

## Richard Darling, DDS

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**From:** National Institute of Allergy and Infectious Diseases [niaid@mail.niaid-nih.info]  
**Sent:** Thursday, November 08, 2007 12:30 PM  
**To:** Richard Darling  
**Subject:** The Release of New Data from the HVTN 502 (STEP) HIV Vaccine Study



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**November 8, 2007**

This is one of the periodic messages you will receive from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. We hope these research findings may be of interest to your organization and its constituents.

The statement below, “**The Release of New Data from the HVTN 502 (STEP) HIV Vaccine Study,**” discusses the disappointing results of the clinical trials, and NIAID’s continuing commitment to developing an effective HIV vaccine.

Please feel free to share this release with your organization and its constituents. Here is the URL:  
[http://www3.niaid.nih.gov/about/directors/news/step\\_11707.htm](http://www3.niaid.nih.gov/about/directors/news/step_11707.htm).

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### **Statement of Anthony S. Fauci, M.D., Director National Institute of Allergy and Infectious Diseases On the Release of New Data from the HVTN 502 (STEP) HIV Vaccine Study**

The new analyses revealed today from the STEP HIV vaccine clinical trial are both disappointing and puzzling. At this time, the data offer no clear explanations as to why the vaccine showed no measurable efficacy or why among individuals with background immunity to the adenovirus vector, there were more HIV infections in the vaccinees as compared to those in the placebo group. Analyses of the STEP data are continuing, and it will take some time before we fully understand these results.

NIAID and its study partners, Merck & Co., Inc., and the HIV Vaccine Trials Network (HVTN), fully recognize the importance of these results to the volunteers who participated in the study and the larger scientific community. We are committed to working together to better understand the data from this study, and disclosing new findings as they become available.

Certainly, the failure of this HIV vaccine product was unexpected. But this setback should not and can not diminish our commitment to developing an effective HIV vaccine. Every day, another 12,000 people become infected with HIV, most of whom live in resource-poor countries. Approximately, 40 million people are currently living with HIV infection, and more than 25 million people with AIDS have died. Last year

alone, an estimated 4.3 million new HIV infections occurred worldwide.

Historically, vaccines have been the most effective weapon against infectious diseases, such as polio, measles, mumps and smallpox. The goal of developing a safe and effective HIV vaccine is a key goal of HIV research today. However, the complex and unique nature of HIV has presented a formidable challenge to developing an effective vaccine.

In the absence of an HIV vaccine, there are proven methods for preventing HIV transmission that we, as a global community, must implement on a wider scale. These methods include HIV/AIDS education and behavior modification; condom usage to prevent sexual HIV transmission; medically supervised adult male circumcision in appropriate settings; needle exchange programs to curb bloodborne HIV transmission among injection drug users; and the use of antiretroviral drugs in HIV-infected pregnant women to prevent mother-to-child HIV transmission. Although none of these interventions is completely effective on its own, when used in combination they can have a significant impact on HIV prevention. Less than 20 percent of the world's population currently has access to proven HIV prevention services, but this figure is growing with the efforts of programs such as the President's Emergency Plan for AIDS Relief, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and many others.

In addition to existing HIV prevention tools, we must create new, evidence-based approaches to HIV prevention, such as topical anti-HIV gels or creams that could be applied prior to sexual intercourse; preventive regimens of antiretroviral medications; and, especially, a vaccine. A setback in a given clinical trial is no reason to lessen our commitment to tackling the scientific challenges inherent in this field of research. What we learn from the STEP study will inform ongoing and future HIV vaccine research.

We must regroup and recommit ourselves to developing an HIV vaccine and other new prevention weapons while providing proven HIV prevention tools to those who need them. In the global fight against the HIV/AIDS pandemic, every prevention tool is of paramount importance.

*Dr. Fauci is director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health in Bethesda, Maryland.*

**Media inquiries can be directed to the NIAID News and Public Information Branch at 301-402-1663, [niaidnews@niaid.nih.gov](mailto:niaidnews@niaid.nih.gov).**

NIAID is a component of the National Institutes of Health, an agency of the U.S. Department of Health and Human Services. NIAID supports basic and applied research to prevent, diagnose and treat infectious diseases such as HIV/AIDS and other sexually transmitted infections, influenza, tuberculosis, malaria and illness from potential agents of bioterrorism. NIAID also supports research on transplantation and immune-related illnesses, including autoimmune disorders, asthma and allergies.

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