Human trials of HIV vaccine to begin

By Perla Astudillo
19 August 1998

At the recent 12th World AIDS conference in Geneva, researchers announced that the US Food and Drug Administration had granted approval for the first Phase 3 or human trials of a vaccine against Human Immunodeficiency Virus (HIV). The vaccine, known as AIDSVAX, is to be tested on 5,000 male and female volunteers in at least 40 sites across the US. The trials will also extend to 2,500 volunteers in 16 clinics throughout Thailand.

Despite years of research, scientists have faced great difficulties in developing a safe and effective vaccine against HIV. The virus undergoes rapid mutation and, as a result, a vaccine may provide some protection against only one of the different HIV varieties. The particular characteristics of HIV have compelled researchers to turn to a number of new techniques in developing a vaccine. Unlike other viruses, the body's natural immune response does not destroy HIV, and thus, a vaccine cannot simply rely on stimulating or priming the body's own defences.

Furthermore, researchers have been very cautious about using whole HIV viruses, whether in live, dead or inactivated forms, in preparing a vaccine. The technique, used to combat other viral diseases, poses dangers if the vaccine causes HIV infection. The start of Phase 3 trials for AIDSVAX is, therefore, a significant step forward. Known as a "subunit" or "recombinant" vaccine, its development has involved the use of advanced biotechnology methods to manipulate the genetic structure of the HIV virus.

Many of the recombinant HIV vaccines currently under investigation focus on a number of particular proteins found on the outer surface of the virus. One such protein gp120 (or glycoprotein 120) is particularly significant as it is part of the means by which the virus attaches itself to the body's immune system cells and infects them.

Other vaccine research targeting gp120 has run into difficulties as the protein differs with the particular HIV variety. AIDSVAX, however, has been created by taking gp120 from the surface of two different types of HIV—one an already tested laboratory strain, and a second from one of the currently circulating virus strains. AIDSVAX B/B uses a type found in the US, and AIDSVAX B/E a type found in Thailand. The vaccine is the first to be designed to target specific HIV strains in different parts of the world.

By using two gp120 types, researchers hope the vaccine will stimulate an immune response in a significant number of people involved in the trials. AIDSVAX has been developed by Genentech, a US company that has invested some $20 million on the vaccine and the preparations for human trials. Scientists are doubtful that AIDSVAX will provide a quick breakthrough in the control and prevention of HIV. Researchers state that the vaccine will only help inhibit the spread of the infection and assist in reducing the incidence of full-blown AIDS.

The theme of the World AIDS Conference was "Bridging the Ever Widening Gap"—an attempt to address the huge gap in the treatment available to AIDS sufferers in rich and poor countries. Of the 30.6 million individuals currently infected with HIV worldwide, over two-thirds live in Sub-Saharan Africa where there are few or no resources available for care or prevention.

A revealing discussion broke out on the implications of vaccine testing in so-called Third World countries. Some of the participants asked whether companies like Glaxo and Genentech were prepared to cover the full costs of treatment, including hospital care and anti-AIDS drugs, if volunteers in the trials become infected.

According to a report in the Science journal, "The majority of the participants at the Geneva meeting agreed with the practical argument that people who
become infected during an AIDS vaccine trial should be offered the 'highest attainable' treatment in their locale that can be sustained after the trial ends."

In other words, the level of medical care will vary significantly depending on whether the trial participant lives in Bangkok or New York. As the article pointed out, "neither the company nor the cash-strapped Thai government plans to give cutting-edge treatments to people who become infected."

The impossible barriers facing those at risk of HIV in backward countries was further highlighted at the conclusion of the conference. Five major pharmaceutical companies, including Roche, Bristol-Myers Squibb and Glaxo Wellcome, agreed to start a $4 million pilot program to provide the anti-AIDS drug AZT to 30,000 pregnant women in 11 countries at a 60 to 75 percent discount.

But the cost of anti-AIDS treatment is estimated to be around $20,000 a year for each patient. The paltry $4 million discount given by the drug companies amounts to a year's anti-retroviral treatment for just 50 people. Even at the discounted price, the companies--which rake in hundreds of millions of dollars a year--will make a profit.

Physician Elly Katabira of the Mulago Hospital in Kampala, Uganda commented: "Even if the price [for combination therapy] was only $200 per month, which is peanuts in Western countries, this is more than many Africans earn in their lifetime."

See Also:
HIV/AIDS epidemic ravages Africa
[25 June 1998]