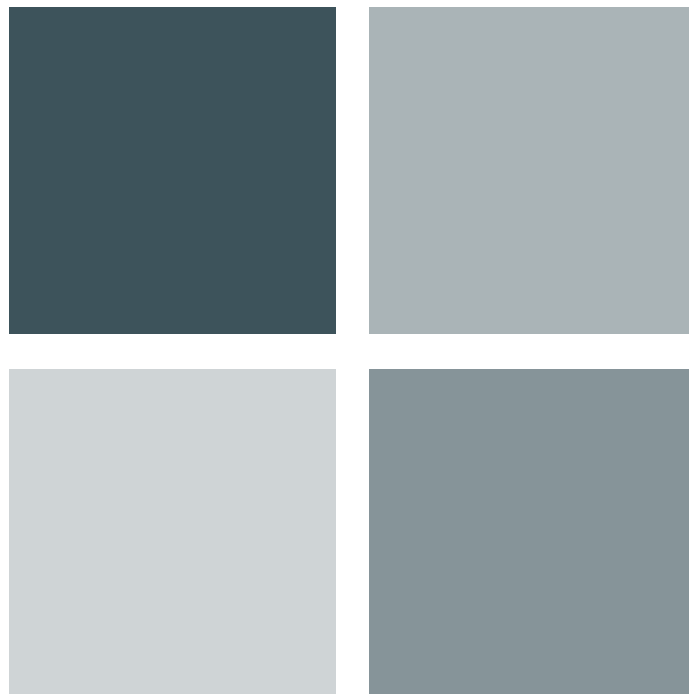


Lessons Learned from Chennai, India



YRG Care

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Study Populations	Sexually active heterosexual men and women, serodiscordant couples
Key Topics	Mutual respect between direct and indirect stakeholders, collaboration between institutional review boards and CABs, CAB networking with other community-based organizations

Introduction

Even though the overall adult prevalence of HIV in India is below one percent, the size of the country's population — over one billion — means that India is home to a large number of people living with HIV/AIDS, second only to South Africa. By the end of 2004, approximately five million Indians were living with HIV. The relatively low national rate also masks much higher regional prevalence rates. Of the 35 states of India, six states, four in southern India (Andhra Pradesh, Tamil Nadu, Maharashtra, Karnataka) and two in northeastern India (Manipur and Nagaland) have generalized epidemics with HIV prevalence rates above one percent among pregnant women. These six states account for nearly 80 percent of all reported AIDS cases in the country. Heterosexual transmission accounts for the majority of reported cases of HIV in the southern states, where more than 50 percent of commercial sex workers in urban areas are HIV-positive. In the northeastern states, injecting drug use is the predominant mode of transmission; in 2003, HIV prevalence among injecting drug users was 56 percent (UNAIDS 2004).

The epidemic in India is dynamic, and a number of distinct epidemics often coexist, sometimes within the same state, with different vulnerabilities, stage of maturity and impact. The highly stratified nature of Indian society, cultural myths about sex, large-scale migration, gender discrimination and huge populations of marginalized people make it extremely vulnerable to the HIV epidemic. HIV 1, subtype C is the most commonly transmitted form of infection in India. Researchers have found that the Indian subtype C is different from C subtypes found elsewhere in the world. (Yale University 2005).

Chennai, formerly known as Madras, is the capital of Tamil Nadu state, and has a population of approximately 7.45 million. YRG CARE serves as the HIV Prevention Trials Unit (HPTU) in Chennai. YRG CARE is a nongovernmental organization established in 1993. It works on issues that include HIV prevention, voluntary HIV counseling and testing, care and support for people living with HIV and their families, and clinical and social research linked to HIV/AIDS.

HPTN Research Studies in Chennai

YRG CARE has been involved in two HPTN research studies. HPTN 033 took place from 2001 to 2004, and is now complete. HPTN 052 has been in operation since 2002. Table 9 contains more information on these studies.

Table 9. HPTN Research Studies in Chennai			
Study #	Protocol and Purpose	Study Population in Chennai	Other Sites
HPTN 033	<p>HIV prevention preparedness study of women and men at risk for heterosexual HIV transmission.</p> <p>Purpose: To establish effective standard operating procedures to recruit and retain high-risk populations in future HPTN trials, and to characterize the HIV risk behaviors and HIV incidence rates in these populations.</p>	500 men and women at risk of heterosexual HIV transmission.	Guangxi and Xinjiang, China; St. Petersburg, Russia
HPTN 052	<p>Phase III trial to determine the effectiveness of two treatment strategies in preventing the sexual transmission of HIV in HIV-serodiscordant couples.</p> <p>Purpose: to determine whether antiretroviral therapy can prevent the sexual transmission of HIV-1 in HIV-1-serodiscordant couples.</p>	1,750 serodiscordant couples in all study sites.	Blantyre and Lilongwe, Malawi; Pune, India; Harare, Zimbabwe; Porto Alegre and Rio de Janeiro, Brazil; Chiang Mai, Thailand; Boston, USA

Community Advisory Board

The YRG CARE HPTN community advisory board (CAB) in Chennai is composed of a group of research study participants and concerned members of the community who articulate the concerns of communities affected by HIV/AIDS and other public health issues related to research. The mission of the YRG CARE CAB is to relay the perspective of the host community to researchers by providing them with informed commentary about strategies to identify, recruit, educate and follow up with individuals participating in research studies. The YRG CARE CAB seeks to:

- Provide community perspectives on issues likely to arise during the conduct of research studies
- Provide informed commentary on study protocols, informed consent processes, and informational, educational, and promotional materials
- Support recruitment efforts and promote referral arrangements associated with the studies
- Represent YRG CARE at regional meetings and other forums, when appropriate

Establishment

YRG CARE formed its CAB in 2000 in preparation for participation in HPTN 033. YRG CARE's experience showed that research studies that are not primarily clinic-based require constant interaction with the community. Not all sections of a given population were aware of the objectives or probable outcomes of the studies in which YRG CARE was involved. YRG CARE therefore sought to create a common forum that would represent a cross-section of the population participating in research and that would effectively convey both community goals and community apprehensions.

To create the CAB, YRG CARE personnel, including outreach workers and both junior and senior staff members, identified and approached key opinion leaders from various sectors of society. Some people nominated themselves for CAB membership, while others were identified by community referral. YRG CARE began by explaining its mission and goal to prospective CAB members.

Originally, the CAB was known as "YRG CARE HPTN CAB," but since May 2004 it is known as "YRG CARE CAB," as the CAB covers all YRG CARE clinical and behavioral projects. Since the inception of the CAB, members have played an active role in mobilizing community involvement in all YRG CARE research studies.

Members

The first YRG CARE CAB consisted of 10 members, including a hospital administrator, a representative of the community of men who have sex with men, a gynecologist, a psychologist, a financial consultant, a lawyer, a Catholic priest, and a representative from a nongovernmental organization. Initial meetings focused on developing the CAB mission, goals and roles, and establishing CAB member requirements for reviewing research studies.

The current CAB has 22 members (15 women and 7 men), and represents several key community groups: people living with HIV, women who work in commercial sex, pimps, injecting drug users, men who have sex with men, members of the transgender community, and housewives. The CAB also includes community service providers such as physicians, religious leaders, lawyers, a public accountant, and a Rotary Club member. The ratio of direct stakeholders to indirect stakeholders is 1:1. The YRG CARE field research team identifies direct stakeholders, while YRG CARE management identifies indirect stakeholders.

YRG CARE staff or CAB members can nominate new CAB members. Nominations accompanied by a brief description of the interests and commitment of potential members are presented to current CAB members and reviewed at CAB meetings. Community advisory board members are appointed for a term of three years, and membership is renewable. Membership is a voluntary, honorary position.

Training

All CAB members have undergone training about research with human participants. The training took place in both English and Tamil and combined a training module of the Johns Hopkins School of Public Health (to enable CAB members to understand the principles of research ethics), and the *Research Ethics Training Curriculum for Community Representatives* of Family Health International. The training was held at the October 2004 Eurasia Regional Working Group

Community Workshop in Beijing, China. The training helped CAB members understand their role as community representatives in the research process.

Some CAB members have also undergone good clinical practices training, when such training was conducted for YRG CARE staff members. When YRG CARE organizes workshops, the organization informs CAB members and invites them to attend. Topics have included project management, research methodology, HIV/AIDS issues, and sexuality, among others. Nearly all CAB members with no research background have stated that they have learned a great deal from the training programs.

Community Advisory Board Activities

Community advisory board meetings are usually held bimonthly, but the frequency of meetings changes depending upon the situation. The YRG CARE research manager and CAB coordinator set the agenda for CAB meetings, after consulting with other CAB members. The two co-chairs of the CAB lead the session.

Apart from CAB members and YRG CARE staff associated with community-related work, observers from YRG CARE's international collaborators (HPTN, AIDS Clinical Trial Group, Family Health International, Fenway Community Health, and Massachusetts General Hospital in Boston, USA) sometimes attend CAB meetings to discuss future protocols and receive feedback from community members. They also make presentations on topics such as ethics, community involvement in research, and case studies. Presentations are simultaneously translated into the local language, Tamil, for the benefit of all CAB members.

YRG CARE provides logistical support to the CAB, including meeting space, office equipment, photocopying, and other administrative and financial support associated with local and regional conference representation. YRG CARE also provides information about study protocols, public health, basic science, vaccine development, local institutional review board procedures and other relevant issues to keep the CAB well informed. Research managers and the community education team are in constant touch with CAB members to update them, seek guidance and discuss community-based issues. Meals or snacks and transportation expenses to attend the CAB meetings are provided.

Community Advisory Board Roles in Research Methodology

Community advisory board members participate in discussion of the following research-related issues:

- Medical, legal, ethical, cultural, social, and religious issues linked to research
- Benefits and risks of research
- Study updates
- New protocols
- Protocol reviews
- Recruitment and retention status
- How to increase awareness of the need for research and how research benefits the community
- Training materials, including those used for information, education, and communication

In addition to protocols, CAB members review consent forms, research methods, brochures, posters and leaflets. Principal investigators present the drafts of new protocols to CAB members during CAB meetings. Members also contribute to the research process by indicating when draft consent forms are too technical and incomprehensible for lay people.

Community advisory board members serve as advocates for participants in HIV treatment programs and behavioral studies. They educate the community about HIV/AIDS, candidate HIV vaccines and therapies, and behavioral science studies. They provide input to researchers on ways to make studies more understandable and appealing to volunteers. They advise YRG CARE about volunteer recruitment issues. They also inform the community about the proceedings of CAB meetings, within the limits of confidentiality. Community advisory board members also provide follow-up to research activities.

Members support research through field activities such as mobilizing participants to attend health camps and organizing group meetings. They solicit the opinions of community members about key questions related to research studies underway at YRG CARE, such as:

- Are study participants happy with the treatment they are receiving in the context of studies?
- Do community members have suggestions for improving services provided to study participants?
- What additional studies should YRG CARE undertake?

Challenges

YRG CARE and its CAB have experienced several challenges in the course of participation in HPTN research studies in Chennai.

CAB members are sometimes not convinced of the need for a particular research study

In Chennai, YRG CARE CAB members needed to understand exactly what purpose research studies would serve, and why their inputs were needed. Until they completely understood these elements, full community involvement was not possible.

Some direct stakeholders are not easily accessible

Some direct stakeholders, such as female sex workers, constitute a “floating population” and cannot be easily contacted for activities such as CAB meetings. YRG CARE and its CAB decided to look for CAB members with a reasonable amount of stability for inclusion in the CAB, in addition to carefully assessing potential members’ interest and community involvement.

Indirect stakeholders often have busy schedules

Community advisory board members who are professionals are sometimes too busy with other commitments to regularly attend CAB meetings. In such cases, they withdraw from the CAB. The YRG CAB now reviews new CAB applications carefully to ensure that potential members will be able to participate fully.

Joint institutional review board/CAB meetings are difficult to schedule

Joint meetings of the institutional review board and the YRG CARE CAB have typically been difficult to schedule. The current practice is to gain a consensus on convenient dates from a majority of the members involved before scheduling a meeting.

Emotional reactions by CAB members sometimes derail meetings from the issues to be resolved

Members sometimes become emotional while discussing sensitive issues, making it difficult to proceed with the meeting agenda. When this happens, the research manager and CAB coordinator facilitate the progress of the session by tactfully intervening to move the agenda forward.

Lessons Learned

YRG CARE and its CAB have learned a number of lessons about community involvement in HIV prevention research.

Creating a nonjudgmental atmosphere can allow all CAB members to experience a feeling of equality and enhances collaboration

YRG CARE CAB members in Chennai come from diverse backgrounds. Yet, several factors have contributed to productive collaboration within the CAB. Foremost among these factors is the atmosphere of mutual respect that CAB co-chairs seek to create. This leads direct stakeholders such as sex workers and men who have sex with men to be able to participate in the CAB on equal footing with indirect stakeholders such as doctors and lawyers. The lack of inhibitions that this atmosphere creates enables CAB members to freely express their views and opinions within the group. When all CAB members are treated equally, there is a sense of common purpose, and potential barriers such as social class differences disappear in the service of the common goal of community involvement.

Networking outside of the community advisory board can increase community involvement in research

While CAB participation in the HPTN has been key to increasing community involvement in research, CAB member networking outside of the CAB has also been important. Members have participated in street plays organized by Nalamdana, a nongovernmental organization with a presence in Chennai. Nalamdana also invited CAB members to attend a telefilm, *Pesu Maname Pesu*, which the organization developed to engage community members in discussion about HIV/AIDS. Sahodaran, another nongovernmental organization, works on issues related to men who have sex with men. Sahodaran has invited CAB members to attend their annual World AIDS Day celebrations, which feature a beauty contest. When Sahodaran's members told CAB members about the problems they experienced in finding employment as men who have sex with men, one CAB member (who is both a Catholic priest and a college professor who heads a department on vocational training) offered to help organize a vocational course that would cater exclusively to the men who have sex with men. Another CAB member now volunteers with Sahodaran to promote awareness of HIV/AIDS.

Joint meetings between institutional review boards and community advisory boards can enhance research quality

One way that YRG CARE has found to bring together researchers and CAB members is to hold joint institutional review board/CAB meetings on a quarterly basis. These meetings give institutional review board and CAB members the opportunity to monitor both the progress of research studies and the progress of community involvement in research.

Reference

Yale University Web site. Available at <http://cira.med.yale.edu/international/indiaepid.html>. Accessed on 21 October 2005.

