Questions & Answers

How is an AIDS vaccine tested?

Both vaccines and pharmaceutical products are tested in stages, each taking a number of years. Initial laboratory work – to establish a scientific concept or platform for research – is followed by animal studies to establish overall safety. During human trials, the candidate vaccine is tested in volunteers to continue to evaluate safety and establish effectiveness.

There are three stages, or phases, of human clinical trials. For an AIDS vaccine specifically, Phase I involves a relatively small number of healthy HIV-negative adult volunteers at low risk of HIV infection. Phase I tests for safety. Phase II involves about 200 to 500 healthy HIV-negative adult volunteers, some of whom are at higher risk of HIV infection. Phase II tests for safety, an immune system response, as well as early information on required dose and route of administration of the vaccine. Phase III trials involve several thousand adult volunteers at high risk of HIV infection to assess the efficacy of the vaccine in preventing HIV infection and AIDS.

What is a clinical trial?

A clinical trial is a study done in humans to find out if a new vaccine or drug will be safe and effective.

Why are scientists testing AIDS vaccines in so many countries?

The search for an AIDS vaccine must be a global effort. Vaccine research must occur in both the developed and developing world, through partnerships between scientists and in-country organizations. Today, there are more than 30 clinical trials running in 24 countries across five continents. The trials are testing different vaccine candidates. As we cannot predict which of these will prove to be effective, it is important that we test different candidates in parallel, as far too much time would be lost if they were tested sequentially. Also, the best way to know if a vaccine will be both safe and effective in a particular population is to test the vaccine in this population. That is why some vaccine candidates are tested in multiple geographical regions across the world.

Are scientists unfairly using people in developing countries to test AIDS vaccines?

Most vaccines are tested in industrialized and developing countries at the same time, and no matter where they are conducted, follow strict international guidelines to ensure ethical conduct. Support and participation of communities vulnerable to HIV infection is fundamental to the success of AIDS vaccine trials and studies, and helps prepare these communities for future access to a vaccine. It is of paramount importance that communities hardest-hit by the pandemic participate in research for a vaccine that is effective in these communities. AIDS vaccine research and trials also increases awareness of HIV prevention and encourages HIV testing. Finally, US and European scientists recognize the value of local

experts in developing countries where trials are being conducted, including scientists, policymakers, community groups, etc. They collaborate with these groups in order to conduct trials in true partnership.

Can AIDS vaccines cause HIV infection when they are tested in people?

No. The vaccines contain either a protein (a small piece) of the outer shell of HIV, or they contain copies of single HIV genes. Scientists know that these small pieces cannot cause HIV infection. AIDS vaccine candidates currently in human trials cannot cause HIV infection or transmission because they do not contain the entire virus in any form.

How are the rights of volunteers in an AIDS vaccine trial protected?

There are established international guidelines for ethical treatment of all volunteers in pharmaceutical and vaccine trials. These guidelines are reinforced by an independent review system on a national and trial-site basis. All potential volunteers must be counselled on informed consent – a written agreement to participate in a trial based on the volunteer's complete understanding of all relevant information. Volunteers in an AIDS vaccine trial receive extensive risk-reduction counselling throughout the trial and access to other prevention methods, such as condoms. A volunteer can decide to leave the study at any time without explanation.

Why is it taking so long to develop an AIDS vaccine?

AIDS vaccines are particularly hard to develop for many reasons. The science involved in designing the vaccines is very complex. First and foremost, researchers must make sure that the vaccine cannot cause HIV infection. This means that they cannot use some of the scientific strategies used to develop vaccines for other diseases.

Once scientists develop a possible vaccine candidate, the process of testing it in animals and humans takes 10 years at the very least. Many vaccines will need to be tested before one or more are proven to be effective. Since the beginning of AIDS vaccine research, close to 100 different possible vaccines have been tested in people.

Despite the challenges, leading experts agree that development of an AIDS vaccine is possible.

How long will it take to develop an AIDS vaccine?

The frank answer is that we do not know. Scientific breakthroughs are unpredictable. If the most promising vaccines we are testing today turn out to work well – and we'll know this in the next few years – then we could move ahead rapidly with final testing and manufacturing. If they are not effective, then we will have to do more 'upstream' research to design other vaccines that work better, and that will take longer. That is why it is important that scientific efforts today focus not only on testing AIDS vaccine candidates in clinical trials but also on developing novel vaccine concepts.