



AIDS Vaccines

For more basic fact sheets in this series on emerging HIV prevention strategies visit www.avac.org/intro.

What is an AIDS vaccine?

An AIDS vaccine is an experimental strategy that aims to teach the body's immune system how to fight HIV to reduce the risk of infection or to reduce viral load in those who get the vaccine and go on to become infected. All of the candidates being studied are experimental; there are no effective AIDS vaccines available today. *None of the vaccines being tested can cause HIV.*

Why are we looking at AIDS vaccines?

Vaccines are one of the world's most effective public health tools. Effective vaccines against polio, measles, mumps, rubella and other diseases have significantly reduced rates of these illnesses in many parts of the world. Today, many scientists, clinical trial teams and communities are working together on the search for an AIDS vaccine.

AIDS vaccine scientists are developing candidates that aim to block HIV infection in HIV-negative people, as well as candidates that aim to reduce viral load in people who receive the vaccine while HIV-negative and go on to become infected. Viral load is linked to disease progression, so a vaccine that reduced viral load could result in improved health and delayed time to initiation of antiretroviral treatment. Scientists are also developing therapeutic vaccines which would build immune strength in HIV-positive people. This fact sheet concentrates on prophylactic vaccines in development for HIV-negative people.

What are the most recent developments in the AIDS vaccine field?

Proof of concept that a vaccine can prevent infection

In 2009, scientists announced the results from RV144, the Thai prime-boost AIDS vaccine trial. The large-scale safety and efficacy study enrolled over 16,000 Thai men and women and showed that the regimen reduced the risk of HIV infection by 31 percent overall. The greatest protection was seen in the first year after the vaccine regimen (six injections) had been administered. This was the first data showing that an AIDS vaccine can block HIV infection in humans.

Clues to the protection observed in RV144

After the initial results from RV144 were announced, an international team of scientist launched a collaborative effort to understand why the vaccine might have reduced risk of HIV infection. Samples from the volunteers were analyzed for clues to which immune responses were linked to vaccine-related effects. Two "correlates of risk" were identified: one correlate, binding antibodies to specific proteins on HIV's outer coat, was associated with decreased risk of infection. Another correlate, an antibody known as IgA, was linked to less protection from the vaccine. Both of these findings are guiding future research.

Building on RV144

Follow-on research to RV144 is planned to begin in Thailand in 2012. Trial participants who remained HIV-negative will be offered the opportunity to enroll in smaller Phase II studies that will look at the safety and effect of late-boost vaccine regimens, meaning that participants will receive additional vaccinations (three different single-vaccine or combination regimens) and scientists will evaluate safety and immune responses. There are also plans to launch additional efficacy trials in Thailand and Southern Africa. These trials would seek to confirm and improve on the efficacy observed in RV-144. They are being organized by a consortium known as the "P-5" or Pox-Protein Public Private Partnership.

Progress on neutralizing antibodies

Most licensed vaccines induce antibodies that neutralize the pathogen in question: hepatitis B vaccine, for example, teaches the body to manufacture potent neutralizing antibodies against the outer coat, or envelope, of

the hepatitis B virus. When a vaccinated individual is exposed to hepatitis B, these antibodies neutralize the invading virus and prevent infection. The RV144 regimen described above did not induce neutralizing antibodies. However, there is a lot of activity in this arena as it relates to AIDS vaccine development. Scientists have identified several broadly neutralizing antibodies that occur naturally in a very small number of people with HIV. They are working on creating vaccines that would teach the body to make these antibodies. This scientific exploration could take many years—it could also lead to a highly effective vaccine.

What is happening now?

There is one large-scale vaccine efficacy trial ongoing—HVTN 505. This trial of a DNA-Ad5 vaccine regimen is being tested in over 2,000 gay men, other men who have sex with men (MSM) and transgender women in the US. Launched in 2009, the trial changed its protocol in 2011, adding HIV acquisition as a co-primary endpoint. The trial is also looking to see if the vaccine strategy reduces viral load in participants who were HIV-negative when they received the vaccine, and later acquired HIV during sex or other risk-related behavior. The trial will thus determine whether the strategy reduces the risk of HIV infection, in addition to asking its original question: does the regimen reduce viral load in people who receive the vaccine and later become infected?

What is in the pipeline for AIDS vaccines of the future?

There are a range of candidates in early stages of development, and a wide range of basic scientific work (work not focused on product development) ongoing in the AIDS vaccine field. For a description of current and emerging research, see www.avac.org/vaccines.

Where are AIDS vaccine trials taking place?

There are over 30 clinical trials of experimental vaccines currently underway in nearly 25 countries, enrolling thousands of participants. Visit www.avac.org/trials/vaccines for a table of ongoing and planned AIDS vaccine trials. And for a view to where AIDS vaccine and other biomedical HIV prevention research is ongoing, visit www.avac.org/globalmap.

Who is participating in AIDS vaccine research?

Like other HIV prevention strategies, AIDS vaccine trials are conducted among different populations, among them gay men and other men who have sex with men, injecting drug users, sex workers and heterosexual men and women in sub-Saharan Africa.

When are results expected?

Data from HVTN 505 is expected in 2013 as are data from the Phase II “late-boost” studies in RV144 participants. The trials being coordinated by the P5 launch are planned to launch in 2014.

Priorities for 2012

AVAC's *Playbook 2012* sets out top strategic goals and priorities in HIV prevention for ourselves—and for the world. Here's what we have to say about AIDS vaccines. For more, visit www.avac.org/playbook.

Global Goals	AVAC Priorities
<ul style="list-style-type: none"> ▪ Maintain funding to build on recent breakthroughs. ▪ Connect the vaccine agenda to combination prevention. ▪ Identify and close funding gaps for RV144 follow-on trials. 	<ul style="list-style-type: none"> ▪ Make the case for sustained funding, including resources to engage community in discussing future trials. ▪ Ensure the AIDS vaccine field develops a comprehensive advocacy agenda that appropriately positions vaccines into the long-term strategy. ▪ Ensure civil society is engaged in preparing for P5 trials in South Africa and Thailand and passive immunization trials.

For more resources on HIV prevention research and for information on AVAC programs, visit www.avac.org.