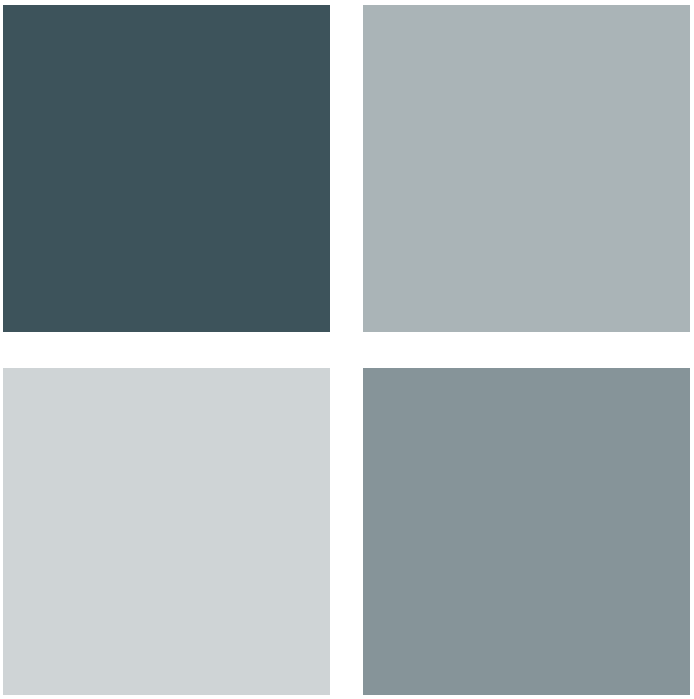
Lessons Learned from Pune, India



National AIDS Research Institute

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U.S. Partner Institution	**Johns Hopkins University School of Medicine**
Study Populations	**HIV-serodiscordant couples, HIV-uninfected partners of people living with HIV, HIV uninfected sexually active women**
Key Topics	**Peer education, dispelling rumors in the community, CAB capacity building, CAB training, CAB participation in research design**

Introduction

The overall adult prevalence of HIV in India is below one percent (0.8), but with a population of over one billion, 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) have prevalence rates above one percent among pregnant women. These six states account for nearly 80 percent of all reported AIDS cases in the country. In the southern states, heterosexual transmission accounts for the majority of reported cases of HIV in the southern states, where over 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).

Pune is an industrial city with a population of nearly three million, situated in the high-HIV-prevalence state of Maharashtra. Baseline feasibility studies on high-risk cohorts (commercial sex workers and people attending sexually transmitted infection clinics) in Pune, have reported HIV prevalence rates of 18 to 26 percent and provided information on the associated biological and behavioral risk factors in the study population (Mehendale et al. 1995). Sentinel surveillance among pregnant women attending government clinics in Pune city indicated HIV prevalence rates ranging from 2.5 to 3.7 percent (based on unpublished data from the National AIDS Research Institute) and about 1.2 percent in rural areas surrounding Pune (Kunte et al. 1999). HIV-1 clade C is the most common subtype in Pune (Gadkari et al. 1998).

The National AIDS Research Institute (NARI) is the HIV Prevention Trial Unit in Pune. NARI began conducting epidemiological research in Pune city in 1993. NARI's early efforts in community involvement were oriented toward gaining community support for biomedical research, with a primary focus

on recruiting and retaining study participants. NARI's current efforts in community involvement center on the ethical principles of autonomy, transparency, justice, equity and nonmaleficence.

HPTN Research Studies in Pune

The Pune National AIDS Research Institute and its community advisory board (CAB) have assisted several ongoing, multinational HIV Prevention Trials Network (HPTN) studies, including HPTN 034, HPTN 047, HPTN 052 and HPTN 059. Table 10 summarizes the study objectives and protocols for these four studies.

Table 10. HPTN Research Studies in Pune

Study #	Protocol and Purpose	Study Population in Pune	Other Sites
HPTN 034	Cohort study of current HIV incidence in patients attending STI clinics in Pune, India. Primary objective: to determine the current incidence of HIV among a cohort of 400 newly identified high-risk women, as well as among 400 HIV-uninfected partners of HIV-infected persons.	400 high-risk women in Pune, and 400 HIV-uninfected partners of HIV-positive persons.	Guangxi, China; St. Petersburg, Russia; Xinjiang, China
HPTN 047	Phase I study to assess the safety of 0.5% PRO 2000/5 Gel (P). Purpose: to assess both the safety and the acceptability of repeated intravaginal doses of 0.5% PRO 2000/5 Gel (P) for 14 consecutive days between menses among sexually active HIV-negative women and their male partners.	60 HIV-uninfected sexually active women.	N/A
HPTN 052	Phase III trial to determine the effectiveness of two treatment strategies in preventing the sexual transmission of HIV in HIV-serodiscordant couples. Purpose: to determine whether antiretroviral therapy can prevent the sexual transmission of HIV-1 in HIV-1-serodiscordant couples.	1,750 HIV-serodiscordant couples in all study sites.	Blantyre and Lilongwe, Malawi; Chennai, India; Harare, Zimbabwe; Porto Alegre and Rio de Janeiro, Brazil; Chiang Mai, Thailand; Boston, USA
HPTN 059	Phase II study of the vaginal microbicide 1% Tenofovir gel. Purpose: to assess the safety of Tenofovir gel for vaginal use in HIV-uninfected women versus a placebo gel.	100 HIV-uninfected sexually active women.	New York, USA

Community Advisory Board

Establishment

Over the last decade, NARI's research focus has changed from descriptive epidemiology to prevention research and clinical trials. This evolution has involved a transition from clinic-based to community-centered research. In 1992, NARI set up its first CAB, which was also the first CAB created by any research institute in the country. Throughout the 1990s, a global debate arose about researchers' obligations to ensure absolute transparency and support for people participating in HIV prevention trials in resource-poor settings. At the same time, NARI began its first major effort at community involvement by mobilizing and revamping the existing CAB as part of new HPTN grants it received in 2000.

NARI's first CAB functioned with limited involvement and input into research studies. At this time, community involvement in the clinic-based cohort studies NARI was involved in did not seem as critical. When NARI began to prepare for participation in the HPTN in 2000, the organization was mobilizing for large clinical trials in which high recruitment and retention rates were essential, leading to the expansion from clinic to community as the research foundation. NARI therefore began exploring ways to create a stronger, more involved and dynamic CAB for the upcoming HPTN studies. Senior-level scientists at NARI held brainstorming sessions to set goals for a new CAB. The goals for the newly envisioned CAB included:

- Involving the community in the design and conduct of the research
- Ensuring community support for ongoing research
- Deciding on approaches for community education and information
- Identifying and recruiting participants for the research studies

Because CABs were such a new concept in India, as a next step, NARI conducted exploratory meetings with community partners, including directors of nongovernmental organizations (NGOs), ethicists, philanthropists, teachers, community opinion leaders, youth, and representatives of men's and women's organizations. People from these organizations were given an open invitation to become a voice for their communities as CAB members and provide help in bridging the gap between the community and the researchers.

Members

Initially the new CAB had 15 members and currently has 33 members, consisting of both direct and indirect stakeholders. The direct stakeholders include commercial sex workers, people living HIV/AIDS, and men who have sex with men. The indirect stakeholders include teachers, ethicists, doctors, nurses, and women from slums, social workers, philanthropists, NGO representatives, and academicians.

One sign that NARI and the CAB have been successful in creating awareness about the HPTN research studies is that conscientious Pune citizens now approach study personnel and ask to become CAB members. To apply for CAB membership, potential members are queried about their past relevant experiences, their motives for becoming members of the CAB, and their commitment. Potential members also receive an application form on which to provide their profile and consent that they understand NARI's mission statement, terms of reference, and confidentiality requirements.

Training

New CAB members receive a one-day orientation training in which they learn about the CAB concept, roles and responsibilities, past experiences from current members, and information on new and ongoing protocols. Community advisory board members also attend international training workshops on topics such as ethics in research. As part of the HPTN Eurasia RWG (currently, Asia RWG), they have attended regional CAB trainings in Pune and in Beijing, China. At the national level, NARI sponsored six CAB members to attend the National Bioethics Conference held in Mumbai, India, in November 2005.

For each specific study, CAB members also receive training during site initiation for that study. Recently, CAB members received protocol training for the new HPTN 052 protocol (on the effectiveness of two treatment strategies in preventing the sexual transmission of HIV in HIV-serodiscordant couples) at Symbiosis College, Pune, India.

Community Advisory Board Activities

Community advisory board meetings usually take place every two months. Between regular meetings, the CAB also holds unscheduled meetings at the investigators' or CAB members' request. At the regularly scheduled CAB meetings, investigators usually brief the members on new protocols and provide updates on continuing protocols. CAB members discuss the protocols with investigators and offer suggestions for research needs, recruitment plans, and language used in documents such as informed consent forms. General CAB duties and responsibilities include:

- Translating informed consent forms and other study forms between local languages (especially Marathi) and English
- Advising the research team on volunteer recruitment strategies
- Developing a community involvement plan involving NGOs, grassroots-level workers, and the community
- Attending protocol development meetings and conference calls;
- Reviewing study protocols
- Writing articles in newspapers and institutional publications about the research
- Participating in field testing of training modules, surveys, and other information/education/communication materials

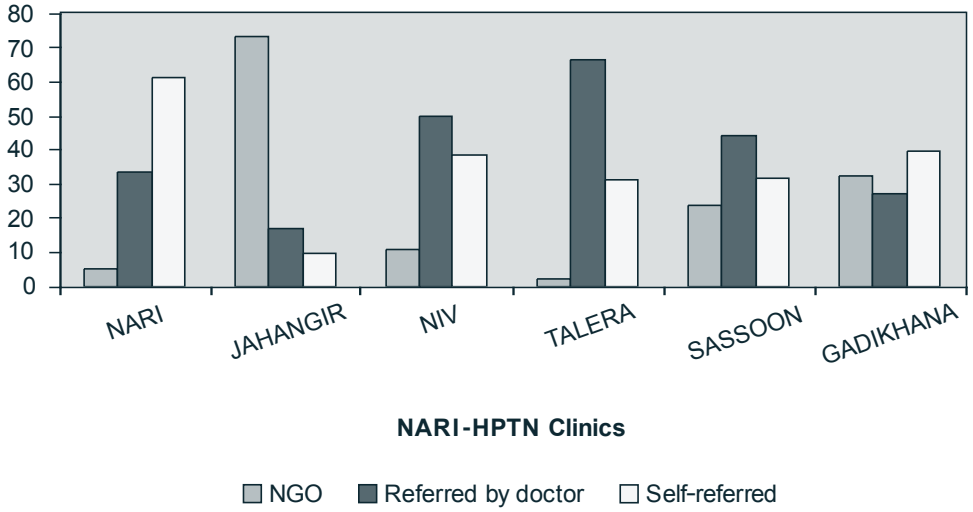
Community Advisory Board Participation in Peer Education Program Design

The Pune CAB helped design a peer education program that has been very successful in reaching the community. Community advisory board members and NARI staff collaborated on the design of a community involvement plan that relied on peer educators to help bridge the gap between the community and the research. NARI partnered with six local NGOs to identify and train a cadre of peer educators who go door to door and hold group meetings to educate the community about the research. Twenty peer trainers have now trained a total of 150 peer educators. These educators have reached more than 1,000 men and women through group meetings and more than 1,000 households through door to door meetings.

The group meetings serve the purpose of sensitizing the community to HIV/AIDS issues and related research. The approach used considers the fact that group meetings simply deliver the messages; focused follow-up can help elaborate on these messages when some people show interest. Door-to-door meetings, on the other hand, are geared toward potential study participants. The door-to-door approach allows peer educators to be attentive to potential participants and engage in a private dialogue in a nonprepossessing and confidential manner. Some women, for example, are relatively free in the afternoon and can talk with educators while performing household chores. Through this approach, women can freely question educators about HIV/AIDS and related issues.

Weekly peer meetings are held to share knowledge and discuss problems and rumors discovered in the community. This peer education approach has extended the reach of the CAB, promoted trust within the community and with partner organizations, increased the study's visibility, and increased self-referrals (see Figure 5, below).

Figure 5. Clinic Referrals at the Pune HPTN Site*



* **The NGO and self-referral bars demonstrate the impact of community peer education, including outreach activities. Prior to peer education and CAB involvement, only members of the medical community issued clinic referrals.**

Challenges

Mobilizing and educating communities for HIV prevention research

One important challenge to mobilizing and educating Pune communities is eliminating rumors within the community about HIV prevention research. Tracking and alleviating rumors is always an important part of community involvement. Peer educators in Pune have been successful at detecting rumors at the grassroots level during their interactions in the community. They then relay this information to CAB members and research staff members who are able to develop plans to address the rumors before they become large problems.

In one case, a peer reported the rumor that NARI was "buying blood." The CAB and research staff members immediately convened a meeting with the NGO director from that area, who is also a CAB member. In consultation with NARI investigators and NGO representatives, the group realized that offering treatment free of cost had led to the initiation of this rumor. Peers pointed out the contradiction: "Why would an institute distribute money (or a reimbursement) when it is doing so many things for free?" Together, CAB members and NARI investigators explained to community members why the research staff collected blood samples and why treatment and tests were offered to research participants free of charge. The rumor subsequently dissolved.

In another challenge to community mobilization and education, a study participant denied her identity to a new NARI staff person during a home visit. Although she was indeed the study participant in question, she insisted that the person the staff person was seeking was out of town. The new NARI staff person would not have known the truth about the woman's identity if a peer educator had not come forward and informed the community staff at NARI. Research personnel realized that the study participant did not want to reveal her identity to an unknown counselor. As a result, research managers developed a new rule whereby study participants meet the entire research team as well as any new staff members.

Developing and maintaining community advisory structures

When NARI established its first community advisory board in the early 1990s, the CAB's role in the research was extremely passive, limited mainly to CAB members listening to researchers' description of studies without questioning research activities or goals. Without participating in discussions, CAB members cannot serve as effective community representatives.

When the new HPTN studies began, NARI made serious efforts to increase the role that the CAB played in the research process. More influential CAB members were enlisted from the community, and CAB members were encouraged to take a more active role in providing input in meetings, protocol reviews, and document reviews. NARI helped build CAB member capacity through activities such as international ethics training and orientation workshops.

Since then, the CAB has taken an active role in identifying participant groups for both HPTN and non-HPTN studies. Overall, the current CAB is much more empowered than the earlier CAB, and its dynamism has been a positive influence on the success of the studies. The sharing of experiences in forums such as regional CAB training for the Southeast Asia region has also helped CAB members to gain a better understanding of research and governance issues and to strengthen their voices as community representatives. CAB members' recent participation in the National Bioethics

Workshop held in Mumbai has also helped develop a sense of camaraderie between researchers and CAB members. CAB members realized that asking questions and having a difference of opinion are part of their responsibility as community representatives; CAB participation in research design and discussion contributes to the conduct of biomedical research in an ethical environment.

Lessons Learned

The Pune HIV Prevention Trial Unit and its CAB have learned the following lessons about community involvement in HIV prevention research.

Community advisory boards are feasible for developing countries

Until a few years ago, involving a CAB as a partner in human subject research was a new concept to India. Over time and with the help of training and experience, the Pune CAB has become successful as a new means of community involvement that addresses community concerns and promotes the conduct of research in partnership with the community.

Training can help empower CAB members

After the Pune CAB members received training, they began to work more confidently in their duties as educators and advocates for communities and liaisons with research staff. Since CAB members received training, such as the one-day CAB orientation, study-specific site initiation training, and international workshops on ethics in research, a clear change in CAB functioning is evident. Community advisory board meetings are now interactive, and CAB members routinely ask questions and request that research staff members schedule meetings to discuss the community aspects of both new and ongoing research.

Installing a facilitator in CAB meetings can help ensure that everyone gets a chance to speak and contribute

In Pune, researchers first faced the challenge of empowering CAB members to participate more actively in research and research-related activities. Another challenge was empowering less experienced, more junior CAB members to speak up in meetings and prevent the meetings from being dominated by more senior, experienced CAB members.

A facilitator can keep track of discussions and intervene in an unobtrusive manner, helping direct discussions toward the agenda. The facilitator can also directly ask less vocal members to speak on issues corresponding to their interests and experience, thanks in part to the availability of CAB member profiles. In the Pune CAB, many direct stakeholders and junior members, while not as vocal or socially prominent as others on the CAB, have provided useful suggestions when they are given the opportunity to offer input.

Community advisory boards have the capacity to foster community support for research on HIV/AIDS

The Pune CAB has been able to promote community support for biomedical research in areas where researchers have failed in the past. Community advisory board members, especially those belonging to nongovernmental and community-based organizations, have succeeded in disseminating scientific information to the community in a nontechnical manner that community members accept more readily. Many of the targeted community members live in the catchment areas of the organizations with which CAB members are affiliated.

Research staff can learn from CAB members about conducting successful HIV prevention research

Many of the Pune CAB members are or were leaders in their own fields and have been able to teach researchers a great deal about approaching and interacting with communities. One CAB member belonged to a youth organization and helped NARI researchers understand that they could reach young people more effectively if they also involved parents.

Community advisory boards can help design programs that directly increase community participation in research

When the Pune National AIDS Research Institute and its CAB faced the task of sensitizing the community to HIV/AIDS issues and related research, the Pune CAB functioned like a think-tank to develop a peer education program to inform communities about the research NARI hoped to undertake. Networking with nongovernmental and community-based organizations helped ensure the successful design of the program. The direct results of the program included education of more than 1,000 individuals through group meetings and more than 1,000 households through door-to-door meetings. The program has also increased the number of clinic referrals that originate from NGO staff members and the number of self-referrals to clinical services.

Conclusions and Recommendations of the HIV Prevention Trial Network on Community Involvement in HIV Prevention Research

As this document illustrates, community involvement is an integral part of successful research. Two primary objectives in collecting and publishing these lessons learned are to achieve a deeper understanding of the role of community involvement and collaboration in research, and to share knowledge and experience for how existing sites can refine and strengthen their community programs.

The conclusions and recommendations provided here are drawn from the combined wisdom of many people. First, we invited research sites to submit articles about their community programs, the challenges they faced in implementing them, and the lessons they learned in the process. Each of the articles identified what they felt were their most important lessons learned on the following topics in HIV prevention trials:

- How to approach the community for involvement
- How to effectively provide training for community members
- How to ensure community involvement with research methodology and design
- How community advisory structures can be developed
- How community representatives can make a difference

In an effort to synthesize the conclusions or recommendations of the lessons learned articles as well as to incorporate experience and knowledge from those sites in the HPTN that did not write an article, the lessons learned from each of the nine sites were consolidated into one document. The HPTN CORE community program staff then presented them to the participants at the 2005 HPTN Combined Regional Working Group Workshop in Rio de Janeiro, October 23-28, 2005. In the workshop's Community Educators session, 30 participants representing community educators, study coordinators, principal investigators and other research staff were asked to create a unified document with recommendations across all of the HPTN. The group was divided into five groups and was asked to:

- Group similar lessons into one and formulate in clear and concise language
- Add lessons that are missing

The following are the consolidated and revised conclusions and recommendations from the nine lessons learned articles with additional input from participants at that workshop.