Community involvement in HIV vaccine research: making it work
Acknowledgement:
First and foremost, we are very grateful to the individuals and organizations who shared with us their time and experiences, without whom this project would not have been possible.

ICASO is also thankful to the International AIDS Vaccine Initiative (IAVI), for their continued support and commitment to community involvement in HIV/AIDS vaccine research and advocacy, and especially for their support to this project.

We are also grateful to Mitchell Warren from the AIDS Vaccine Advocacy Coalition (AVAC) and Steve Wakefield, HIV Vaccine Trial Networks (HVTN) for their invaluable advice and feedback throughout the project.

Project Manager: Mary Ann Torres (ICASO)

Writers: David Garmaise, Yana Avdeeva and Mary Ann Torres

Project Advisor: Alexandre Menezes (IAVI)

Editors: Renata Rutman (IAVI) and Kieran Daly (ICASO)

Copyright: ICASO 2006
This publication may be freely reproduced and distributed in printed or digital format. The International Council of AIDS Service Organizations (ICASO) should be acknowledged as the original author. We would also appreciate receiving a printed copy or website address of any reproductions or adaptations of this publication.

Copies of this document are available in English and Spanish on the ICASO website: www.icaso.org

This project was made possible through the financial assistance and partnership of the International AIDS Vaccine Initiative (IAVI).

REPRINTED 2009
# TABLE OF CONTENTS

Executive Summary ................................................................. 2

SECTION 1: Introduction ........................................................... 3
Background ................................................................................. 3
HIV Vaccine Research ................................................................. 3
Why NGOs and Communities Need To Be Involved ......................... 4
Rationale and Methodology for This Project ..................................... 4

SECTION 2: Country Stories ......................................................... 6
Brazil: The role of AIDS NGOs in early HIV vaccine development efforts in Brazil ......................................................... 7
India: Petri Dish ........................................................................... 10
Kenya: Educate and Involve the Communities ................................. 12
Peru: Participating in a CAB – From Theory to Practice ..................... 15
South Africa: Equal Partnership – Key to Success! ......................... 17
Thailand: Make Ethics Matter ....................................................... 20
Uganda: The Importance of Trust ................................................. 23

SECTION 3: Lessons Learned and Recommendations ....................... 26
Education and Capacity Building for Community Leaders ................. 27
Awareness and Education of Potential Trial Participants .................. 28
Structured Mechanisms for Consultation ....................................... 30
Monitoring, Advocacy and Partnership Building ............................... 32
Ongoing Challenges .................................................................... 34

Notes ......................................................................................... 36

Resources .................................................................................. IBC

---

**A Note on Terminology**

The term “NGO” is used in this report in its broadest sense to refer to any non-governmental organization, including community-based organizations and faith-based organizations.

The term “researchers” refers to the principal investigators and other researchers associated with the vaccine trials.

The term “sponsors” refers to the company or organization that is funding the trials.

The terms “trial participants” and “trial volunteers” are used interchangeably.

The terms HIV vaccine and AIDS vaccine are used interchangeably.
HIV/AIDS is one of the greatest public health emergencies of our time. Currently available HIV prevention interventions are effective, but in many regions of the world, their impact has not been significant enough to curb the spread of HIV, especially in developing countries. Antiretroviral treatment has extended the lives of people living with HIV/AIDS, but treatment does not provide a cure and still reaches only 20% of those who need it in low- and middle-income countries. A comprehensive approach that includes scaled-up prevention, treatment and care is needed to reverse the global pandemic. The combination of these factors makes for an ethical imperative to develop, as quickly as possible, globally effective vaccines to prevent HIV/AIDS.

In countries where HIV vaccine trials are planned or already underway, non-governmental organizations (NGOs) and communities have an important role to play in all stages of the design, planning and implementation of the trials. This involvement is key to ensuring the ethical and scientific quality of the research, its relevance to the affected communities and the rapid dissemination of and actions based on research results. In the case of large-scale trials, where thousands of volunteers must be recruited, the involvement of the community is especially important.

The International Council of AIDS Service Organizations (ICASO), in collaboration with the International AIDS Vaccine Initiative (IAVI), undertook a community-based project to conduct an in-depth assessment of the role that communities play in efforts to develop and test an HIV vaccine, especially in low- and middle-income countries. This report presents the main findings of the project, and serves as a stepping-stone for the creation of an action plan for greater involvement of communities in the vaccine research and development process.

The findings from our study reveal that community involvement in HIV vaccine related activities can be increased and strengthened when the following elements are incorporated into the clinical trial process:
• education and capacity building for community leaders;
• awareness and education of potential trial participants;
• structured mechanisms for consultation (such as community advisory boards); and
• monitoring, advocacy and partnership building.

The report is divided into three sections.

Section 1 introduces the main issues and provides background information on community involvement on vaccine research

Section 2 provides case studies from seven countries where HIV vaccine trials have taken place or are planned.

Section 3 discusses the key lessons learned and main recommendations for community involvement in current and future HIV vaccine trials. The analysis in the section is based on case studies presented in this publication.
Background

Despite increased funding and growing political commitments to reversing the pandemic, the spread of HIV around the world continues to outpace the global response. An estimated 38.6 million people worldwide were living with HIV in 2005, and an estimate 4.1 million became newly infected with HIV in that year alone.\(^1\)

Currently available HIV prevention interventions are effective, but they have not been sufficient to curb the spread of HIV worldwide, especially in developing countries. Social stigma associated with HIV, and inadequate public health systems severely impede the availability and delivery of effective interventions such as prevention education, risk-reduction counselling, condom distribution and needle exchange programmes. While advances in the treatment of AIDS have extended the lives of people living with HIV/AIDS, antiretroviral medicines do not represent a cure. Tragically, AIDS treatments are still not readily affordable or readily accessible for the vast majority of people living with HIV/AIDS. The combination of these factors makes for an ethical imperative to develop, as quickly as possible, globally effective vaccines to prevent HIV/AIDS,\(^2\) as a key component of a comprehensive approach to fight the epidemic.

HIV Vaccine Research

Any vaccine licensed for use must first pass rigorous evaluations to determine its safety and effectiveness—a process that requires that the vaccine candidate be tested first in small-scale trials (Phase I and II), and then in large-scale trials (Phase III) (see box 1). The number of AIDS vaccine candidates in small-scale human trials has doubled since 2000. Currently, there are more than 30 trials, spanning 19 countries on six continents. The first large-scale AIDS vaccine trials (in Thailand and North America) were completed in 2003. A third large-scale trial began in 2005 in Thailand and a fourth (a phase IIB) is currently underway in North and Latin America, with at least another phase IIB being planned for Africa. Developing countries, which participated in vaccine research and development only marginally just six years ago, are now at the forefront of AIDS vaccine research, playing a central role in advancing the field. In 2000, Uganda was the only African country to conduct an AIDS vaccine trial. Today, five African countries have small-scale trials underway, and four others are preparing for trials. The first AIDS vaccine trials in India started in early 2006.\(^3\)

---

**BOX 1**

**PHASES OF CLINICAL TRIALS**

**PHASE I** looks primarily at safety and side effects, and measures immune responses (immunogenicity) in a small group of low-risk HIV-negative volunteers.

**PHASE II** looks at safety and immunogenicity in a larger group, and helps determine the number of doses needed. In some Phase II trials, information might be gained about whether the vaccine works, or has efficacy, but not enough for licensure or widespread use.

**PHASE II-B** or proof of concept trials. Phase IIB trials may provide an indication of an experimental vaccine’s efficacy but are less costly in terms of money, time and number of volunteers, than a phase III. Phase IIB trials are not designed to provide enough information for licensing a vaccine at the end of the trial.

**PHASE III** looks at efficacy (how well the vaccine can protect against HIV infection) in large groups of at-risk HIV-negative individuals. Thousands of participants must be recruited.
Why NGOs and Communities Need To Be Involved

Clinical trials for AIDS drugs and HIV prevention technologies have highlighted the importance of involving NGOs and communities in medical research. The inclusion of communities in research activities not only leads to better science (as it is likely to impact the enrolment, retention and trial practices), but it can also play an important role in ensuring that research findings are translated rapidly into accepted and effective programmes. History also demonstrates that when medical and public health research is planned and conducted without considering the cultural context of such work, or without regard for human rights, the individuals who participate in research activities, along with the communities they belong to, may well be harmed.

In countries where HIV vaccine trials are planned or are already underway, NGOs and communities have an important role to play in all stages of the design, planning and implementation of the trials, as well as follow up after the trial is over. Their involvement is key to ensuring the ethical and scientific quality of the research, and its relevance to the affected communities.

In the case of Phase III trials, where thousands of volunteers must be recruited, the involvement of the community is critical. Communities must be seen not merely as potential volunteers for the trials, but rather as equal partners in the endeavour to find an effective HIV vaccine.

Rationale and Methodology for This Project

Until now, one of the main barriers to effective community involvement in HIV vaccine trials has been the lack of documented information regarding how communities have been involved, what they have learned and what they have contributed, resulting in limited knowledge of the community’s influence on clinical trials for HIV/AIDS vaccines. To address this challenge, ICASO, with support from the International AIDS Vaccine Initiative (IAVI), undertook a community-based project to conduct an in-depth assessment of the role communities play in vaccine research. The report presents the main findings of the project in participating countries, focusing on salient issues surrounding community involvement in trials, and serves as a stepping-stone for the creation of an advocacy plan for greater community involvement in the vaccine research and development processes. The findings and recommendations from this project will be shared with communities, researchers, trial sponsors and policy makers.

While few clinical trials took place in developing countries in the 1990’s, today they are conducted in countries all over the world, having a direct impact on the community level. Once regarded as a responsibility of research organizations, the conduct of trials and the infrastructure that supports them is now seen as a multi-

“Researchers cannot get a vaccine without the community, and the community cannot get a vaccine without researchers. We must all be actively involved.” — Rev. Fr. Christopher Kiwanuka Parish

Priest, Entebbe Catholic Parish, and Chair, Community Advisory Board
sector effort in which NGOs and other community-based structures are playing an increasingly active role. This report outlines the lessons learned from the actual experiences of community groups working in this field, offering a basis for building on these pioneering efforts.

The project focused on HIV vaccine related activities taking place in Brazil, India, Kenya, Peru, South Africa, Thailand and Uganda. ICASO identified seven vaccine advocates and asked them to write about their involvement in AIDS vaccines research, and the effect their participation had on the outcomes of vaccine trials and on the overall environment for vaccine efforts.

We hope this publication will improve the overall understanding of the community’s involvement and role in HIV vaccine research in low and middle income countries, including the barriers to effective involvement. The project’s long-term goal is to use the lessons learned from these experiences to promote effective community involvement in current and future HIV vaccine research.
This section of the report contains stories of community involvement in HIV vaccine research and development from seven countries: Brazil, India, Kenya, Peru, South Africa, Thailand and Uganda. The narratives were written by the authors listed and were edited by ICASO’s staff for consistency in length, format and language.

The accounts describe issues that project partners have faced in each of the seven countries. The stories reflect the views and opinions of these individuals and organizations, and not necessarily those of ICASO or IAVI.
The role of AIDS NGOs in early HIV vaccine development efforts in Brazil

Adapted from a chronicle prepared by Jorge A. Beloqui (GIV, ABIA, RNP+, IME-USP)

BACKGROUND

In August 1991, the World Health Organisation’s Global Programme on AIDS (GPA) visited Brazil as part of a selection process of developing countries for future trials of an HIV vaccine. A number of NGOs were involved in these meetings and it was later announced that Brazil and three other countries had been selected as preferred locations to host vaccine trials.

Around the time of those discussions, the Minister of Health stated that he was against vaccine trials conducted from abroad in the country and announced to the press that Brazil would not offer “guinea pigs” for these trials. However, AIDS activists understood that it was very important to be involved and that this opportunity could not be wasted. That is why activists suggested continuing the discussions in order to implement the needed infrastructure for the trials. It was our responsibility – as AIDS advocates – to ensure that Brazil was not used simply as a source of test subjects. We decided that we would not accept anything less than scientific and ethical excellence. We also introduced the issue of access to a future vaccine, especially if such a vaccine was the result of the trials in Brazil.

The NGOs that participated in these meetings decided that all coalition members needed to receive some basic information on vaccines, in order to improve their knowledge and allow them to make informed decisions. ABIA, Grupo pela Vidda-RJ and Grupo pela Vidda-SP published in 1992 a document on vaccines, the first of its kind produced by NGOs.

In November 1992, a coalition of NGOs working on AIDS elected five NGOs (one for each of the proposed vaccine trial location) to sit on the Vaccine Committee. It was the first time that NGOs were elected to be part of an AIDS-related Committee in Brazil and offered a promising indication that it was possible for NGOs to work with the government and other stakeholders on key issues, such as research. In 1994, NGOs were elected to be part of the National AIDS Commission, which was formed before the Vaccine Committee, but previously did not have elected community representation.

Meanwhile, the NGO members of the National AIDS Vaccine Committee focused on public awareness and vaccine education. At a conference in 1994, attended by more than 120 NGOs, we discussed the consent form to be used in the first vaccine trial in Brazil. That was, without a doubt, an historical moment. Never, before (or after) did we have so much transparency on the discussion of ethical issues related to research in Brazil.

At the same time, the National AIDS Vaccine Committee helped to develop a four-part vaccine plan, focusing on the epidemiological, clinical, behavioural and molecular-biology areas as they related to vaccine research. A network of laboratories was created to expand research capacity and data collection on issues related to HIV subtypes, behavioural data and HIV incidence, thus contributing to a better understanding of the HIV epidemic in Brazil, the impact of which was much broader than just facilitating the vaccine program.

THE IMPORTANCE OF ETHICS IN RESEARCH

Involvement in the HIV vaccine research provided us with an opportunity to confront ethical issues in clinical research. After becoming familiar with the Declaration of Helsinki,1 the Council for International Organizations of Medical Sciences (CIOMS) Guidelines2 and the Nuremberg Code,3 which contributed to our understanding of medical research ethics, we raised ethical and technical concerns over the 1996 trial of the therapeutic AIDS drug Indinavir. Among the issues we found ethically objectionable was the position taken by researchers to continue to provide Indinavir mono-therapy after results of another trial released at the time showed that dual-therapy provided greater benefit. Another issue was the refusal of researchers to provide viral load test results to participants; even though researchers had already shown those results at the 1996 International AIDS Conference in Vancouver. After...
Some examples of how Brazilian community groups have embraced a comprehensive approach are mentioned below:

- People living with HIV/AIDS have been leaders of vaccine activism in the country, having been involved from the beginning in the search for a preventive vaccine.

- Specific information about vaccine research can be included in workshops or meetings on prevention or treatment issues generally (and specific information on other prevention issues and on treatment issues can be included in workshops or meetings on vaccine research).

- Vaccine research issues can be discussed at national and regional meetings. In fact, national meetings of NGOs working on HIV/AIDS incorporated into their advocacy agenda issues related to vaccines, particularly around community involvement and governmental funding for vaccine research and development.

- Lessons learned from HIV vaccine trials and advocacy can inform future research on vaccines, ARVs and other related areas.

A comprehensive response to the epidemic – combining prevention and care – is fundamental but, it brings along challenges in managing the multiple priorities and the diverse degrees of urgency of the issues that need to be addressed by AIDS organizations. It is important to keep an eye on the problems of today, while ensuring that we support strategic research that will bring us new tools in the future.

However challenging, through this approach we have been able to create a sustainable environment for vaccine research and community involvement that has lasted for over a decade. Today we continue to work on education and mobilization of NGOs by hosting meetings and publishing regular newsletters. NGOs still actively participate in the National AIDS Vaccine Committee. In recent years Brazil has seen increased vaccine trial activity with NGOs actively participating through CABs and advocacy. All these efforts are building on the foundations that were established in the early 90’s when vaccine issues were first discussed with communities in the country.

JOINT ADVOCACY FOR PREVENTION, TREATMENT AND HUMAN RIGHTS

Brazilian NGOs working on HIV vaccine issues are not divorced from other areas of HIV/AIDS work. While promoting vaccine research and development, organizations involved in vaccine advocacy are also actively engaged in HIV/AIDS prevention, treatment, care and support initiatives.

Although a number of international agencies and ‘experts’ from developed countries have cited lack of resources and other constraints as prohibitive challenges to providing antiretroviral treatment to people living with HIV/AIDS in developing countries, NGOs working on HIV/AIDS in Brazil successfully advocated for a full implementation of the Brazilian Constitution that protects the right to health of all citizens. This constitutional right has been the platform to ensure access to ARVs for all people living with HIV who need them. Thus, the Brazilian STD-AIDS Program, as a part of the Brazilian response to HIV/AIDS, became a reference on AIDS.

It has been our experience that an integrated, inclusive approach offers the most effective way to address the multiple challenges in this epidemic. An agenda that includes an expansion of current advocacy, prevention, treatment and care initiatives to address immediate needs, coupled with parallel medium-term objectives, such as AIDS vaccines to prevent new infections, offers the most promising path to reversing the epidemic.
CONCLUSIONS AND LESSONS LEARNED

- Community involvement in HIV vaccine research can lead to greater involvement in AIDS policy making. Advocacy on AIDS vaccines opens the door for a formal dialog with governmental bodies on other relevant health issues.

- Communities in Brazil were pioneers as independent watch dogs for ethical compliance in AIDS research. This experience lead to greater community involvement in promoting ethical research in AIDS treatment and other areas.

- Community groups have to promote the integration of prevention, treatment, and care as part of the comprehensive response to HIV/AIDS.

- NGOs can self-organize around AIDS vaccine issues and embrace scientific research as an important priority on their own agendas.
When I first heard that India was going to start a process for AIDS vaccine trials, the news sent a shiver down my spine.

I was concerned on two fronts. One was the rather disturbing history of trials with humans in our country, and the second was the ethical dilemma one is faced with when one has to deal with an issue that is so sensitive and open to misconduct, manipulation and coercion. All this made me unsure, and I found myself asking the question: “Do I really want to get involved in this process?”

The answer to that vexing question came to me as I looked at the reality of the HIV/AIDS epidemic in India. It has been very clear to me that to fight this epidemic we need a range of interventions among which a preventive vaccine would be one. I, therefore, felt it imperative that I make a commitment to ensure that whenever a vaccine trial process takes place, I will do what it takes to ensure that the rights of the people involved will be safeguarded and protected. This meant having to understand the issues and concerns of those who would eventually participate in these trials.

CONCERNS

There are many concerns. Who will conduct the trials? Who will participate in the trials? Will there be true access to information? Will there be total accountability and transparency on the part of both the government and the scientists? What about care and treatment issues for those who sero-convert during the trial? How informed is the informed consent for participation? Then there are issues of reimbursement vs. compensation – when does it become inducement to participate? What about the stigma and discrimination associated with participating in a trial for someone who wants to get a visa or find a job? And if a vaccine is found, what about access and availability of the vaccine for the people of India?
Developing a vaccine of this kind is clearly a long process and it could mean anywhere up to a decade before we come close to finding one that works. It is not around the corner, which is why it is very important that communities know and have all the available information every step of the way.

The history of trials like the Tuskegee trials in the US or the cancer drug trial in India in 2001 involving M4N and G4N, bear testimony to the fact that if we are not ever-vigilant, people can suffer in ways that we cannot even begin to fathom.

One of the ways to address this has been the formation of community advisory boards (CABs) where they do not exist, or the need to empower existing ones to act as strong links between the scientific researcher and the community. These boards are meant to represent the interests of the community.

The Pune trial already has such a board in place. The trials in Chennai are being conducted partnering an NGO which has a robust CAB in place. The research institute in Chennai will also have its own CAB by the end of this year.

We stand at crossroads today. The questions before us are many as are the challenges. But our people have the right to access an array of interventions that will protect them from a life-threatening, highly stigmatized infection.

**CONCLUSIONS AND LESSONS LEARNED**

- NGOs can work in partnership with researchers to help overcome initial suspicions and create opportunities for dialog across the diverse groups involved.

- Gender and other relevant vulnerability issues must be integrated into vaccine programs to make sure that the specific needs of the population being recruited are addressed in the process.

- Community consultations must happen locally as well as nationally. It is important to consider regional differences when reaching out to local groups.

- Constant sharing of information with partners on the progress of the research program helps sustain interest and keep stakeholders engaged.

ORIENTATION MEETINGS

Given the commitment of the programme to transparency and complete information sharing, orientation meetings were held with a diverse group of stakeholders, such as the medical fraternity, media, scientists and NGOs, to create awareness and set up systems for the complete sharing of information. Various issues and complex details of the programme were shared at these meetings. Keeping in mind the cultural diversity of the country, beginning in 2003 state-level meetings were held in the six high-HIV-prevalence states such as Tamil Nadu, Manipur and Nagaland (the latter through Assam) and the above-mentioned states.

These large, open-house meetings were held to hear the voices and concerns of the people who could possibly participate in the trials. Concerns did emerge. But so did a need for expert groups to address each of these concerns. It was also clear that there might be the need to formulate a national NGO coalition that could be a watchdog for any clinical trials that may be conducted in India and also ensure true engagement of the community. It is hoped that this body will always take the social responsibility to ensure that the rights of our people are never violated and the process remains transparent. The NGO Coalition members are those who are at the forefront of implementing HIV/AIDS programmes in the country today.

Consultations with gender experts had also shown that the programme would need to incorporate gender specific concerns regarding the involvement of both women and men in the trial process. There is now an expert group that is watching out for gender-related concerns in this process. A gender training manual for AIDS vaccine trials a first of its kind was developed and used for training trial site staffs. Meanwhile, elected representatives at the state-level have been engaged in an ongoing debate so that they have all the information they may need to look into community-based concerns as and when they arise. This is being done through legislators’ workshops and one on one meetings in the high prevalence states.

Two Phase I trials are currently ongoing in Pune and Chennai. These trials were initiated after stakeholder consensus on concerns that had emerged like appropriate care and treatment for the volunteers, informed consent issues, adequate gender representation, and community involvement. Phase II and III trials which follow Phase I are far more complicated because of the large numbers of volunteers required from vulnerable communities. Keeping this in mind, consultations have already been initiated to understand the nuances of this.
Kenya is a sub-Saharan African country that is severely affected by the AIDS epidemic. HIV prevalence in adults 15 to 49 rates range from 5.2 percent to 7 percent (UNAIDS Report on the Global AIDS Epidemic, 2005). For Kenyans, there is an urgent need to tackle the epidemic in an urgent way.

Since 2001, Kenya has hosted several vaccine studies. As exciting as it is to have a variety of different experimental AIDS vaccines under trial in Kenya and preparatory activities for an eventual efficacy trial, one of the greatest challenges still to be overcome has to do with the community. Without the involvement of local populations, HIV vaccine research and development does not stand a chance. This is because the only way to discover what will protect a person from HIV is to test experimental vaccines in human beings by conducting Phase I, II, III and IV clinical trials.

Because of the large numbers required to be recruited for trials, reaching and informing volunteers can be a daunting challenge. A large scale vaccine trial needs to enrol thousands of people and must keep them committed for several years. Knowledge and perceptions of HIV vaccines plays a critical role. A recent study by the NIH in the US found that one out of five persons surveyed believed that an HIV vaccine already exists, but is being kept secret. About half of those surveyed had not heard anything about HIV vaccine research over the past year. This means that few people are aware of the current effort to develop an HIV vaccine, which would help to explain the challenge of finding people who are willing to volunteer for clinical trials. People cannot volunteer for something they do not even know is going on. Similar efforts to survey individuals about their beliefs and opinions in other parts of the world, particularly in the global south are unknown.

Prior to participating in trials, communities from which volunteers will be recruited must be mobilised. This is a project in itself. In the densely populated Kangemi region in Nairobi, for instance, mobilising the high risk groups was difficult – the groups thought the researchers had sinister motives (that they were hired to repatriate them to their rural homes) and it took months of working among them, participating in their activities, until they finally bought into the idea of participating in the vaccine trials. This exercise alone took one year.

In a few cases, the issue of volunteers being treated like ‘guinea pigs’ has been raised by Kenyan communities. This was in light of the theories and myths which are prevalent surrounding the origins of HIV itself. Many people have heard the theory that HIV was created in a laboratory as a means to annihilate the African race. The idea of volunteering for HIV/AIDS vaccine trials did not go down well initially in the vaccine study located in Majengo Nairobi which has heavily featured in the local media. Where the study has been accepted, constant assurance from researchers and community workers was needed. What has helped was the visibility of the partnerships which have been formed by the international and Kenyan researchers from the University of Nairobi.

Information for communities and volunteers is extremely important. In some cases, volunteers have claimed to have developed diseases such as cancer during the trials and have demanded that the research study finance the treatment. In others, close family members get ill and the volunteer believes the project should cover their medical treatment in addition to his own. Very clear lines have to be drawn and information regarding the liabilities of the project specified. Being able to refer and network with organisations that can provide supplemental assistance to patients on the trials is critical.

In most Kenyan communities, rumours play a big role in decision-making. Rumours left unattended can have disastrous effects on a sensitive project like the HIV and AIDS vaccine trials. No rumour can be treated as nonsensical. All rumours generated in the community are listened to, analysed and responded to promptly. A case in point – there was a rumour that researchers were “drawing blood for devil worship activities.” Volunteers threatened to withdraw from the study. An urgent meeting of the volunteers and other members of the community was called to allay these fears.
COMMUNITY INVOLVEMENT IN HIV VACCINE TRIALS: MAKING IT WORK • ICASO • 2006

As such, the community plays an indispensable role in participating in vaccine development and the Kenya AIDS NGO’s Consortium (KANCO) is one organisation which has focused on strengthening the community’s capacity to respond and be involved.

INTRODUCING KANCO

KANCO is a national membership network of over 600 NGOs, faith-based organisations (FBOs) and community based organisations (CBOs) involved in or having an interest in HIV/AIDS and sexually transmitted infections (STI) in Kenya. KANCO was created in 1990 to enhance networking between NGOs, religious institutions and the Government for the purpose of controlling the spread of HIV/AIDS and sexually transmitted infections, and helping in care and support of people who are infected and affected.

KANCO works with community members, researchers the government, media, funding collaborators and civil society in an effort to ensure active participation of the community. Its major programme areas are networking and information exchange, capacity building and policy advocacy and development. Although KANCO has been involved in HIV and AIDS vaccine research and development since 2002, in October 2003 KANCO initiated a project entitled “Preparing Kenyan Communities for HIV and AIDS Vaccine Development and Testing.”

The goal of KANCO’s programme is to inform and educate Kenyan communities on HIV vaccine development, trials and delivery processes through culturally appropriate medium for increased involvement in the process of development, testing and eventual access to the vaccines when they are available.

At the core of the strategy for strengthening community participation and involvement in HIV/AIDS vaccine research and development are the requirement to know, to disseminate, to advocate, to negotiate and to interact. These form the basis of KANCO’s key activities which are focused in three areas, as follows:

• capacity and skills building of communities through working with local NGOs, CBOs and FBOs;
• creating links between research institutions and community organisations; and
• creating links between research institutions and community organisations for vaccine policy formulation.

KANCO’s capacity building efforts have been spearheaded using an exciting new approach and initiative called the Vaccine Support Network (VSN). The primary goal of the VSN is to advocate for and support HIV and AIDS vaccine development and testing within the communities. In areas where HIV/AIDS vaccine trails are not immediately planned and awareness is low, the messaging is adjusted to build a foundation for eventual HIV/AIDS vaccine education. It is hoped that the VSN will develop into a strong network of organisations interested in incorporating AIDS vaccine messages into their existing programmes and supporting clinical trials when they take place.

KANCO organises education sessions for CBOs which enable their members to have a thorough understanding of issues surrounding vaccine trials. These organisations are then able to interact with the communities and are responsible for creating awareness and soliciting volunteer participation support from the communities. This process is dubbed the Expanded Community Outreach (ECO) programme. KANCO’s capacity building and sensitisation efforts are targeted at managers, trainers of trainers, community members and the media.

KANCO repackages information on HIV/AIDS vaccines. The information is disseminated through culturally appropriate mechanisms such as awareness walks, newsletters, newspapers and media campaigns during special events like the International World AIDS Vaccine Day.

Training of trainers (TOT), using a standardized training manual, has also been conducted in collaboration with IAVI and Walter Reed projects. Over 36 members of the five VSN have undergone a TOT in vaccine development and trials. Members of the VSN, in turn, reach other organisations in the community through the expanded community outreach programme.

To date, 163 organisations whose members have been trained through KANCO’s Expanded Community Outreach programme. Those trained include managers of NGOs, CBOs and FBOs as well as journalists. Several organisations are now interested in AIDS vaccine research outcomes. KANCO has been receiving requests from individuals and non-members for training in vaccine research.

CAPACITY BUILDING FOR NGOS/CBOS

KANCO's capacity building efforts have been spearheaded using an exciting new approach and initiative called the Vaccine Support Network (VSN). The primary goal of the VSN is to advocate for and support HIV and AIDS vaccine development and testing within the communities. In areas where HIV/AIDS vaccine trials are not immediately planned and awareness is low, the messaging is adjusted to build a foundation for eventual HIV/AIDS vaccine education. It is hoped that the VSN will develop into a strong network of organisations interested in incorporating AIDS vaccine messages into their existing programmes and supporting clinical trials when they take place.

KANCO organises education sessions for CBOs which enable their members to have a thorough understanding of issues surrounding vaccine trials. These organisations are then able to interact with the communities and are responsible for creating awareness and soliciting volunteer participation support from the communities. This process is dubbed the Expanded Community Outreach (ECO) programme. KANCO's capacity building and sensitisation efforts are targeted at managers, trainers of trainers, community members and the media.

KANCO repackages information on HIV/AIDS vaccines. The information is disseminated through culturally appropriate mechanisms such as awareness walks, newsletters, newspapers and media campaigns during special events like the International World AIDS Vaccine Day.

Training of trainers (TOT), using a standardized training manual, has also been conducted in collaboration with IAVI and Walter Reed projects. Over 36 members of the five VSN have undergone a TOT in vaccine development and trials. Members of the VSN, in turn, reach other organisations in the community through the expanded community outreach programme.

To date, 163 organisations whose members have been trained through KANCO's Expanded Community Outreach programme. Those trained include managers of NGOs, CBOs and FBOs as well as journalists. Several organisations are now interested in AIDS vaccine research outcomes. KANCO has been receiving requests from individuals and non-members for training in vaccine research.
NATIONAL ADVOCACY AND SUPPORT FOR VACCINES

The successful development of an AIDS vaccine requires collaboration between researchers and communities. KANCO is actively participating in HIV and AIDS Vaccine Research policy formulation and development in Kenya, and expresses community concerns to researchers and government. The Ministry of Health created an HIV/AIDS Vaccine Subcommittee (VSC) which advises on HIV/AIDS vaccine research and development. KANCO is recognised as representing the interests of the community and is the only NGO that sits on the advisory body.

Apart from educating the communities and creating linkages, KANCO is also engaged in trust building. The ‘gate-keeper’ approach is used to interface the researchers with the communities. An effective feedback system has been established to ensure that all the concerns of the community are responded to swiftly and transparently.

KANCO has facilitated the creation of links between the research teams and the CBOs and NGOs involved in HIV/AIDS activities, including being an active facilitator between the communities and trial sponsors and local research teams. KANCO creates regular fora for exchange of ideas and understanding of vaccine trials by communities.

Through the joint efforts of the members of the VSC, the draft Kenya National Guidelines for the Development of HIV/AIDS vaccine were developed by May 2004 and officially launched in May 2005. Kenya is one of the few countries in the developing world which has national guidelines on HIV/AIDS vaccine development. The VSC will work to expedite review of vaccine research in the country and hence contribute to the speedy development of vaccines.

KEY CHALLENGES

- Some health workers are known to have spread the wrong messages on the vaccine trials, leading to unrest and mistrust in the community. The challenge is in educating these workers and ensuring that they read and disseminate messages from a standard text.

- Meeting the high expectations of the community members is also a challenge. Many times the community members do not fully understand that the end of a trial does not mean that the vaccine will be available for immediate use. Thus, innovative ways of sustaining the volunteers’ and communities’ commitment over the long haul need to be explored.

- Resources available for community education are totally inadequate to prepare communities for vaccine research and development. KANCO’s programme for community education is grossly under-funded and they are not able to reach the communities as effectively as they would like to.

- Although WHO/UNAIDS have developed guidelines on HIV preventive vaccine research, attempts at adhering to the guidelines have been constrained by inadequate resources and support. The care and support system in Kenya is terribly overloaded and unable to implement vaccine research guidelines without additional resources.

CONCLUSIONS AND LESSONS LEARNED

- Mobilising the community takes time, and is a slow process that requires serious long-term commitment and strategy, therefore, it is important to use existing networks and structures to distribute messages and train stakeholders over time.

- National mobilization can generate broad support for AIDS vaccine efforts, it’s important to have systems in place to prepare communities beyond those supporting the specific trials.

- Working with the media is critical for the success of mobilisation programmes in this field. Maintaining transparency and hope despite disappointing results, has been one of the biggest challenges.

- Vaccine messages need to be integrated into all messages regarding HIV/AIDS.
PERU

Participating in a CAB – Avoiding misunderstandings and false expectations

Adapted from a story prepared by Manuel Rouillon Insúa, CAB Member, Via Libre

Impacta, Salud y Educación, an NGO dedicated to scientific research, was in charge of conducting a Phase II research study to test an HIV vaccine. This study was sponsored by the HIV Vaccine Trials Network (HVTN), an international collaboration of scientists and educators searching for an effective and safe HIV vaccine. Impacta was the local organisation in charge of the operations, including overall implementation of the trial, preparation of personnel, protocol, the laboratory and, most importantly, the recruitment of volunteers. This process started more than a year before the first volunteer was enrolled. Impacta also dealt with community participation and involvement, capacity building and information sharing.

THE PERU CAB

Impacta created a community advisory board (CAB) – following good research practices – to review protocols, monitor the trial, and help educate the community. In the beginning, 15 people were invited to be part of the CAB, but they only attended the first meeting, perhaps for lack of interest, but also because they did not understand the reason and the importance of being part of a CAB. Given that the concept of a CAB was new in Peru, and to the people at Impacta, it was felt that the functions of the CAB and the importance of its functions were not clearly explained to the participants. Initial invitations were also unrealistic, as many of those invited to participate did not have the time to be involved.

This first effort to create a CAB was not successful, therefore the research team extended an invitation to a second group of individuals. The individuals selected came from NGOs specializing in prevention, as well as a variety of vulnerable groups including people living with HIV/AIDS, bisexuals, the gay and transsexual community and sex workers. The Ministry of Health was represented, as well as the media.

Although this was a very diverse group, there was still a general lack of clarity about the CAB functions and expectations. Most of the members wanted to learn about the process and support the work of the researchers in search of a vaccine, but members of the CAB needed training and capacity building to understand their role, their responsibilities and the expectations of their involvement.

In order to better understand the purpose of the CAB, it was suggested that members of the CAB prepare terms of reference (ToR) to guide our work. We worked on the ToR using the work already underway in Brazil and the United States. Two months later, it was reviewed by Impacta, and a month later it was finalized.

When we first started, we met once a month. We asked the researchers to provide the documentation at least seven days in advance of the meetings so we would have time to review it beforehand and provide comments during our monthly meeting. In the beginning, this process was not very smooth, and sometimes we ended up receiving the documents at the meeting. Of course, our feedback was not very useful, as we did not have time to read all the information in detail. This situation improved as months went by, and we started receiving the documentation well in advance of the meetings, making them more useful and our input more valuable.

In the beginning, we were asked to comment on different educational brochures that had already been printed, so our comments could not be taken into consideration. We documented this issue and communicated with the researchers. We did not want to be seen as just an ‘opinion’ – we wanted to have an impact on the research. This situation illustrates the main challenge we faced in the CAB. We had the expectation that our inputs and recommendations were going to be taken into consideration. Perhaps the problem was in interpreting the role we were asked to play; we provided guidance and advice, but our opinions had little weight.

The misunderstanding about our role created frustration among the members of the CAB, who thought they were going to make decisions regarding the trial. It also created friction with researchers, as we felt they did not appreciate our efforts,
did not see the need for having a CAB, and viewed our efforts as trying to interfere with the research.

Language barriers also presented a challenge. Only those fluent in English were selected to participate in international meetings, and not all the CAB members were able to read the documents written in English. This discouraged those who did not speak English from being fully involved in the CAB, and created tensions among those who spoke English and therefore could participate in all the meetings. We insisted that all members of the CAB had the right to participate in meetings and conferences – not only those who spoke English – and that the organizers needed to include simultaneous translation to allow wider participation.

Travelling to these meetings also became a reward, rather than an opportunity to send the best person for the job. One of the main lessons learned was that people need to be chosen to attend meeting not based on how hard they work, but rather based on their knowledge of the specific issues to be discussed, the group they represent and their ability to commit time to report back to the group. Although alternating people to attend the different meetings served the purpose of increasing participation and involvement, it also hindered efforts of continuity, institutional memory and follow up. We were unable to find a balance between both.

**CONCLUSIONS AND LESSONS LEARNED**

- It is important to have diversity in the CAB. All sectors of society should be represented: people living with HIV/AIDS, members of the most vulnerable groups, the media, universities, the church and other stakeholders involved in HIV/AIDS.

- The CAB needs to be formed before the trial starts, and its members need to be educated as early as possible. They need to understand their role, their responsibilities, the expectations of their involvement and the challenges they will face. They also need to understand issues related to HIV infection, vaccines, research on humans, vulnerability, ethics, human rights, and other issues.

- Language barriers need to be addressed up front to facilitate and encourage ample participation and involvement or all CAB members in the different processes. Materials need to be translated into local languages and international meetings should include interpretation support for those who do not speak English. Language issues should not be a barrier for involvement.

**REPRESENTATION**

Another critical challenge we faced was the conflict between representing the CAB group, the community at large, and our own opinions. We did not have the opportunity to seek the feedback of groups we were representing, so we had to act as individuals, with their best interest in mind. We also signed a confidentiality agreement that we understood, prohibited us from answering questions from our constituency. This in our minds defeated one of the main functions of the CAB, which is to build community trust in the research and the researchers. Later we understood that the purpose of the confidentiality agreement – that all CAB members signed – was not to preclude our interaction with the communities we were representing, but to protect the details of the trial and the confidentiality of the process, particularly regarding the trial participants. This misunderstanding illustrates the need for better and more transparent communication between the researchers, the sponsors and the CAB members.
SOUTH AFRICA

Equal Partnership – Key to Success!

Adapted from a story by Matilda Mogale and Gloria Malinidi

The HIV Vaccine Division (HADV), a division of the Perinatal HIV Research Unit (PHRU) of the University of the Witwatersrand, is situated on the campus of Chris Hani Baragwanath Hospital. Chris Hani Baragwanath Hospital is considered the biggest hospital in the southern hemisphere. It has a capacity of 3,800 beds and is based in Soweto, a vast sprawling urban community of approximately one million people, 15 km northwest of central Johannesburg. Dr. Eftyhia Vardas, a physician and clinical virologist, has directed the HADV group since its inception in 2001.

HADV was initiated with the primary aim of conducting multiple, parallel Phase I and II trials according to Good Clinical Practice (GCP) guidelines as quickly and as efficiently as possible, in order to identify appropriate Phase III vaccine candidates for efficacy testing for South Africa. In addition, this group also aims to develop multi-centred Phase III clinical trial capability both in rural and urban areas of Africa using existing research infrastructure, and to develop the relevant expertise to work with special groups like adolescents for the testing of HIV vaccines.

EDUCATION AND RECRUITMENT

The HADV site has an extremely active Community Education Team that was established almost a year before any HIV vaccine research actually began in the Soweto community. The long lead-in time to discuss and prepare the community for HIV vaccine research was very advantageous since information sharing was not rushed. The Vaccine Discussion Group (VDG) sessions have been designed to cover the basics about vaccines and, in particular, HIV vaccines, how vaccines in general work, the risks and benefits of participating in HIV vaccine research, the rights of a participant and what will happen in case of any adverse event.

The vast majority of potential HIV vaccine trial participants are recruited from the free Voluntary Counselling and Testing (VCT) service attached to the HADV clinic, which sees almost 3,500 individuals per year, over half of whom are HIV-positive (which highlights the pressing need for an effective HIV vaccine for this country). Counsellors that offer pre- and post-test counselling offer HIV-negative clients the opportunity to enter preventative HIV vaccine trials and HIV-positive clients the opportunity to enter therapeutic HIV vaccine trials or other treatment trials being conducted at the PHRU. HIV-positive individuals are also referred to the Wellness Clinic, a clinic run by the PHRU for HIV-positive individuals who are not yet eligible for antiretroviral drugs, according to the national guidelines, to screen and treat them for opportunistic infections.

Individuals who have agreed to participate receive training conducted by the community educators. At all stages it is...
emphasised that participants are free to decide whether they want to participate in the actual HIV vaccine trials, and they only need to make that decision once they have enough information to enable them to make an informed choice. A formal assessment of understanding is conducted for each participant before they are assigned to a particular HIV vaccine trial to ensure that they are comfortable with all the information that has been given to them.

**THE COMMUNITY ADVISORY BOARD**

The Community Advisory Board (CAB) is the "umbilical cord" that connects the researchers and the community. The current Soweto Vaccine CAB is a diverse group of people who volunteer their time to represent the Soweto community. The CAB consists of, among others, representatives from traditional healer organisations, youth groups and women’s groups, priests and nurses. The CAB plays a pivotal role in advising the researchers on all matters concerning the community, specifically about community norms and concerns. The CAB advises on possible areas of support, and makes significant input into aspects of the informed consent documents. The CAB also plays a vital role in informing the community about HIV vaccine research and evaluating the impact of the research in the community. It represents the interests of the community and the rights of individuals, and also provides a supportive environment for those involved in HIV vaccine trials and their families.

The CAB is composed of individuals democratically elected by their constituencies – various community-based and non-governmental-based organisations in Soweto – for a two-year term of office to represent the Soweto community in HIV vaccine research. These individuals are independent volunteers who donate their time to ensure that community needs and concerns are addressed as HIV vaccine trials are conducted in this community.

**BUILDING AWARENESS IN THE COMMUNITY**

International HIV Vaccine Awareness Day, which is celebrated annually around the world, featured an event on 18 May 2005 organized jointly by the HAVD staff and the CAB members. It was a resounding success. There was a float that left from the hospital, comprised of representatives from the fire brigade, the police, HAVD staff and CAB members. As the float drove through Soweto, a loud hailer was used to inform the Soweto community about what the procession was all about. It is a strategy that worked because it had people talking about HIV Vaccine research, and those whose curiosity was aroused followed the procession up to the venue where the final ceremony was to be held. Upon arrival at the venue, some of the CAB members gave talks to the community about HIV Vaccines. The day’s events ended with the Department of Health giving certificates of thanks to past and current HIV vaccine trial participants to signify their contribution to science and to finding a globally effective HIV vaccine.

**Nonhlanhla Zwane** said that as a counsellor, she has told people about safe sex practises, and advised them to know their status. She wanted to practise what she preached. The first time she joined the HIV vaccine clinical trial, Nonhlanhla said that it was very scary, even though the site staff had explained all the steps to her. She was entering into unknown territory, and was scared of the fact that she will have to have her blood drawn more than once. All the fear has been now put behind her because of the information provided by HAVD staff, which empowered her.

"The clinic staff takes good care of us, they do telephonic monitoring, and we have regular follow up visits. They are very supportive because they also give physical and emotional support to us. I am always hoping high; the vaccine is going to work. I have a vision of a world free of HIV/AIDS."

For **Emmanuel Maheso**, introduction into the world of HIV vaccines was through the media. The first HIV vaccine trial participant he ever read about was a priest who was taking part in one of the studies conducted at the HAVD in Soweto. This prompted him to ask for more information and he went to the trial site in Soweto to become a participant. He, like the other trial participants, knows people who are infected and affected and wanted to help them. The vaccine trials were a big challenge.

"The good thing is we were given a lot of information and told we were free to withdraw at any time during the trials. There is a chance for vaccines to work, only if there are people like us who are willing to be a part of the trials. I thought I should join the trials and be part of the answer and solution to the HIV/AIDS problem. It is only a matter of time, we the participants, the community and the scientists will find an effective vaccine."
Other strategies used for community preparedness and recruitment include the following:

**MURAL/WALL ADVERTISING:** A huge mural advertising HIV vaccines and the VCT service is painted on the wall facing the main road outside the hospital. The message is clearly visible to every passing motorist and pedestrian. The wall is also visible from the Soweto taxi rank just opposite the hospital that services the whole of Soweto, the inner city of Johannesburg and the surrounding areas. From this rank, buses depart for most destinations within Southern Africa. All of these commuters can very clearly see the writing on this wall, and many people have said that they came to the HAVD clinic in response to seeing the advert.

**COMMUNITY OUTREACH WORKSHOPS:** HAVD staff have organised workshops with key community leaders (youth organisations, women’s groups, health workers, general practitioners, church groups, police and traditional healers) to spread information and address important issues about HIV vaccines. These workshops are used to fight misleading information generated in the popular media and to demystify the commonly held belief/myth by some individuals that the HIV vaccine can infect them with HIV. This opportunity is also used to counter (a) unrealistic expectations that a preventative vaccine is actually already available, and (b) the notion that practising safe sex is no longer a priority. The message that the HIV vaccine research being conducted is preliminary and that condoms must still be used to prevent HIV infection is strongly emphasized. Many individuals volunteer for the VDG programme of the Pre-screening Protocol at these events.

**MEDIA:** Numerous articles are published about HIV vaccines and HIV vaccine research in the local press, and often the trial site staff are asked for interviews as experts. The site has an excellent relationship with most local papers. Sometimes, trial participants volunteer to be interviewed and this is a tremendously important way to report back to the community about activities taking place at the research site. Radio and television has also been used successfully by the site as an outreach technique. CAB members, trial participants, and HAVD staff have been interviewed on local radio and television stations to spread the word about HIV vaccines.

**PAMPHLETS, FLYERS AND BROCHURES:** Pamphlets have been printed containing basic information about HIV vaccines and vaccine trials. These pamphlets are given out to every client who comes to the clinic and can be taken home and used as a source of information to help couples, families, and partners to discuss HIV vaccine issues and HIV/AIDS in general. These pamphlets have also been distributed to libraries, taxi ranks and bus stops.

**PRINTED T-SHIRTS:** The site has printed T-shirts, which the CAB members and the HAVD staff wear whenever there is an awareness campaign, like World AIDS Day and International HIV Vaccine Awareness Day. The message on these T-shirts was devised by the CAB and creates an impact and a lasting impression on the mind of the reader. It reads: “Joining hands together to find an effective HIV Vaccine.” These T-shirts are also given to trial participants, and to some of the people who attend our events to raise awareness about the HIV Vaccine trials.

**CONCLUSIONS AND LESSONS LEARNED**

- A multi-pronged comprehensive approach towards community mobilization – that includes media, outreach, marketing and training – has proven successful in engaging communities in vaccine trials.
- Giving volunteers a voice to speak about AIDS in their communities and explain the reasons behind their involvement in vaccine research has proven a good strategy to involve more people.
- Forming, strengthening and maintaining relationships between HIV vaccine researchers and the communities they work in are essential to ensure true community participation in HIV vaccine trials.
- True community participation in research involves the creation of transparent systems that enable affected communities to become full collaborative partners in the research process.
- An open dialogue and formation of a formal and representative ‘mediating’ structure, like a Community Advisory Board (CAB) that functions as a conduit between the researchers and communities is a very effective way to ensure that communities and individual research participants are fully informed when making the decision to participate in HIV vaccine research.
THAILAND

Make Ethics Matter

Adapted from a story by Nimit Thien-Udom/Aids Access Foundation

Thailand has been the site of more than 10 AIDS vaccine trials over the past decade. This includes the BMA-Thailand Trial in Bangkok, which involved 2,500 injection drug users, and the ongoing Prime-Boost HIV Vaccine Phase III Trial in Chon Buri and Rayong provinces, which is the world’s largest AIDS vaccine efficacy trial to date with 16,000 volunteers. When HIV vaccine trials started in Thailand, there was not much involvement of communities, except for being ‘trial subjects.’ Three major reasons were identified: (1) AIDS vaccine researchers and their sponsors have kept a low profile with limited publicity via the mass media or other channels; (2) few educational materials to raise public awareness were produced and disseminated; and (3) the process of community participation was not institutionalized.

Looking back at the first decade of the AIDS epidemic in Thailand, the priority was to reduce the incidence rate by empowering people to know about HIV/AIDS and their prevention options, and improve access to care and treatment for PLHIV. Most NGOs and the community at large were involved in the former, with only a few interested in the latter. Most of us then saw little prospect for a safe, efficacious and accessible AIDS vaccine for Thailand in the foreseeable future.

PARTNERSHIPS

Beginning in 2002, ACCESS, Médecins sans Frontières (MSF) and the Thailand Network of People Living with HIV/AIDS (TNP+) joined together to serve as the focal point to coordinate members of the Thai NGO Coalition on AIDS (TNCA) in advocating the inclusion of care and treatment, including ARVs for persons living with HIV/AIDS into the National Health Insurance System (NHIS). This effort opened our eyes to the subject of the rights of persons living with HIV/AIDS who were trial subjects in ARVs trials. Many presented drug resistance and were left with limited ARV options in Thailand. The drugs which suited them were imported and expensive, and not covered by the national health insurance system.

In addition to these three organisations, the Centre for AIDS Rights (CAR), which has been providing legal aid to those affected by HIV/AIDS for several years, became aware of human trials of ARVs and AIDS vaccines taking place in Thailand. The key question was what and how ‘the facts’ were provided by researchers in the recruitment and retention of potential trial subjects.

We began by learning more about the issues from the scientific presentations by Thai researchers and their foreign colleagues at international conferences overseas. Our foreign NGO colleagues also helped us keep track, by raising questions about the trials in Thailand. For example, they helped us formulate questions and raise concerns around the ethics of the BMA-Thailand Trial, which was implemented through the Bangkok Metropolitan Administration’s drug rehabilitation centres using its patients as trial subjects. Several foreign organisations had raised the issue of whether the processes of recruitment, counselling, vaccination and retention could be ethical given the trial subjects’ dependency on the drug rehabilitation centres’ methadone treatment. They also asked if these patients could really be free of coercion to make their own decision whether or not to join. Thai NGOs joined forces with their foreign counterparts and began exploring the facts of the trial.

The controversy over the conduct of the trial led to the appointment of independent external monitors, which provided the first official entry point for Thai NGOs to get involved and learn first hand about the process of AIDS vaccine research.

The Project for Appropriate Technology in Health (PATH), CAR and ACCESS decided to join efforts to motivate the involvement of TNCA members. A series of three workshops were held to explain the scientific facts of AIDS vaccine research, trial processes including protocol submission and review and, finally, community participation. The key objective was to enable these members to prepare their respective community to be able to voice their stance should AIDS vaccine researchers visit them in the future. Special attention was given to issues...
such as if a trial volunteer could be infected by the candidate vaccine and the possibility of a false sense of security by trial participants, generated by immunization.

PATH, ACCESS and CAR then focused on the Prime-Boost Trial, which was being implemented by the Thai Department of Disease Control, the Thai Ministry of Public Health with funding from the US Military HIV Research Programme and the US National Institute of Allergy and Infectious Diseases (NIAID) of the US National Institutes of Health (NIH). We held several rounds of talks with the researchers urging them to open up and allow the process of community participation, other than as trial subjects. This is because in the early stage of preparations, the researchers had planned to do everything by themselves. The community was on the receiving end, their role limited to receiving whatever information the researchers chose to publicize and to serving as trial subjects. There was no way for the community to voice their opinion and contribute to the implementation of the trial.

COMMUNITY EDUCATORS PROJECT

After several rounds of talks, a Community Educators Project was conceptualized by ACCESS and CAR, while the Prime-Boost Trial opted to use ‘Village Health Volunteers’ as the primary engine to publicize the trial and recruit subjects. The project’s primary objective was to address the lack of awareness of HIV/AIDS and AIDS vaccine research in the two provinces which would serve as the study site for the Prime-Boost Trial. We believed that for the community to play a meaningful part in any project, it must first understand the problem and also know its role and responsibility in the solution.

The project was officially launched at the end of 2003, and has been implemented jointly by ACCESS, CAR and the Prime-Boost Trial. A team of community educators, who are locals of the Chon Buri and Rayong provinces, was formed. For nearly two years, these community educators have hosted small group empowerment forums which were specifically designed to stimulate dialogue and identify potential leaders to form a Community Advisory Board (CAB). Though funded by the Prime-Boost Trial, and though several activities are jointly implemented, we are independent from it. In addition to our work to empower the community, we also monitor the conduct of the trial and serve as the link between the communities in Chon Buri and Rayong and the researchers of the Prime-Boost Trial.

BOX 2

THE AUSTRALIAN-THAI HIV VACCINE CONSORTIUM

The ATHVC has employed a novel model of community involvement in the development and clinical evaluation of candidate vaccines. The AFAO, the national non-government agency representing the community-based response to HIV/AIDS in Australia, is an equal partner in the Consortium. The AFAO’s role is to provide the community perspective at all stages of the project’s development, from preclinical and clinical development through to planning a commercialisation strategy. This includes active participation in clinical trial design and ensuring that the risk of adverse consequences for both volunteers and communities is understood and minimised.

The ATHVC is made up of an equal partnership of the following members:
- University of New South Wales (incorporating National Centre in HIV Epidemiology and Clinical Research, National Centre in HIV Social Research, Sydney Children’s Hospital)
- Australian Federation of AIDS Organisations
- Australian National University (John Curtin School of Medical Research)
- Commonwealth Scientific and Industrial Research Organisation – CSIRO (Australia)
- University of Melbourne
- University of Newcastle
- Thai Red Cross Society

Building on our experience with community engagement from the above project, both ACCESS and CAR have had the chance to work with the Australian Federation of AIDS Organisations (AFAO) in planning for a Phase I/II trial in Bangkok of an Australian-designed prime-boost vaccine by the Australian-Thai HIV Vaccine Consortium (see box 2).

This Australian-Thai trial is unprecedented in Thailand for its community engagement policy. A team from AFAO visited Thailand several times to identify organisations and individuals to work in community engagement. Funds were also provided for activities and material production. Unfortunately, after one year, the Phase I trial in Sydney did not generate the expected immune response and the trial’s sponsors have withdrawn their support, including that allocated to the community engagement efforts in Thailand. However, ACCESS and CAR are continuing their efforts to empower communities in Bangkok and are seeking other sources of funding.
One starting point to overcome distrust as a result of the different challenges that make it difficult to work together has been the common wish of all concerned to have an AIDS vaccine for Thailand. However, from our perspective this wish has to be realized by implementing and respecting ethical principles and community participation in the design, implementation and monitoring of the trial. Regular dialogue will lead to partnership in the future.

**CONCLUSIONS AND LESSONS LEARNED**

- Alliances and collaboration with international organisations are needed to strengthen a national response (agenda setting, highlight priority issues, technical support and transfer of knowledge and skills).

- Advocacy is fundamental to ensure researchers are appropriately involving communities – which leads to changes in the research landscape for community participation.

- Suspicion is unavoidable; it is important to be proactive and prepare communities before and during the trial.

- There are three key elements for the success of community preparedness for AIDS vaccine trials: HIV/AIDS awareness, ability to assess one’s own risk of infection, and ability to identify options for one’s own protection against infection. Clear and complete information on the candidate vaccine, the trial process, and participants’ rights must be disseminated to the public. The design must include participatory process of all concerned.

- Despite initial difficulties, partnerships between researchers and communities can often be built to overcome some of the hurdles identified earlier on.
THE FIRST TRIAL

In February 1999, Paul Wetaka, a Ugandan soldier, became one of the first persons to be injected with an experimental HIV vaccine in the African continent. Wetaka was one of the 40 volunteers enrolled for the Phase I trial of the ALVAC vCP205 candidate vaccine in Kampala. At that time, it required great courage to take the injections. “We heard negative rumours that the vaccine was meant to wipe out the African race and that it would affect our fertility. But I went through the trial and nothing went wrong with me,” he recalls.

Initially, there was no Community Advisory Board (CAB). Most of the 40 volunteers were drawn from a cohort of soldiers who had expressed readiness to avail themselves for a vaccine trial. The cohort received detailed education and counselling about HIV infection and vaccine research before the trial began. The researchers then held three open workshops to educate scientists, policy makers, community representatives and the media about the trial and try to build consensus.

However, this was not enough to prevent suspicion, hostile propaganda and stigma against the vaccine trial. These problems were reported by the principal investigator, Prof. Roy Mugerwa and his colleagues in the British Medical Journal. Many laypersons thought the volunteers would be deliberately exposed to HIV in order to test the vaccine. Some politicians actively campaigned against the trial, arguing that Ugandans should not be used as guinea pigs. The trial was delayed by one year as the investigators engaged the public, policy makers and the media in dialogue to clear the misconceptions and allay fears. The planned vaccine trial was debated in public fora, Parliament and Cabinet, before the President approved it.

Midway through the trial, a CAB was formed, recalls Emmanuel Mugisha, one of the founders. It had 20 members, including opinion leaders, nurses, a volunteer, a policeman, a prisons officer and representatives from some organisations involved in HIV/AIDS activities. Ms Dorothy Akurut, who facilitated the CAB activities while she was an employee of the Joint Clinical Research Centre, where the trial was conducted, says: “They did a good job to keep the volunteers on and reassuring them.” Whenever volunteers were not feeling well, they thought it might be the effect of the candidate vaccine, and they would contact the CAB, who would then counsel them and liaise with the scientists to investigate it. When faced with myths, volunteers contacted CAB members, who sought answers from the scientists.

However, the CAB did not have the opportunity to achieve all that it was capable of doing. Preparations for the ALVAC trial had been done for several years without a CAB. The trial itself had already progressed for about a year by the time the CAB was formed, so the members were left with just less than a year to make an impact in a trial they had not participated in planning.

This was the first HIV vaccine trial on the African continent. After Phase I, there was not further testing of this product because the vaccine was not sufficiently immunogenic. However, even a failed experiment is useful for subsequent vaccine trials. The ALVAC investigators recommended that “doctors planning trials of HIV vaccines need to interact closely with representatives from the communities involved, the media, volunteers and other stakeholders.”

THE SECOND TRIAL

The second HIV vaccine trial in Uganda was Phase I of the DNA-MVA candidate vaccine sponsored by the International AIDS Vaccine Initiative (IAVI), between February 2003 and February 2005. Based on lessons learned from the ALVAC trial, IAVI formed a CAB during the planning phase. The CAB was chaired by a Catholic priest, Rev. Fr. Christopher Kiwanuka, Parish Priest of the Entebbe Catholic Parish, located near the trial site. Day after day, Fr. Kiwanuka is called to pray at the funeral of someone who has died of AIDS. This motivates him to participate in efforts to find a vaccine. His parishioners respect and trust him, which makes it easy to
Kaleebu observes that, being neutral, CAB members are more trusted than scientists. His concern is that the value added by CABs in Uganda has not been measured scientifically. “They have been helping us by linking us with the communities and telling us what the communities think, but we don’t have documentation in a scientific form,” says Kaleebu.

Emmanuel Mugisha, the IAVI official who facilitates the CAB, agrees that a study needs to be carried out qualitatively and quantitatively to document the usefulness of CABs in Uganda. But he cautions that some of the effects of a social intervention may not be measurable quantitatively. “When I greet you it adds value, but how do you measure the effects of that greeting?” he says. “They (CAB) have achieved lots of small things that are difficult to measure.”

Mugisha suggests that CABs should be formalised and harmonised. At the moment, there are two vaccine trial CABs in Uganda: the IAVI one and another trial that began recently through collaboration between Makerere University in Kampala and the Johns Hopkins University in the US. Each trial has its own guidelines. Mugisha suggests that CAB guidelines be harmonised at national level and that CABs should have a way of sharing experiences regularly. Efforts to facilitate the networking of Ugandan CABs and help them share experiences are already underway: a national meeting and the formation of a CAB network happened in November 2005.

Ideally the CAB, being a neutral body, is not supposed to be seen as part of the sponsor. If you keep them too close, they might lose neutrality. But if they are kept aloof, they might lose steam, Mugisha fears. Finding the right balance is important. Since serving on the CAB is a voluntary activity, the cost of maintaining a CAB is low. IAVI pays for the meeting venue and CAB members’ transport to the meetings. Initially the meetings took place monthly but, as the intensity of activities reduced, they started meeting less frequently.

An important lesson cited by the CAB members is that convincing the communities requires patience and good explanation. It takes time to develop trust. Most importantly, investigators need to involve the community early enough. “Researchers cannot get a vaccine without the community, and the community cannot get a vaccine without researchers. We must all be actively involved,” says Fr. Kiwanuka.
CONCLUSIONS AND LESSONS LEARNED

- It is necessary to have balance on the level of involvement/collaboration between the CAB and the researchers to ensure independence of the CAB.

- CAB members are leaders in their respective communities and therefore have the trust, respect and confidence of the community members, built overtime. They are directly linked to those most affected.

- The success of the [second] trial shows the importance of a pro-active community approach instead of a reactive one (which was the approach in the first trial).

- A study needs to be carried out qualitatively and quantitatively to document the usefulness of CABs. However, some of the effects of a social intervention may not be measurable quantitatively.

- CAB guidelines should be harmonised at national level and that CABs should have a way of sharing experiences regularly.

COVER FROM A UGANDAN MAGAZINE (SEPTEMBER 1996) THREE YEARS BEFORE THE LAUNCH OF AFRICA’S FIRST AIDS VACCINE TRIAL. AN EXAMPLE THAT HIGHLIGHTS THE NEED TO DEBUNK MYTHS AND MISUNDERSTANDINGS.

This section discusses the key lessons learned and main recommendations for community involvement in current and future HIV vaccine trials. The analysis in the section is based on case studies presented in this publication.

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.

Each of these elements is described below. The section concludes with a discussion of the challenges to successful community involvement.
1.

Education and Capacity Building for and by Community Leaders

In countries where little HIV vaccine research has been conducted, or where organised 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.

Capacity building can sometimes take the form of training-of-trainers sessions (see box 3), 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 HIV/AIDS already have existing networks of partner organizations and constituents, NGOs 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.

Recommendation

- Researchers and others involved in AIDS 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.

---

**BOX 3**

**MAKING IT WORK**

- In Thailand, a series of three workshops for NGOs were organised 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 organisations (including NGOs and FBOs) as part of its Expanded Community Outreach programme.
2. Awareness and education of potential trial participants

Because of the need to recruit large numbers of people for most HIV vaccine trials, identifying appropriate groups, raising awareness and educating potential trial participants and communities can be a daunting challenge. However, as case studies in this report have indicated, a number of strategies have been successful in raising awareness and engaging communities to increase HIV vaccine literacy.

One example of an awareness initiative undertaken in countries included in this survey 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 in countries included in this survey 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. (see box 4)

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

Experiences in countries involved in this survey have taught us that educational initiatives are most successful when:

- the initiatives are conducted well in advance of the scheduled start of the trials;
- the initiatives include complete information on candidate vaccines, trial processes and participants’ rights;
- the initiatives include information on issues associated with HIV vaccine research generally, including “after-trial” issues, such as patents, who can access the vaccines, and how the vaccines will be delivered;
- workshops and public meetings involve multiple sessions, spread out over time;
- trial volunteers are given an opportunity to speak about why they decided to get involved;
- existing networks and structures are used as vehicles for the educational initiatives;
- information sharing approach and educational materials are adapted to local cultures;
- educational material simplify the complex scientific language related to vaccines; and
- an assessment is conducted after the initiative to see if it was effective.

Lessons learned from the educational initiatives conducted in countries surveyed include:

- 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/AIDS messages (see box 5).
- Multi-pronged approaches to awareness and education are very helpful in engaging communities in the trials.

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

In some instances, educational initiatives may be combined with attempts to directly recruit volunteers for the trials.

Recommendation

Researchers, NGOs and other stakeholders should ensure that broad-based and targeted awareness and educational initiatives are undertaken in communities where HIV vaccine trials are planned. 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; and
• be monitored and evaluated to determine effectiveness.

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).

A. Community Advisory Boards (CABs)

As community representatives in South Africa have learned, “[t]he CAB is the ‘umbilical cord’ that connects the researchers to the community.” 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.17

Forming, strengthening and maintaining good relationships between the HIV vaccine researchers and the community is essential to ensure genuine community participation.

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. The expertise of CAB members about what may or may not be appropriate in a particular context is instrumental in developing strategies to ensure that research is done in a manner than is appropriate for the community in which it is conducted.18

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);
Activists in Brazil stress the importance of ensuring that activities related to HIV vaccine research and development are not divorced from other areas of HIV/AIDS work. Some of the advantages of this approach are that:

• people living with HIV/AIDS can become vaccine activists;
• it reinforces the message that prevention and treatment are part of a continuum;
• it highlights the fact that issues like the right to health apply equally to vaccines, other prevention measures and treatment; and
• it makes it easier to ensure that issues concerning HIV vaccine research are discussed at national and regional HIV/AIDS meetings.

Activists in Brazil report that community involvement in HIV vaccine development leads to greater involvement in HIV/AIDS policy making. The same mobilization that earned NGOs a seat on the Vaccine Committee later opened the door for other formal links with the National AIDS Programme and other governmental bodies dealing with AIDS.

As leaders in their respective communities, CAB members usually have the respect and confidence of community members (see box 6) and therefore the local community feels more at ease to be involved in efforts lead by their own peers.

The experiences of the countries involved in this survey 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;
• membership on the CAB reflects the diversity of the community;
• the members of the CABs are appointed through a transparent process;
• members are selected based on their background and commitment and not solely on their knowledge of HIV vaccine issues;
• members are clear from the outset about their roles and responsibilities;
• language issues are addressed up front; and
• the CAB has support from the researchers to perform its functions.

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.

B. 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 (see box 7) 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. As public interest groups, NGOs have a stake in how vaccine research is conducted and that mechanisms are in place to ensure that research happens swiftly and with the highest ethical standards.

A. Monitoring

HIV/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 (see below).

B. 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, as highlighted in the Brazilian case study.

When HIV vaccine trials started in Thailand, community involvement in the trials was minimal. The community was on the receiving end, their role limited to accepting whatever information researchers made available. Several Thai NGOs urged researchers to open up the process (see box 8) and allow for a more meaningful involvement of the community. As a result of their efforts, a Community Educators Project was established, which aimed to address the lack of awareness around HIV/AIDS and AIDS vaccine research in the two provinces which would serve as the study sites for the trial.

In Brazil, HIV/AIDS NGOs challenged what they considered to be unethical practices by HIV treatment researchers (see Brazilian story), 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.

C. 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, community-based 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.

**Recommendation**

- 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.

- 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.
5. Ongoing Challenges

A. 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 HIV/AIDS issues alike. In countries included in this survey, common myths included 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.
- 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.19

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 ‘mobilisers’ 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.

B. 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.

C. 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.
NOTES

5. World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. It was first adopted in 1964 and has been amended five times since, most recently in 2000
7. The Nuremberg Code is a set of principles for human experimentation set as a result of the Nuremberg trials at the end of the Second World War. Specifically, they were in response to the inhumane Nazi human experimentation carried out during the war by individuals such as Dr. Josef Mengele. The Nuremberg code includes such principles as informed consent and absence of coercion; properly formulated scientific experimentation; and beneficence towards experiment participants.
8. The text has been updated for this publication. An older version by the same author was published in The Hindustan Times, November 26, 2003.
9. Phase IV trials are normally conducted after a drug or vaccine is licensed for sale.
10. The trial took place in the city of Lima, Peru. This Phase II clinical trial was oriented to measure the safety and the immune response to a combination vaccine that could prevent HIV infection through sexual intercourse. This study used 40 volunteers with low risk of infection, eight of them women.
11. BMA-Thailand trial was Thailand’s first efficacy trial of a preventive AIDS vaccine, involving over 2,500 injection drug users. It was sponsored by the vaccine manufacturer, VaxGen Inc. and the US Centers for Disease Control, and implemented by the Bangkok Metropolitan Administration (BMA) and the Faculty of Tropical Medicine, Mahidol University.
12. The Prime-Boost Trial is the world’s largest efficacy trial of an AIDS vaccine, involving 16,000 volunteers. It is sponsored by the US government, and implemented by the Ministry of Public Health, the Faculty of Tropical Medicine, Mahidol University, and the Armed Forces Research Institute of Medical Sciences (Thai and US components).
13. Incidence peaked at over 120,000 new infections per year in early 1990s.
14. TNP+ is an umbrella organisation of NGOs and associations of persons living with HIV/AIDS nationwide.
15. TNCA is a national umbrella organisation of NGOs, CBOs, and groupings of non-profit organisations working in AIDS nationwide.
16. Village Health Volunteers is an old infrastructure of the Ministry of the Ministry of Public Health, set up three decades ago. The main objective was to enlist villagers to volunteer their time free of charge to help understaffed health personnel provide primary health care, monitor health situation and publicize prevention measures in their villages, in exchange of free medical care at state-owned medical institutions. Though village health volunteers are “ordinary villagers” who were trained by health personnel, they have a special standing in their community because of their better knowledge of health care, their voluntarism to help the community, and especially their connection to the government. There are about 13,000 registered village health volunteers in Chon Buri and Rayong, though only 30-40 percent remain active.
18. Ibid
For more information:
AIDS Vaccine Handbook (http://www.avac.org/primer2.htm), especially:
• Why We Need Vaccine Activism, Still
• Being a Trial Volunteer: What Happens?
• Community Advisory Boards
• Community Education: Working Together
• Ensuring Community Participation and Readiness: A Conversation with Janet Fröhlich
• Vaccine Trials: Leaving Communities Better Off
• HIV Vaccine Trials in Uganda: Personal Experience as an Investigator
• Facing Failure on the Way Towards Success: Lessons Learned from the VaxGen Trial
• Testing Vaccines in Injecting Drug Users: VaxGen’s Efficacy Trial in Thailand
• Community Matters: (Re)-defining Our Advocacy
• From Trial Volunteer to Vaccine Advocate
• Speed and Equity: Why Political Leadership is Important
• Ensuring Rapid Global Access to AIDS Vaccines
• Terms of Engagement: How Communities Helped Shape Brazil’s AIDS Vaccine Agenda

AIDS Vaccine Clearinghouse, especially the section on Community Involvement.
http://www.aidsvaccineclearinghouse.org/involvement.htm

“Community Involvement in International Research – Lessons learned from the HIV Prevention Trials Network (HPTN)”. http://www.aidsvaccineclearinghouse.org/pdf/LessonsLearnedHPTN.pdf

Developing Vaccines for HIV and AIDS: an introduction for Community groups. ICASO.


Vaccine Literacy Toolkit: Core Content a comprehensive source of information on AIDS vaccines. IAVI. http://www.iavi.org/viewpage.cfm?aid=228


Joint Advocacy on HIV/AIDS Microbicides, Treatment and Vaccines, the Canadian HIV/AIDS Legal Network (www.aidslaw.org)