HIV Vaccines for Developing Countries: Advancing Research and Access

Advocacy Tool

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Background information for:

- support of the HIV vaccine effort in a human rights framework
- advocacy for national plans and funding commitments
- advocacy for public awareness, support, and involvement
- advocacy for HIV vaccine development
- advocacy for future HIV vaccine access

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Supporting the HIV vaccine effort in a human rights framework

International human rights law defines what governments should:

- prevent (such as torture, arbitrary imprisonment, or malnutrition),
- allow (such as freedom of expression and movement) and
- promote (such as individual autonomy, high standards of health, and advancement of scientific progress for benefit of humankind).

Health is a basic human right, and has been defined as such at least since the 1948 Universal Declaration of Human Rights.

HIV vaccine development can be considered an international human rights obligation. Many States have recognized, through statement and action, an obligation under international treaty and joint declaration to pursue and share technological advancements, including vaccines and treatments, against major diseases such as HIV.

For more information *on HIV vaccines and health in a human rights context, go to:*

Resolving Legal, Ethical and Human Rights Challenges in HIV Vaccine Research. Canadian HIV/AIDS Legal Network, 2000. www.aidslaw.ca

Health and Human Rights. FXB Center for Health and Human Rights, Working Paper #10, 2000. www.hsph.harvard.edu/fxbcenter/working_papers.htm

HIV vaccines are needed. The AIDS crisis is still beginning. HIV is the fastest spreading lethal infectious disease in the world today, and is, by itself, a major global health catastrophe. At an estimated current rate of 14,000 new HIV infections per day around the world, the HIV epidemic has already claimed the lives of approximately 20 million people and has infected an additional 40 million. HIV/AIDS is now the leading cause of death in sub-Saharan Africa and is the fourth biggest killer worldwide. The human and economic cost of the existing AIDS epidemic is already enormous. The cost of the coming epidemic will be greater, especially if the world takes insufficient action.

Vaccines work. Vaccines have helped to dramatically reduce or control many diseases, including diphtheria, plague, rabies, tetanus, typhoid fever, whooping cough, and yellow fever. Smallpox has been eradicated as a public health threat through vaccination campaigns. During the coming decade, vaccination campaigns might soon eliminate the scourge of polio. Newer vaccines, such as those developed against Hepatitis B and *Haemophilus influenzae* type B (Hib disease), are beginning to have a global impact on those diseases.

HIV vaccines are possible. Experimental HIV vaccines have protected monkeys against HIV infection. Experimental HIV vaccines generate immune responses in people. Much more research is needed. But the scientific case for moving forward is clear.

For more information *on the need and potential of HIV vaccines and other vaccines, go to:*

World Health Organization (WHO). www.who.int/vaccines

Global Alliance for Vaccines and Immunizations (GAVI). www.vaccinealliance.org

Advocating for national plans and funding commitments

A successful effort to develop and ensure access to HIV vaccines will require commitment, accountability, and coordination for another ten years or more.

International accountability and coordination can happen if all organizations clearly define their plans, including intended and assigned responsibilities, resources, and implementation timeframes.

National plans and commitments are a first step for accountability, and coordination. Brazil, Nigeria, Thailand, Uganda, and a few other countries have successfully developed national HIV vaccine plans. However, of the dozens of countries involved in HIV vaccine development, most have **not** yet produced public plans and commitments.

For more information *on model plans and commitments for HIV vaccine development, go to:*

National HIV Vaccine Plan. Brazil Ministry of Health, June 2000. www.aids.gov.br

Workshops Toward a Nigerian National HIV Vaccine Plan. WHO-UNAIDS HIV Vaccine Initiative. www.who.int/HIV-vaccines/HVI_Pages/Recent_Events

Accelerating the development of an AIDS vaccine for the world: an opportunity for G-8 leadership. International AIDS Vaccine Initiative (IAVI), July 2001. www.iavi.org

Current global investment in HIV vaccine development is far less than 1% of all global health research and development, and is probably less than 10% of all AIDS research and development worldwide.

The major sources of investment in HIV vaccine development are the national government research agencies of the United States, France, the United Kingdom, and other high-income countries. Other significant sources of investment include five private-sector pharmaceutical companies, and the Bill and Melinda Gates Foundation.

Major increases in investment are possible and are needed. National governments in particular can:

- increase national research agency funding for academic and private-sector efforts,
- increase funding for international development agencies to support multilateral HIV vaccine efforts such as those of the African AIDS Vaccine Programme (AAVP), European Union, World Bank, and the WHO-UNAIDS HIV Vaccine Initiative,
- increase funding for public-private partnerships such as IAVI,
- increase funding for direct bilateral aid to low-income and middle-income country governments to support HIV vaccine research and delivery infrastructure.

For more information *on funding for HIV vaccine development, go to:*

Scientific Blueprint for Accelerating Global Efforts in AIDS Vaccine Development. International AIDS Vaccine Initiative (IAVI), June 2000. www.iavi.org

December 2001 Report. Commission on Macroeconomics and Health. www.who.int/cmhreport

Accelerating an AIDS vaccine for developing countries: Recommendations for the World Bank. World Bank AIDS Vaccine Task Force, 2000. www.iaen.org

Advocating for public awareness, support, and involvement

Public support for HIV vaccine development is based on public understanding about, and support for public health, HIV prevention, vaccination programs, biomedical research, and human rights.

Opinion leaders such as political leaders, journalists, community advocates, research trial participants, researchers, government officials, and company representatives can play an important role in supporting accurate public understanding of current HIV vaccine issues.

Basic HIV vaccine information can and should be integrated into standard AIDS and public health messages.

For more information *about basic educational materials related to HIV vaccines, go to:*

Developing Vaccines to Prevent HIV and AIDS: An Introduction for Community Groups. International Council of AIDS Service Organizations (ICASO), June 2000. www.icaso.org

HIV Vaccine Handbook. AIDS Vaccine Advocacy Coalition (AVAC), April 1999. www.avac.org

Networks and coalitions can be useful at a local, national, and international level to provide information about HIV vaccine development, clinical trial plans, clinical trial design, and experimental HIV vaccine products.

Informing the media about HIV vaccine development, and developing sound communications strategies to regularly inform a broad audience about HIV vaccine efforts, can also enhance public awareness and support.

Bylaws and guidelines governing membership and participation in clinical trial planning committees, vaccine development partnerships, and ethical and regulatory review committees, are also important in allowing new people to become involved in the HIV vaccine effort in a meaningful way.

For more information *on HIV vaccine coalitions, communications, and participation, go to:*

African AIDS Vaccine Programme (AAVP). www.who.int/HIV-vaccines

AIDS Vaccine Advocacy Coalition (AVAC). www.avac.org

HIV Vaccine Trials Network (HVTN). www.hvtn.org

International AIDS Vaccine Initiative (IAVI). www.iavi.org

South African AIDS Vaccine Initiative (SAAVI). www.sahealthinfo.org/hivaids

Advocating for HIV vaccine development

HIV vaccine development involves designing vaccine products and manufacturing processes so that experimental HIV vaccines can be tested in clinical trials and then, if found to be safe and effective, licensed and manufactured for global use.

Expertise and resources from all sectors is needed for this effort, including the private, for-profit sector. Private-sector pharmaceutical companies have unique capabilities related to vaccine manufacture, licensure, delivery, marketing, and field effectiveness research. However, these companies face a range of economic disincentives and opportunity costs, including uncertain costs of HIV vaccine research, development, and production. Only five pharmaceutical companies and a dozen smaller biotechnology companies are now involved in HIV vaccine development.

Government funding for private-sector efforts is one way to bring industry expertise into HIV vaccine development. For example, the US National Institutes of Health (NIH) now has contracts with Chiron, Wyeth, and at least twelve other companies to develop and produce HIV vaccines. In another example, eight governments now provide funding to the International AIDS Vaccine Initiative (IAVI), which has contracts with at least six industry partners. Both the US NIH and IAVI include pricing and intellectual property provisions in their contracts to support future HIV vaccine access.

Research tax credits can also support private-sector HIV vaccine development. Tax credit legislation has been proposed in the United States and other countries to support research and development efforts on vaccines against HIV, malaria, and tuberculosis.

Public-private partnerships are an additional strategy for HIV vaccine development. IAVI is using one model of public-private partnerships to advance candidate HIV vaccines into clinical trials. Other notable examples exist at the French Agence Nationale de Recherche contre le SIDA (ANRS), the South African AIDS Vaccine Initiative (SAAVI), the US Military HIV Research Program, and the US NIH.

Direct government funding of research and delivery infrastructure is also essential for HIV vaccine development. Vaccines such as *Haemophilus influenza* type B (Hib) vaccine were invented and developed largely through government efforts. HIV vaccine research at hundreds of academic research centers around the world, such as Mahidol University in Thailand, the Uganda Virus Research Institute, the University of Cape Town, and University of Nairobi, depends on support from national and international government support. Clinical trial sites and networks, such as the HIV Vaccine Trials Network (HVTN) or the European AIDS Clinical Trials Platform (EACTP) rely entirely on government funds.

For more information *on strategies to support HIV vaccine development, go to:*

About the African AIDS Vaccine Programme. World Health Organization (WHO). 2002. www.who.int/HIV-vaccines

Five Years and Counting. AIDS Vaccine Advocacy Coalition (AVAC), May 2002. www.avac.org

International AIDS Vaccine Initiative (IAVI). www.iavi.org

The policy of HIV vaccines: exploring legislative options. University of California at San Francisco, April 2001 Policy Monograph. http://hivinsite.ucsf.edu

US National Institutes of Health (NIH). www.niaid.nih.gov/vaccine

Advocating for future HIV vaccine access

Future global access to HIV vaccines is fundamental to the goal of HIV vaccine development. Current advocacy for access to treatments, vaccines, and other health interventions can lay the foundation for future access to HIV vaccines.

Intellectual property rights for HIV vaccine manufacture and delivery will be an important component of future global access. Clarification of existing patents on HIV vaccines and associated technologies and processes could help to ensure combined low-cost licensing of these patents for global vaccine manufacture and access. International property rights law and international trade law can be used to facilitate access to new HIV vaccine technologies while preserving the incentive of ownership for profit. These issues fit well with current advocacy for global access to AIDS treatments and other health technologies.

Improved regulatory capacity is needed in most countries to review and approve new Phase I vaccine safety studies, and to review and license new HIV vaccines if and when any are determined to be effective. Regulatory capacity can be increased by supporting new training and technical expertise in national regulatory agencies, defining review processes and procedures, and increasing resources dedicated to review of vaccines.

Measures to increase vaccine sales revenues and reduce liability costs can also accelerate access. These measures include sales tax credits, liability compensation systems, and differential pricing for vaccines. Liability compensation systems for standard pediatric vaccines already exist in several countries and have ensured low-cost manufacture and access to those vaccines. Differential pricing also exists for pediatric vaccines, with prices in low-income countries as low as 5% of prices in high-income countries, but still high enough to cover costs of vaccine production.

Global demand for HIV vaccines is an important part of future access. Clarity is needed now about who will pay for HIV vaccines, either in bulk purchase through the Global Alliance for Vaccines and Immunizations (GAVI) or through national vaccination programs, or at a smaller retail level. The decision and commitment to pay for HIV vaccines will depend on politics as well as science, and will depend on the views of public health officials in national vaccine advisory committees, health professionals, and the general public in many countries.

Infrastructure for vaccine delivery will be necessary to ensure that HIV vaccines will be delivered appropriately to those who need it in the context of public health promotion and care. Development of this public health infrastructure is the common concern and goal of many health and human rights advocates.

For more information on issues related to future access to HIV vaccines, go to:

AIDS vaccines for the world: preparing now to assure access. Report for the Durban International AIDS Conference, IAVI, July 2000. www.iavi.org

A new access paradigm: public sector actions to assure swift, global access to AIDS vaccines. IAVI, June 2001. www.iavi.org

Immunization Focus. Global Alliance for Vaccines and Immunizations (GAVI) quarterly newsletter. www.vaccinealliance.org

Web sites

AIDS Vaccine Advocacy Coalition
Contains useful resources, including the HIV Vaccine Handbook and an annual advocacy report.
www.avac.org

Canadian HIV/AIDS Legal Network
Contains several publications related to HIV vaccine policy.
www.aidslaw.ca

Global Alliance for Vaccines and Immunizations
Contains updated information and articles about access and use of vaccines around the world.
www.vaccinealliance.org

HIV InSite
Contains useful references on HIV vaccines, including a 2001 monograph on access.
http://hivinsite.ucsf.edu

Immunization Action Coalition
An US-based advocacy site with materials supporting vaccination programs
www.immunize.org

International AIDS Economics Network
Information on the economic aspects of vaccine development
www.iaen.org

International AIDS Vaccine Initiative
A major resource on HIV vaccine development
www.iavi.org

International Council of AIDS Service Organizations
Contains a community primer on HIV vaccines
www.icaso.org

National AIDS Manual
A central source of HIV/AIDS information on the internet.
www.nam.org.uk

United States National Institutes of Health
Contains a wealth of background information about the science of HIV vaccine development
www.niaid.nih.gov/vaccine

UNAIDS
Contains documents including 2000 ethics guidelines and the 2000 Nairobi Declaration
www.unaids.org

World Health Organization
Contains useful information about vaccine development and deployment
www.who.int/vaccines

World Medical Association
Contains the revised version of the Declaration of Helsinki
www.wma.net