent it from progressing into full-blown AIDS. This therapy—a combination of drugs—helps people stay well for a longer time, but it is not a cure. Treatments are complex and costly, and they can sometimes cause serious side effects. They also require people to take pills every day for the rest of their lives.

## Could vaccines help people who are already infected with HIV?

Researchers are also looking to see whether HIV vaccines could help people who are already infected with HIV. If effective, such a vaccine would teach the body to control HIV infection, so the progression from silent HIV infection to full-blown AIDS would happen much more slowly—or even be stopped. Vaccines used in this way would be called “therapeutic” vaccines. We don’t know if a vaccine that prevents HIV infection would also be therapeutic for HIV-infected individuals. It is possible that different types of vaccines might be needed for both HIV prevention and HIV therapy. Researchers are working to develop and test both kinds of vaccines.

**VACCINES DRAMATICALLY REDUCE DISEASES** Vaccines have played an important part in the elimination of diseases like diphtheria, smallpox, and paralytic polio. They have also helped to dramatically reduce several other diseases.

For example, vaccines helped reduce the number of cases of mumps from 152,209 in 1968 to 6,584 in 2006—that's a 95.7 percent decrease.




*Source: MMWR 2007;56(33):851-64*
1. Average number of reported cases per year 1951-1954
2. Average number of reported cases per year 1958-1962
3. Average number of reported cases per year 1966-1968
4. Number of reported cases in 1968

## What is happening in preventive HIV vaccine research?

- There is still no preventive HIV vaccine.
- Many agencies are working together to develop and test preventive HIV vaccines. These include U.S. government agencies such as the National Institutes of Health (NIH), foreign governments, universities, foundations, nonprofit organizations, and biotech and drug companies.
- It takes many participants to do HIV vaccine research. Already more than 28,000 volunteers have participated in research supported by the National Institute of Allergy and Infectious Diseases (NIAID), a part of the NIH.
- In 2009, a vaccine tested in Thailand was able to cut down HIV infections by about one third. This gives us hope that we can one day find a vaccine that works well for everyone.
- Each new research discovery helps guide future efforts in vaccine design and testing.

## Why is it taking so long to create an HIV vaccine?

More than 25 years to develop an HIV vaccine might seem like a long time, but most vaccines we use today took at least 30 years to develop.

HIV is a tricky virus:

- HIV can "hide" from the antibodies that protect the body.
- There are many different types of HIV, and the virus changes rapidly, even in a single infected person.
- Vaccines don't always work in humans the same way they work in animals. Human efficacy trials are needed, and they are costly and take a lot of time.

## What's in HIV vaccines?

- The preventive HIV vaccines tested in people do not use weakened or dead versions of HIV.
- Instead, HIV vaccines contain genes or proteins that look like those found in the real virus. They do not have all the parts of the HIV virus needed to cause infection. The vaccines cannot give people HIV.

## What are the risks of participating in an HIV vaccine study?

- All clinical trials have some risks, but there is no risk of getting HIV from preventive vaccines tested in people.
- Like many vaccines, the HIV vaccines used in clinical trials may cause side effects such as soreness from the shot, a mild fever, and/or body aches. These side effects tend to go away quickly on their own.

### Vic Sorrell

Nashville, TN

"I currently educate people in my community about and recruit for an HIV Vaccine Trails Network sponsored vaccine study called 'Hope Takes Action.' It's my job to ensure that the Nashville gay community is aware of the opportunity to volunteer for HIV vaccine studies at Vanderbilt.

It's also key for our program to keep accurate educational information about HIV vaccine research moving through the local conversation. Maintaining consistent visibility at events and using social media to engage those we hope to reach have proven successful to our mission here in Nashville.

**An HIV vaccine is important in our generation because it appears to be the single most effective tool in development for eradicating the HIV pandemic we have come to know."**

### Kevin Jones

Philadelphia, PA

"I'm a past participant of an HIV vaccine research study.

**I think it's important that we find an HIV vaccine in our generation because we've already lost too many of our brothers and sisters to this epidemic.**

A safe and effective HIV vaccine will add additional tools to our prevention toolkits. Having additional options to prevent the spread of this deadly disease will allow us to live our lives more freely and more responsibly."

- Most HIV tests look for antibodies that the body makes to fight off the virus, rather than testing for the presence of the virus itself. Some HIV vaccines in clinical trials could cause participants to test "positive" on an HIV antibody test even if they're not infected with HIV. This is because the vaccine caused their body to make antibodies against HIV. Other tests can tell whether someone is actually infected with HIV or is just making antibodies in response to a vaccine.

## How do you know if the research is being done right?

- Clinical trial researchers have to follow the same ethical and legal rules that doctors do, and clinical research must follow federal laws that protect study participants.
- All of the possible known risks are fully described as part of the informed consent process. All participants must acknowledge that they understand these risks and then sign a consent form before they can join the clinical trial.
- A clinical trial follows a carefully designed protocol, a study plan that details what researchers will do.
- A group of independent experts regularly reviews the clinical trial to oversee patient safety and make sure the study follows the protocol.
- Side effects are reported to the study investigator, who takes appropriate medical action, if needed. Side effects are also reported to study reviewers who monitor the study closely for participant safety.
- Participants can leave the study at any time.

## How do we know a vaccine works?

Once a test vaccine (called a vaccine candidate) has passed safety tests in laboratory and animal studies, it is tested in studies with human participants. Healthy, HIV-negative participants sign up and are picked at random to get either the vaccine or a placebo. A placebo, in this case, is a substance that looks just like the vaccine but does not have vaccine in it. Participants do not know whether they are getting a placebo or the vaccine. Studies are done first with small numbers of participants at low risk for HIV infection to confirm a vaccine's safety and test human immune responses to it. An immune response shows that the body has detected the vaccine and has begun reacting to it.

If the vaccine passes the first rounds of testing, it may be tested among a larger number of participants at risk of HIV infection to see if the vaccine works. All participants in these trials get counseling and services to prevent HIV infection. Even so, some participants still become infected through unprotected sex or injection drug use. When the trial ends, researchers compare the HIV infection rate of those who got the test vaccine with the infection rate of those who got a placebo to see if there are fewer infections among the group who got the vaccine.

### Carmen Zorrilla

San Juan, Puerto Rico

"I'm Carmen Zorrilla and I'm an Obstetrician Gynecologist who has been working with women living with HIV for the past 25 years and with HIV vaccine studies for the past 8 years. I explain to the individuals I see in my practice the importance of an HIV vaccine and how we study vaccine candidates to find the one that would work and protect people.

After it is tested in low risk people, a vaccine needs to be tested in volunteers at higher risk of infection to see if it works. These vaccines are usually tested in communities with a high rate of HIV. Despite receiving counseling during the trial and their own risk reduction efforts, some volunteers may still become infected. Therefore, these studies follow participants over time to see if the vaccine provides any level of protection."