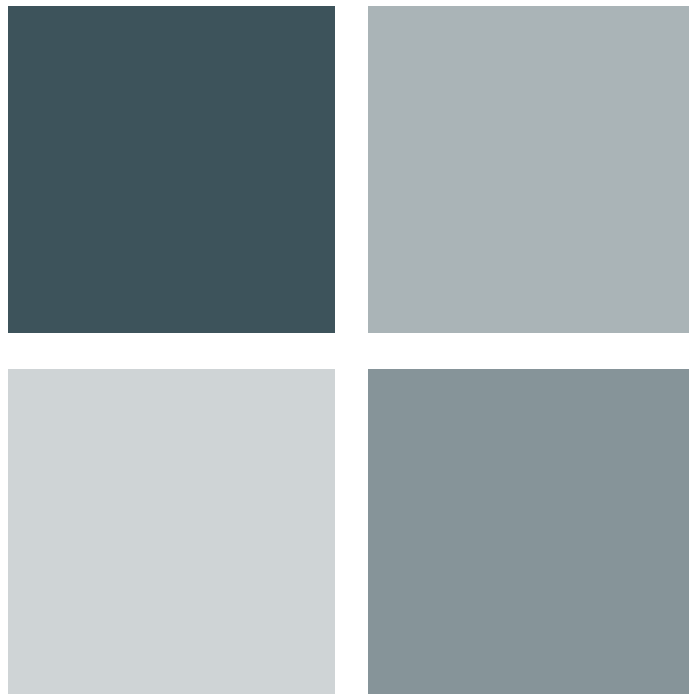


Lessons Learned from Lusaka, Zambia



Zambia Center for Infectious Disease Research

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Study Populations	HIV-positive pregnant women, HIV-negative pregnant women, women who are HSV-2-positive and HIV-negative, women participating in the HPTN 039 study who become HIV-positive, women of reproductive age
Key Topics	Male involvement, volunteerism, dispelling rumors in the community, research misconceptions, CAB recruitment

Introduction

Zambia is located in southern sub-Saharan Africa and has a population of about 10 million people, with most living in urban areas. The HIV prevalence rate among adults aged 15 to 49 is approximately 16.5 percent, with an estimated total of 830,000 adults living with HIV. An estimated 470,000 of these are women, with women between the ages of 19 and 25 constituting the population most affected by the virus. An additional 90,000 children under the age of 15 are believed to be infected with HIV (UNAIDS 2004).

HIV Prevention Trials Network (HPTN) research is being conducted in the Lusaka districts of Chilenje, Kamwala, George and Matero. During screening for the HPTN 055 study (described in greater detail below) in Chilenje and Kamwala, it was found that about 33 percent of the potential participants who presented at the clinic were infected. In locations like George and Matero, the prevalence rate among potential participants is about 46 percent. Chilenje, with a population of 204,000, has mostly upper-middle-class residents, with a smaller proportion of poor residents. George is a densely populated shantytown with very poor socioeconomic status and a population of 120,000. Kamwala has a population of 117,000, including both poor and middle-class residents. Matero is a middle-class, mostly working-class town with a population of 100,000.

The HIV Prevention Trials Unit (HPTU) in Zambia is the Center for Infectious Disease Research.

HPTN Research Studies in Zambia

The Zambia Center for Infectious Disease Research and its community advisory boards (CABs) have been involved in a total of four HPTN studies (Table 5).

Table 5. HPTN Research Studies in Zambia			
Study #	Protocol and Purpose	Study Population in Zambia	Other Sites
HIVNET 024	<p>Phase III trial of antibiotics to reduce chorioamnionitis-related perinatal HIV transmission.</p> <p>Purpose: to determine if low-cost antibiotic treatment aimed at reducing chronic and acute chorioamnionitis, given twice during pregnancy, will reduce perinatal HIV transmission.</p>	780 pregnant HIV-positive women; 200 pregnant HIV-negative women were enrolled and treated in the same way as the HIV-positive women.	Blantyre, Malawi; Lilongwe, Malawi; Dar es Salaam, Tanzania
HPTN 039	<p>Phase III trial of acyclovir for the reduction of HIV acquisition among high-risk HSV-2-seropositive, HIV-seronegative individuals.</p> <p>Primary objective: to measure the efficacy of twice daily acyclovir suppressive therapy in preventing HIV infection among HSV-2-seropositive, HIV-negative women and men who have sex with men at high risk for HIV infection.</p>	525 HIV-negative women who have sex with men who are infected with the HSV-2.	Lima, Iquitos, and Pucallpa, Peru; New York, San Francisco and Seattle, USA; Harare, Zimbabwe; Johannesburg, South Africa
HPTN 039-01	<p>Study of HPTN 039 seroconverters: the effect of HSV-2 suppression on HIV-1 viral set point.</p> <p>Primary objective: To measure the efficacy of twice daily acyclovir suppressive therapy on HIV plasma viral RNA levels during the first six months after determination of HIV infection.</p>	81 seroconverters from the HPTN 039 study.	Lima, Iquitos, and Pucallpa, Peru; New York, San Francisco and Seattle, USA; Harare, Zimbabwe; Johannesburg, South Africa
HPTN 055	<p>HIV prevention preparedness study.</p> <p>Primary objective: to estimate rates of HIV seroincidence among women targeted for inclusion in HPTN 035.</p>	240 sexually active HIV-uninfected women aged 16 to 49.	Durban and Hlabisa, South Africa; Moshi, Tanzania

Community Advisory Board

Establishment

In 2003, the Zambia Center for Infectious Disease Research began work on two HPTN research studies at clinics in four communities in the Lusaka district. At the request of the principal investigators, the district sister-in-charge and each study's senior research nurse nominated and interviewed potential community advisory board (CAB) members. Members of the CAB were selected from a pool of people with at least two years of experience as community health workers,

neighborhood health committee members, nutrition promoters, or community health promoters. The second study, HPTN 055, is located in communities that were not familiar with research activities. None of the individuals recruited for the HPTN 055 CAB had any kind of formal employment.

Members

The CAB consisted of 20 members, and the chairperson receives a monthly stipend. The chairperson serves a two-year term and can serve up to two terms in office. Other CAB members can serve as long as they are able. Members with three unexcused absences are asked to leave the board. Meetings are generally held monthly. Members are reimbursed for transport at the end of each scheduled meeting and at the end of each community activity. The transport reimbursement provided a strong incentive for them to join, as it was comparable to that of a salary. The study also provided bicycles to facilitate community mobilization activities. There is only one CAB, but it is divided into sub-groups to address study specific areas. The geographic distance between the HPTN 039 and the HPTN 055 research clinic areas is about 15 km one way. The CABs hold all the same sorts of activities, and they meet once a month to share experiences.

Training

Once CAB members agreed to serve, community educators and research staff trained them about the role of the CAB and their specific responsibilities. Training topics included research ethics, confidentiality, informed consent process, community facilitation skills, computer skills, and how to review the specific protocol for their study. Much of this training was based on Family Health International's *Research Ethics Training Curriculum*. Once they completed this training, they accompanied the community educator for a day to observe the typical conduct of the study.

Community Advisory Board Activities

Once the CAB members were identified and trained, they began holding monthly meetings to review the progress of the studies and address problem issues. Joint CAB meetings for both studies were held quarterly so that members could share experiences. These joint meetings helped build the capacity of all CAB members, especially newer ones.

Key CAB activities

- Identifying existing structures, stakeholders, and leaders in the community, including faith-based groups, NGOs, and influential members of the community
- Reviewing study work plans, protocols, consent forms, brochures, and posters
- Holding regular meetings with stakeholders to update them on the studies
- Identifying target groups for the studies and offering ideas for retaining participants
- Tracking recruitment records to monitor how many women had been recruited from each clinic
- Developing the community education plan with the community educator
- Helping community educators keep their communities informed through various activities, such as hosting community meetings and drama groups, distributing pamphlets, and discussing research activities with members of the community
- Participating in regional and international meetings, such as the HPTN Annual Meeting in Washington, DC, and the Africa Regional Working Group meetings in Zambia and Tanzania.

Challenges

The Zambia Center for Infectious Disease Research and its CABs has faced a number of challenges as the studies moved forward. Most of the challenges fall into the following categories.

- The concept of research was new and confusing to the communities.
- An initial challenge was to address the communities' lack of understanding about how and why the research was taking place. Communities and key stakeholders asked many questions:
 - Why should the community participate and what would we gain?
 - Why are only women included in the study?
 - What are placebos?
 - Why are you collecting blood?

To address these questions and others at the beginning of the studies, CABs hosted sensitization meetings with key stakeholders to explain the research objectives, answer stakeholders' questions, and gain their support. The response from the key stakeholders was generally very positive and supportive; only a small number of church leaders chose not to support one of the studies because of misconceptions that the study was a type of forbidden faith healing.

Basic rumors and misconceptions abounded

A number of rumors and misconceptions about the research, which seemed to come from a handful of church leaders and a few women who were screened out of the study, circulated through the communities. Most rumors concerned issues related to blood collection, which were commingled with superstitions about blood and Satanism. The rumors often exaggerated the amount and frequency of blood samples collected, as well as why they were collected. When study participants were reimbursed for travel expenses, some people circulated rumors that they were being paid for their blood, which is generally not condoned in these communities. Another rumor was that the pills given to participants were "coated with HIV." These misconceptions hindered participant enrollment somewhat, and occasionally led to hostility when educators went door-to-door or tried to distribute brochures. Some husbands in the community were upset that their wives participated in the study.

To address these rumors, the CAB assisted with several actions:

- Research staff and CAB members updated a drama script that community educators presented to the communities to address issues of Satanism and show the size of the collecting tubes.
- A door-to-door education campaign was very successful in dispelling the rumors.
- Research staff and CAB members held regular meetings with key stakeholders, traditional health practitioners, and other members of the community to address rumors and misconceptions.
- Research staff held meetings with women's partners to educate them on general research and HIV information.
- Research staff received training from community educators and the study coordinator to deal more sensitively with women who were screened out of the study.

Start of the study (HPTN 055) was delayed

The communities were prepared to begin the HPTN 055 study on HIV prevention preparedness, but a delay of almost a year frustrated community members; they grew impatient and began to lose interest after the initial excitement. An initiation site visit that took place in July 2003 concluded that the site was not ready to begin the study. The planned medical supervision was insufficient, so research management decided to hire a clinical officer, three study nurses and an investigator of record. The study coordinator resigned a week before the initiation visit and another was hired. Due to these changes, research staff had to resubmit the consent forms to the ethics committees. When some systems changed within the clinic, standard operating procedures were reformulated. A pharmacy was built at each clinic, a utility room and a reception room were provided, and the data room was separated from the general study administration room; all of which added substantial time to the planned start of the study.

The composition of the community advisory board created some tension

The CAB for the HPTN 024 study on reducing mother-to-child HIV transmission was heavily male-dominated and chaired by a man, which led to a number of tensions. The CABs for the new studies appointed a female chairperson, and the CABs were balanced with 10 women and 10 men. This balanced composition has allowed current CAB members to work together better than the earlier CAB members did. However, the current CAB still contains an imbalance of direct stakeholders (participants/potential participants) versus indirect stakeholders (community leaders, service providers, church leaders), but the CAB hopes to recruit more direct stakeholders in the future to balance member perspectives and concerns.

The CAB had difficulty recruiting and retaining volunteer members

Overall, CAB members did not fully understand the concept of volunteerism, and finding dedicated volunteers was difficult. Unemployment in the Lusaka district is very high, and many of the CAB members did not have regular employment. In this situation, many CAB members sought payment or allowances for their work and developed a deep resentment when the chairperson began receiving a monthly stipend.

To encourage volunteer participation, research staff members are now working closely with the sister-in-charge to identify members of the community who are truly willing to volunteer for the CAB. Once they complete their training, CAB members are given a bicycle to help them with their transportation needs. Research staff continue to send clear messages to the CAB members that they are volunteers and not employees of the study.

Defining the role of CAB members proved challenging

Many CAB members initially saw themselves as study employees and assumed the roles of community educators and recruitment/retention staff, which are paid positions. They often went beyond their advisory roles and actively recruited participants on-site, which is the responsibility of the research staff (currently, the study employs two community educators). To build a more autonomous, volunteer CAB that represents and advocates for the community, research management decided to form a new CAB and offer the old CAB members the choice of becoming outreach workers or peer educators (since they were already functioning in that role), or applying to be a member of the new CAB. As part of the CAB reform process, the community educators from the study also visited the HPTN CAB in Zimbabwe to share and exchange experiences.

Lessons Learned

In the course of the Zambia HPTN studies, the current Lusaka CABs learned a number of valuable lessons for future CABs in dealing with community education, rumors, and CAB and participant recruitment.

Communities should receive adequate information and education about research before it starts.

In Zambia, the Center for Infectious Disease Research and its associated CABs learned about the importance of ensuring that communities are informed about research and understand what it involves before a study is initiated. Meetings with key stakeholders to explain the research goals and processes helped secure both their understanding of and their support for the study.

Community advisory board members should review research protocols before studies begin

Community advisory board members need to understand how they can offer input and influence research protocols. In Zambia, the CAB did not review the protocols of early studies. In one study, the CAB was established just before research initiation. Members knew very little about research at the outset, so it was very difficult to train them in a short period of time and expect them to work effectively.

Community advisory board members and research staff should address rumors as soon as they arise

The Zambia Center for Infectious Disease Research and its CABs found that unexpected rumors and misconceptions can arise at any time within the community. Community advisory board members and research staff should always remain attentive and address these rumors as soon as they appear. Identifying the source and reasons for the rumor are important when developing a response. When the rumor began to circulate that blood collection was Satanic and that blood samples were being sold, learning that the rumors emanated from church leaders and some women who were screened out of the study helped researchers to refine and target their response in Lusaka.

Capacity building within CABs is vital, so that members are prepared to address rumors, offer ideas for participant recruitment, and promote studies

Many of the Lusaka CAB members had limited education and little understanding of research and how to review study protocols. Training, including periodic refresher training, can help improve their abilities, as research is still a relatively new concept, and an initial and ongoing investment in training is required.

Active CAB members can mobilize communities, assist in participant recruitment, and smooth the research process because of their status and relationships with communities

In Zambia, CAB members are usually well known and trusted within their communities, because of their involvement with the neighborhood health committees. As integrated members of the community, CAB members have been successful in promoting research study objectives and explaining the research to their communities. Although labor intensive, door-to-door education has proven very effective in educating communities about research and dispelling rumors.

District health staff, key leaders, and neighborhood health committees should be involved from the inception of research studies

Key community leaders and health-oriented groups are already familiar with community members, who are likely to be less suspicious of research if these individuals are involved. The Zambia Center for Infectious Disease Research and its CABs hold regular feedback meetings with community stakeholders to learn how the community perceives the research and to make adjustments as needed. These meetings began when the rumors and misconceptions about drawing blood and Satanism first emerged, and they now take place at least once a month at the study sites.

Even when research focuses only on female participants, men in the community should also be involved from the beginning

As decision-makers within homes, men should be informed about the research in which their spouses or partners are participants. This is important for moral support and to minimize social harm to female participants. When HPTN research first began in Lusaka, it was very difficult to have open discussions with men about HIV-related issues. Partners of women participating in the studies sometimes raised objections. The partner meetings held by the Center for Infectious Disease Research and its CABs helped to educate men about the research and HIV/AIDS in general. The men became more accepting of the research and were even active in inviting other men without partners to come to the meetings.

Research staff and CABs should clarify the concept of volunteerism to potential CAB members, but also address issues of economic need among community volunteers

The issue of volunteerism was often problematic for CAB members of the Zambia research studies. Most were confronted with the local reality of high unemployment and low income. Many felt that they should receive payment or an allowance for their contributions. Research staff have had to work hard to both clarify the concept of volunteerism and find community members who are willing to serve on the CAB on a volunteer basis. Research staff felt that CAB members should remain autonomous in their advisory roles and not become employees of the studies. They believed that acting as employees was a conflict of interest for CAB members and interfered with their ability to function as advocates for the community. Research managers were able to employ some CAB members as outreach workers or peer educators, but they have sought new members who do not expect employment with the studies. At the same time, CAB members' economic needs are as real as the need for community volunteers. Offering each new CAB member a bicycle and a small allowance to facilitate their work has had a positive influence on productivity and morale.

Research staff and CAB members should maintain strict confidentiality to protect the privacy of participants

Failure to maintain participant confidentiality can lead to stigmatization and harmful rumors. In the Chilenje Clinic of Lusaka, one woman participating in the HIV prevention study to prepare for a later study on the effectiveness of vaginal microbicides (HPTN 055) became pregnant and began missing her visits to the clinic. The tracking team tried to find her, but ended up dealing with her sister-in-law instead. On one visit, the sister-in-law grew hostile, and accused the tracking team of being "Satanists," and called one tracking nurse a "prostitute," because she was wearing blue jeans.

The sister-in-law's accusations eventually drew a crowd, which menaced the members of the tracking team. After the team was able to escape unharmed, they met with research management, who arranged a meeting between research staff, CAB members and the area councilor responsible for the community. The councilor agreed to support the study by organizing a community meeting to clear up misconceptions and allow community members to ask questions and express their views. The meeting revealed that community members were unaware of the study in Chilenje. As a result of the meeting, the Center for Infectious Disease Research and its CABs decided to step up their community sensitization efforts, hold more frequent community meetings, and introduce a dress code for members of the tracking team.

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