



Why an AIDS Vaccine?

Background

Since the US Centers for Disease Control reported the first cases of a novel immunodeficiency disease a quarter of a century ago, the need for a vaccine to prevent HIV/AIDS has never been clearer. Out of an estimated 38.6 million people living with HIV worldwide by the end of 2005, 4.1 million were newly infected last year alone, 95% of them in developing countries.¹

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Mark Henley/Panos Pictures

A school boy in Langtau Gou, China. Chinese scientists recently completed the country's first Phase I AIDS vaccine clinical trial

With dramatic increases in funding and technical assistance from the Global Fund to fight AIDS, Tuberculosis, and Malaria, the US President's Emergency Plan for AIDS Relief (PEPFAR), and the WHO's '3 by 5' program, antiretroviral drugs (ARVs) now reach 20% of those who need them in low- and middle-income countries, and coverage continues to expand.² But drug treatment is expensive, difficult to manage on a large scale, and becomes ineffective over time as the ever-evolving virus becomes resistant. Unless new infections are reduced drastically through expansion and strengthening of existing HIV prevention initiatives, underpinned by new tools like AIDS vaccines, the financial burden of AIDS treatment will continue to escalate, pushing adequate supplies of medicines increasingly out of reach for poor nations.

The Challenges of Developing an AIDS Vaccine

The science of designing AIDS vaccines remains complex. The traditional vaccine development approach—utilizing a weakened version of a virus to prompt a protective immune response against the real disease—has not been feasible with HIV. Unlike many other epidemics for which successful vaccines have been developed, there are no known cases of HIV-

infected individuals recovering from the virus and gaining protective immunity. Scientists are thus attempting to develop a vaccine without a definitive roadmap.

The biology of HIV infection presents other obstacles. Like other retroviruses, HIV inserts copies of its genetic material into human cells to create a persistent, yet immunologically invisible, reservoir of infection. Most importantly, HIV is also a moving target: the ability of the virus to evolve and mutate rapidly to escape immune responses and the enormous diversity worldwide of HIV pose monumental challenges to the development of an effective vaccine.

Progress Towards an AIDS Vaccine

Nevertheless, scientists believe that an AIDS vaccine is possible. Virtually all persons' immune systems are able to keep the virus in check for a number of years, some for over two decades. There is also good evidence that some rare individuals have a natural ability to avoid HIV infection despite repeated exposure to the virus. Furthermore, experimental vaccines have successfully protected monkeys from simian immunodeficiency virus (SIV), a virus that causes a disease in monkeys that is much like AIDS.

Thanks to increased political and financial commitment over the past few years—from US\$160 million spent annually in 1993 to \$759 million last year³—new scientific consortia comprising leading HIV researchers are tackling crucial scientific questions in vaccine development.

A wide range of major players are coming together under the umbrella of the Global HIV Vaccine Enterprise to further enhance scientific coordination and information sharing and to identify new strategies and mechanisms to accelerate the global vaccine development effort. The Bill & Melinda Gates Foundation, for example, established the Collaboration for AIDS Vaccine Discovery (CAVD), a network of laboratories focused on designing AIDS vaccines. The US government, through its National Institute of Allergy and Infectious Diseases (NIAID), is focusing consortia work on examining virologic, genetic, and immunologic responses to HIV infection. For its own part, the International AIDS Vaccine Initiative (IAVI)'s Neutralizing Antibody Consortium is analyzing how antibodies work to neutralize different HIV subtypes. Bringing together five leading scientific laboratories, researchers in IAVI's Live Attenuated Consortium (LAC) also are studying successful immunization and antiretroviral strategies against SIV in the non-human primate model.

As of June 2006, there are close to 30 ongoing trials with preventive AIDS vaccine candidates in approximately two dozen countries,⁴ with advanced testing now taking place or planned for several candidates. Much of this cutting-edge research is being conducted in Africa and Asia, where most new HIV infections are occurring. Over the past couple of years for example, clinical teams from several countries—India, China, Rwanda, and Zambia among them—have launched the first AIDS vaccine trials in their respective countries, and in doing so increased global site preparations for future AIDS vaccine efficacy trials. Other Phase I and II studies of preventive AIDS vaccines currently under way also stand to significantly inform the field in coming years.

The Way Forward

IAVI estimates that even a modestly effective AIDS vaccine could slash the number of new infections over a decade by one-third, saving tens of millions of lives.⁵ But in addition to scientific roadblocks, economic and political barriers impede vaccine development progress. In the past 30 years, the scientific community has not been able to develop and license a vaccine against any disease without industry involvement. Yet today, only a handful of pri-

vate companies are engaged in AIDS vaccine research and development (R&D), with less than 10% of vaccine R&D spending coming from the private sector.⁶ New government incentives, including advance market commitments and tax credits, are urgently needed to spur private-sector involvement in new vaccine discovery.

Global spending on AIDS vaccine development, although growing, is still falling short of what is needed. Recent figures on the overall funding gap for AIDS vaccine R&D estimate the deficit to be between \$340 and \$400 million annually.⁷ Expanded R&D capacity in developing countries where AIDS is taking its greatest toll, investments in scientific teams and clinical trial site infrastructure, and stronger ethical and regulatory agencies would also speed research and development and help prepare communities for the distribution of a safe and effective preventive AIDS vaccine.

With 14,000 persons becoming newly infected with HIV each day, accelerating the timetable towards a vaccine is a global health and development priority. A comprehensive approach to HIV/AIDS that includes adequate and sustained attention to the development of new AIDS prevention technologies is the best path to eventually reversing the 25-year-old pandemic.

The International AIDS Vaccine Initiative (IAVI) is a global not-for-profit organization whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. Founded in 1996 and operational in 23 countries, IAVI and its network of collaborators research and develop vaccine candidates. IAVI's financial and in-kind supporters include the Alfred P. Sloan Foundation, the Bill & Melinda Gates Foundation, The New York Community Trust, The Rockefeller Foundation, and The Starr Foundation; the Governments of the Basque Country, Canada, Denmark, European Union, Ireland, The Netherlands, Norway, Sweden, United Kingdom, and the United States; multilateral organizations such as The World Bank; corporate donors including BD (Becton, Dickinson & Co.), Continental Airlines, DHL, Merck & Co. Inc., and Pfizer Inc.; leading AIDS charities such as Broadway Cares/Equity Fights AIDS, Crusaid, Deutsche AIDS-Stiftung, and Until There's A Cure Foundation; other private donors such as the Haas Charitable Trusts; and many generous individuals from around the world. For more information, see www.iavi.org.

¹UNAIDS, 2006 Report on the Global AIDS Epidemic, May 2006, available from http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp.

²WHO, Progress on Global Access to HIV Antiretroviral Therapy - A Report on "3 by 5" and Beyond, March 2006, available from http://www.who.int/hiv/fullreport_en_highres.pdf.

³HIV Vaccines and Microbicides Resource Tracking Working Group, Adding It All Up: Funding for HIV Vaccine and Microbicide Development, 2000-2006 (New York: IAVI, August 2006).

⁴International AIDS Vaccine Initiative, IAVI Database of AIDS Vaccines in Human Trials, February 2006, available from <http://www.iavireport.org/trialsdb/>.

⁵Stover J., Estimating the Global Impact of an AIDS Vaccine (New York: International AIDS Vaccine Initiative, October 2005).

⁶HIV Vaccines and Microbicides Resource Tracking Working Group (2005).

⁷International AIDS Vaccine Initiative, Investing in AIDS Vaccines: Estimated Resources Required to Accelerate R&D (New York: International AIDS Vaccine Initiative, June 2005).

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