Fact Sheet: AIDS Vaccines
August 2008

What is a vaccine?
A vaccine teaches the immune system how to protect itself against a disease-causing agent like a virus or bacteria. Vaccines are one of the world's most effective public health tools. Effective vaccines against polio, measles, mumps, rubella and other diseases have helped to slash rates of these illnesses in many parts of the world. The introduction of the smallpox vaccine led to the elimination of this disease worldwide. Today many scientists, clinical trial teams and communities are working together on the search for an AIDS vaccine that could prevent HIV infection or, perhaps, reduce the severity of HIV infection in people who receive the vaccine and go on to be infected with HIV. The vaccines themselves cannot cause HIV.

Is there an AIDS vaccine?
No. Today there are no effective AIDS vaccines.

What is the state of AIDS vaccine research?
At present, mid-2008, there are over 30 clinical trials of experimental AIDS vaccines underway in 25 countries around the world. The majority of these trials are small Phase I and II safety and immunogenicity studies. There is one large-scale (Phase III) efficacy trial ongoing in Thailand. This prime-boost trial is testing a combination of two vaccines, ALVAC and AIDSVAX. None of the wide variety of vaccine strategies being tested can cause HIV. Each uses small, synthetic fragments of HIV that cannot lead to infection.

What are some of the recent developments?
The field is currently seeking to learn from the disappointing results of a study called STEP that halted immunizations in 2007 after a planned interim review of the data showed that the candidate in that trial had no efficacy. A companion study of the same candidate in South Africa also stopped immunizations. For more information visit: http://avac.org/step.htm.

How long will it take to find an AIDS vaccine that works?
We don't know. History tells us that it has taken many trials and many years to develop effective vaccines against other infectious agents. HIV is a retrovirus that attacks the immune system—the very same defenses that a vaccine raises to help protect against disease. This makes it different from the other diseases for which vaccines have already been found. However, there is scientific evidence to show that an AIDS vaccine is indeed possible—and the scale of the AIDS epidemic demands that the search for an effective vaccine continue.

What could an AIDS vaccine do?
Many scientists predict that the first effective AIDS vaccines that are developed will provide limited forms of protection, or what is commonly called partial protection. This prediction comes after nearly twenty years of AIDS vaccine research. For example: An AIDS vaccine might be developed that does not block infection, but does lower the amount of HIV virus in the blood, thereby slowing disease progression in people who get the vaccine and go on to become infected. An AIDS vaccine might also be developed that works for some people but not for others. This could be due to genetics, or route of exposure to HIV (anal versus vaginal sex, injection drug use, or breastfeeding).

How are AIDS vaccines tested?
AIDS vaccines are not tested by exposing people to HIV. Vaccines go through a series of evaluations, first in laboratories then in animals before they move into humans. The animal studies help provide safety information on the candidate and no candidate moves into humans if there are any signs of side effects or problems caused by the vaccine. When there are strong safety data from animals, the candidate moves into small safety studies in humans. Small safety studies are followed by expanded safety studies which gather more information. Only after these initial studies are vaccine candidates considered for large-scale "efficacy" trials that continue to evaluate safety and also test

whether the vaccine protects against HIV infection or reduces viral load for those who later become infected. All of these trials enroll healthy, HIV-negative people.

Right now there are no animal or laboratory models that can allow us to know with certainty whether a vaccine will provide any kind of protection against HIV. The only way to get this information is by studying the vaccine in large-scale human efficacy trials. Before an efficacy trial begins, researchers typically spend two or more years studying communities where a trial may take place. They gather a great deal of information, including how many people get HIV each year, commonly referred to as incidence rate.

Once this information has been collected, people from the community are asked to enroll in the trial. Those who enroll are randomly assigned to receive either the vaccine or a placebo (an inactive substance). Neither the researchers nor the trial volunteers know who has received the vaccine and who has received the placebo.

The trial volunteers are followed for a long period of time—usually two to three years or more. Despite intensive risk-reduction counseling, and the provision of condoms to trial participants, there will be some volunteers who become infected with HIV during the study due to their own personal risk behavior or environment. To determine whether the vaccine was effective, at the end of the trial, researchers look to see whether the incidence rate is lower in the group of people who were given the vaccine compared to the group of people who were given the placebo. For example, if there were a 2% incidence rate in people who received the vaccine and a 5% incidence rate in people who received the placebo, that might mean that the vaccine was protecting some people against HIV.

Do vaccine trials do anything to help reduce the volunteer's risk of becoming infected with HIV?
Yes. All trials provide a package of prevention services to volunteers who enroll in the study. This package varies depending on the population that is being enrolled, but includes male condoms, treatment for sexually-transmitted infections, regular HIV testing and counseling and risk-reduction counseling. Trials in injection drug users provide additional counseling on safe injection practices and drug-replacement therapy, although it is still a challenge to ensure that all volunteers with injection drug use as a risk factor have access to needle exchange programs due to the legal and political realities of many countries where injection drug users are at high risk of HIV.

Vaccine trials also provide a lot of information to people who are thinking about volunteering and to people who decide to enroll in the trial. One of the key messages is that there is no way of knowing whether the vaccine is effective, so it is important that everyone who decides to take part in the trial continues to protect themselves using existing methods like condoms or clean needles.

I have HIV—why do AIDS vaccines matter to me?
Most candidates being developed are preventive vaccines that would be used by HIV-negative people. However, a few trials are testing therapeutic vaccines in HIV-positive people to find out whether the vaccine can strengthen their immune defenses against the virus.

Why do AIDS vaccines matter to women?
Over 25 years into the epidemic, women still don't have access to a range of HIV prevention methods that are private and woman-initiated. The female condom is one such option but it still requires some discussion with partners and access to it is unfortunately low worldwide. There is an urgent need for additional methods that could be used by a woman, with or without negotiation with her sexual partners. An effective AIDS vaccine would be an option that a woman could seek out, possibly without her partner's consent, in order to reduce her risk of acquiring HIV.

For more information about HIV/AIDS vaccines, please visit: AIDS Vaccine Advocacy Coalition at www.avac.org; International AIDS Vaccine Initiative at www.iavi.org; HIV Vaccine Trials Network www.hvtn.org; and the Caucus for Evidence-Based Prevention at www.hivprevention.org.