

# AIDS Vaccines and the Developing World



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## What are the main concerns?

- An AIDS vaccine for the developing world is many years away, yet research for a vaccine may reduce research into and funding of other HIV prevention activities at a time when such efforts must be increased.
- The vaccine initiative does not address underlying issues such as poverty and gender imbalance that drive HIV-infection, AIDS and other preventable diseases.
- Respect for human rights is key to the development and distribution of HIV vaccines, yet vaccine research on human subjects in developing countries raises considerable ethical and human rights concerns.

## What are the key issues?

**An AIDS vaccine for the developing world is many years away.** It is well known that vaccines have been used successfully to fight serious infectious diseases such as small pox and poliomyelitis. These public health victories have raised hopes for an inexpensive and effective vaccine against HIV-infection or AIDS. Yet many scientific, ethical, legal and economic obstacles remain - for example, research to establish the efficacy of a vaccine could last 15-20 years, or longer. HIV sub-types found in Africa (which has over 70% of the global population of people living with HIV/AIDS) can differ from those in Europe and North America. Even when a vaccine suitable for developing countries is found, the inoculation of communities most vulnerable to HIV-infection and AIDS will take many years more.

**Prevention efforts must continue today.** HIV-prevention strategies that are already known to be effective today, such as safer sex education and the reduction of drug-related harm, must be continued and expanded. We must also continue to fight discrimination and social inequality. Research into

new technologies, particularly those which can be controlled by women (such as microbicides and the female condom) must not be side-tracked by the promise of an AIDS vaccine.

**Research in developing countries must benefit developing countries.** Some ethicists say that it is unethical to conduct vaccine research on people living in poverty unless there is also a credible plan and financial resources to make the successful products of such research (i.e. the vaccines) available to those people. They say we should presume the valid consent of people living in poverty *cannot* be obtained without such a plan (Annas & Grodin, 1998). In this view, vaccine research which does not include a plan and resources for the distribution of the benefits of the research should not be permitted. This is because the prior informed consent of the trial participants is recognised as a basic ethical requirement of medical research.

Others have suggested that informed consent *can* be obtained without a plan and resources to make the benefits available to the communities in which the trials take place. In this view, vaccine trials may benefit trial participants both directly (by providing personal protection against HIV infection) and indirectly (by reducing the incidence of HIV in the community at some future time). The benefits of research should be made reasonably available to counter any charge of exploitation. However the availability of a vaccine to poor communities which participated in the research may be justifiably limited by factors such as price, difficulties of manufacture and distribution, and the infrastructure required for delivery (Harris, 1998).

## Human Rights and Ethical Concerns about Vaccine Research in Developing Countries

- Vaccine research on impoverished populations may conflict with current ethical guidelines, such as the requirement for individual informed consent without undue inducement.

- Market driven vaccine research may focus on HIV sub-types prevalent in wealthier countries, leaving aside those developing countries which cannot afford expensive remedies.
- Vaccine trial participants may take more risks because they think they are protected, even though they may be part of the placebo group, or the test vaccine may be ineffective.
- For participants who become infected with HIV during a trial, the test vaccine may reduce symptoms but still leave the person infectious, leading to the increased spread of HIV in the longer term.
- Inoculation with an early test vaccine may render the trial participant unable to benefit from more effective vaccines developed later on.
- Participants may face societal discrimination if they test HIV-antibody positive as a result of the vaccine, or even as a result of participating in the trial.
- There is a tension between an ethical requirement for HIV prevention and education of the trial participants and the need to maintain some degree of risk behaviour to ensure meaningful results.
- There is disagreement about the standard of medical care that should be offered to trial participants who become infected with HIV during the trial. Some ethicists argue that the standard of care for all participants world-wide should be the best proven treatment (to date, ARVs - combination anti-retroviral drugs). In this view, any compromise of this standard, even to reflect local conditions where ARVs cannot practically be provided, will result in an unacceptable weakening of the protection for the subjects of medical research developed over the last 50 years. Others maintain that the best local treatment standards are all that is ethically required, and that international research guidelines should be revised to reflect this. A related difficulty is that treatment with ARVs makes it difficult to ascertain whether the test vaccine reduces progression to AIDS.
- Plans are not yet in place to ensure that a suitable vaccine, once developed, can be purchased, distributed and administered widely in the developing world.

## Conclusion

**Respect for human rights is key to the development and distribution of HIV vaccines.** There is no conflict between respect for human rights and the speedy development of an effective vaccine:

It is possible to underplay the human rights concerns that accompany HIV vaccine research and argue that, with over 15,000 new infections each day in the world, social issues must not be allowed to slow research and testing. But this perspective gets it backwards. Until participants and communities can be assured fair treatment and the fruits of research in which they are participating, there is little reason to expect that they can be willingly recruited and retained for trials. HIV vaccine research may require a series of large-scale human trials over years or decades. In order to launch ethical trials that sustain the support and interest of the affected communities, ongoing attention to human rights will be critical (Collins, 1998).

Vaccine research in developing countries must be based upon partnerships between developed and developing countries, so that developing countries have a strong voice in deliberating issues such as the availability of a successful vaccine, and the many other ethical issues.

## Further information:

*Ethical Issues in HIV Vaccine Trials* (1997) Kerns T., St Martin's Press, New York / Macmillan Press, London. A clear presentation of the scientific and ethical obstacles to HIV vaccine development.

*The Search for an AIDS Vaccine: Ethical Issues in the Development and Testing of a Preventive HIV Vaccine* (1995) Grady G., Indiana University Press, Bloomington. Provides an historical overview from a U.S. perspective, and explores community consultation and decision-making around difficult ethical issues.

*Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement, Health Economics and Drugs*, DAP Series No. 7 (1999) World Health Organization, 2nd edition. An overview of the limitations on pharmaceutical patents provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Under TRIPS, national law may provide for the granting of a compulsory licence

for essential new pharmaceutical products, such as a vaccine against AIDS. Contact: Documentation Centre, Essential Drugs and Other Medicines, World Health Organization, 1211 Geneva 27, Switzerland. Email: darec@who.ch

HIV Vaccines and Human Rights' Collins C., in *HIV Vaccine Handbook: Community Perspectives on Participating in Research, Advocacy and Progress* Snow B., ed, (1999) AIDS Vaccine Advocacy Coalition (see web reference below).

'Human Rights and Maternal-Fetal HIV Transmission Prevention Trials in Africa' Annas G. & Grodin M. in Mann J. et al, eds, *Health and Human Rights* (1999) Routledge Press. The authors present the ethical arguments for ensuring that the subjects of research in developing countries will benefit from that research.

'Preparing for HIV vaccine trials in developing countries' Heyward W., Osmanov S. & Esparza J. in Mann J. & Tarantola D, eds. (1996) *AIDS in the World II* New York, Oxford University Press. A concise discussion on the rationale and approaches for the conduct of scientifically and ethically appropriate HIV vaccine trials in developing countries.

'Guidance document on ethical considerations in international trials of HIV preventive vaccines' (UNAIDS, to be finalised late 1999)\*

'Ethical issues in clinical trial collaborations with developing countries - with special referent to preventive HIV vaccine trials with secondary endpoints', (1998) Lie R., UNAIDS working paper.\*

'Ethical implications of Phase III Clinical Trials of HIV Vaccines. Justice issues: burdens, benefits and availability', (1998) Harris J., UNAIDS working paper.\*

(\*These documents will be available on the UNAIDS web site in late 1999.)

## Key Organisations and Web sites

- AIDS Clinical Trials Information Service  
<http://www.actis.org/actis.asp?URL=vaccine&VIEW=general>  
Contains the AIDSTrials database  
<http://www.actis.org/actis.asp?URL=aidstrial&VIEW=technical>
- AIDS Vaccine Advocacy Coalition  
<http://www.avac.org/>
- Consumer Project on Technology:Health Care and Intellectual Property  
<http://www.cptech.org/ip/health/>
- Insite - Gateway to AIDS  
Information: Vaccines  
<http://hivinsite.ucsf.edu/topics/vaccines/>  
Contains a useful Glossary  
<http://hivinsite.ucsf.edu/topics/vaccines/2098.2488.html>
- International AIDS Vaccine Initiative  
<http://www.iavi.org>  
National Institute of Allergy and Infectious Diseases (NIAID)  
<http://www.niaid.nih.gov/daids/vaccine/default.htm>
- UNAIDS  
<http://www.unaids.org/>  
Contains a list of Key Materials on vaccines  
<http://www.unaids.org/highband/bpc/keymaterials/vaccine/index.html>

## Selected documents on the Web

- Vaccine Vexations : The have-nots are getting less than they bargained for (1999)  
[http://www.thebody.com/poz/columns/1\\_99/gilden.html](http://www.thebody.com/poz/columns/1_99/gilden.html)  
Dave Gilden discusses two of the ethical dilemmas noted above and the limitations of a vaccine for developing nations.

- HIV Vaccines and Human Rights (1998)

<http://www.avac.org/readings/handbook/>

Chris Collins argues that respect for human rights is key to the development and distribution of HIV Vaccines.

- Dying for a Vaccine (1998)

[http://www.thebody.com/poz/7\\_98/vaccine.html](http://www.thebody.com/poz/7_98/vaccine.html)

Patricia Kahn provides an overview of scientific, political and financial challenges identified by US and international researchers.

- Nine Years and Counting: Will we have an HIV Vaccine by 2007 (1998)

<http://www.thebody.com/avac/9years/9years.html>

The AIDS Vaccine Advocacy Coalition provides a comprehensive agenda for action.

- Paralysis in AIDS Vaccine Development Violates Ethical Principles and Human Rights (1998)

<http://hivinsite.ucsf.edu/topics/vaccines/2098.3940.html>

Jonathan Mann argued the failure to proceed to field trials is unethical and violates human rights. The failure to act, like silence, has moral consequences.

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