

FACT sheet

Four Ways for Communities and NGOs to Contribute to the HIV Vaccine Research and Development Process¹

Experiences of advocates and people working on community engagement initiatives indicate that increasing community involvement in HIV vaccine trials requires the following elements:

1. Education and capacity building for community leaders;
2. Awareness and education of potential trial participants;
3. Structured mechanisms for consultation (such as community advisory boards); and
4. Monitoring, advocacy and partnership building.

1. Education and Capacity Building for and by Community Leaders

In countries where little HIV vaccine research has been conducted, or where organized community involvement in such trials has been minimal, community leaders and other stakeholders who are knowledgeable about vaccines and clinical research ethics can be instrumental in encouraging greater community involvement.

Building capacity of NGOs working directly with communities and expanding vaccine and clinical research literacy are important steps toward mobilizing community participation. Expanding vaccine and clinical research literacy involves knowledge and understanding of:

- how vaccines work;
- the status of HIV vaccine research;
- the clinical trial process;
- research ethics;
- the importance of community involvement in HIV vaccine trials; and
- ways to raise awareness of HIV vaccine trials among the community at large.

HIV vaccine researchers, specialists and organizations involved in HIV vaccine trials can play a role in providing some of the information or the support required.

¹ Information contained in this Fact Sheet was sourced from the ICASO publication 'Community Involvement in HIV Vaccine Research: Making it Work' http://www.icaso.org/publications/Comm_Involv_VaccineResearch2006.pdf

Making it Work

- In Thailand, a series of workshops for NGOs was organized to explain the scientific facts of HIV vaccine research, trial processes (including protocol submission and review) and community participation.
- The Kenya AIDS NGO's Consortium (KANCO) conducted training of trainers sessions on HIV vaccine development and trials for 36 members of five Vaccine Support Networks. KANCO also trained managers of 163 organizations (including NGOs and FBOs) as part of its Expanded Community Outreach programme.

Capacity building can sometimes take the form of training-of-trainers sessions, where members of community-based NGOs are trained first, and they then use this training to train or educate other stakeholders. As many NGOs working on AIDS already have existing networks of partner organizations and constituents, NGOs (particularly NGO support organizations) often embrace this task and play an active role in disseminating information to their peers.

In some cases, the use of the media is critical. When a trial yields disappointing results, there is need to maintain transparency and hope. In Kenya, after the headlines read 'Vaccine trial flops' the enormous task of retaining trial participants required frank discussion as to why the program was deemed 'flopped' by the media, the need to have realistic expectations regarding research and what the way forward must be. Soliciting media support becomes critical in such cases.

Recommendations

- Researchers and others involved in HIV vaccine trials should ensure that NGOs in countries where HIV vaccine trials are planned are fully educated on vaccines, clinical trials, the role of communities in HIV vaccine trials, ways to raise awareness and educate communities about the trials, and how NGOs can participate in CABs and similar mechanisms.
- Community representatives/leaders should be engaged to prepare their communities for the research process and to lay the foundation for future vaccination programs.

2. Awareness and education of potential trial participants

Recruiting large numbers of people for most HIV vaccine trials, identifying appropriate groups, requires raising awareness and educating potential trial participants and communities.

One example of an **awareness initiative** undertaken are street-based mobilization events on International HIV Vaccine Awareness Day, using large murals and printed T-shirts to draw attention to HIV vaccines. Examples of **educational initiatives** undertaken are workshops; public meetings; printed media articles; radio and television appearances; pamphlets, flyers and brochures; and community education and outreach teams tasked with increasing knowledge about HIV, vaccines and the clinical trial process.

Making it Work

- In South Africa, the HIV Vaccine Division of the University of Witswatersrand conducted outreach workshops with community leaders to provide information and address concerns about HIV vaccine research in Soweto. These workshops were used to combat misleading information generated in the popular media and to demystify commonly held beliefs that an HIV vaccine can infect people with HIV. This opportunity was also used to reiterate that a preventive vaccine is not yet available and to urge community members to practice safe sex. The message that the HIV vaccine research being conducted is preliminary and that condoms must still be used to prevent HIV infection was strongly emphasized.
- In India, NGOs recognized that programmes to educate and recruit potential trial participants need to address gender issues. As a result: (a) an expert group on gender issues was established; and (b) a gender training manual was developed for training the staff at trial sites.

These initiatives to raise awareness about AIDS vaccines and improve understanding of the vaccine research and the clinical trial process are important because they:

- give potential trial participants knowledge about the trials;
- empower potential participants to make an informed choice about whether to participate in the trials;
- counter unrealistic expectations;
- help to de-bunk myths; and
- help to get more people involved in working on HIV vaccine issues

Lessons learned from the educational initiatives conducted by partner organizations show that:

- It takes time to develop relationships with community members and to earn the community's trust, both of which are necessary to mobilize communities effectively;
- Working with the media is critical to success, especially if an earlier vaccine trial has been declared unsuccessful;
- Vaccine education is easier if vaccine messages are integrated into all HIV and AIDS messages; and
- Multi-pronged approaches to awareness and education are very helpful in engaging communities in the trials.

Recommendations

The educational initiatives should:

- be spread over several sessions;
- be conducted in advance of the start of the trials;
- include full information on the candidate vaccine, the trial processes and participants' rights;
- include information on HIV vaccine research generally (including after-trial issues);
- use lay language to describe complex scientific language;
- make use of existing networks and structures;
- be adapted to local cultures;
- involve the use of the media;
- respond to the myths and suspicions in the community concerning HIV vaccine research;
- be monitored and evaluated to determine effectiveness.

It should be noted that educational initiatives can be organized by NGOs, researchers, other stakeholders, or a combination. It is sometimes necessary to ensure that educational initiatives target audiences other than the community – for example, health care workers and the media.

3. Structured Mechanisms for consultation

Because of the complexity of HIV vaccine trials, the amount of work involved, and the long duration, establishing mechanisms to help coordinate the involvement of the community is very useful. Frequently, these mechanisms take the form of community advisory boards (CABs).

Community Advisory Boards (CABs)

A CAB is a group of volunteers and/or elected representatives from the community where the trial is taking place. They are people who represent the interest of the community to the researchers, help researchers to understand and respect local customs, work to protect volunteers' rights, create opportunities to inform potential participants of requirements and conditions for participating in a trial, and listen closely to concerns expressed by community members about the trials. Although the principles of a CAB often remain the same, there are significant variations across countries and sites on how the CAB is organized. A CAB should reflect its local context, and the communities it links with. Typically, the role of the CAB involves the following:

- building understanding between researchers and the community;
- advising researchers on all matters concerning the community (including community norms and concerns, cultural issues, informed consent, education and awareness);

- relaying community concerns to the researchers (and bringing answers back to the community), and informing the community about HIV vaccine research and specific trials (e.g. by organizing and/or participating in educational initiatives);
- supporting the research team in advancing the rights of trial participants, and providing support (when requested) to trial participants;
- assisting in the development of culturally appropriate approaches and materials (including the consent form);
- advocating for vaccine research and development; and
- supporting recruitment efforts and promoting health care arrangements for trial participants, and addressing fears and avoidance of HIV testing.

Making it Work

- In Uganda, the CAB was chaired by a Catholic priest, Rev. Fr. Christopher Kiwanuka. Day after day, Fr. Kiwanuka was called to pray at the funeral of someone who has died of AIDS. This motivated him to participate in efforts to find a vaccine. His parishioners respect and trust him, which makes it easy to build confidence.

Experiences have taught us that CABs are most successful at mobilizing community involvement when:

- the CAB is formed well in advance of the start of a trial;
- the CAB is independent of the researchers and trial sponsors, and has support from the researchers to perform its functions;
- membership on the CAB reflects the diversity of the community, with the members appointed through a transparent process. Members are selected based on their background and commitment and not solely on their knowledge of HIV vaccine issues; and
- members are clear from the outset about their roles and responsibilities, and are trained to carry out their responsibilities.

We also learned that language barriers should not preclude active participation on a CAB. In some countries, where different languages are spoken, this may mean providing translation and interpretation services for CAB meetings and exchange activities with other sites.

Other Mechanisms

CABs are not present at every clinical trial site. Where CABs have not yet been established, other mechanisms, such as town hall meetings and other existing community bodies can be used in place of or in addition to CABs to provide input on trial conduct and community involvement. It is essential, however, to ensure the existence of a functional, independent communication channel between researchers and affected communities.

4. Monitoring, Advocacy and Partnership Building

In addition to HIV vaccine awareness and education initiatives, and the existence of community advisory boards, mobilizing greater community involvement in HIV vaccine trials also requires monitoring, advocacy and partnership building.

Monitoring

AIDS NGOs and other community stakeholders have a ‘watchdog’ role to play in monitoring the conduct of HIV vaccine trials, and of research in general. This role is independent of the roles that NGOs play in raising awareness about HIV vaccine research, educating the community, and helping to facilitate the recruitment process. By following and monitoring clinical trials, stakeholders can identify ethical or other concerns regarding the conduct of the trials, and to raise these concerns with researchers conducting the trials.

Making it Work

- When HIV vaccine trials began in Thailand, three international and domestic NGOs – the Project for Appropriate Technology for Health (PATH), ACCESS, and the Centre for AIDS Rights (CAR) – worked together with the Thai NGO Coalition on AIDS to increase vaccine literacy and improve understanding of the trial process to equip the coalition to advocate on issues concerning community participation in the trials.
- In Brazil, AIDS NGOs challenged what they considered to be unethical practices by AIDS treatment researchers, combining their role as ‘watchdogs’ with a more vocal role of public advocates of research ethics. In India, a national NGO coalition was formed to act as a watchdog to ensure that HIV vaccine clinical trials addressed issues of concern to the community.

Advocacy

In countries where investigators may not acknowledge the importance of involving the community in the vaccine research process, advocacy with trial researchers can be used as a powerful tool to shape how HIV vaccine trials are conducted. Advocacy can also be directed at the national and local authorities who play a role in regulating, facilitating, funding and monitoring the research.

Partnership Building

Partnership building ensures that community members have a stake in how vaccine trials are conducted and enables community members to participate in vaccine research at all stages of the process. Working with researchers, through structured mechanisms like CABs or on community education initiatives, provides both researchers and community members with a valuable tool for preparing for vaccine trials. To maximize the success of the collaboration, it is important to ensure that these partnerships are established early in the clinical trial process, ideally before the trial starts to ensure community participation at all stages of the process.

Work around HIV vaccine issues, especially when they have national policy implications, can also bring communities into partnerships with government. In Brazil and Kenya, for example, NGOs now advise their respective Ministries of Health through participation in formal committees. In many countries, NGOs have also acted as facilitators, bringing government, researchers and sponsors together, and promoting collaboration and partnership. In this way, NGOs have not only played a key role in expanding public visibility of research, but also raised support for and awareness of the importance of finding a vaccine.

Recommendations

- NGOs should monitor the conduct of HIV vaccine trials to identify ethical or other concerns;
- NGOs should advocate with researchers who are conducting HIV vaccine trials to (a) ensure that the researchers understand the importance of community involvement, and (b) address any ethical or other concerns related to the conduct of the trials; and
- NGOs, researchers, governments and other stakeholders should partner to ensure the successful planning and implementation of HIV vaccine trials. These partnerships will take different forms in different countries. At a minimum, NGOs should be represented on committees and other bodies working on HIV vaccine research.

Ongoing Challenges

Addressing suspicions

The need to combat myths concerning HIV vaccine trials and overcoming suspicions on the part of potential trial participants is among the most significant challenges faced by researchers and NGOs working on AIDS issues alike. Common myths include the following:

- the candidate vaccine can infect participants with HIV;
- trial participants are being used as guinea pigs;
- an HIV vaccine already exists but is being kept secret;
- HIV was created in the laboratory to infect Africans; and
- the researchers are drawing blood for the purpose of devil worship.

Educational initiatives help to counter the myths, overcome suspicions and secure the trust of the community. It is important to ensure that these initiatives provide clear and full information on the trials, as rumours left unattended can have disastrous consequences for trial enrolment and overall support for research on vaccines. In Uganda, one HIV vaccine trial was delayed for a year while researchers tried to counter misconceptions such as those listed above. In Kenya, constant reassurance from researchers and community workers was required before enrolment for one trial could be completed.

The Kenyan AIDS Vaccine Initiative (KAVI) spent a full year interacting and building relationships with a target group in Kangemi, Nairobi, before they even started the recruitment of volunteers, highlighting the amount of time involved in mobilizing the community. Because the amount of time required to establish community entry may be a prohibitive factor for some researchers, building relationships with community ‘mobilizers’ who are already a part of the community offers researchers an invaluable tool for maintaining close contact with the communities and facilitating community participation in the research process, while ensuring communities that their concerns are accurately relayed to researchers.

Sustaining comprehensive community engagement

Another significant challenge is finding funding to allow for meaningful NGO and community involvement in HIV vaccine research. Currently, there is very limited funding available for capacity building, the production of educational materials, the translation of these materials to local languages, and operational costs of CABs and similar structures. There is also insufficient funding for advocacy and vaccine literacy initiatives that are not related to specific trials.

Other challenges that were identified during the project include:

- the need to address issues of trust between the communities and the researchers (i.e., some researchers may think that the community cannot understand the complexities of vaccine research);
- the difficulty of reaching and educating large numbers of potential trial participants;
- the risk associated with not being able to meet the high expectations of communities;
- finding ways to re-kindle interest in vaccine trials after a product does not prove immunogenic in trials;
- creating ways for trial participants to feel empowered enough to raise issues;
- ensuring that women and other vulnerable groups are adequately represented in the trials and on CABs;
- finding ways to allow CABs to share experiences; and
- evaluating and showing evidence of the impact of community involvement in this effort.

For more information on the issues covered in this FACT sheet, visit *Community Involvement in HIV Vaccine Research: Making it Work*
http://www.icaso.org/publications/Comm_Involv_VaccineResearch2006.pdf