

# HPTN CORE Community Program — Lessons Learned

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## Introduction

This article provides a history of HPTN's community program, including its general approach to community involvement. It also describes the community program's main activities, which include information exchange, education and training, technical support and advocacy. Finally, the article highlights some of the challenges that program staff have encountered, some of the techniques used to meet these challenges, and the valuable lessons learned.

## History of the HPTN Community Program

The HIV Prevention Trials Network (HPTN) is a worldwide collaborative clinical trials network that develops and tests the safety and efficacy of primarily nonvaccine interventions designed to prevent the transmission of HIV. Established in 1999 by the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), the HPTN carries out its mission through a network of expert scientists and investigators. HPTN is comprised of more than two dozen U.S. and international sites, with leadership by three U.S.-based institutions. One of these, Family Health International, serves as the Coordinating and Operations Center (CORE) of the network.

Since the beginning, the HPTN has addressed its goal of developing a collaborative, multisite, multidisciplinary prevention science research agenda across six scientific disciplines: antiretrovirals, behavioral, microbicides, perinatal, STI control, and substance use. In addition, the HPTN has made major investments of both human and financial resources to build international research structures, enhance collaborative community partnerships, and address issues in research ethics in the context of HIV prevention research.

HPTN site awards were made in July 2000, but the first community CORE staff member was hired seven months earlier, to begin forming an interim Community Working Group (CWG). The CWG was made up of community-minded representatives from the HPTN's Executive Committee (EC), HIV Vaccine Trials Network, and other relevant organizations involved in HIV prevention research. By August 2000, the HPTN CORE community team was fully staffed, with two community

program managers and one community program specialist. The initial responsibility of the community HPTN CORE staff and the interim CWG was to refine and shape the overall HPTN community involvement plan.

The key components of the HPTN community involvement approach included:

- Development and implementation of an overall HPTN community involvement plan
- Establishment of an integrated domestic/international HPTN CWG and community advisory boards (CABs) at each of the HIV Prevention Trial Units (HPTUs)
- Development and implementation of a realistic and culturally appropriate community involvement strategy at each HPTU
- Provision of ongoing technical assistance and training and educational materials in support of these community involvement plans and activities
- Active participation of community representatives at every level of HPTN research planning and network operations
- Monitoring and evaluation at both the network and at HPTU levels

A key responsibility of the CWG is to promote information exchange between the six scientific working groups, the EC and the HPTN sites, or HPTUs. The scientific working groups represent the six scientific disciplines addressed by the HPTN. The CWG informs and advises the EC on emerging issues of concern and provides leadership to HPTU community program staff in addressing them. These issues cut across culturally diverse populations, communities and technical areas that form the focus of HPTN research, including ethics. The CWG also promotes and develops research relevant to improving community involvement in the HPTN research agenda.

The purpose of the HPTN CORE community program is to ensure sustained communication and information exchange between community members and researchers, with the aim of creating community investment in HPTN research and fostering a positive and open environment for the conduct of HPTN research. The HPTN research plan addressed community involvement in each of the six scientific areas, and community involvement is integrated into every level of the proposed network structure and operation.

The three dedicated CORE community staff members provide technical assistance, training and support relative to studies underway to the HPTU community program staff and the HPTN CWG.

With CWG leadership, the CORE community program staff developed a logic model that illustrates its approach to community involvement. In the logic model, the CWG provides leadership and guidance, and the CORE community program staff provides training and technical support on the following topics:

- Community preparedness, including needs assessment, mapping, stakeholder analysis
- Community advisory board organization and governance (including by-laws, project planning and management, monitoring and evaluation)
- Strategic education and communications (including networking, materials development, disseminating HIV research findings throughout multilevel communities)

- Community mobilization (including advocacy, World AIDS Day, and other events)
- Other key topics (including research literacy, research ethics, stigma and discrimination).

The upcoming *HPTN Community Guidance Manual* will provide comprehensive detailed guidance on many community involvement planning and implementation activities.

## **CORE Community Program Activities**

The CORE community program is divided into four main areas of work: information exchange and education, technical support and training, materials production, and advocacy.

### **Information Exchange and Education**

The HPTN CORE community program hosts calls on a quarterly basis for the CWG and RWGs of the Americas, Africa and Asia. The one-hour calls cover a variety of topics agreed to by the participants, including updates from each of the sites on their community involvement activities, updates from HPTN CORE protocol specialists, and a discussion of upcoming events at the local, national or international level. These calls are an opportunity for sites to learn from each other's efforts and to exchange information and ideas. The annual network meeting and regional workshops are also important vehicles for information sharing. These in-person meetings provide an excellent opportunity for community educators and CAB members from many sites to share their experiences or ask for guidance on resolving difficult issues — from each other as well as from the CORE community program staff and the CWG.

### **Technical Support and Training**

Technical support and training are provided to sites in a number of ways. In collaboration with local community staff, various tools for planning and monitoring/reporting activities were developed: the community involvement workplan, the community involvement annual snapshot and the community involvement quarterly report. These documents provide an outline and structure for planning and monitoring/reporting community involvement activities. Instructions about completing the forms were also developed. Additionally, in collaboration with the University of California, San Francisco, the Community Indicators Survey has been conducted annually since 2004 to assess community involvement and partnerships between researchers and HPTN research communities; its ultimate goal is to enhance community partnership at the site level.

About once a year, a member of the community program team visits the sites to provide technical support to the research team and to staff involved with community involvement activities and with the local CABs. CORE community program staff typically review the aforementioned planning and monitoring/reporting tools, address challenges faced at the site in involving communities, visit venues where study activities and community outreach and education take place, and provide training on a variety of topics such as research ethics, stigma and discrimination, and planning methodologies.

Appendix 1 provides an overview of (1) training topics covered either at the HPTN Annual Meeting or at the RWG workshops and (2) national and international conference sessions that were implemented by HPTN CORE community program staff.

## Materials Production and Dissemination

In addition to the planning and monitoring/reporting tools mentioned previously, the HPTN CORE community program has produced or collaborated on the production of a number of materials on community involvement in research. In collaboration with Family Health International's Office of International Research Ethics, the HPTN CORE community program helped produce the *Research Ethics Training Curriculum for Community Representatives*. It was field-tested by community representatives in Brazil, China, India, Malawi, Tanzania, the United States, Zambia, and Zimbabwe. The curriculum provides training on the components of the research process, the roles and responsibilities of community representatives in that process, universal ethical principles, informed consent, and the workings of ethics committees. It was recipient of the 2005 Distinguished Award of the Society for Technical Communication and the 2005 Award for Excellence in Human Research Protection of the Health Improvement Institute.

The HPTN CORE community program also facilitated the production of the document titled, *Community Involvement in HIV Research: Lessons Learned from the HIV Prevention Trials Network*. Additionally, the HPTN CORE community program is completing the *Community Guidance Manual*, which will outline in detail how to promote community involvement in research at a site level. The manual was written to assist staff at HPTN trial sites as they plan and implement activities to involve and educate the community about HIV prevention research.

Additionally, the community program maintains a small clearinghouse of materials on topics related to community involvement that can be photocopied and sent to sites as requested. The community section of the HPTN Web page also is a source of information for key documents, such as the monitoring/reporting forms, minutes of the conference calls, and other documents.

## Advocacy

Since the idea of community involvement in scientific research is still a relatively new one both for researchers and communities, there is still a need for advocacy activities on the topic at the local and network levels. The HPTN CORE community program advocates for the meaningful participation of community representatives in the research process of the HPTN from the site level to the EC. Community program staff work with researchers to clarify the stages at which community involvement is needed. For instance, whereas researchers know to consult with the community on the informed consent process, they might not think to invite community representatives to meetings that are considered purely "scientific" in nature. The HPTN CORE community program has advocated for community representatives to be invited to protocol-specific trainings when invitations had not been extended.

The HPTN CORE provides a budget guidance document that is sent each year to site principal investigators for their annual budgets. The HPTN CORE community program staff drafts the section on how to budget for community involvement activities. This includes advocating for funds for a community educator working at least half-time, materials for community outreach and education, and participation of a community education staff person and between two and three community representatives at the HPTN Annual Meeting.

## Challenges

The HPTN CORE community program staff encountered a series of challenges to ensuring meaningful community involvement in research activities and learned a number of valuable lessons.

### Diverse Communities

No single approach or model was considered appropriate for ensuring true community involvement in research planning and activities across the culturally diverse domestic and international HPTU sites. The definition of community differed greatly across populations as varied as U.S. inner-city injecting drug users and pregnant HIV-infected African women, for example. The definition was even inconsistent within a single HPTU, since a number of the HPTUs focused on research in more than one scientific area or in more than one study population. An accepted definition of community for HPTN became “the group of people who will participate in or are likely to be affected by or have an influence on the conduct of the research.”

To ensure success, community involvement plans have to be tailored to the specific setting and culture in which they are to be implemented. Therefore, each HPTU was responsible for assessing local needs and developing and implementing a community involvement strategy that was realistic and appropriate for its particular situation. The strategy included goals, objectives, specific activities, a timeline for implementation, and a plan for monitoring and evaluation.

### Technology / Communications

The prevailing reliance upon virtual means of communications such as teleconferences and email poses a number of difficulties:

- Phone lines, particularly within the Africa region, are frequently plagued by noise interference, disconnects, or inability to make initial connections. Much time is spent trying to get through, often with little success.
- Internet connections are also often extremely slow at some sites, making it difficult for community educators to use this technology effectively, and nearly impossible for them to download attachments. Materials then have to be faxed or couriered to the site, which incurs additional costs and creates logistical challenges.
- Community educators are unable to call each other directly due to budget restrictions. This results in reliance upon HPTN CORE community program staff to set up calls between sites.

### Language

One of the main challenges that we face in working with communities is language barriers. Whereas researchers invariably need English skills to serve as a local principal investigator, community representatives are chosen for their knowledge and linkages to local communities, not for their English language skills. The HPTN works with communities that speak English, Spanish, Portuguese, Marathi, Hindi, Thai, Uighur, Mandarin, Swahili, Zulu, Shona, Bemba, Baganda, Chichewa, and other local languages. Although the community educator at the site usually speaks fluent English, often many of the CAB members at international sites do not speak or understand English. How, then, can community representatives participate if their native language is not English? Conference calls, one of the main modalities of communication of the HPTN, are held

in English, so only English speakers can participate. Community representatives who speak both English and the local language are then tasked with relaying information from conference call participants to their local colleagues and vice versa, which presents logistical challenges.

### **Turnover of Personnel / Attrition**

Frequent turnover of CAB members can create a strain on community participation. Establishing and sustaining a CAB requires continuous and ongoing community education for CAB members. On-going community education for a CAB plagued by attrition is difficult at best. There is a never-ending need for new member orientation, which hinders CABs from proceeding through the education continuum so that they can support their local communities, the unit research staff, and study participants in the research process.

### **Staffing Limitations**

The current budget is designed for one visit to each site per year, with each member of the HPTN CORE community program staff responsible for an average of nine sites. It is challenging to provide meaningful technical support to sites when visits are scheduled only once per year. More substantive support could be provided to sites on their community involvement activities if visits were scheduled twice a year, with HPTN CORE community program staff responsible for a maximum of five sites.

### **Community Advisory Mechanisms**

There is little operational guidance on effective community participation in research, and initially the focus was on implementing the NIH mandate that every site should establish a CAB. It did not take long to realize that the CAB approach, while an effective model within the United States, was not necessarily appropriate, adequate or relevant in some international settings to implement authentic community participation. Issues of representation, gender balance, autonomy and accountability arose and required clarification. Some early CABs were hand-picked by the investigator and other study staff, and hence easily co-opted by the research process. Ensuring that the voices of potential study participants were not only represented on the CAB, but heard, meant in some cases challenging existing cultural norms — for example, in settings where men are the decision-makers and the research involves women. It became necessary to recognize and accept the limitations of the CAB model, and expand the notion of “advisory” to include broader partnership approaches that aim towards true collaboration.

## Lessons Learned

### ***Community education must precede community participation and must be continuous and ongoing***

In order to achieve engaged and substantive community participation, HPTU CAB members must receive continuous and on-going education about HIV prevention and protocol-specific research. Without community education, CAB members are not equipped to assist their communities in understanding general information about research or inform them about specific studies that will take place in their local communities. Continuous and ongoing community education for CAB members is necessary to enable them to provide site research teams with informed comments regarding study protocols, informed consent documents and processes, informational and educational materials, and recruitment and retention plans. Community education for CAB members facilitates their ability to collect and make available to research staff and to the HPTN information that can be used to address any rumors and misconceptions arising before and during research trials.

### ***Partnerships for community participation should be formed at HPTN CORE***

HPTN CORE community program staff must actively cultivate partnerships with their clinical research colleagues in order to accomplish community participation in research. Community program staff can encourage partnerships with the clinical research team by including them on correspondence with unit research and community program staff, inviting their participation on conference calls to provide study-specific updates, participating in study-specific training opportunities at the sites, convening pre- and post-community site visit meetings to assess training and technical support needs, and exchanging site visit reports.

### ***Community education must include “realities of research”***

Care must be taken in crafting messages to the community so as not to raise false hopes and undermine the community’s trust in the researchers. The reality of clinical trial research is that unforeseen delays and suspensions or the need to stop studies early can happen at any time. Care should be taken not to make promises that may not be fulfilled. In other words, we need to manage community expectations upfront by building partnerships, yet at the same time be realistic about all the possible scenarios and outcomes.

### ***Earlier development of community SOPs would have been crucial for greater collaboration***

Hindsight is perhaps always “20/20.” It is clear now that more detailed guidance on how to facilitate community involvement activities at a site level is vital. *Defining Best Practices for Community Involvement in Clinical Research Trials* — the report of the cross-CAB Working Group meeting that took place in Washington, DC, May 5-6 — was an important first step in providing that guidance to all involved. Additionally, the HPTN CORE community program is developing standard operating procedures (SOPs) on different aspects of community involvement in research and is reviewing the existing SOPs to identify any revisions that may be necessary. Standard operating procedures must explicitly state that communities should be involved in the different stages of protocol development, implementation, and dissemination of study results.

***Resources must be allocated for translators and interpreters***

To ensure participation of community representatives at the HPTN Annual Meetings or Community RWGs, translators are hired at great cost. The only way to facilitate meaningful community participation is to ensure that adequate resources are allocated for translation of materials and for interpreters at network meetings, regional community workshops, and community program site visits when community representatives do not speak English.