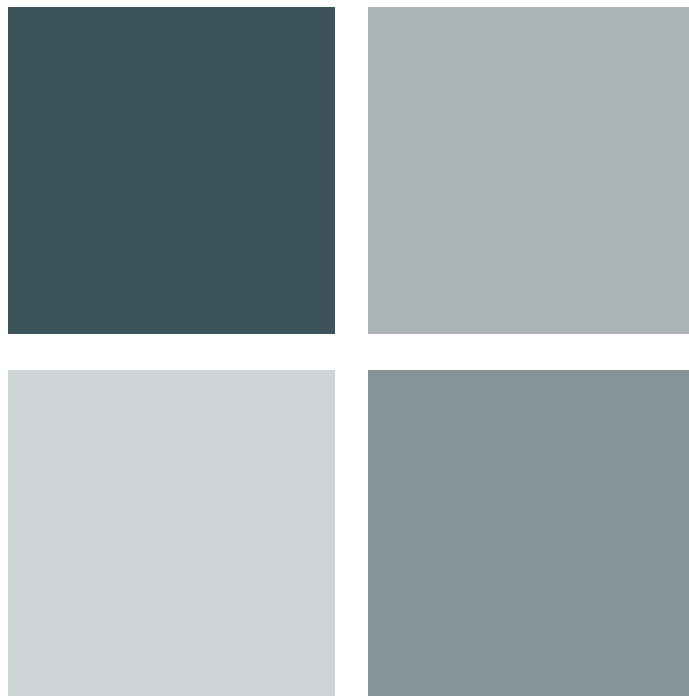


Lessons Learned from Kampala, Uganda



MU-JHU Research Collaboration

Makerere University

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U.S. Partner Institution	Johns Hopkins University School of Medicine
Study Populations	New mothers living with HIV, infants born to women living with HIV-positive pregnant women
Key Topics	CAB training, dispelling rumors in the community, male involvement, communication between CAB members and researchers

Introduction

Uganda is located in eastern sub-Saharan Africa and has a population of approximately 27 million people. The HIV prevalence rate for adults aged 15 to 49 is approximately 4.1 percent, which means that about 450,000 Ugandans are living with HIV, including 270,000 women. An additional 80,000 children under the age of 15 are infected with the virus. Over two million Ugandans have been infected with HIV since 1982 and close to one million have died from the disease. Recent studies show that Ugandan women aged 15 to 19 are five times more likely to be HIV-infected than men in the same age group. It is estimated that more than 18,000 children are infected with HIV annually through mother-to-child transmission, which is largely responsible for the infection of children under 15 (Policy guidelines on feeding of infants and young children in the context of HIV/AIDS, 2001; UNAIDS 2000; UNAIDS 2004).

The HIV Prevention Trials Network (HPTN) Unit in Uganda is Makerere University (MU), which collaborates with Johns Hopkins University (JHU), located in Baltimore, USA.

HPTN Research Studies in Uganda

The HIVNET-012 research study sought to determine the effectiveness of oral AZT and nevirapine in preventing mother-to-child HIV transmission. It was conducted at the Mulago National Referral and Teaching Hospital from 1997 to 2004 in one of Kampala's densely populated areas with low- and middle-income urban dwellers. Preliminary results of the study showed that the intervention reduced transmission among breastfeeding women in Uganda by 47 percent, and this regimen has become the standard of care in many resource-poor countries (Guay et al. 1999). See Table 3 for more information on HIVNET 012, as well as the other two HPTN studies to be carried out in Uganda (027 and 046).

Table 3. HPTN Research Studies in Uganda			
Study #	Protocol and Purpose	Study Population in Uganda	Other Sites
HIVNET 012	<p>Phase IIB trial to determine the efficacy of oral AZT and nevirapine for the prevention of vertical transmission of HIV-1 infection in pregnant Ugandan women and their neonates.</p> <p>The overall goal of the study was to identify a safe and cost-effective means of preventing mother-to-infant HIV transmission that would be applicable and affordable in resource-limited settings.</p>	1,500 HIV-1-infected women and their infants.	N/A
HPTN 027	<p>Phase I study to evaluate the safety and immunogenicity of a preventive vaccine against HIV-1 in infants born to HIV-1-infected women in Uganda.</p> <p>The general clinical approach is to identify a safe, simple, cost-efficient intervention to prevent mother-to-infant HIV transmission while allowing for breastfeeding.</p>	50 infants born to HIV-1-infected mothers.	N/A
HPTN 046	<p>Phase III trial to determine the efficacy and safety of an extended regimen of nevirapine in infants born to HIV-infected women to prevent vertical HIV transmission during breastfeeding.</p> <p>Primary objectives: 1) to compare the rate of HIV-1 infection at six months in infants determined to be HIV-uninfected at birth in each arm (nevirapine vs. placebo); 2) to evaluate and compare the safety and tolerance in infants in each arm.</p>	1,576 HIV-1-infected women and their breastfeeding infants.	South Africa, Tanzania, Zimbabwe

Community Advisory Board

Establishment

At the beginning of the study in 1997, the principal investigators and staff of the MU-JHU research team in Kampala generated a list of communities and institutions from which to identify potential community advisory board (CAB) members. These included AIDS organizations and institutions of higher learning, religious institutions and media. The research team contacted leaders in these organizations individually and provided them with guidelines to help identify potential CAB members within their institutions. Desired CAB member qualities included:

- Willingness to participate in CAB activities voluntarily
- Willingness to talk about HIV/AIDS
- Ability to represent their community in a culturally sensitive and self-motivated manner

Members

Ten CAB members were initially identified and trained. The current CAB consists of 12 members, including church, media, and women's leaders, people living with HIV, study participants, and people working with HIV/AIDS organizations. Since the CAB's inception in 1998, some members have left due to new jobs, time commitments or death, and new CAB members were recruited to replace them. The current ratio of direct to indirect stakeholders stands at 1:4, with an equal number of men and women.

Training

Members of the Uganda CAB attend an annual three-day training and orientation workshop with the principal investigators of the HPTN research studies. Most CAB members come to the studies with minimal understanding of clinical research. Training topics specific to clinical research include the following:

- Protocols and how to review them
- Informed consent
- Placebos
- Randomization
- Blind studies
- General HIV/AIDS information
- Prevention of mother-to-child transmission of HIV
- Voluntary counseling and testing for HIV
- Infant feeding
- HIV stigma and discrimination
- Male involvement
- Research ethics

Additional topics discussed during training include the HPTN structure, CAB roles and representation in research, CAB by-laws, the role of the local institutional regulatory board, psychosocial group dynamics, community education and mobilization, community involvement site updates, and work plans.

These annual training workshops are conducted by community staff members, principal investigators, and identified experts. Training has served as an important first step in bridging the gap between research and the community. Community advisory board members are able to spend time with researchers, ask them questions, share their concerns, and understand the researchers' objectives and the benefits for the community. Most training sessions are characterized by questions, discussions and learning on both sides. The basic concepts of research, such as placebos, protocols and benefits, are the most commonly queried and discussed topics. A continuing challenge for investigators and trainers is to develop ways to present these complex ideas and scientific terms in simple language that CAB members can understand and present to their communities.

At a typical training workshop, principal investigators and site staff update the CAB on implementation activities linked to prevention of mother-to-child HIV transmission, including clinic-based routine confidential counseling and voluntary testing; male partner involvement in reproductive health and associated problems; issues related to discordant couples; and how the CAB can support mother-to-child transmission prevention activities. Typical CAB member queries include more information on the side effects of nevirapine, the benefits for study participants, nevirapine doses for pregnant women, and the effectiveness of mother and baby dosages and repeated dosages for subsequent pregnancies.

Community advisory board members also receive training based on Family Health International's *Research Ethics Training Curriculum for Community Representatives*. The training focuses on respect, beneficence, and justice as the three core values in community-based clinical research.

Two or three CAB members have attended the annual HPTN meeting every year since 2001. These meetings enable the Uganda CAB to learn more about clinical HIV prevention trials at other international HPTN sites, interact with a cross-section of CABs in other countries, and share experiences and approaches on how to involve communities in HIV research.

Other capacity-building efforts for the CAB have included an exchange visit to an institution conducting similar clinical research in Uganda. The experiences from these training and orientation workshops are being used to develop a comprehensive package for training future CABs in Uganda.

Community Advisory Board Activities

The CAB tries to meet monthly and averages nine meetings per year. Completed CAB activities include:

- Writing and approving the CAB's mission statement and by-laws
- Reviewing and approving CAB brochures, confidentiality statements, and informed consent statements for the study protocols
- Helping design recruitment materials for study participants
- Developing plans for retaining study participants
- Helping create community messages on prevention of mother-to-child HIV transmission
- Working with research staff to understand key community concerns that need to be addressed, such as male partner involvement, couples counseling and testing, disclosure of HIV test results, and postnatal follow-up

The CAB played a vital role in reviewing informed consent statements. When translating the forms back into English, CAB members refined the language to improve the informed consent form. The CAB has also recently revised its by-laws.

The CAB has held 12 community outreach meetings in the past three years, three of which specifically targeted men in an effort to involve men and increase the number of women who participate in the mother-to-child HIV transmission prevention program. Women who fail to participate usually want to seek the approval of their partners on whether to be tested. Unlike typical HIV/AIDS community education events, CAB-hosted community meetings target small, homogenous groups

of 20 to 30 people of childbearing age and address practical issues related to the mother-to-child HIV transmission prevention program. Important issues for expectant couples discussed at CAB-hosted community outreach meetings have included the following:

- Reasons why couples do not disclose their HIV status to one another
- Why expectant couples should go for counseling and testing before the birth of their child
- Why so few mothers return for postnatal checkups

The CAB also provides feedback to principal investigators about how the community feels about the research and about possible problem issues, such as the community's confusion about research and whether treatment was a treatment for HIV rather than a prophylaxis. The CAB members discovered these problems during community education events and meetings and compiled a list of frequently asked questions that revealed the misconceptions and misinformation.

The Uganda HPTN CAB is also part of the effort to create a national network with other CABs that are doing similar activities in the country. The first CAB national network forum is planned for 2006 and will bring together CAB members from six research sites around Uganda.

Challenges

The Uganda HPTN CAB has faced a number of challenges as the studies moved forward, including the following.

CAB members' performance was often hampered by external roles and responsibilities

Several CAB members were burdened with too many other commitments that prevented them from attending scheduled meetings or devoting enough time to fulfilling their CAB roles. Meetings are now held on days that CAB members determine are convenient for everyone. As an incentive to fulfill their duties, CAB members are reimbursed for transportation costs and meals. Time continues to be a problem for several high-profile members of the CAB, but the principal investigators believe that their expertise and reputation in the community outweigh their limited involvement.

Low turnout among men at community meetings

During the initial CAB meetings, CAB members noticed that few men were attending. When the CAB and community educators later held community information meetings, the same problem occurred. Community advisory board members and research staff recommended creating a male access clinic with evening hours to involve more men in treatment. The male access clinic is now being implemented to provide reproductive health services with a special focus on prevention of mother-to-child HIV transmission for men and their wives. Men now receive information about preventing mother-to-child HIV transmission; infant feeding; family planning and condom use; treatment of sexually transmitted infections during pregnancy; nutrition for pregnant women; sexual issues during pregnancy and after delivery; preparation for safe delivery and prevention of complications during pregnancy, delivery, and postdelivery.

Low response from men

The CAB is now mobilizing men by reaching out to organized groups of men such as mechanics and factory workers, and by using male leaders. So far turnout for male outreach events has been promising. The board plans to evaluate its male involvement strategy.

Community advisory board members and their communities were not well informed about research and protection of human subjects

To better educate CAB members, investigators held annual training and orientation workshops and increased the number of regularly scheduled meetings between the principal investigators and CAB members. The investigators developed short, simple PowerPoint presentations on research concepts and specific research protocols to present to CAB members. These presentations were occasionally repeated as a refresher for CAB members, which helped them retain the information and present it to their communities.

Inactive periods between protocols and the CAB's high expectations sometimes frustrated CAB members

Motivated CAB members were sometimes frustrated by the lack of CAB activities during periods when no protocols were being actively researched. Some CAB members also wanted to be more involved in research decision-making. To maintain momentum in the absence of active protocols, several guest speakers were invited to present on issues such as infant feeding, follow-up of study participants, serodiscordant couples, and coping strategies and treatment for AIDS.

Some CAB members felt that they had very limited input into the studies beyond reviewing documents and brochures

Community advisory board members felt that their input into informed consent documents and other materials should be acknowledged so that study participants would know that research discussion with the community had taken place. The CAB also requested periodic feedback from the researchers of ongoing studies. Principal investigators have now made an effort to acknowledge community input and follow up on some CAB suggestions.

Some CAB members lacked the mobilization and networking skills to successfully reach out to and advocate for their communities

Community advisory board orientation training now includes information for CAB members on how they can learn more about their communities, as well as activities to help them reach their communities, suggested channels of communication, and ways to assess the communities' overall involvement in the research.

Lessons Learned

Members of the Uganda CAB have made steady progress in their knowledge and ability to represent their communities and assist the research teams. Important lessons learned include the following.

Community representatives need adequate training to make sure they are well informed about research concepts and protection of human participants and are able to relay this information to their communities

In Uganda, CAB members benefit from annual training and orientation workshops as well as meeting regularly with principal investigators to learn more about research concepts, including protection of human participants. Keeping the training simple and easy to understand (for example, by using simplified PowerPoint presentations) and offering refresher training made it possible for CAB members to explain research concepts to their constituents.

Community misperceptions about the research and the CAB members' roles must be addressed before research can move forward

The Uganda CAB had to first address and dispel the community's suspicions about the research, such as rumors that the research was secretly intended to spread the virus. Community advisory members also had to work hard to remove the perception that they were merely employees and advocates for the researchers. Through community meetings, CAB members were able to gain the trust of the community and demonstrate that their role was to advocate for community concerns.

Community advisory board members can help lessen the stigma that prevents people from accessing information and effective treatment

Through community meetings and advocacy, CAB members can sensitize their communities to the importance and need for HIV prevention, HIV counseling and testing, and programs to prevent mother-to-child HIV transmission. In Uganda, the CAB was also instrumental in initiating the male access clinic, which has encouraged men and their partners to seek testing and treatment.

Community advisory board members need adequate training on how to successfully reach out to and advocate for their communities

Several Uganda CAB members were dedicated to their mission but lacked the mobilization and networking skills to conduct successful outreach and advocate for their communities. Community advisory boards should adjust their criteria for CAB member selection so that members have these skills, or they must build the capacity of current members through training and other activities.

A well-established CAB can serve the same function for other, similar studies and/or provide useful guidance and experiences for new CABs in the country

The CAB originally created for the HIVNET 012 study also helped mobilize the community and served as a CAB for a clinical HIV vaccine trial in a separate collaboration between Makerere/Johns Hopkins University and Walter Reed University, beginning in 2003.

More direct stakeholders should be involved in research design, due to their practical, “real-life” knowledge of the issues and pitfalls involved in research in their particular communities

At the start of the HIVNET 012 study in Uganda, the issue of male involvement was not adequately considered. As a result, when the program to prevent mother-to-child HIV transmission began, mothers reported that they could not make decisions concerning HIV testing and infant feeding without consulting their husbands. The study might have begun more successfully if stakeholders had had the opportunity to point out the need to involve male partners.

The CAB can provide essential feedback to enable researchers to gauge community support and avoid potential problems in their research

Community advisory board members can help researchers realistically assess how the community is accepting the research and identify potential problem areas, such as rumors in the community. Problems that CAB members helped researchers confront included the rumor that the research was secretly intended to spread HIV, and the rumor that there was a hidden agenda to “wipe out” women living with HIV.

To keep CABs actively engaged during lulls in studies, principle investigators should identify interesting activities and learning updates for CAB members

In Uganda, CAB members were motivated to participate in research but experienced frustration when no research studies were actively taking place. The HPTU responded by inviting guest speakers to give presentations on issues that related directly to CAB members’ research interests. These included infant feeding, follow-up of study participants, serodiscordant couples, and coping strategies and treatment for HIV/AIDS.

By engaging community partners such as community leaders, women’s advocates, opinion leaders, and community workers, CAB members can reach a greater proportion of their communities

The Uganda CAB found that these community partners had a more far-reaching, daily presence in the community and were able to engage more community members than the CAB’s one-time meetings could.

Psychosocial peer support drama activities can successfully deliver key messages during CAB community meetings

At CAB-sponsored community meetings in Uganda, peer mothers and peer fathers gave testimonials and used drama and music to deliver key messages about HIV to the community. Audiences were extremely receptive to this educational and entertaining approach to sharing real-life experiences.

The community advisory board format can serve as the foundation for larger-scale efforts to involve communities in HIV research

In Uganda, six CABs around the country are now joining forces to create a national CAB network with the goal of improving and expanding their advocacy efforts. In this way, the HPTN CAB expects to share experiences with others and improve its effectiveness in advocating for communities.

References

Guay LA, Musoke P, Fleming T, et al. (1999). Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet* Sep 4;354(9181):795-802.

STD/AIDS Control Program Uganda Ministry of Health (2001). HIV/AIDS surveillance report. Available at www.health.go.ug/docs/hiv0603.pdf

Uganda Ministry of Health (2001). Policy guidelines on feeding of infants and young children in the context of HIV/AIDS.

UNAIDS (2000). Meeting on prevention of mother-to-child transmission of HIV. Draft recommendations for scaling up interventions in pilot countries. Gabarone, Botswana, 27-31 March.

