Community action kit

HIV vaccines and human rights

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This is one a series of 12 info sheets on human rights issues related to HIV vaccines.

Canadian HIV/AIDS Legal Network | Réseau juridique canadien VIH/sida

HIV/AIDS vaccines: The basics

In modern history, vaccines have achieved dramatic results in fighting diseases. Vaccines today are estimated to prevent up to three million deaths per year. Smallpox used to kill millions of people annually but has been effectively eradicated, and polio is near eradication, as a result of vaccines. Vaccines against diseases such as rabies, tetanus, measles, mumps, rubella, whooping cough, diphtheria and hepatitis B save millions of lives. Mass vaccination of populations is one of the most cost-effective means of preventing disease. An effective vaccine would be of great benefit in the global fight against HIV/AIDS.

Why a community action kit?

This kit is a plain-language guide to human rights issues related to HIV vaccines. It is intended especially to assist communities in which HIV vaccine trials may be planned or are taking place. It is mostly introductory material for people who have little or no previous experience in HIV/AIDS and vaccines issues or in human rights analysis, but we hope it will also be useful for policy-makers, health service providers and researchers. It is a guide to action and advocacy, particularly for members of community advisory boards and others who represent community interests in vaccine trials and vaccine dissemination.

This tool proposes and explains a human rights framework for advocacy and analysis. It places a strong emphasis on the importance of community engagement in decisions about HIV vaccines and vaccine trials as an essential element of a human rights-based approach. We hope it will stimulate discussion more broadly about human rights and the potential benefits and risks of HIV vaccine research, and thereby help to generate a broader base of understanding and support for human rights-based approaches to vaccine research.

How to use this kit

The kit comprises 12 information sheets that can be used together or separately. The info sheets introduce a variety of concepts essential to an understanding of HIV vaccines and human rights in what we hope is understandable language. They can be used to develop educational and training materials, media articles, posters and flyers. Each info sheet includes a list of key sources of further information on the topic, including websites. The last sheet has a glossary of terms and a consolidated list of sources of further information.

Throughout the kit, specific technical terms are often indicated in bold-face text; these terms are defined in the glossary found in info sheet 12.

An introduction to vaccines and vaccine trials

Vaccines enable the body to defend itself against organisms such as viruses that cause disease. Many vaccines are preparations derived from a non-living or non-infectious form of the organism that the vaccine is fighting. They are designed to produce or increase **immunity** to that organism. Most vaccines are meant to keep uninfected people from being infected in the first place (**preventive vaccines**), but some are designed to make the infection or disease less severe for people who already have the disease (**therapeutic vaccines**). These info sheets cover mostly preventive vaccines, the type that most vaccine researchers are seeking for HIV.

Developing a vaccine is a long and highly regulated process. **Candidate vaccines** are preparations developed in laboratories and usually tested on animals before they reach the stage of being ready to test in people. A vaccine generally cannot be licensed for use until it has gone through

three stages of testing on human beings:

Phase I: This is the first test for safety in humans, conducted on a small number of people (20 to 60); side effects and any other drawbacks are monitored. A Phase I trial usually lasts 12 to 18 months.

Phase II: The vaccine is tested on larger group (50 to 500 people) for another assessment of safety and to help researchers understand the immune response generated by the vaccine and thus determine the right dose and frequency of giving the vaccine. Phase II trials usually include a mixture of people, some with higher and some with lower risk of getting the disease. This phase should also give some information on the effect of the vaccine on the immune system. Usually lasts two years or longer.

Phase III: This stage consists of very large trials involving several thousand people at high risk of a disease to determine the vaccine's effectiveness in preventing disease. Usually lasts three years or more.

At all stages of vaccine trials, a subset of volunteers may receive a **placebo**, or a preparation known to have no disease-prevention effect, as a point of comparison. Trials using placebo preparations are usually **double-blinded**, meaning that neither those receiving nor those administering the vaccine know if a given person is receiving a placebo or the candidate vaccine. (Researchers usually use an anonymous coding that reveals which group received the placebo at the data analysis stage.)

State of HIV vaccine research

As of mid-2005, there were over 30 candidate vaccines for HIV being tested in human beings, of which three had reached Phase III trials. Human trials were being conducted in virtually all regions of the world – in 19 countries on six continents, according to the International AIDS Vaccine Initiative. Trials are taking place in five sub-Saharan African countries.

There is not yet any effective vaccine against HIV, the virus that causes AIDS. It will likely take many years to develop a vaccine, in part because HIV itself poses special scientific challenges compared to some other viruses. HIV is a very complicated virus compared to most others for which vaccines have been developed. There are many subtypes of HIV, and it is not yet well known whether a vaccine developed to immunize people against one subtype will work against others. HIV mutates, or changes its genetic form, rapidly, a great challenge to the immune system and to a vaccine. There is also not a completely satisfactory satisfactory animal model for testing HIV vaccines.

Why is a preventive HIV vaccine needed?

There is no cure for AIDS: Antiretroviral (ARV) drugs do not cure HIV/AIDS but rather can suppress its symptoms. ARV treatment is expensive, is associated with serious side-effects, and is still not available to the majority of people living with HIV/AIDS in the world, especially in developing countries. A vaccine could reduce dramatically the number of people needing treatment by preventing new infections.

A wider range of HIV prevention options is needed: People's access to HIV prevention services and information is sometimes blocked by poverty, stigma or other factors. Many women, for example, are not able to ensure that their sexual partners use condoms. In many places, the legal or social status of prisoners and former prisoners, drug users, sex workers and men who have sex with men makes it difficult for them to get the HIV prevention services they need. There has simply been too little public and private investment in adequate prevention services for the whole population in some countries.

An effective vaccine would make a big difference in places where not everyone has access to existing prevention services. Vaccines are part of a comprehensive approach to HIV prevention.

Challenging myths

Unfortunately, some myths have emerged about HIV vaccines in some parts of the world. It is important to fight these with accurate information. For example:

MYTH: *There is already a vaccine for HIV.*

Although some candidate vaccines have been tested, none have proven to be effective. Research to find an HIV vaccine is likely to be a long-term effort.

MYTH: *HIV vaccines can cause a person to get AIDS.*

It is not possible for the current candidate HIV vaccines that are being investigated by researchers to cause a person to become infected with HIV or to develop AIDS develop AIDS. These candidate vaccines do not contain HIV but rather only copies of small non-infective parts of the virus, so they cannot cause HIV transmission.

MYTH: *An HIV vaccine would cure HIV/AIDS*

Because of their likely effect on the immune system, certain HIV vaccines in development might eventually prove to have some

therapeutic benefit to people living with HIV/AIDS that would complement existing treatments. For example, a vaccine might boost the immune system of a person living with HIV/AIDS so that starting ARV therapy could be delayed. But no such vaccine has yet been developed.

MYTH: *Developing countries are being unfairly used to test experimental HIV vaccines.*

HIV vaccines should be tested where they are most needed. Including developing countries in HIV vaccine trials is the only way to ensure that any vaccines offered on the market will be effective among populations in developing countries. People in resource-poor countries have a right to be part of vaccine research and to benefit from it.

Actions for community groups

- Learn more and find ways to share information with all in the community on the importance of HIV vaccines and the benefits and risks of HIV vaccine research (see resources in info sheet 12).
- Challenge myths and misconceptions about HIV vaccines and their roles.

Further information

International AIDS Vaccine Initiative
www.iavi.org

AIDS Vaccine Advocacy Coalition
www.avac.org

WHO-UNAIDS HIV Vaccine Initiative
www.who.int/vaccines

Global Alliance for Vaccines and Immunization
www.gavi.org

The science of HIV/AIDS vaccines: an introduction for community groups. International Council of AIDS Service Organizations, 2003, www.icaso.org/VaccinesSciencePrimer_eVersion_En.pdf

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These info sheets were written by John Godwin and Joanne Csete. UNAIDS, the World Health Organization and the International AIDS Vaccines Initiative (IAVI) provided financial support for their production. We are grateful to the following persons who provided helpful comments: Susan Timberlake and Noerine Kaleeba, UNAIDS; José Esparza, Bill and Melinda Gates Foundation; Jonathan Cohen, Human Rights Watch; and Alex Menezes. Vanita Gowda and colleagues, IAVI.

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HIV/AIDS, vaccines and human rights

The World Health Organization (WHO) and the Joint United Nations Program on HIV/AIDS (UNAIDS) recommend that a human rights-based approach be adopted by those advocating for and developing HIV vaccines. But what does this mean? This info sheet gives basic information about human rights and why they matter when we think about HIV vaccines.

What are human rights?

Human rights are entitlements that all human beings have. Human rights are obligations of governments to individuals – governments are obliged to ensure that people can enjoy their rights. Human rights that are classified as **civil and political rights** include freedom from discrimination and physical abuse, freedom of expression and religion, equality of everyone before the law, and the right to a prompt trial when one is charged with a crime. **Economic, social and cultural rights** include the right to adequate shelter, education and food, the right to the highest attainable standard of health, and the right to enjoy the benefits of scientific progress and its applications.

Human rights are:

- *universal* – they apply to all people everywhere;
- *interrelated* – for example, the right to be free from poverty is linked to the right to be free from discrimination;
- *legally binding* – they are set out in **treaties** that are legal documents. The treaties become legally binding on governments that have signed them and endorsed them by an act of law called ratification, which demonstrates a government's commitment to a treaty's provisions.

Vaccines and the right to health

All people have the right to the "highest attainable standard" of health (Article 12 of the *International Covenant on Economic, Social and Cultural Rights,* and other treaties). The same treaties that guarantee the right to an "adequate" or "reasonable" standard of housing, education and food also state that for health the relevant right is to the "highest attainable standard." This is an indication of how important health is for the enjoyment of other rights. The right to health is not the right to be healthy. Those who developed human rights treaties understood that states cannot provide protection against every possible cause of human ill-health. People may have individual susceptibility to illness and may choose to do some things that undermine their health and that go beyond the responsibility of governments. Rather, the right to health is the right to a variety of health facilities, goods and services that are needed to achieve the highest attainable standard of health.

As with other economic, social and cultural rights, governments are not expected immediately to ensure the fulfilment of the right to health. Rather, they are required to show that they are working toward "progressive realization" of this right within the constraints of the resources available to them. This is a distinction between the right to health and, for example, the

right to be free from torture, where governments must act immediately to end abuses, according to human rights law.

Vaccines have been demonstrated to be highly effective in preventing diseases, and there is good reason to believe that a vaccine against HIV would be a very important part of preventing and fighting HIV/AIDS. Therefore, as part of guaranteeing people's right to the highest attainable standard of health, governments should, according to the resources at their disposal, take steps to ensure the availability of HIV vaccines to all people once they are proven effective. *Governments should also contribute to the development of these vaccines, within their available resources.*

The UN expert committee that monitors and advises countries on their progress in realizing the right to health has commented that health facilities, goods and services should be accessible to everyone without discrimination, be *affordable* to everyone, be available in *sufficient quantities* for everyone and be of consistently *high quality*. These are important criteria to remember with respect to the right to enjoy the benefits of HIV vaccines.

In addition to the right to health, all people have the *human right to enjoy the benefits of scientific progress and its applications* (Article 15 of the *International Covenant on Economic, Social and Cultural Rights*). An effective HIV vaccine would be an important scientific breakthrough for the world, and everyone should be able to share in the resulting benefits.

States have also legally committed to undertake "international assistance and cooperation, especially economic and technical" to fully realize the human rights to health and to benefit from scientific progress (Article 2 of the *International Covenant on Economic, Social and Cultural Rights*). This means that governments in wealthier countries with more scientific and technical expertise have an obligation to assist in addressing health needs in resource-poor countries, including through funding research for, and the provision of, public goods for health such as HIV vaccines.

In 2001, all member states of the UN General Assembly agreed on a *Declaration of Commitment on HIV/AIDS*, which calls on governments to increase investment and accelerate research on the development of HIV vaccines. It underlines the importance of building national research capacity, especially in developing countries and especially for HIV subtypes in countries with high HIV prevalence. These commitments are not legally binding on governments, but all member states have to report periodically on their progress toward meeting these commitments, and communities can use these commitments to help advocate for action by governments.

HIV/AIDS and human rights

HIV/AIDS is a disease that from its beginnings has especially affected people who were already likely to face abuse of their human rights, including prisoners, sex workers, drug users, men who have sex with men, and women and girls. This is one reason why it is important to address HIV/AIDS through measures that are based on respect for human rights. For example:

- People have a *right to full information* about HIV, including information with regard to sex and drugs. When that right is violated, people are more vulnerable to HIV infection.
- When people face *stigma and discrimination* linked to HIV, they may be less able to seek health services and to assert their rights.
- When *women do not have the same rights as men*, including the right to be free from violence in the home or to demand condom use, they face a high risk of HIV.
- Without the *participation of people at risk of, and affected by, HIV/AIDS* (which is their right), including people who are marginalized by society or by the law, programs to prevent HIV and to provide care and treatment are less likely to be effective.
- *Prisoners* are completely dependent on the government to protect them from violence (such as coerced sex that carries a high HIV risk), to provide the services they need to protect themselves from HIV, and to provide them with health care. Failure to fulfil these rights has made HIV a serious problem in prisons in most countries.

Human rights-based approaches are effective in fighting HIV/AIDS

A human rights-based approach to HIV/AIDS aims to ensure that people living with, and at risk of, HIV/AIDS have a voice in decision-making about programs that affect them and that they have the power to protect themselves from HIV and its social impacts. In this way, they are able to gain the full benefits of prevention, testing, treatment, care and support measures, and HIV/AIDS programs are more effective overall.

For example, measures to protect people from discrimination linked to HIV/AIDS and to protect the right to privacy and informed consent for HIV testing, have been important in encouraging people to come forward for testing and treatment. Sex workers, drug users and men who have sex with men may fear abuse from the police or from service providers. Services must be provided for them in a way that is respectful of them as persons and does not contribute to the stigma they already face. Stigma may also keep people from participating in HIV/AIDS research, including vaccine research. If it is clear that a vaccine trial includes human rights protections and involves affected people in decision-making, people will be more likely to participate in the trial.

Guidelines on HIV/AIDS and human rights

The United Nations (UNAIDS and the Office of the High Commissioner for Human Rights) have produced guidelines for governments on protecting, respecting and fulfilling human rights linked to HIV/AIDS. These *International Guidelines on HIV/AIDS and Human Rights* state that a human rights-based approach to addressing HIV/AIDS includes people's right to safe and effective vaccines for HIV (Guideline 6). These guidelines are available in English, French, Arabic, Chinese, Russian and Spanish from the UNAIDS web site, www.unaids.org.

Participation and accountability

People in communities where HIV vaccine trials take place have a right to participate in decision-making about policies and programs that affect them, as well as in monitoring and evaluation of policies and programs. For HIV vaccine trials, the participation of those living with HIV/AIDS and persons vulnerable to HIV/AIDS is especially important. People who use drugs, sex workers, men who have sex with men, and others who are vulnerable may face severe stigma in society and in some cases legal barriers to social and political participation. The stigma they face may be intensified by their participation in vaccine trials. Researchers, government leaders and community leaders have a responsibility to do everything possible to reduce stigma so that these persons can be full participants in vaccine trials.

Much of the rest of the information in these info sheets is advice to individuals and communities where trials take place about how to ensure that their interests are represented in all stages of the approval and conduct of vaccine trials.

Actions for community groups

- Promote human rights education for HIV/AIDS advocates, and assist human rights organizations in learning more about HIV/AIDS.

- Help bring about human rights-based approaches to HIV/AIDS by:
  - helping vulnerable populations to learn about their human rights;
  - educating community leaders as to how protecting and promoting human rights improves the effectiveness of HIV/AIDS responses;
  - advocating for redress when human rights violations and occur;
  - scrutinizing government laws, policies and programs to ensure they are consistent with human rights obligations.
- Call on human rights organizations to help inform people about:
  - the human rights to health and to enjoy the benefits of scientific progress;
  - the legal obligation of governments to respect, protect and fulfil human rights relating to HIV/AIDS; and
  - the legal obligation of governments to ensure that non-state actors such as corporations and research centres do not violate human rights.

Further information

HIV/AIDS and human rights: international guidelines. UNAIDS and Office of the High Commission for Human Rights, 1998.

HIV/AIDS and human rights: international guidelines – revised guideline 6: access to prevention, treatment, care and support. UNAIDS and Office of the High Commissioner for Human Rights, 2002.

Human Rights Watch, HIV/AIDS and Human Rights Program www.hrw.org

Canadian HIV/AIDS Legal Network www.aidslaw.ca

Canadian HIV/AIDS Legal Network. *HIV vaccines for developing countries: advancing research and access – advocacy tool,* 2002, available via www.aidslaw.ca/Maincontent/issues/vaccines.htm#vacc.

UN General Assembly. *Declaration of Commitment on HIV/AIDS*, 2001.

UN Committee on Economic, Social and Cultural Rights. *General comment 14: the right to the highest attainable standard of health*, 2000.

UN Committee on the Rights of the Child. *General comment 3: HIV/AIDS and the rights of the child*, 2003.

UN Committee on the Elimination of Discrimination Against Women. *General recommendation no. 24: women and health*, 1999).

The website of the UN High Commissioner for Human Rights (www.ohchr.org/English/issues/hiv/document.htm) contains all the formal UN documents on HIV/AIDS and human rights, including the *International guidelines, Declaration of Commitment*, and *General comments* from various UN human right bodies.

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Getting started: Approval of HIV vaccine trials

Multiple sponsors of trials

The sponsor of a vaccine trial is the entity that provides the money to carry out the trial. In the past, private corporations have been the sponsors of many vaccine trials. But many private companies do not see research on an HIV vaccine to be profitable. This may be partly because the large majority of customers for an HIV vaccine would be in resource-poor countries where purchasing power may be too weak to pay the prices that companies would charge to recover their investment. Thus, many trials of HIV vaccines are sponsored by other entities, sometimes including a government body, a pharmaceutical company, an international agency, or some combination of these. Communities that are approached for vaccine trials should be told who the sponsors of the trial are as well as who owns the rights to the candidate vaccine, which may be a different person or group from the trial sponsor.

The obligation of government to protect the rights of people involved in vaccine trials is clear. When governments collaborate in research with for-profit corporations or contracted research firms – arrangements sometimes called "public-private partnerships" – governments still have the responsibility to protect their people's rights. This includes protection from infringements of rights by any private entity, even one that is working in collaboration with the government.

Whoever the trial sponsors are, communities that are envisioned to be part of the trials should have, from the very first stages, a way to express their concerns and points of view about the research. It is difficult enough to establish this kind of communication and shared decision-making with governments that should be accountable to their people. With private corporations and outside organizations, it may be even harder. Private corporations may not always make it a high priority to ensure that the communities are well represented in decision-making related to the trial. In all cases, the government has a responsibility to ensure that people in affected communities are consulted at all stages of the process.

Government approval of vaccine trials

Vaccine trials must be approved by governments in the countries where they are to take place, whether the government is one of the sponsors of the trial or not. Governments interested in having vaccine trials take place within their borders need to have the capacity to ensure that:

- the ethics of the proposed trial can be thoroughly reviewed in the country, especially being sure that the rights of the trial participants are protected and that trials are conducted without discrimination or other abuse;
- the scientific merit of the proposal can be adequately assessed by experts in the country;
- the laboratories, clinics and other infrastructure required for the trial are adequate and up to standard, and the health workers involved are adequately trained and equipped;

- the population of the country is adequately informed about what vaccines trials are all about;
- the communities where the trial is proposed to take place can be represented in all decisions regarding the trial;
- there will be adequate regulation and oversight of the marketing, distribution and use of the vaccine once it is finally approved; and
- there is clarification before the trial begins of any issues related to patents on the vaccine or the ownership of scientific data, where lack of clarity might affect the eventual availability and affordability of the vaccine.

For some developing countries, resources and capacities may be inadequate in some of these areas. International donors should make it a priority to assist countries that are keenly interested in hosting vaccine trials to build the capacities needed to do so.

With support from the International AIDS Vaccine Initiative (IAVI), a non-profit organization, the central African country of Rwanda has been building its capacity to conduct vaccine research. Part of this multifaceted task is being sure the HIV vaccines laboratories are well stocked, well staffed, and able to resist power outages.

To ready a laboratory site in Kigali in 2004, IAVI and its collaborators spent US $250,000 over 21 days to make extensive improvements to the building chosen – providing new floors, new air conditioning systems, freezers, generators and back-up generators, a special "safety hood" where technicians could work with potentially infectious materials, a centrifuge, radio-controlled temperature monitors and liquid nitrogen, among other things.

The elaborate preparation of the lab was estimated by IAVI staff to constitute less than one quarter of what needed to be done before the first trial could start. Among the many other tasks were constructing new water tanks to be sure the lab and clinic would have a reliable water supply, developing and translating informed consent forms (see info sheet 5) in French and Kinyarwanda, and organizing training sessions for laboratory and clinic staff – and this for a relatively small-scale trial. Rwanda joins Uganda, Kenya, South Africa and Botswana in sub-Saharan Africa as a site for HIV vaccine research.[1]

Reviewing the ethics of a proposed HIV vaccine trial

From a human rights perspective, ethical review of vaccine proposals is especially important. Medical ethics and human rights embody many of the same principles of protection of individuals who participate in medical research. A government must have the capacity to ensure both ethical and scientific review of trial proposals and of the trials themselves to ensure that the rights of trial participants and those in their communities are protected. UNAIDS recommends building this capacity as a high priority for international donors because without it, vaccine research cannot take place in the country in question. But, according to UNAIDS, the trial sponsor is responsible for ensuring that ethical and scientific review capacity exists in a country before trials take place.

Most countries have general guidelines regarding the ethical standards and review of research. Ethical review bodies (known variously as ethical review boards, human research ethics committees, human subjects committees, or institutional review boards) usually exist in governments, research institutions and universities. The ethical review body should include representatives who are independent of the sponsors of the trial and the research agency, and usually comprises scientists, academic ethics experts and community representatives. Research proposed by a private corporation must undergo ethical review by a body that is designated by the host government and whose members are independent of the corporation.

In addition, there are internationally recognized standards and guidelines that apply to research wherever it is conducted that have been produced by organizations such as the World Health Organization, the World Medical Association, and the Council for International Organizations of Medical Sciences (see below for further information). If community members have doubts about the independence or the qualifications of review bodies in their country or the ethical review conducted by a private company, the standards proposed by these organizations are a good guide.

As described in greater detail below and in other information sheets in this package, an ethical HIV vaccine trial should include these elements: a mechanism for meaningful participation of community members in the places where the trial takes place; an informed consent process that provides complete information about the trial to potential volunteers (see info sheet 5); voluntary HIV testing with pre-test and post-test counseling;

provision of antiretroviral drugs and other medical care for those found to be HIV-positive; measures to ensure that regular health services in the community are not negatively affected by the trial; measures to ensure the participation of women and marginalized persons in the trial and to minimize the stigma that trial volunteers may face (see info sheets 7 and 9); complete information about the trial for the whole population of the community where it takes place; and measures to compensate trial participants for any injury or other adverse effects associated with the trial.

Deciding whether to allow a trial to take place in a country

Ideally, government approval of vaccine trials should be a process that involves not only the ministry of health and the sponsor proposing the trial, but other stakeholders as well, including:

- members of ethical review boards;
- local health authorities;
- representatives of communities where the trials might take place;
- representatives of people living with HIV/AIDS; and
- representatives of people vulnerable to HIV transmission, including organizations of women, sex workers, men who have sex with men, drug users and others if these exist.

National HIV vaccine plans

It can be useful for countries to establish a national plan for HIV vaccine research, particularly if such a plan ensures that people vulnerable to HIV and those affected by the disease will be consulted in the planning of research trials.

Brazil, Thailand and nine African countries have developed national HIV vaccine plans. Some countries have integrated vaccine plans into their national HIV/AIDS strategies. In countries where an HIV vaccine plan does not exist, governments should ensure that a plan is developed through a process in which people with HIV/AIDS and those vulnerable to the disease are represented and have a voice.

National plans should explain in detail how the government intends to ensure the ethical and scientific review, the adequacy of health facilities and personnel, community participation at all stages of the trial, access to the vaccine if it proves effective. The plans should also address the other factors noted above. The Brazilian National Vaccine Plan, for example, requires the sponsor to guarantee that if a vaccine candidate being tested in Brazil proves to be effective, the manufacturer will provide the vaccine to Brazil at a discounted price.

What a vaccine trial proposal should include

UNAIDS has made detailed recommendations on the content of a sponsor's proposal for a vaccine trial. All such proposals should include explanations of the following points:

- why the sponsor wants to conduct the trial in that country or in a certain community;
- potential risks and potential benefits to those in the trials and in communities where trials take place, and how the two balance out;
- how the trial sponsors will ensure that the trial will not crowd out or adversely affect regular health services in the community;
- how the particular needs of persons at high risk of HIV and others with special needs will be addressed;
- what safeguards are proposed to protect trial participants from any harms and to respect their rights.

Actions for community groups

- Get a copy of the national HIV vaccine plan. If one does not exist, consider organizing advocacy for developing a national plan in a process that would include representatives of populations at risk of HIV, especially women, and persons living with HIV/AIDS. If a national HIV vaccine plan exists, review what it says about protecting the rights of trial participants and community roles in decision-making about the trial. If these areas are not well covered, advocate for a better plan.
- If your community is asked by a trial sponsor to participate in an HIV vaccine trial, demand information and documentation on government ethical and scientific review of the trial. Insist that a community advisory board or other representative group be part of all decisions related to the set-up and conduct of the trial.
- Advocate for governments to monitor and appropriately regulate the involvement of the private sector in HIV vaccine development.

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Further information

A new access paradigm: public sector agencies to assure swift, global access to AIDS vaccines. International AIDS Vaccine Initiative, 2001, available via www.iavi.org.

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HIV Vaccine Handbook: Global Perspectives (2nd ed.). AIDS Vaccine Advocacy Coalition, 2005, available via www.avac.org.

Developing vaccines for HIV and AIDS: An introduction for community groups (2nd ed.). International Council of AIDS Service Organizations, 2002 available via www.icaso.org.
Brazilian National HIV Vaccine Plan, www.aids.gov.br/final/diagnostico/documentos.htm

Thailand National Plan for HIV/AIDS Vaccine Development (1999) www.aidsthai.org/download/planvacine_eng.doc

African AIDS Vaccine Program, www.who.int/vaccine_research/diseases/hiv/aavp

Ethical principles for medical research involving human subjects (*Declaration of Helsinki*). World Medical Association, available via www.wma.org.

International ethical guidelines for biomedical research involving human subjects. Council for International Organizations of Medical Sciences (CIOMS), available at www.cioms.ch/frame_guidelines_nov_2002.

Guidelines for good clinical practice (GCP) for trials on pharmaceutical products. World Health Organization, 1995, available at www.who.int/medicines/library/par/ggcp/GCPGuidePharmatrials.pdf.

Guidelines on ethics in HIV vaccine research. Medical Research Council of South Africa, available at www.sahealthinfo.org/ethics/book5.htm.

NOTE

1 Source: AIDS Vaccine Advocacy Coalition, *Getting the Global House in Order: Report 2004*, p. 9, available at www.avac.org.

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Community action kit

HIV vaccines and human rights

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Ensuring community participation in making decision about HIV vaccine trials

A human rights-based approach means that trial sponsors must respect and protect trial participants' human rights, such as the rights to health, non-discrimination and personal liberty and autonomy. Measures should be in place relating to informed consent, confidentiality, prevention of coercion, community participation in making decisions about trials, and protection from social, psychological or physical harms (see info sheets 5 through 9).

A vaccine trial can also affect members of communities who are not in the trial but who live in the community where the trial takes place. Care must be taken to ensure that clinical trials enhance the care and support services available to local populations, rather than divert resources away from local needs.

Community involvement is essential to a human rights-based approach

A human rights-based approach to vaccine development requires measures to be in place that ensure community participation in decision-making about trials in the community. Community involvement is important for several reasons:

- to ensure that enough volunteers are recruited, and that they are recruited and retained in the trial without coercion;
- to protect trial participants from social or psychological harms of the trial, and to ensure they are compensated and assisted if any such harms occur;
- to ensure that affected communities have a voice throughout the long research process, which is essential to maintaining community support for the research; and
- to lay the ground for the future delivery of HIV vaccines in ways that are both ethical and acceptable to diverse populations, and thereby encourage widespread vaccination.

Mechanisms for community involvement

In some cities, towns or villages, the population's level of trust in local officials may be great enough so that people can be confident that the local town council or other authorities can adequately represent the people's interests in dealing with the sponsors of a vaccine trial. In most circumstances, however, local authorities are not likely to include sufficient representation of the people most affected by or at risk of HIV/AIDS to ensure that their interests are put forward. Existing government bodies may have many other priorities and may not be able to devote adequate time to actively participate in all aspects of the vaccine trial.

Communities will likely find it in their interest to establish a special body to represent the interests of trial participants and others in the community who are affected by the research – a **community advisory board** (CAB). The CAB is the liaison between the community and the sponsors of the trial and should be part of decision-making about all aspects of the trial. CABs should ideally include people who legitimately represent the interests of the most affected members of the community, including:

- those participating in the trial;
- people living with HIV/AIDS;
- people from highly HIV-vulnerable populations, such as men who have sex with men, drug users, sex workers, prisoners and former prisoners, women and adolescents;
- local health workers in whom the community has confidence;

- community service organizations;
- cultural and religious organizations; and possibly
- representatives of local news media.

People living with HIV/AIDS and those in vulnerable populations may require support and encouragement to be part of CABs, but their participation is essential. They can provide unique insights into ethical aspects of trials, help assess the behavioural impacts of trials, and help educate the community about the importance of including all people at risk of HIV in the trial.

The work of a CAB requires time and money. Trial sponsors should make resources available to support the work of the CAB and of its members.

Keeping the community informed

A central role of the CAB is to help ensure that the community is informed about HIV/AIDS and the HIV vaccine trial that is planned or occurring in the community. Trial sponsors have a responsibility to ensure that the resources are available to inform the entire community about HIV vaccine trials, and the CAB should remind the sponsors of this responsibility. Governments also have a responsibility to ensure that community members have all the information they need about vaccine trials. Normally, the CAB should take the lead in developing and implementing a plan for community information and awareness-raising, with the support of the sponsors and local authorities.

Education for the community should focus on basic information about HIV/AIDS and HIV vaccines as well as the kinds of risks and benefits the community will face in being part of a vaccine trial (see below). Working with local news media may be useful to ensure accurate coverage of the research and debates about the local impact of conducting vaccine trials. Community organizations can work with the trial sponsor in developing a media strategy to ensure accurate and balanced coverage, to promote recruitment of participants, to ensure that potential or actual trial participants are fully informed about the risks and benefits of a trial and that their rights are respected, and to help to communicate results of the trial.

Assessing risks and benefits of participating in a vaccine trial

A CAB or other community body should provide leadership in helping the community to assess risks and benefits of participating in vaccine trials. Many of the remaining info sheets in this series provide guidance on how the risks of trials for communities can be minimized and the benefits maximized. But we can summarize here some of the early concerns that CABs and communities will have to weigh.

South African AIDS Vaccine Initiative (SAAVI) Community Preparedness Program

SAAVI is an initiative of the South African Medical Research Council (a government body) that is meant to coordinate HIV vaccine trials in the country. It involves some private sector and NGO collaborators. In its work with communities where HIV vaccine trials are planned, the SAAVI Community Preparedness Program disseminates information, raises awareness and promotes human rights through these activities:

- preparing a community education plan that defines the actions required in order to ensure broad community support for, and participation in, vaccine research;
- developing a bill of rights (see info sheet 6) for volunteers in trials through extensive consultation with community stakeholders and research into legal issues;
- conducting negotiations with the insurance industry to ensure that people who participate in HIV vaccine trials do not face discrimination if they seek health, life or travel insurance;
- Providing support to CABs and researchers;
- Conducting information exchange via workshops, forums, lectures and seminars to AIDS organizations, other NGOs and interested stakeholders including unions, media and youth groups;
- Preparing educational materials, including a comic book aimed at training community advisory groups and a manual for people involved in general HIV/AIDS training to integrate vaccines into their programs; and
- Assisting trial sites with development of flyers, brochures and adverts for recruiting potential trial participants.

Among the important potential *risks* to communities associated with HIV vaccine trials are:

- *Increase in risky behaviours:* People in the trial and the community may believe they are protected by the vaccine and may increase their risk-taking through unsafe sex or sharing syringes (see myths in info sheet 1).

- *Increase in stigma faced by vulnerable persons:* Sex workers, men who have sex with men, drug users and others may face increased stigma or legal sanctions through their participation in a vaccine trial (see info sheet 9).

- *People will be inappropriately induced to participate:* In spite of the best efforts at informed consent (see info sheet 5), some people may be led to participate in the trial without understanding all the consequences or with false expectations of benefits.

- *Confidentiality will not be respected* for trial participants or will not correspond to acceptable norms of privacy protection (see info sheet 6).

- *Health services will be unduly diverted to the trial:* Local health services and health workers may be diverted away from normal service to the community in order to support a large trial. The trial sponsors may offer better compensation or better working conditions. This is a concern that should be part of pre-trial negotiations among the CAB, local authorities and the trial sponsors.

On the other hand, there are significant potential *benefits* to trial participation that the CAB might help the community to keep in perspective – for example:

- *Decreased risk behaviour and HIV stigma:* Ideally, the community education associated with a trial and the strengthening of HIV prevention services (see info sheet 6) should reduce behaviour in the community that carries Hiv risks. If well supported, this education should reduce HIV-related stigma.

- *Improved health services:* Ideally, hosting a vaccine trial should result in the strengthening of laboratory and clinical services in the community. Local health workers and HIV counsellors should benefit from training and exposure to new methods and ideas. The community should learn a great deal about continuous advocacy for better and more ethical services. The AIDS Vaccine Advocacy Coalition notes that trial sponsors have a responsibility not to leave health services in a community worse off than before the trial.

- *Early access to a new vaccine:* It is a principle of research ethics and simple justice that those who have helped to generate new knowledge by participating in research should be among the first to benefit from the fruits of that research (see info sheet 10). Before a trial is approved, the government should negotiate with the trial sponsor(s) to ensure that communities where trials take place are guaranteed access to an eventual vaccine.

Actions for community groups

- If an HIV vaccine trial is proposed that would include people in your community, form a CAB (or a similar structure) to represent the interests of the community and of trial participants in decision-making at all stages of the trial and in all interactions with the researchers.

- Support the CAB in including representatives of all groups whose interests are important in the trial, especially those persons who are particularly vulnerable to HIV and to HIV-related stigma and discrimination.

- Support the CAB in designing and implementing a plan for community education and awareness-raising about the trial.

- Support the CAB in assessing risks and benefits of trial participation for the community and in working with local authorities and trial sponsors to ensure respect of the community's decisions.

Further information

HIV Vaccine Trials Network: Community activities
www.hvtn.org/community/index.html

South African AIDS Vaccine Initiative: Community activities
www.saavi.org.za/communitygroup.htm

HIV vaccine handbook: community perspectives on participating in research, advocacy, and progress. AIDS Vaccine Advocacy Coalition, 1999, available at www.avac.org/primer.htm.

The science of HIV/AIDS vaccines: an introduction for community groups. International Council of AIDS Service Organizations, available via www.icaso.org.

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Informed consent and voluntary participation in HIV vaccine trials

Governments have an obligation to ensure that people who participate in vaccine trials enjoy certain human rights protections. For the most part, these protections are well established in human rights law and in internationally recognized guidelines on medical ethics (see info sheet 3). Many of them are also explained and endorsed in the document ***Ethical Considerations in HIV Preventive Vaccine Research (UNAIDS, 2000)***.

The right to informed consent

Everyone who is approached to be part of an HIV vaccine trial or who is thinking about it has the *right to informed consent*. This means that every such person must be informed about what it means to participate in the trial, including the risks involved, must have the chance to reflect on this information, and must give explicit consent before being enrolled in the trial. There must be no coercion or undue inducement involved.

In particular, the information provided in the process of seeking informed consent should include:

- the purpose of the trial (to test efficacy or safety/side effects), the phase of the trial, and the trial history of any vaccine product being tested;
- any possible risks associated with being in the trial, including possible side effects of the vaccine, as well as any possible benefits (such as improved access to health services);
- for women, information about restrictions on becoming pregnant during or after the trial;
- details on the nature of medical treatment to be provided for side effects or injuries that participants may experience, including the process by which it is decided whether treatment will be provided;
- details on what is required of people in the trial: clinic visits, other time commitments, the number of injections, the number of HIV tests required, the overall duration of the trial, details on compensation for travel to clinic sites, etc.;
- the nature of counselling and informed consent that will be part of all HIV tests associated with the trial;
- detailed information on HIV prevention and the fact that trial participants will have access to all available means of prevention (see info sheet 6);
- the possibility that a **false positive HIV test** (see text below and glossary) may result from participation in the trial, and the sponsor's plan for assisting persons who experience this result;
- a detailed plan for a continuous flow of information to participants about the trial – not just at the time of clinic visits or HIV tests;
- for participants in Phase II and III trials, an indication that they may have been chosen because they are at relatively high risk of HIV, and what the criteria for judging risk are; and
- the information that all participants have the right to leave the trial at any time.

Three important elements of the *process* of obtaining and ensuring informed consent are these:

1 • Informed consent must be demonstrated by *signing a document* indicating consent or, for those who cannot sign, an equivalent indication witnessed by someone they trust.

2 • Informed consent should be obtained from an interaction that includes counseling and detailed discussion with the potential trial volunteer, including the opportunity for him or her to ask questions.

3 • The trial should include a mechanism for assessing how well volunteers have understood key information about the research, not only at the time of early interviews but throughout the trial.

It is important to note that HIV testing is involved in HIV vaccine trials. This includes both testing of potential trial participants and testing of trial participants during the course of the trial and at the end of the trial. HIV testing before, during and after the trial should only occur with fully informed consent. Pre-test and post-test counselling should also be part of HIV testing in vaccine trials. Care should be taken to ensure that people understand the medical and social consequences of a positive test result. These may include exposure to discrimination and violence, particularly for women.

The right to informed consent is a central feature of international guidelines on research ethics and is derived from several human rights principles:

- the right to privacy (Article 17, *International Covenant on Civil and Political Rights*);
- the right not to be subjected involuntarily to medical experimentation (Article 7, *International Covenant on Civil and Political Rights*);
- the right to security of person – that is, to be in control of what happens to one's own body (Article 3, *Universal Declaration of Human Rights*); and
- the right to enjoy the highest attainable standard of physical and mental health (Article 12, *International Covenant on Economic, Social and Cultural Rights*).

Ensuring that trial participation is truly voluntary

Informed consent is an important part of ensuring that the participation of every person in the vaccine trial is truly voluntary. In some circumstances, however, it is very hard to eliminate coercive pressures. For example, for people who are so poor that even the chance to receive travel money to go to a clinic is an inducement to participate in a trial, there may be no way to ensure that their participation is truly voluntary. According to UNAIDS, in cases where poverty is so great that almost any benefit of the trial is a potentially coercive inducement, it is probably better to conduct trials elsewhere, even though the community may benefit greatly from the trial.

In some communities, the trial sponsors or the medical establishment may be perceived to be so powerful or high in the social hierarchy that some individuals may be reluctant to refuse the offer to be part of a trial. Where people are so socially marginalized that they would not normally dare to say no to such an offer or they would not feel free to express their concerns before or during a trial, it may be difficult to ensure truly voluntary participation. In this case, the involvement of the community advisory board (CAB), trusted authorities or others who can bridge the power divide may be helpful.

In some places, *individual informed consent* may be a difficult concept. People may be used to making decisions collectively as a family, or younger adults may routinely seek the consent of elders before making decisions. Where individual informed consent is not accepted, the CAB should work with the research sponsors to formulate a process for obtaining consent that reflects the will of the individual but also, as necessary, incorporates other levels of approval. For challenges faced by women in this area, see info sheet 7.

Actions for community groups

- Support the community advisory board (CAB) in its role of helping to develop an informed consent process that is understandable, comprehensive, culturally appropriate and non-threatening even to socially marginalized persons.
- Assist in community education so that all potential trial participants are aware of the requirements of informed consent and are able to assert their right to full information and counselling.

Further information

Guidance document: ethical considerations in HIV preventive vaccine research. UNAIDS, 2000, available via www.unaids.org.

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The right to prevention, care and confidentiality for vaccine trial participants

The right to all means of HIV prevention

Phase III trials are meant to test whether a vaccine is effective in preventing HIV. This is why trial sponsors carrying out Phase III trials try to recruit as trial participants people who are considered at high(er) risk of HIV infection. If people in the trial are practicing other means of HIV prevention, such as condom use, they will be less likely to be exposed to HIV, and the vaccine may not undergo a real test. Nonetheless, even though it may hinder the ultimate goal of the trial to test the vaccine's effectiveness in preventing HIV infection, it is unethical and disrespectful of people's human rights to deny them the possibility to protect themselves from HIV just because they are in a vaccine trial.

Therefore, it is agreed by UN bodies and medical ethicists that those in HIV vaccine trials must be provided access to all HIV prevention tools, services and information – including risk-reduction counselling, condoms, sterile syringes and treatment of sexually transmitted infections. These services should be strengthened as necessary to ensure access for everyone in the trial and in the community. If medically indicated, people in the trial should also have access to **post-exposure prophylaxis** services (see glossary) if they are raped or otherwise exposed involuntarily to HIV.

Confidentiality and privacy

People's participation in HIV vaccine trials may be stigmatizing if being in the trial is associated in the public mind with being at high risk of HIV, or if it is mistakenly thought that being in the trial can cause HIV infection. It is for this reason that UNAIDS has recommended that vaccine trials be conducted only where it is possible to establish and maintain a system of keeping confidential the names of those in the trial and any data about them, which may include sensitive information about a person's drug use or sexual behaviour. Participants have the right to access to all data that relates to them.

Potential social and psychological effects of trial participation

Because getting the vaccine may cause the person's immune system to produce antibodies to HIV and because the HIV tests most commonly used actually reveal the presence of antibodies rather than the virus itself, it is possible that a person in an HIV vaccine trial will test positive for HIV, even if he or she is not actually infected with HIV. A **false positive test** may have negative social and economic consequences. People living with HIV, or perceived to have HIV, continue to experience stigma, abuse and even violence in many parts of the world. Although they should not do so, some employers, life and health insurance companies, and national armed forces still require HIV testing for employment or participation, opening the door to possible discrimination. People with a false positive test may experience emotional trauma or depression.

With respect to HIV testing of volunteers in a vaccine trial,

UNAIDS and IAVI have made some important recommendations:

- During the trial, volunteers in the trial should not have HIV tests outside the trial clinic because other test centres are less likely to be able to distinguish false positives from true HIV infection.
- If an HIV test from a clinic other than the trial's clinic shows a positive result, the volunteer should go to the trial clinic for another test.
- If study participants need an HIV test for insurance or another purpose, they should get it from the clinic of the trial site. Study participants should generally not donate blood or organs during the trial.
- The trial sponsor should ensure that all trial participants have access to counselling, support groups, legal support and other psychosocial services linked to false positive tests.
- Consideration should be given to having an ombudsperson in the community who can help explain a false positive test and provide documentation of the link of the false positive to the vaccine research.

The rights to treatment, care and support for trial participants who acquire HIV

The HIV candidate vaccines currently being tested do not use live virus, nor any part of a virus, and they will not cause HIV infection. However, vaccine trials, especially Phase III trials, are likely to include people exposed to HIV in other ways, such as through sexual activity or through sharing needles when injecting drugs. This means some people participating in the trial may, during its course, be diagnosed as having HIV.

Treatment, care and support should be provided to trial participants who become infected with HIV during the course of a vaccine trial. In addition, in screening the population for an HIV vaccine trial, research sponsors may find people who volunteer for the trial believing themselves to be HIV-negative, but who are actually HIV-positive. These people also have a right to medical care.

There is currently no international agreement on the standard of treatment to be provided in these cases. UNAIDS notes that sponsors must provide some level of medical treatment for HIV vaccine trial participants, with the ideal being the provision of the best proven therapy, including antiretroviral (ARV) therapy, and the minimum being the provision of the highest level of care attainable in the host country. Treatment, care and support services that the sponsor will provide should be agreed to by the sponsor and the community or local government before the trial starts.

Consideration needs to be given to how to ensure access to ARVs many years after the trial concludes. ARVs may not be needed for a person infected during the trial or an HIV-positive person identified in the screening until several years after the infection occurs. However, once ARV therapy begins, it is necessary to continue it for life. New mechanisms may be required to guarantee funding of future access to ARVs, such as establishment of special trust funds or insurance schemes by trial sponsors working with host governments.

The International AIDS Vaccine Initiative (IAVI) recommends that as part of allowing trials to take place in their borders, governments should guarantee that trial participants' communities of origin are a national priority for scaled-up care and ARV therapy and that international donors should recognize and support this priority. IAVI notes that if treatment is available to the whole community, the government can avoid the decision of whether to provide treatment to a trial participant's whole family or extended family. This approach also reduces the likelihood that individuals will feel pressure to be part of vaccine trials just for the possibility of getting treatment.

The right to compensation for other harms

The trial protocol should address participants' right to compensation should they experience injury or illness from their participation in the trial. Usually the trial sponsor arranges free medical care and secures insurance for any injuries suffered as a result of trial participation. This would include adverse physical reactions to the vaccine product, as well as compensation for psychological harms and legal support for discrimination and other abuse directly associated with trial participation.

The use of placebos in vaccine trials

UNAIDS has concluded that as long as there is no existing vaccine that is proven to be able to prevent HIV, it is ethically acceptable to use placebos in HIV vaccine trials. Assigning about half of trial participants to a group that gets a placebo (especially in Phase III trials) means that these persons receive a preparation that is created to have no effect but that looks exactly like the experimental vaccine. This allows researchers to conclude more strongly that any difference between the two groups is due to the vaccine. UNAIDS urges trial sponsors to provide another benefit to persons in the placebo arm, such as vaccination for

hepatitis or tetanus, which should not upset the interpretation of the HIV vaccine results.

Trial participants' "bill of rights"

The HIV Vaccine Trials Network and the South African AIDS Vaccine Initiative have developed a "bill of rights" for HIV vaccine trial participants that may serve as a guide for communities outside South Africa as well.

The HIV Vaccines Trials Network "Bill of Rights and Responsibilities" recognizes the following rights of trial participants:

- the right to have all known information including potential risks and benefits of trial participation, presented in a way which can be understood;
- the right to leave the trial at any time;
- the right of non-discrimination in the trial environment;
- the right to referral to available counselling, support, medical and treatment services if infection occurs during the study;
- the right to assistance in resolving study-related social harms and discrimination;
- the right to treatment and compensation for medical costs for any physical injury directly related to study vaccine or procedures;
- the right to free HIV testing during the study;
- the right to assistance in meeting study commitments;
- the right to confidentiality;
- the right to be informed at the end of the trial, or when medically necessary, of whether a placebo or vaccine was received;
- the right to decide to participate or refuse to participate in any sub-studies that may arise after enrolment in the initial trial;
- the right to be updated about progress of studies and to learn about study results;
- the right to be offered a study identification card that shows that you are in the study.

Actions for community groups

- Consider development of a local bill of rights for participants in HIV vaccine trials through a consultative process with HIV-affected communities and the researchers.
- Work with trial sponsors to ensure that confidentiality procedures are effective and culturally appropriate.
- Seek to establish a community consensus on the standard of care that should be provided to trial participants who acquire HIV during prevention trials, including access to ARV therapy.

Further information

Guidance document: ethical considerations in HIV preventive vaccine research. UNAIDS, 2000, available via www.unaids.org.

The ethics of research related to healthcare in developing countries. Nuffield Council on Bioethics, 2002, available via www.nuffieldbioethics.org/go/ourwork/developingcountries/publication_309.html.

Ethical principles for medical research involving human subjects (*Declaration of Helsinki*). World Medical Association, available via www.wma.org.

International ethical guidelines for biomedical research involving human subjects. Council for International Organizations of Medical Sciences (CIOMS), available at www.cioms.ch/frame_guidelines_nov_2002.

S. Berkley. Thorny issues in the ethics of AIDS vaccine trials. *The Lancet* 2003; 362: 992.

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Human rights concerns for women in HIV vaccine trials

Women are especially affected by HIV/AIDS

It is well known that women are physiologically more vulnerable to HIV transmission in unprotected heterosexual sex than are men. This is due in part to the higher concentration of HIV in semen than in vaginal fluid, the large surface area of the vagina and cervix, and the fragility of membranes in the vagina and cervix. In addition, it is clear that in most parts of the world, women are socially more vulnerable to HIV. They often do not have the power in sexual relations to negotiate condom use. Women are more likely to encounter sexual abuse and violence that can raise their HIV risk. Because they are often economically dependent on men, they sometimes cannot leave marriages or other unions even when they know they are at high risk of HIV transmission. In many countries where the HIV/AIDS epidemic is generalized, HIV prevalence among young women is several times that of young men. In sub-Saharan Africa, nearly 60% of persons living with HIV/AIDS are women and girls.

Since the second-class status of women in many countries particularly limits their ability to ensure condom use or to use other HIV prevention tools, an effective vaccine would be crucially important for women and girls. Women and girls have a human right to enjoy the benefits of HIV vaccine research without discrimination based on sex.

Barriers to participation by women in vaccine trials

It is especially important to be able to detect the efficacy of an HIV vaccine in women. There is some scientific evidence that suggests that the preventive effect of HIV vaccines may differ between men and women. It is urgent for scientists to be able to understand these differences and account for them in any eventual vaccine product. Participation of women in HIV vaccine trials is, then, crucial.

International organizations working on HIV vaccine trials have observed that many trials have been unable to recruit adequate numbers of women.

There are many reasons why participation in vaccine trials may be especially difficult for women, including the following:

- Generally, women enrolled in HIV vaccine trials should not be pregnant and should not become pregnant during the trial. But in many settings, women's social status is based on their fertility, and women may face abuse or rejection if they cannot become pregnant.
- Child care, agricultural work, household duties, and other responsibilities make it difficult for women in many parts of the world to be able to leave the household to attend clinic sessions.
- Women may justifiably have a greater fear of HIV-related stigma than men in some communities. Because of their subordinate status, if women are associated in any way with HIV, they may face abuse, violence or rejection in ways that men do not experience. In addition, some people might presume that a woman participating in an HIV vaccine

trial would only do so if she knew herself to be at high risk, leading perhaps to the stigmatizing perception that women in these trials are promiscuous.

- If a woman participates in an HIV trial, her sexual partner may have the mistaken idea that there is no need for safer sex, and women may then face more pressure than usual to have unprotected sex.

- In some cultures, women may not feel or understand that they have the ability to decide for themselves to be part of something like a vaccine trial. They may feel that they need permission from their husband or another person, and they may be fearful or reluctant to ask for that permission for research related to HIV.

- Because of discriminatory barriers, women may also be on average less educated than men, more likely to have low levels of literacy, and more likely to have been deprived of basic health information in their lives.

All efforts should be made to honour women's right to decide on their own whether they wish to participate and stay in a trial. Similarly, all efforts must be made to ensure that women are given all the information they need, in a format that is accessible, to ensure their informed consent to participate in a trial and, as part of that participation, to get tested for HIV.

Overcoming barriers and ensuring gender equity in vaccine trials

The community advisory board (CAB) for the trial should include persons from women's organizations or others who legitimately represent the interests of women in the community. In some cases it may be useful to form a gender advisory board or committee to work with the CAB. The trial sponsors should work with the community and government officials to provide information and raise awareness of the importance of inclusion of women in vaccine trials and to help reduce HIV-related stigma faced by women. Education of men and community leaders can reduce resistance to women's participation and can address stigma. Setting clinic hours to suit women's needs and providing childcare are practical steps that can support women's participation in vaccine trials. Other actions are suggested below.

Trial sponsors must inform women and others in the community of any risks for women that are associated with the trial, as well as risks to the foetus if a woman does become pregnant and to children who are breastfed. If it is determined that the trial may pose risks to a breastfed child, women should be given the option of receiving support to discontinue breastfeeding, including breast-milk substitutes and clean water.

Actions for community groups

- Ensure that women are well represented on the CAB and in all dialogue and decision-making with the trial sponsors. CABs should work closely with women's groups in the community.

- Advocate with the trial sponsors to be sure that the trial staff includes adequate numbers of women and that counsellors on the staff are trained to address women's concerns.

- Work with the trial sponsors and government officials to inform all community members of the importance of including women in vaccine trials and the unacceptability of HIV-related stigma for women or men.

- Ensure that the sponsors provide the resources to enable legal and social support to be provided for women in vaccine trials who face abuse or rejection in their families or communities because of their participation in trials.

Further information

IAVI brief: women, aids and vaccines. International AIDS Vaccine Initiative, 2005, available at www.iavi.org.

Gender in AIDS vaccine trials. International AIDS Vaccine Initiative, 2004) also available at www.iavi.org.

Guidance document: ethical considerations in HIV preventive vaccine research. UNAIDS, 2000, available via www.unaids.org.

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HIV vaccines and human rights

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This is one a series of 12 info sheets on human rights issues related to HIV vaccines.

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Human rights concerns for children and adolescents in HIV vaccine trials

In human rights terms, a child is defined as any person under the age of 18 years. That is the definition used in the UN ***Convention on the Rights of the Child*** (CRC), which is the most widely ratified human rights treaty in the world (only the USA and Somalia have not ratified it). But 18 years is an arbitrary figure, and it is clear that in many parts of the world, people under the age of 18 are at high risk of HIV transmission because they are sexually active, because they are subject to sexual coercion, because they inject drugs, or for other reasons.

Children enjoy the same right to the highest attainable standard of health facilities, goods and services as do adults (*CRC*, Article 24). Because HIV risk does not respect any age cut-off, it is crucial for control of the HIV/AIDS epidemic that persons under the age of 18 also be able to benefit from the disease protection that would result from an effective HIV vaccine.

Ethical concerns in participation of children and adolescents in vaccine trials

Informed consent is an idea that presumes a capacity to understand risks and benefits of a vaccine trial and the autonomy to make a judgment about whether to participate. In most medical research, it is assumed that children and adolescents do not have this capacity or autonomy, and therefore that they cannot be said to have given informed consent. It is for this and other reasons that UNAIDS and many international organizations recommend that *HIV vaccines should first be tested on adults who can give informed consent.*

If a vaccine is determined to be safe and effective in adults, it important that it be tested in a population of persons under age 18. The AIDS Vaccine Advocacy Coalition (AVAC) recommends the following guidelines to make this happen:

- Adolescents and other children old enough to understand something of the purpose of an HIV vaccine should themselves agree to take part in the trial before they can be enrolled.
- At least one parent or guardian of any child or adolescent should also consent after being given full information about the trial (see info sheet 5).
- The community where the trial is taking place should be informed about the importance of including children and adolescents and, through its community advisory board (CAB) or other such mechanism, should also give its consent before children are enrolled.
- Large numbers of children and adolescents should be recruited only after the successful completion of Phase II trials among adults, which provide some preliminary confirmation of the safety and effectiveness of the vaccine.

UNAIDS notes that in some communities, persons under the age of 18 who are married, who are already parents or are pregnant, or who live independently on their own may be considered to have the maturity to give informed consent in spite of their age. If the government authorizes these persons to have adult responsibilities, they may be allowed to decide on their own, without parental consent, whether to participate in a vaccine trial.

Adolescents have the same right to privacy and confidentiality as do adults. Adolescents in an HIV

vaccine trial will be asked about their sexual histories. Some parents may not wish to give consent for their children's participation without being promised access to such information. AVAC suggests that where this is a problem, it may be worth considering limiting the inclusion of adolescents to Phase III trials where in general participants are considered to be at risk and it may not be necessary to recruit based on whether a young person is sexually active. As an alternative, young people who have previously been diagnosed with a sexually transmitted disease or girls who have already been pregnant can be recruited without questioning them as to whether they are sexually active.

Actions for community groups

- Ensure that children's and adolescents' interests are represented on the CAB, preferably by having adolescents as members of the board.
- Advocate with the trial sponsors to ensure that the trial staff are sensitive to the confidentiality rights and other protections required for children and adolescent participants.
- Work with the trial sponsors and government officials to inform all community members of the importance of including children and adolescents in the trial, and of the equal right of children to confidentiality and other protections.

Further Information

Guidance document: ethical considerations in HIV preventive vaccine research. UNAIDS 2000, available via www.unaids.org.

AIDS vaccine trials: getting the global house in order – report 2004. AIDS Vaccine Advocacy Coalition, esp. pp. 33-41, available via www.avac.org.

"Vaccine readiness", a learning module for young people on HIV vaccines. UCSF Centre for HIV Information, available at www.whatudo.org/whatudo?page=learn-vaccine.

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Human rights and involvement of vulnerable populations in HIV vaccine trials

HIV/AIDS is a challenging disease partly because those who are disproportionately affected include people who are already socially or economically marginalized. But to ensure that a vaccine can benefit all persons at risk of HIV infection, it is especially important that all persons at risk have the chance to participate in vaccine trials if they choose to do so. Sponsors of trials, government officials and communities must be aware that some persons may need extra attention and support to ensure that they have the opportunity to be part of a trial and that their rights are protected if they are enrolled.

Some vulnerable populations – especially sex workers, drug users and men who have sex with men – are especially important as trial participants because of the HIV risk they face. But being part of an HIV vaccine trial may serve to heighten the stigma they experience as it may reinforce the public perception of these persons as dangerous HIV "carriers" or "transmitters." Community advisory boards (CABs) should be especially vigilant to ensure that the situations of these persons are understood by trial sponsors and that local authorities are engaged actively in the protection of their human rights. The AIDS Vaccine Advocacy Coalition notes that even for people with good social networks, it is a challenge to find enough volunteers who will stay with a trial for the duration. This is even more of a challenge for socially marginalized people. The protection of their rights is essential to the task of finding an effective HIV vaccine.

Persons at particular risk of human rights abuse

Sex workers – men, women and transgender persons – live at the margins of "respectable" society in many communities. Their work or some aspects of it are against the law in many countries. Sex workers have shown that, given the opportunity, they can be very effective agents of HIV/AIDS education and prevention, but still many communities do not think to include them in important efforts to respond to HIV. Trial sponsors should understand the ways in which laws and custom may criminalize sex workers and make them reluctant to participate in research.

Drug users are often subject to harsh laws that keep them from enjoying the benefit of HIV prevention services and HIV/AIDS care and treatment. They may be reluctant to participate in vaccine trials due to the same fear of the authorities that keeps them away from other services. They have an especially acute need for confidentiality about their drug-using behaviour. But the participation of drug users in research is crucial to the development of an effective vaccine, particularly for countries where unsafe use of injection drugs is the principal means of new HIV transmission.

Because of social stigma or repressive laws, *men who have sex with men* in some communities are required to keep their sexual orientation a secret. They may fear that participation in a vaccine trial will expose their sexual preference or, if it is already known, expose them or their sexual partners to abuse or discrimination. Trial sponsors should understand the legal and social marginalization faced by these persons.

Prisons are high-risk environments for HIV in almost all countries, but *former prisoners* may be reluctant to participate actively in an HIV vaccine trial because of the stigma they face or a lingering fear of authorities. As for *prisoners*,

it is nearly impossible in their circumstances to ensure that their participation in any medical experiment is truly voluntary. Trial participants must be guaranteed, for example, that they can withdraw from a trial at any time without any fear of punishment. This is difficult if not impossible to achieve in prisons.

Women and girls face particular barriers to participating in vaccine trials, and also particular risks of reprisal and abuse if they are associated with HIV research in some settings (see info sheet 7).

Persons who cannot read or cannot read well should not be excluded because of their low literacy skills. Those who may feel socially inferior because they are not highly educated should also not be excluded. If many potential trial participants have low literacy skills, the trial sponsor should provide resources to ensure that informed consent processes are developed that enable people to receive all the necessary information and give consent without needing to read or write. Trusted witnesses may need to be part of such processes.

Government employees, those in military service, students, low-income persons in government welfare programs, refugees and asylum-seekers may not feel they are able to say no to a proposal by the government to be part of a vaccine trial because they are so dependent on the state for their livelihood or their future. Governments must take the initiative to ensure that these persons are secure in the knowledge that they may refuse to participate or may withdraw from a trial at any time without fear of reprisal.

In principle, CABs should be able to support all these persons, but the very marginalization of these populations may make that unlikely. Government authorities and the trial sponsors have a responsibility to raise awareness of the whole community concerning the importance of not excluding these persons from trials and of protecting their rights before, during and after vaccine trials. In some countries, sex workers, drug users and men who have sex with men face routine police harassment and abuse. In these cases, trial sponsors, local authorities and the CAB must take the initiative to inform the police and other law enforcement officials of the importance of the trial and should negotiate a policy of non-harassment. The CAB may wish to call on human rights organizations for help in such a process.

Actions for community groups

- Support the CAB in raising community awareness of the importance of inclusion of vulnerable and socially marginalized persons in vaccine trials and respecting their human rights.
- Support the CAB in advocating against police harassment of, and community-level discrimination against, sex workers, drug users, former prisoners, men who have sex with men, and others who may be fearful of participation in research.

Further information

Guidance document: ethical considerations in HIV preventive vaccine research. UNAIDS, 2000, available via www.unaids.org.

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Human rights and access to licensed HIV vaccine

Everyone has the right to benefit from an HIV vaccine that is licensed and proven effective. It is an accepted principle of medical ethics and a matter of simple justice that those who give of themselves to participate in research trials to generate new knowledge and new vaccines must be able to benefit from the fruits of that research. UNAIDS recommends that governments negotiate with trial sponsors before trials begin to ensure that communities in which trials take place are included in vaccine programs and are among the first recipients if vaccine programs need to be scaled up over time to cover all those who should receive the vaccine.

Beyond the matter of those who have participated in trials, there are many challenges that can arise in ensuring that a licensed vaccine reaches all who should have access to it. The vaccine for hepatitis B was licensed and available in many wealthy nations for over a decade before it became accessible in much of the developing world. There have often been unacceptable delays of many years between licensing of new vaccines in rich countries and their availability in developing countries. Policy-makers need to address access and delivery issues well in advance to ensure that unconscionable delays do not arise in access to an HIV vaccine.

Universal access to a future safe and effective HIV vaccine is necessary to realize fully the human right to the highest attainable standard of health. Vaccine delivery and dissemination should be guided by the requirements of international human rights law that health facilities, goods and services be accessible on a non-discriminatory basis and in adequate quantity, and be affordable, culturally acceptable, and of good quality (see info sheet 2). If an HIV vaccine is developed that is safe and effective, all people vulnerable to HIV have a human right to equitable access to that vaccine.

Actions by governments to prepare for access to an HIV vaccine

Community groups may find it useful to understand the role that governments should take in preparing for vaccine access. Community advisory boards (CABs) should seek clarification from governments about steps being taken to prepare for equitable distribution of vaccines, including these issues:

Supply of vaccines to countries with poor purchasing power: HIV vaccines may be expensive to produce compared with other vaccines. Developing countries have limited resources for purchase of HIV vaccines; many will require financial support from international donors. International organizations are considering establishing special funds to buy HIV vaccine for resource-poor countries. If their scientific and financial resources allow it and if barriers related to patents or other aspects of intellectual property law can be overcome, some governments may consider building the capacity for local manufacture of HIV vaccines.

Distribution to resource-poor or politically marginalized areas: Underdeveloped health care infrastructure in many low- and middle-income countries presents a major barrier to rapid delivery of new vaccines. All countries should be planning ahead for distribution systems that will ensure prompt delivery to all who need an HIV vaccine, including the most socially marginalized.

Overcoming social taboos: Mass immunization programs must reach the risk groups that need an HIV vaccine most urgently. Current vaccine programs in developing countries focus on reaching young children, but it is sexually active adolescents and adults who are most in need of a vaccine for HIV. Part of the challenge will involve overcoming taboos and the

reluctance of adults in many communities to acknowledge that young people are sexually active. Many barriers will be faced in ensuring delivery of an HIV vaccine to persons who are highly vulnerable to HIV/AIDS, such as sex workers, drug users and men who have sex with men (see info sheet 9). Delivery of vaccines to these populations will be assisted by measures to address the stigma associated with HIV/AIDS, to challenge negative moral attitudes towards these populations, and to improve their social and legal status.

Pricing: Countries in which vaccine trials take place should negotiate a fair price before the trials begin. Experience with expensive medicines has shown that trial sponsors can make reasonable profits on sales of vaccines in wealthy countries while selling vaccines at much lower prices to governments in resource-limited countries or to international health institutions. This approach is known as tiered pricing, differential pricing or equity pricing. By whatever means, governments have a duty to negotiate prices that are compatible with universal access for all those at risk of HIV. International organizations and donors should make it a high priority to support those countries that find HIV vaccines unaffordable even after price negotiations.

Patents: Patents give their holders rights to exclude others from making or marketing an invention such as a new vaccine for a certain period, usually 20 years. Patents essentially create a monopoly that allows the holder to charge a price higher than what a free market would dictate. The existence of a patent can prevent the development and sale of generic versions of vaccines that would be more affordable than patented versions. Fortunately, some vaccine trials are being run by non-profit entities that will presumably not be seeking large profits if their vaccines are licensed. In addition, the World Trade Organization has recognized that even where patents exist, public health needs allow patents to be overridden, and governments should be able to make this case for HIV vaccines, although there will certainly be political pressure brought to bear on countries to refrain from taking such steps. In discharging its responsibility to provide the facilities, goods and services that are needed to achieve the "highest attainable standard" of health, a government will need to negotiate overcoming the patent and pricing barriers that can keep an HIV vaccine out of reach for its people.

Advance planning for vaccine supply: Even if price issues are worked out, if there is insufficient manufacturing capacity for global production of a vaccine by the time it is licensed, access may be limited. Governments, trial sponsors and manufacturers should work together ahead of time to plan for adequate production of the vaccine. Similarly, governments should do everything possible to ensure that they will be able to register a new vaccine product for use without undue administrative delays.

Partially effective vaccines

The first generation of HIV vaccines may be effective only for some people, for certain subtypes of the virus, or for a limited time. If this is so, it will be important to counter the possibility that risk behaviours may increase because some people will mistakenly assume themselves to be completely protected by a vaccine that is really only partially effective. If the vaccine is only partially effective in preventing HIV, then any prevention benefits from vaccination might be cancelled out by less condom use, more syringe sharing, or other risky practices. In this case, the introduction of a vaccine will require reinvigoration of prevention information and services so that people maintain safer sex and safer drug use behaviour. It will be particularly important to maintain prevention education, condom availability and harm reduction programs such as syringe exchanges. A vaccine that only provides limited protection against HIV infection could still have an important impact in HIV prevention if it reaches enough people who are at risk. For example, at current levels of HIV prevalence, a vaccine that is only 60 percent effective would still protect a significant number of people.

Actions for community groups

- Advocate for governments to plan well in advance the systems required to procure and deliver HIV vaccines swiftly to poor communities that are highly vulnerable to HIV.
- Advocate for donors and international organizations to provide guarantees that financing will be forthcoming to ensure that vaccines are available to developing countries without undue delay.
- Support policies on pricing and patents that will maximize affordability of HIV vaccines.
- If a partially effective HIV vaccine becomes available, work to support the strengthening of other HIV prevention services and to improve understanding of the notion of partial effectiveness.

Further information

AIDS Vaccine Clearinghouse
(from the AIDS Vaccine
Advocacy Coalition)
www.aidsvaccineclearinghouse.org

AIDS vaccines for the world, preparing now to assure access. International AIDS Vaccine Initiative, 2000, available via www.iavi.org.

A new access paradigm: public sector agencies to assure swift, global access to AIDS vaccines. International AIDS Vaccine Initiative, 2001, available via www.iavi.org.

S Avrett. *HIV/AIDS vaccines for developing countries: advancing research and access.* Canadian HIV/AIDS Legal Network, 2003, available via www.aidslaw.ca.

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HIV vaccines and human rights

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HIV vaccines, microbicides and treatment: a common agenda

HIV vaccines will complement other measures to fight HIV/AIDS

Vaccine research and development efforts complement the development of other new prevention and treatment products and are part of a comprehensive response to the epidemic. Once developed, an HIV vaccine should also be delivered in such a way that it complements other prevention and treatment measures.

An HIV vaccine alone should not be thought of as a "silver bullet" solution to HIV/AIDS. Firstly, it is likely that the first HIV vaccines may be only partially effective in preventing HIV. Secondly, it will be a huge challenge to be sure that any HIV vaccine gets to all the people who need it. Thirdly, even if a fully effective vaccine were available, it would still be necessary to provide treatment and care for the millions of people living with HIV/AIDS around the globe. The quest for a vaccine is part of a comprehensive response to HIV/AIDS that encompasses the full continuum of prevention, treatment, care and support measures.

Aligning vaccine advocacy with support for microbicides and treatments

There are mutual benefits to be gained from aligning vaccine advocacy efforts with advocacy for other new prevention technologies, such as microbicides (see below), and advocacy for expanded treatment access and new treatment options. A human rights approach provides a conceptual framework for linking advocacy agendas. Those involved in advocating new prevention technologies and those advocating for HIV/AIDS treatment share the common goal of the realization of the human right to health of all people living with or affected by HIV/AIDS. A unifying factor for advocates is their commitment to broadening the range of options available to fight HIV/AIDS.

In addition to HIV vaccines, new approaches to prevention include:

- New female-controlled prevention products, in particular microbicides, which are chemical preparations that would act as barriers to sexual transmission of HIV when applied to the vagina or rectum. A microbicide might be used in several forms, including gels, creams, suppositories, films, or as a sponge or ring that releases the active ingredient over time. Several microbicides are being tested in human populations, and there may be an approved microbicide before there is a licensed, effective HIV vaccine.

- So-called **pre-exposure prophylaxis** (PREP) or the provision of antiretrovirals (ARVs) to those at risk of HIV in order to prevent HIV infection from occurring. Trials are planned to test the use of ARVs by people who are HIV-negative but at high risk. PREP has similar goals to a preventive vaccine. Unlike a vaccine, PREP may require taking ARVs before every exposure to

HIV. PREP research builds on the widespread use of ARVs for mother-to-child prevention of HIV.

Vaccine trials in developing countries present opportunities to invest in clinics and laboratories, train staff, and expand treatment services for communities where trials take place. Treatment access also involves investments in health infrastructure and training that can enhance capacity to test and eventually deliver vaccines and microbicides. Treatment access programs strengthen the health sector, as health care workers gain skills, and community confidence in services is generated. A strong health sector that is accessible to and supported by local communities is important for testing and delivering new prevention and treatment products and services.

Aligning vaccine advocacy with advocacy for access to existing prevention and treatment

Vaccine development is a long-term quest. It can be difficult to gain support for vaccine development when the benefits are unlikely to be seen for a decade or more to come. Vaccine advocacy should be positioned as part of advocacy for a comprehensive response to HIV/AIDS, including both short- and long-term goals. Experience from fighting the epidemic in diverse settings around the world has shown that the most effective responses to HIV/AIDS are those that simultaneously address prevention, treatment, care and support, as well as measures to address the underlying social causes of the epidemic, including human rights violations. Therefore, it is important that people engaged in work to promote HIV vaccine development understand and support advocacy relating to other elements of the HIV/AIDS response.

People living with HIV/AIDS and poor communities around the globe should not have to wait any longer to gain access to the treatments and prevention methods that we know work well. Additionally, research efforts in the vaccine, treatment and microbicide fields hold great promise to deliver powerful new tools for fighting the epidemic. But there is also an urgent and immediate need to vastly expand access to existing HIV/AIDS services, particularly in developing countries. There are still major gaps in access to treatments, prevention education and the basic tools necessary for protection – condoms and clean needles and syringes.

There are two broad aims common to vaccine, treatment and microbicide advocacy:

- **to accelerate progress in developing new products and approaches for fighting HIV, including by advocating for more research and funds;**
- **to ensure that interventions that are safe and effective against HIV/AIDS are made available and accessible without delay to those in greatest need.**

A common advocacy agenda for vaccines, treatments and microbicides

A common agenda shared by vaccine, microbicide and treatment advocates includes the following objectives:

- Resource mobilization:
  - efforts to make ARV therapies universally available to people living with HIV/AIDS in the developing world;
  - financing the development, purchase and delivery of future HIV vaccines and microbicides for use in developing countries; and
  - increased contributions to the Global Fund to Fight HIV/AIDS, TB and Malaria.
- Research and development:
  - greater commitments to HIV vaccine and microbicide development, including support for multiple, large scale clinical trials;
  - greater commitments to research into new treatment strategies, including treatment regimens, and diagnostic and monitoring tools and methods, designed for use in resource poor settings;
  - expanded research capacities in low- and middle-income countries, through investments in laboratory and clinical infrastructure, staff training and the transfer of technology and expertise to support the growth of centres of excellence in low and middle income countries;
  - strengthened networks amongst researchers in low- and middle-income countries to provide a framework for capacity building and sharing of expertise and lessons learnt in areas such as ethics, human rights and community preparedness; and
  - economic, epidemiological, cultural and behavioural research to understand the complexities and dynamics of the social aspects of the epidemic.
- Expanded access:
  - increased investment in health delivery systems, to support treatment scale up and to prepare for the rapid delivery of new therapeutic and preventive technologies as they become available;

- community education about new treatment and prevention products and approaches, and community participation in decision making about delivery options; and
- action by governments to ensure the affordability of products for the prevention and treatment of HIV/AIDS, including through stimulating generic competition, use of compulsory licensing provisions under patent laws, equity pricing of products so that they are cheaper in lower-income markets, and adoption of trade and investment policies that actively promote the enjoyment by poor communities of the human right to health.

Actions for community groups

- Community groups should advocate for HIV vaccines as part of a comprehensive and integrated HIV/AIDS response that addresses all aspects of the prevention-care-treatment continuum.
- Groups involved in vaccines, treatments and microbicides advocacy should develop links, identify opportunities for collaboration, and align their advocacy priorities.
- Advocates for HIV vaccines, microbicides and treatments should share information regularly and update each other on developments in their respective fields.

Further information

Global Campaign for Microbicides
www.global-campaign.org

International Partnership
for Microbicides
www.ipm-microbicides.org

WHO "3 by 5" Initiative
www.who.int/3by5/

Canadian HIV/AIDS Legal Network
www.aidslaw.ca/Maincontent/
issues/vaccines.htm

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4. Ensuring community participation in making decisions about HIV vaccine trials
5. Informed consent and voluntary participation in HIV vaccine trials
6. The right to prevention, care and confidentiality for HIV vaccine trials participants
7. Human rights concerns for women in HIV vaccine trials
8. Human rights concerns for children and adolescents in vaccine trials
9. Human rights and involvement of vulnerable persons in HIV vaccine trials
10. Human rights and access to licensed HIV vaccines
11. HIV vaccines, microbicides and treatment: a common agenda
12. **Glossary and resources for additional information**

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Glossary and resources for additional information

This sheet provides definitions of the technical terms that appear in bold-face text throughout infosheets #1 to 11, as well as, a consolidated list of resources where further information can be found.

Glossary of terms

antibody – an infection-fighting molecule in the body that helps destroy viruses and other pathogens by binding to antigens.

antigen – a substance such as a virus (or part of it) that stimulates the immune system to produce antibodies.

candidate vaccine – an experimental vaccine that is to be tested through animal studies and clinical trials involving people.

community advisory board (CAB) – body that serves as liaison between the community and the sponsors of the vaccine trial and that should be part of decision-making about all aspects of the trial. CABs should include representatives of those participating in the trial, people living with HIV/AIDS, people who are at high risk of HIV; local health workers trusted by the community; community service organizations and leaders, and perhaps local media.

effectiveness – the ability of a vaccine to stop the spread of a disease in a population when the vaccine is used in routine conditions.

efficacy – the ability of a vaccine to protect a person from infection (usually refers to experimental conditions in phase III vaccine trials).

false positive HIV test – a test that indicates a person is HIV-positive (because they test positive for antibodies to HIV) when the person does not in fact have HIV. This result can be experienced by people in HIV vaccine trials; although the vaccine itself is not able to cause HIV infection, it can stimulate the person's immune system to produce antibodies to HIV. A false positive may be a temporary result. There are tests requiring expensive equipment that is not available in all communities that allow this kind of false positive test to be identified.

human rights – entitlements of every person to a range of protections from abuse and to a range of factors related to a decent quality of life and to human dignity.

immunity – the condition of being able to resist a particular disease, especially through preventing development of a disease-causing agent in the body.

placebo – inactive substance given to some participants in a clinical trial rather than the candidate vaccine that is given to other participants. Some participants in clinical trials may receive a placebo so that researchers can compare the effect of the vaccine to the effect of the placebo.

post-exposure prophylaxis (PEP) – a short course of antiretroviral (ARV) medicines, given usually for several weeks, that follows exposure to HIV and reduces the risk that HIV infection will occur. Post-exposure prophylaxis is used in many countries for health workers or emergency workers who are occupationally exposed to HIV on a single occasion, as well as for victims of rape or sexual assault.

pre-exposure prophylaxis (PREP) – the provision of antiretrovirals (ARVs) to those at risk of HIV in order to prevent HIV infection from occurring. PREP has similar goals

to those of a preventive vaccine. Unlike a vaccine, however, PREP may require taking ARVs before every exposure to HIV.

preventive HIV vaccine – a vaccine designed to be given to a person who has not already been infected with HIV to prevent him or her from being infected.

subtype – a classification scheme based on genetic differences in HIV that are found in different parts of the world. Subtypes of HIV are also called "clades".

therapeutic HIV vaccine – a vaccine designed to be given to a person who already has HIV to boost his/her immune response and thereby prevent the person from becoming sick.

treaty – a contract in writing between or among two or more political authorities (usually national governments), signed by authorized representatives. A treaty normally becomes legally binding when the law-making authority of the government ratifies it through an act of law.

vaccine – a substance that stimulates an immune system response that can prevent an infection or create resistance to infection.

Key publications

S Avrett. *HIV/AIDS vaccines for developing countries: advancing research and access*. Canadian HIV/AIDS Legal Network, 2003, available via www.aidslaw.ca.

HIV vaccine handbook: community perspectives on participating in research, advocacy, and progress. AIDS Vaccine Advocacy Coalition, 1999, available via www.avac.org.

HIV Vaccine Handbook: Global Perspectives (2nd ed.). AIDS Vaccine Advocacy Coalition, 2005, available via www.avac.org.

AIDS vaccines for the world: preparing now to assure access. International AIDS Vaccine Initiative, 2000, available via www.iavi.org.

A new access paradigm: public sector agencies to assure swift, global access to aids vaccines. International AID Vaccine Initiative, 2001, available via www.iavi.org

Developing vaccines for HIV and aids: an introduction for community groups, 2nd Edition. International Council of AIDS Service Organizations, 2002, available via www.icaso.org.

Ethical considerations in HIV preventive vaccine research: guidance document. UNAIDS, 2000, available via www.unaids.org.

D Patterson. *Resolving legal, ethical and human rights challenges in HIV vaccine research*. Canadian HIV/AIDS Legal Network, 2000, available via www.aidslaw.ca.

Websites

Vaccine policy and programs

African AIDS Vaccine Program **www.who.int/vaccine_research/diseases/hiv/aavp**

HIV Vaccine Trials Network **www.hvtn.org**

WHO-UNAIDS HIV Vaccine Initiative **www.who.int/vaccine_research/diseases/hiv**

AIDS Vaccine Advocacy Coalition **www.avac.org**

International AIDS Vaccine Initiative **www.iavi.org**

US National Institute of Allergy and Infectious Diseases **www.niaid.nih.gov/daids/vaccine/**

AIDS Vaccine Clearinghouse **www.aidsvaccineclearinghouse.org/advocacy.htm**

Global Alliance for Vaccines and Immunizations **www.vaccinealliance.org**

South African AIDS Vaccine Initiative **www.saavi.org.za**

European Vaccine Effort Against HIV **www.eurovac.net**

National AIDS Manual **www.nam.org.uk**

The Body **www.thebody.com**

HIV InSite **hivinsite.ucsf.edu**

Harvard School of Public Health AIDS Initiative **aids.harvard.edu/research/vaccine.html**

Human rights and ethics

UNAIDS and human rights **www.unaids.org/en/in+focus/hiv_aids_human_rights.asp**

Canadian HIV/AIDS Legal Network **www.aidslaw.ca/Maincontent/issues/vaccines.htm**

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Ce feuillet d'information est également disponible en français et en espagnol. La siguiente publicación esta igualmente disponible en francés y en español.

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