

**Recommendations for Community Involvement  
in National Institute of Allergy and Infectious Diseases  
HIV/AIDS Clinical Trials Research**



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## Preface

The world of clinical trials research is highly regulated, with an array of documents guiding the conduct of clinical trials research. This includes policy documents and procedural guidelines covering all aspects of clinical research generally referred to as Good Clinical Practice (GCP). The topic of community involvement, however, is not covered in these guidelines, and many community representatives have increasingly felt that another type of “GCP” was needed, with the initials in this case standing for “Good Community Practice.”

This document is the product of extensive community experience and expertise from around the world. With it, the National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) and Community Partners hope to provide a tool for researchers and community representatives to further expand and deepen existing partnerships and forge new ones in clinical trials research in our common quest to find better ways to prevent, treat, and find a cure for HIV/AIDS.

## Purpose

These recommendations are geared toward the global needs and experiences of NIAID’s HIV/AIDS clinical trials networks. Nonetheless, they will undoubtedly have uses beyond these groups.

Although community representatives and advocates have been involved in NIAID’s HIV/AIDS research endeavors for nearly 20 years, little formal guidance has been provided to community representatives or to NIAID-funded researchers on how community

involvement might best be achieved. In order to streamline the community’s role across NIAID’s HIV/AIDS clinical trials networks, and without losing the individuality and autonomy at each site or within each network, Community Partners has tried to define the roles and responsibilities of the community engaged with the research process and identify best practices for effective community involvement.

*The mission of DAIDS is to help ensure an end to the HIV/AIDS epidemic.*

## Background

DAIDS, a component of NIAID at the National Institutes of Health (NIH), was established in 1986 to develop and implement the national research agenda to address the burgeoning HIV/AIDS epidemic. DAIDS supports research on the basic knowledge of the pathogenesis, natural history, and transmission of HIV through fundamental, basic, and epidemiological research; pre-clinical and clinical research; development of therapies for HIV infection and its complications and co-infections; discovery and development of HIV vaccines; and development of non-vaccine prevention strategies, including topical microbicides and methods to prevent mother-to-child transmission of HIV.

DAIDS created its first HIV/AIDS clinical trials network in 1987, the AIDS Clinical Trials Group (ACTG), which was charged with developing and evaluating treatments for HIV-infected adults and children. Over time, DAIDS established additional clinical trials research networks to address: pediatric HIV research (Pediatric AIDS Clinical Trials Group or PACTG); therapeutic

research in community-based settings (the Community Programs for Clinical Research on AIDS or CPCRA); vaccine research (the AIDS Vaccine Evaluation Group or AVEG); prevention research (HIV Network for Prevention Trials or HIVNET). Later, the AVEG and HIVNET were reconfigured into the HIV Prevention Trials Network (HPTN) and the HIV Vaccine Trials Network (HVTN).

In 2006, in response to new scientific challenges and opportunities, DAIDS restructured its HIV/AIDS clinical trials networks and established the: ACTG, HPTN, HVTN, International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT), and the Microbicide Trials Network (MTN). Individually and in collaboration, the networks address DAIDS' six areas of highest scientific priority:

- HIV vaccine development
- Translational research/drug development
- Optimization of clinical management including co-infections and co-morbidities
- Microbicide development
- Prevention of mother-to-child transmission of HIV
- The development of new strategies for HIV prevention

**National Institute of Allergy and Infectious Diseases Division of AIDS HIV/AIDS Clinical Trials Networks**

*Highest Research Priorities*

**AIDS Clinical Trials Group (ACTG)**

- *Optimization of treatment/clinical management of HIV and its co-morbidities in adults living with HIV/AIDS*
- *Translational research and drug development*

**HIV Prevention Trials Network (HPTN)**

- *Evaluation of HIV prevention strategies, including use of antiretroviral therapy, treatment and prevention of sexually transmitted infections, substance abuse treatment, and behavior change to reduce HIV transmission and acquisition*
- *Validation of methods to detect acute/early HIV infection*

**HIV Vaccine Trials Network (HVTN)**

- *Evaluation of preventive HIV vaccine candidates*

**Microbicide Trials Network (MTN)**

- *Evaluation of the safety, effectiveness, and acceptability of microbicide candidates to prevent HIV infection in women*

**International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)**

- *Optimization of treatment/clinical management of HIV and its co-morbidities in adults living with HIV/AIDS*

**International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT)**

- *Prevention of mother-to-child transmission of HIV (PMTCT)*
- *Optimization of treatment/clinical management for HIV and co-morbidities for HIV-infected children, adolescents, and pregnant women*

Each of the HIV/AIDS research networks and their affiliated clinical research sites are required to include community representatives in their organization, working at the network level to help develop research plans and set research priorities, and at the site level to exchange information on community needs and concerns as well as planned and ongoing research. This is accomplished through the establishment of a network Community Advisory Board (NCAB) and a local Community Advisory Board (CAB) at the clinical trials unit (CTU) or clinical research site (CRS).

A unique component of DAIDS' most recent restructuring of its clinical trials networks was the creation of Community Partners, an overarching body of community representatives designed to address cross-network concerns and the needs of the diverse communities working within each of the clinical trials networks.

In doing this, DAIDS has taken the community's participation to a new level and has established a formal role for community members across all of the networks, providing an opportunity for regular interaction and communication with both network and DAIDS' leadership.

## What We Know<sup>1</sup>

### Defining “Community”

Finding a common definition of “community” is not as simple as one might think, as the views and perspectives of what constitutes community and the role community should play in the research process are widely divergent. In reality, communities are not homogeneous and may have competing interests and priorities; they may not always fit a single definition.

DAIDS and its HIV/AIDS clinical trials networks and sites tend to define community by the population in and for which the research is being conducted. For example, HIV vaccine research and other prevention research focus on healthy uninfected volunteers; however, some prevention research studies are conducted in populations with high incidence of HIV. For therapeutic research, the community clearly encompasses HIV-infected individuals, but may be further segmented into communities of adults, adolescents, and children, depending on the nature of the research. Key stakeholders, political leaders, and decision makers, who comprise part of the broader community, are often included in educational and outreach activities so that they can be informed of research plans, goals, and the potential impact. The support of this broader community is essential to the ongoing success of the clinical research process and partnerships within any given region.

### Rationale for Community Involvement

Collaboration with, and inclusion of, community representatives in the research process help to build trust and increase the likelihood that affected communities are invested in and supportive of the research being done.

- People who form a community provide the most direct opportunity for making a difference within that community; public health research that aims to be successful cannot afford to overlook this resource when planning strategies (Merzel and D’Afflitti 2003).
- Collaboration between researchers and communities helps to ensure that communities invest themselves in the research, making data and results more significant for the community, thereby “increas[ing] the likelihood for a successful project with mutual benefits” (Leung et al. 2004).
- Community participation also helps researchers achieve “better penetration of communities with more acceptable and culturally relevant messages, and greater sustainability of the intervention activities and effects” (Beeker et al. 1998).
- Community participation in HIV/AIDS research can be instrumental in raising awareness about influences on HIV transmission within the community, producing attitude changes in community leaders and strengthening leadership capacity in the parts of the community most affected by HIV/AIDS.

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<sup>1</sup> The information in this section is based on excerpts from a comprehensive literature review on community involvement in HIV/AIDS clinical trials research compiled by Benjamin Weil, MIA, LaHoma Smith Romocki, MPH, PhD, and Stella Kirkendale, MPH.

- A common perception in many communities is that researchers disregard the perspectives and needs of the community. Community participation can help build trust between the researchers and those being researched.

### **Community Advisory Board Model**

The Community Advisory Board (CAB) model was initiated in 1990 when NIAID invited a group of AIDS activists to participate in an annual meeting of the ACTG. It was truly the first time that community representatives—AIDS activists—were invited to meet with research scientists to discuss specific aspects of the HIV/AIDS treatment research agenda. The nature of this group evolved over time and became a model for community involvement not only in AIDS research but in other areas of research as well. The group was formally established as the Community Constituency Group (CCG), with the primary goal of facilitating an exchange of information about the network’s research plans and activities. Over time, CCG representatives were given the opportunity to play an active role on scientific committees, in the development of specific protocols, and to truly have input into the research process. Eventually, all NIAID-funded research networks were required as part of their award to have a CCG or CAB. By 1996, local CABs were established at each of NIAID’s funded HIV/AIDS clinical trials sites as well. These “local” CABs were established to ensure that those who were affected at the local level had a way of voicing their needs and concerns and could learn firsthand about ongoing research studies and related activities at their local site.



Currently, NIAID’s network and local CABs serve a number of different functions. Most importantly, they are a link among researchers, trial participants, and the broader community. At the global network level, CAB members provide valuable input in setting the research agenda and can contribute to improving the quality of research protocols by offering feedback and constructive criticism. At both the network and site level they may explain possible advantages and drawbacks of participation in research to community members and may help identify and resolve ethical issues related to a research project (Morin et al. 2003). CAB members can also work with site staff to develop materials that explain a research project in lay language to potential participants and establish recommendations to help them decide whether or not to participate (Strauss et al. 2001).

While volunteer recruitment or retention are not the responsibility of local CAB members, their knowledge of how to best reach the community— where and how—can be of significant help to researchers and research staff as they seek to inform the community about upcoming and ongoing trials and recruit potential study volunteers.

CABs generally consist of community members who represent those who have a stake in the research being conducted. They may include representatives of non-governmental and community-based organizations, local government officials, members of patient advocacy groups, health care workers, trial participants, family members, and others.

<b>Chronology of Community Involvement in NIAID-funded HIV/AIDS Research</b>	
<b>1987</b>	<b>NIAID established its first clinical trials network—the AIDS Clinical Trials Group</b>
<b>1989</b>	<b>ACT-UP attended an ACTG meeting (uninvited) to voice community concerns about the research process</b>
<b>1990</b>	<b>Community representatives were invited to an ACTG meeting and formed the CCG, the first network CAB</b>
<b>1994</b>	<b>DAIDS brought together the leadership of the CCG and other network CABs that were subsequently established, to exchange ideas and concerns</b>
<b>1996</b>	<b>DAIDS convened an external panel to review network CABs NIAID required CABs at each research site affiliated with a clinical trials network</b>
<b>1997</b>	<b>First cross-network CAB training on clinical trials research</b>
<b>1998</b>	<b>Model regional training for researchers and community held in Chicago on how to establish a CAB</b>
<b>2001</b>	<b>Second cross-network CAB training on ethics in clinical research</b>
<b>2003</b>	<b>First Cross-CAB Working Group conference call Cross-CAB Working Group established</b>
<b>2007</b>	<b>Establishment of Community Partners</b>

## Principles of Community Engagement<sup>2</sup>

The following principles lay the foundation for effectively involving community representatives in the research process.

- Be clear about the purposes or goals of the community engagement effort and the populations and/or communities to be engaged.
- Become knowledgeable about the community in terms of its economic conditions, political structures, leaders, norms and values, demographic trends, history (overall and regarding research), and experience with engagement efforts. Learn about the community's perceptions of those initiating the engagement activities.
- After going into the community, establishing relationships, and building trust, seek commitments from community-based organizations' formal and informal leadership in order to mobilize the community.
- Allow the community to express itself independently during the community engagement process.
- Partnering with the community is necessary to create change and improve health.
- Sustainable community engagement can only be achieved by identifying and mobilizing the community and by developing the capacities and resources within the community.
- Community collaboration requires long-term commitment by the research organization and its partners.

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<sup>2</sup> These principles were adapted from guidelines developed by the Centers for Disease Control and Prevention (CDC) Agency for Toxic Substances and Disease Registry (ATSDR) Committee for Community Engagement. They are based on practical experiences and are designed to help guide community leaders and researchers in designing, implementing, and evaluating community engagement efforts.

## **PART I. Recommended Roles and Responsibilities**

There are clear advantages to involving the community in HIV/AIDS clinical research. It helps ensure that the larger community understands the site's research plans, how these plans will immediately impact their community, and the potential impact on the community in the future.

The recommendations provided in the following sections are organized around the process of protocol development. They represent an ideal level of involvement and communication among the researchers, research staff, and CAB members. They include a broad range of activities, and no individual CAB member can, or is expected to, do them all. It is recognized that CAB members' time is extremely valuable and often limited. Thus, CABs will need to set priorities for how they will participate in the research process, and these priorities may change over time.

### **Overview**

CABs are required by all DAIDS-funded HIV/AIDS clinical trials networks and sites to ensure that there is community input into the research process and to foster a partnership between researchers and the communities in which and with whom the research is being conducted.

At a network level, CAB members work with the network leadership on scientific, operational, and oversight committees, and on protocol teams. In so doing, CAB members play an important role in helping to shape network research plans, identifying scientific priorities, reviewing site performance issues, and in designing and implementing the clinical trials. They are representatives of the broader community and, as such, have a responsibility to share information about the research with the broader community and relay community concerns, needs, and priorities with the network leadership.

At a local site level, CABs may represent the local demographics of the HIV epidemic or the larger community; ideally they would include those infected and affected by HIV, service providers, advocates, and other stakeholders. They help researchers ensure that protocols are designed ethically and feasibly, and are reflective of the interests and needs of the local community. Local CAB participants can facilitate an information exchange between researchers and the larger community by sharing community concerns and priorities with researchers and research staff and helping them better understand community norms and needs. This helps researchers reach the target population in culturally and linguistically appropriate ways, and provides the community with information about the need for HIV/AIDS clinical trials research in general, as well as the goals of, and plans for, specific trials. The CAB works in partnership with researchers and research staff to solicit support and guidance from the populations they are seeking to help, and toward the common goal of combating AIDS.

### **Whether at the network or local level, CAB members should be:**

- Culturally sensitive to populations traditionally underrepresented in HIV/AIDS clinical trials, i.e., women, people of color, youth, and injecting drug users
- Knowledgeable about the medical and social aspects of HIV and willing to expand and maintain their knowledge base
- Self-motivated and committed to independently pursuing knowledge and information about trends in the treatment and/or prevention of HIV/AIDS

- Familiar with, or eager to learn about, clinical trials that are being conducted and the types of research questions relevant to the communities that are being targeted by their network or site

**General responsibilities of network and site CAB members may include:**

- Working with researchers and research staff to help the community understand the need for and goals of the research being planned
- Providing information about communities’ research needs and concerns based on knowledge of the community and feedback about the research (planned and ongoing)
- Providing information that will help researchers improve study participants’ compliance and quality of life through personal experience and knowledge of community-wide needs
- Reviewing concepts for clinical trials, informed consent plans, and other related documents
- Providing information that may help researchers and research staff better understand the community so that they can devise effective strategies for outreach, recruitment, and retention
- Participating in the protocol development process and study implementation
- Providing linkages to targeted communities and assistance in forming partnerships
- Translating scientific information into lay language
- Informing the broader community (for network CAB members this may encompass local CABs as well as others) about the various studies being conducted, their importance to the community, and their potential impact on treatment or prevention
- Advising on how best to disseminate information about research results in a timely manner and reviewing materials to ensure that they are appropriately crafted

**Roles and Responsibilities of Researchers and Research Staff**

Each clinical trials network should ideally have an identifiable employee serving as the liaison to the network CAB; similarly, each clinical trials site should identify a staff member who is responsible for working with the local CAB. These individuals would serve as a bridge between the researchers and the CAB and could be responsible for:

- Coordinating CAB activities, including conference calls, forums, trainings, operational meetings, educational sessions, and briefings
- Ensuring that the CAB is kept apprised of all relevant research plans—studies that are being considered, status of ongoing studies, and research results
- Facilitating the exchange of information among the CAB, researchers, and other research staff
- Identifying training needs of the CAB, planning appropriate sessions, and assembling educational materials to address these needs. This could include the provision of regular educational opportunities for CAB members as well as programs on clinical trials research or on various aspects of HIV/AIDS for the benefit of the broader community

- Identifying training needs of researchers and research staff to ensure their effectiveness in working with the community
- Developing strategies for recruiting CAB members
- Developing strategies for recruiting and retaining study volunteers

### **Role of the Network Leadership and the Division of AIDS**

Each network is responsible for evaluating its clinical research sites, and community involvement should be one of the many evaluation criteria. It is not enough for a site to simply have a CAB; having an active, effective CAB that functions in partnership with researchers and research staff is the goal. In turn, DAIDS should have network evaluation criteria pertaining to CAB activities.

### **Management and Support Needs**

CAB members need resources and support from their respective network or research sites so that they can participate as equal and valued members of the research team. However, many community representatives do not and cannot operate like individuals in academia, whether because of hierarchy, resources, or other constraints. Therefore, flexible support is critical. For example, if CAB members are expected to participate on every protocol team call, they may need regular and reliable telephone access at a site. In order to assess and meet support needs, it is recommended that a staff person be assigned to work with a CAB at both the site and network level. Because this support is essential to CAB effectiveness, adequate funding would ideally be integrated into network and site budgets.

#### **Management and support needs would ideally include:**

- Network and/or CTU/CRS staff person(s) assigned as the point person to work with the CAB
- Dedicated staff person(s)' duties may include:
  - maintaining call and meeting schedules and CAB member contacts
  - coordinating CAB member transportation and travel needs
  - troubleshooting logistical and technical needs of CAB members
  - acting as general liaison to CAB
- Telephone and internet access availability for all CAB members. One option is to arrange for CAB members to access telephone and internet directly at the site, which may include transportation support to and from the site
- Language interpretation for CAB-related calls and meetings, as appropriate

- Travel needs for CAB members:
  - transportation to and from all local CAB meetings. May also include transportation to and from the site for CAB-related calls or internet access
  - travel, lodging, and per diem for regional and international CAB meetings
  - travel, lodging, and per diem for CAB leadership participation at all network meetings
  - Visa and passport application assistance and fees
- Training of new CAB members, at the site, regional, and network level
- Translation of materials and documents for all calls, meetings, and trainings
- Meeting costs, including meeting space facilities that are accessible to all, presentation equipment and materials, audio visual assistance, and refreshments
- General office supplies
- Child or family care support for participation at meetings
- Message or suggestion box, or other mechanism for collection of community responses
- Other technical support, such as evaluation of community activities

## Laying the Foundation for Community Involvement

### 1. Introduction

Because NIAID relies on the CAB model as a tool for community involvement, the following recommendations pertain to establishing a CAB at a CTU or CRS. However, researchers and community representatives may want to become familiar with alternative models for community involvement that may be more appropriate in a given region or setting, or that may help address a specific aspect of the community/researcher partnership.

### 2. Roles and Responsibilities:

#### 2.1 Site CAB and Research Staff

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<i>Gather Information for Community Profile</i>	<ul style="list-style-type: none"> <li>▪ Help researchers and research staff to better understand the community (e.g., characteristics and organization)</li> <li>▪ Identify key community leaders</li> <li>▪ Build partnerships with community-based organizations</li> </ul>	<ul style="list-style-type: none"> <li>▪ Conduct formative research and stakeholder analyses to “map” the community, which includes identifying:               <ul style="list-style-type: none"> <li>○ community dynamics</li> <li>○ key decision makers and community leaders</li> <li>○ research needs and interests in the community</li> <li>○ with whom/and how best to build partnerships</li> </ul> </li> <li>▪ Facilitate community consultative meetings to solicit questions, opinions, and identify key concerns about the research, and address these in a transparent fashion</li> </ul>
<i>Educate and Train</i>	<ul style="list-style-type: none"> <li>▪ Educate research staff about the needs of the community and best ways to reach specific segments of the population</li> <li>▪ Provide the research staff with simple, culturally appropriate terms for complex scientific language</li> <li>▪ Educate researchers about community concerns and research priorities</li> </ul>	<ul style="list-style-type: none"> <li>▪ Educate community about research goals, potential benefits to the community, and overall public health</li> <li>▪ Provide opportunities to get involved in various aspects of the research process, e.g., study participant, CAB member</li> </ul>

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<i>CAB Development and Recruitment</i>	<ul style="list-style-type: none"> <li>▪ Work with researchers and research staff to clarify the mission as well as roles and responsibilities of the CAB</li> <li>▪ Coordinate organization and governance of the CAB by addressing the: <ul style="list-style-type: none"> <li>○ frequency and facilitation of meetings</li> <li>○ agenda development</li> <li>○ engagement of broader community (non-CAB members)</li> </ul> </li> <li>▪ Identify training needs of CAB members and help organize and facilitate these trainings</li> <li>▪ Identify criteria for self-evaluation</li> <li>▪ Discuss evaluation criteria with researchers and research staff</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ensure that CAB development is transparent and inclusive of all relevant community groups</li> <li>▪ Determine the most appropriate ways to recruit CAB members: <ul style="list-style-type: none"> <li>○ extend invitations to community members to participate in the CAB</li> <li>○ ask local organizations and/or community groups to nominate a representative</li> </ul> </li> <li>▪ Discuss CAB membership requirements, which might include knowledge and cultural understanding of the relevant and diverse communities</li> <li>▪ Distribute materials to the community with notification of the first CAB meeting</li> <li>▪ Work with the CAB to: <ul style="list-style-type: none"> <li>○ clarify its mission and role</li> <li>○ provide an orientation for all new CAB members</li> <li>○ provide training to ensure effective CAB engagement in the research process</li> <li>○ identify evaluation criteria and process</li> </ul> </li> </ul>
<i>Sustain Community Structure</i>	<ul style="list-style-type: none"> <li>▪ Advocate for continued support of the CAB by researchers and research staff to ensure optimum output by CAB members</li> <li>▪ Advocate for research staff involvement in CAB activities</li> <li>▪ Hold regular meetings with set targets for frequency, attendance, and community feedback</li> </ul>	<ul style="list-style-type: none"> <li>▪ Support CAB activities and be actively engaged in meetings, trainings, and other programs</li> <li>▪ Help motivate and sustain CAB interest and development</li> </ul>



## 2.2 Network CAB, Research Network, and DAIDS

Role	Responsibilities of Network CAB	Responsibilities of Network Leadership	Responsibilities of DAIDS
<i>Guidance</i>	<ul style="list-style-type: none"> <li>Provide local CABs with information about how other CABs are organized and methods for interacting with CTU/CRS staff and the broader community</li> </ul>	<ul style="list-style-type: none"> <li>Provide CTU/CRS with guidance about the role of the CAB, recommended training needs, and level of support (for supplies, training, ongoing meetings, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Ensure sufficient level of staff support and availability of resources needed to sustain CAB activities</li> </ul>

### 3. Training

It is important to identify and utilize the skills that community representatives bring to the CAB and to provide training so that the CAB members can be more effective. To be most successful, CAB members would ideally have the following skills:

- Ability to communicate well and work in an inclusive and participatory way
- Open to constructive criticism and willing to be accountable to communities
- Capacity to listen and learn from both community representatives and researchers to gain understanding about the local HIV epidemic, community concerns and priorities, clinical research plans and protocols, and ethical concepts and issues
- Strong and enduring interest in community involvement in research and commitment to advancement of ethics, scientific research, and prevention, treatment, and control of HIV/AIDS

#### 3.1 Recommended training topics for CAB members:

- Communications training
- Presentation and public speaking skills
- Listening skills
- Report writing and information technology (IT) training
- HIV treatment and/or prevention (relevant to the research at the specific CTU/CRS and/or network), beginning with an introductory overview of HIV science and clinical research challenges
- Principles and structures for ensuring ethics and human rights, including processes for review and implementation of research plans
- Overview of DAIDS-funded clinical research structures, research priorities and plans, funding processes, and history of community involvement
- Other models of community participation
- Adult learning and education in order to better organize and facilitate meetings

- Building informal and formal mentoring relationships (within and across networks)
- Review of planned and current HIV clinical protocols as a way to train community representatives about how to read and evaluate a protocol
- Introduction to research design and analysis so that CAB members can better understand trial design and results
- Introduction to monitoring and assessment tools
- Interpreting research results and their impact on community

### **3.2 Recommended training topics for research staff:**

- Value of community involvement in research process
- History of community involvement in research and in NIAID-supported research
- How “community” is defined
- Different models of community involvement in the research process
- Potential role of the CAB in working with the site
- Role of the CAB at network level and role of Community Partners

## **4. Indicators of Success**

Research staff and CAB members might discuss the purpose of an evaluation, the need for developing reasonable and fair evaluation criteria, and how evaluation results would be used to strengthen the CAB. The value of using the evaluation to identify and document CAB success and to help guide future decisions related to support, training, or need for other resources should be emphasized. Documenting the CABs’ practices, particularly those that are effective, will also help provide guidance to other CABs as they implement various aspects of their organization or role. Methods for evaluation could incorporate both external review processes and self-evaluation. Evaluation criteria should be established during the initial organization of the CAB. The evaluation process should always be transparent.

### **4.1 Potential indicators of success:**

- Number of community events held to talk about CAB formation and role
- Establishment of a CAB
- Development of a CAB mission statement
- Implementation of a CAB orientation plan

## Community Preparedness

### 1. Introduction

Community preparedness is a process whereby the researchers and community staff explore how the community may respond to a proposed study, how the community will obtain information, and how to reach out to potential volunteers. This is fundamental to allaying potential fears and misconceptions that may increase reluctance to participate in a study. Addressing these issues will enhance recruitment and retention of study participants.

Many factors should be taken into consideration when preparing a community for clinical research, including 1) size and type of trial(s) to be conducted; 2) location, language, and demographics of the community; 3) socio-economic and cultural factors; 4) whether the community is new to, or experienced with, clinical trials research; and 5) whether the community has had previous involvement with a CAB. Additional factors to consider are whether the community is being prepared for one specific protocol or participation in the overall research agenda, and if multiple networks or study organizations will be involved.

### 2. Roles and Responsibilities

#### 2.1 Site CAB and Research Staff

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<p><i>Consult:</i></p> <p><i>Communication streams between staff and CABs need to be open and transparent</i></p>	<p>Introduce the researchers and the community to one another. Discussions may include:</p> <ul style="list-style-type: none"> <li>▪ Overview of the organization/network</li> <li>▪ General information about research</li> <li>▪ Research experiences in the community</li> <li>▪ Perceived research benefits</li> <li>▪ Community perspective on need for HIV research, areas of research needed, etc.</li> <li>▪ Overview of the research question</li> <li>▪ Introduction of new research plan</li> <li>▪ Difference between research and clinical care</li> </ul>	<p>Consider some or all of the following questions:</p> <ul style="list-style-type: none"> <li>▪ Does the trial target a specific population in the community?</li> <li>▪ What are the characteristics of the target population?</li> <li>▪ How much information should be given to the community? Consider education requirements by evaluating information gaps and needs in the community</li> <li>▪ How will the community be affected by the conduct of the trial? Who else might be affected by the conduct of this trial?</li> <li>▪ What other trials are taking place in the same community?</li> <li>▪ What role is the CAB going to play in preparing the community for the up-coming trial?</li> <li>▪ What are some of the community ethical concerns/issues?</li> </ul>

<b>Role</b>	<b>Responsibilities of Site CAB</b>	<b>Responsibilities of Research Staff</b>
<i>Strategize: Formulate a community involvement plan that serves to capture how the site will engage the community and the CAB</i>	<ul style="list-style-type: none"> <li>Identify and meet with community members and community-based organizations</li> <li>Conduct awareness campaigns and propose innovative ways to reach out to the community</li> </ul>	<ul style="list-style-type: none"> <li>Identify, establish, maintain, and nurture partnerships with local organizations such as clinics, churches, schools, non-profits, organizations, etc.</li> <li>Plan for community education sessions; encourage community input and suggestions on culturally accepted ways of conducting research</li> <li>Plan focus group discussions or community meetings for input that helps shape the research</li> </ul>
<i>Prepare</i>	<p>Educate the community about:</p> <ul style="list-style-type: none"> <li>Importance of research to the public health</li> <li>Clinical trials research</li> <li>Specific objectives of this research</li> <li>Possible impact, risks, and benefits of proposed research</li> <li>Role of a CAB</li> </ul>	<ul style="list-style-type: none"> <li>Consider which training topics are most appropriate for, or of greatest interest to, CAB members; invite CAB representatives to participate in protocol-specific trainings so they can have a better understanding of the research</li> <li>Take an active role in providing information about the research to local organizations</li> </ul>

## 2.2 Network CAB, Research Network, and DAIDS

<b>Role</b>	<b>Responsibilities of Network CAB</b>	<b>Responsibilities of Network Leadership</b>	<b>Responsibilities of DAIDS</b>
<i>Inform</i>	<ul style="list-style-type: none"> <li>Train site CABs in community preparedness strategy: what it is, how to do it, why it is important</li> </ul>	<ul style="list-style-type: none"> <li>Support network CABs (NCAB) in their work with sites</li> <li>Support sites in utilizing NCAB expertise</li> </ul>	<ul style="list-style-type: none"> <li>Require sites and networks to have CABs and encourage involving them in community preparedness efforts</li> </ul>
<i>Share Information</i>	<ul style="list-style-type: none"> <li>Help sites share best practices, challenges, and successes they have experienced</li> </ul>	<ul style="list-style-type: none"> <li>Share community preparedness best practices among CRS/CTU Principal Investigators (PIs)</li> </ul>	<ul style="list-style-type: none"> <li>Promote cross-network sharing of community preparedness best practices</li> </ul>
<i>Advocate</i>	<ul style="list-style-type: none"> <li>Ensure that community preparedness activities are defined in the CTU's development plans and that they are budgeted for</li> </ul>	<ul style="list-style-type: none"> <li>Advocate with DAIDS for adequate funding in the CTU budget to address community preparedness</li> </ul>	
<i>Evaluate</i>	<ul style="list-style-type: none"> <li>Participate in evaluating site and network CABs and community engagement activities</li> </ul>	<ul style="list-style-type: none"> <li>Evaluate sites' CABs and broader community engagement activities</li> </ul>	<ul style="list-style-type: none"> <li>Ensure that networks assess their network sites' CABs and community engagement activities</li> </ul>

### **3. Indicators of Success**

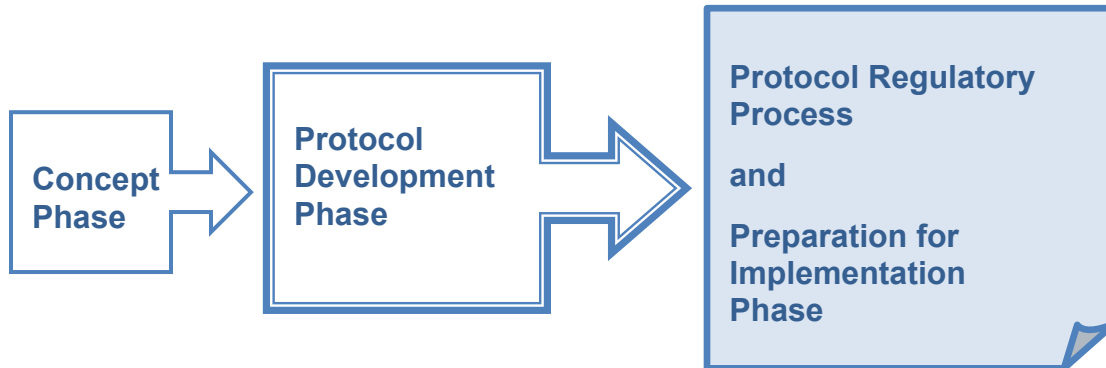
The success of community preparedness efforts can be evaluated by considering the following:

- Feedback from CAB about informed consent, protocol, and recruitment materials
- Community suggestions for conducting the study are shared with researchers and research staff
- Researchers and research staff respond to inquiries from the community about the study and address fears and suggestions
- Participation in educational events/forums
- Researchers and research staff know and understand target communities, including the socio-economic situation (through community mapping reports)
- Community knows where study is being conducted and who the key players are, most notably, the Principal Investigators
- Community understands research concepts such as the difference between research and care
- The community knows the importance of volunteers' contribution to the research process
- Partnerships have been established within the broader community and among other researchers

## Developing the Research Protocol

### 1. Introduction

Ideally, community involvement occurs at all levels of the research process in all NIAID-funded HIV/AIDS clinical trials networks. Community input starts when the research concept/question is first developed and continues until the results are discussed and published. This section focuses on the role of the community in developing the research protocol.



### 2. Roles and Responsibilities

#### 2.1 Site CAB and Research Staff

<b>CONCEPT PHASE</b>		
<b>Role</b>	<b>Responsibilities of Site CAB</b>	<b>Responsibilities of Research Staff</b>
<i>Community and Public Health Considerations</i>	<ul style="list-style-type: none"> <li>Contribute public health and community information generated from interactions between the CAB and potential trial participants that will help researchers shape the research concept</li> </ul>	<ul style="list-style-type: none"> <li>Investigate and prioritize research needs and develop a research plan accordingly</li> </ul>
<i>Research Question Considerations</i>	<ul style="list-style-type: none"> <li>Help determine the importance of the research being proposed to the community</li> </ul>	<ul style="list-style-type: none"> <li>Provide context for the research concept and describe it in general terms so that the purpose and benefits of the research to the community are understood</li> </ul>

<b>PROTOCOL DEVELOPMENT PHASE</b>		
<b>Role</b>	<b>Responsibilities of Site CAB</b>	<b>Responsibilities of Research Staff</b>
<i>Context for Research Question</i>	<ul style="list-style-type: none"> <li>Learn what is known about the research question</li> </ul>	<ul style="list-style-type: none"> <li>Share information related to the research questions/research area with the CAB</li> </ul>
<i>Study Design</i>	<ul style="list-style-type: none"> <li>Contribute community-relevant information that would help with designing a research protocol that can be implemented within a proposed time frame</li> </ul>	<ul style="list-style-type: none"> <li>Invite community input on study design through CAB involvement</li> </ul>

<b>PROTOCOL REGULATORY PROCESS AND PREPARATION FOR IMPLEMENTATION PHASE</b>		
<b>Role</b>	<b>Responsibilities of Site CAB</b>	<b>Responsibilities of Research Staff</b>
<i>Consents</i>	<ul style="list-style-type: none"> <li>Understand the reason for the informed consent document and the implication of signing it</li> <li>Ensure that the informed consent document is understandable and in lay language</li> <li>Ensure that the informed consent clearly states that consent to participate in a study may be withdrawn anytime</li> <li>Help the community understand all aspects of informed consent</li> </ul>	<ul style="list-style-type: none"> <li>Ensure that informed consent documents reflect the benefits and risks of participation</li> <li>Consider translating informed consent forms into the local language/ language of study participants and back-translating into English to ensure that the information is accurate</li> <li>Send informed consent to the CAB to ensure that clear, understandable language is used</li> <li>Submit all versions of the document to the local ethical and regulatory bodies (i.e., Institutional Review Board or IRB) and implement only on approval</li> </ul>
<i>Material: Education</i>	<ul style="list-style-type: none"> <li>Contribute to educational material by identifying gaps in existing material and suggesting needed topics for community education</li> </ul>	<ul style="list-style-type: none"> <li>Provide adequate, relevant, and culturally appropriate educational material in as many of the local languages as possible</li> <li>Receive updates/training from the community on their norms and systems for addressing health issues and needs; use information to help guide study implementation and conduct</li> </ul>

## 2.2 Network CAB, Research Network, and DAIDS

Role	Responsibilities of Network CAB	Responsibilities of Network Leadership	Responsibilities of DAIDS
<i>Participate on Scientific Committees</i>	<ul style="list-style-type: none"> <li>Bring community perspective to all discussions; bring information to network CAB about scientific committee considerations</li> </ul>	<ul style="list-style-type: none"> <li>Identify CAB members as part of protocol teams</li> <li>Seek out CAB members' opinions and consider their suggestions</li> </ul>	<ul style="list-style-type: none"> <li>Encourage networks to incorporate community feedback into research and/or network/site activities</li> <li>Evaluate networks on community involvement</li> </ul>
<i>Participate on Protocol Teams</i>	<ul style="list-style-type: none"> <li>Help protocol team consider participant issues when defining criteria for inclusion, exclusion, schedule of evaluations, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Ensure CAB representation and participation on protocol team</li> <li>Take CAB concerns into account as soon as protocol is developed, e.g., inclusion/exclusion criteria, study procedures, sample size, recruitment, data collection and management, and sample storage</li> </ul>	<ul style="list-style-type: none"> <li>Evaluate networks on community involvement/</li> </ul>

### 3. Training

Educational materials on the study and study products should be made accessible to the study population and the community in general. The materials should preferably be easy to understand and in the languages that are most used by the study population and community in which the research is being conducted.

### 4. Indicators of Success

Whether working at the site or network level, CAB members should document their input, noting ways in which protocols have been modified to address their concerns or ideas. Examples may include:

- Informed consent language has been simplified into more appropriate lay language
- The study design has been revised so that it would be more acceptable in the community (specify what changes were made, e.g., number of tests required)
- Eligibility requirements for the study have been altered

#### Indicators of success at the local site level:

- CAB meetings held to review protocol design
- Depending on size and nature of study, CAB review of communication materials to announce study and/or promote study participation



- Review of informed consent forms by CAB

**Indicators of success at the network level:**

- CAB member(s)' participation on protocol teams and scientific committees

## Implementing the Research Study

### 1. Introduction

Community involvement and collaboration with researchers should have begun well before study implementation. Once a research study has received regulatory approval, implementation can begin. Throughout study implementation, researchers and community representatives continue working together, providing each other feedback (e.g., if any new questions or concerns emerged, or if enough people are enrolling in the study) and ensuring that it is being implemented as planned (e.g., in accordance with local and national regulatory and ethical standards.)<sup>3</sup>

### 2. Roles and Responsibilities

#### 2.1 Site CAB and Research Staff

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<i>Inform</i>	<ul style="list-style-type: none"> <li>▪ Become informed about the research study including the reason the study is being done, the products being tested, the study design, and the implementation plan</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ensure that all study information has been provided to community representatives, including study implementation timelines</li> <li>▪ Inform community representatives about the research study, including the risks and benefits of participating in it, and the informed consent process</li> </ul>
<i>Educate</i>	<ul style="list-style-type: none"> <li>▪ Share information with and educate the community about the value of the research</li> <li>▪ Develop a tool (such as a suggestion box) to give researchers monthly feedback concerning the study's impact on the community</li> <li>▪ Advise researchers and research staff on how to improve outreach to the local target population</li> <li>▪ Identify and facilitate communication pathways with the local site target population(s)</li> <li>▪ Learn about myths and misconceptions about the trial and report back to the research staff</li> <li>▪ Learn about Data and Safety Monitoring Boards (DSMBs)</li> <li>▪ Educate the community about the role/importance of IRBs and DSMB recommendations</li> </ul>	<ul style="list-style-type: none"> <li>▪ Provide the CAB with training on research methods, local ethical and regulatory systems, and community roles and responsibilities in trials</li> <li>▪ Update community representatives about progress made with the ongoing research, including studies at the local site and other relevant studies</li> <li>▪ Update the community on concerns raised by participants and any resulting changes in study procedures</li> </ul>

<sup>3</sup> DAIDS provides site monitors, independent of the site and the community, who regularly review site records to ensure that the highest scientific, regulatory, and ethical standards are being met throughout the implementation and conduct of the study.

<b>Role</b>	<b>Responsibilities of Site CAB</b>	<b>Responsibilities of Research Staff</b>
<i>Advocate</i>	<ul style="list-style-type: none"> <li>Ensure that concerns are addressed appropriately, including any issues with the informed consent process</li> </ul>	<ul style="list-style-type: none"> <li>Discuss accrual and retention issues with community representatives</li> <li>Consider any information and insights provided by community representatives about reaching local target populations and for addressing any potential recruitment and retention issues</li> <li>Identify barriers to accrual and retention, and share information with protocol teams</li> </ul>
<i>Oversight</i>	<ul style="list-style-type: none"> <li>Stay abreast of study progress, enrollment, and interim reports from the DSMB</li> </ul>	<ul style="list-style-type: none"> <li>Report study progress and unanticipated problems to the IRB and protocol team</li> <li>Share study progress, enrollment, and DSMB reports with the CAB</li> </ul>

## 2.2 Network CAB, Research Network, and DAIDS

<b>Role</b>	<b>Responsibilities of Network CAB</b>	<b>Responsibilities of Network Leadership</b>	<b>Responsibilities of DAIDS</b>
<i>Oversight</i>	<ul style="list-style-type: none"> <li>Stay abreast of study progress, enrollment, and interim reports from the DSMB</li> </ul>	<ul style="list-style-type: none"> <li>Discuss any challenges that arise with the study, such as enrollment issues, and how they should be addressed</li> </ul>	<ul style="list-style-type: none"> <li>Review all safety reports</li> <li>Support site monitoring activities to ensure participant safety and ethical study conduct</li> <li>Support independent DSMBs that conduct regularly scheduled reviews of data to ensure participant safety and study feasibility</li> </ul>

### 3. Training

Ideally, there should be a structured training for CAB members before and during study implementation, including ethics training, Good Clinical Practice (GCP), and the role of CABs.

### 4. Indicators of Success

- CAB meeting(s) held with community to discuss study design, eligibility, and implementation
- Number of outreach and education sessions conducted by researchers

## Communicating Research Results

### 1. Introduction

CAB members play a critical role in ensuring that research results reach all members of the community, particularly those who may be most directly affected. Each site should consider developing a communications plan that includes how study results will be disseminated. The CAB can play an active part in those communications; CAB members can help provide the right language and advice on appropriate and timely channels of communication.

### 2. Roles and Responsibilities

#### 2.1 Site CAB and Research Staff

Role	Responsibilities of Site CAB	Responsibilities of Research Staff
<i>Gather Information</i>	<ul style="list-style-type: none"> <li>▪ Participate in research updates; learn about the potential impact of study results</li> </ul>	<ul style="list-style-type: none"> <li>▪ Update community representatives about the research study and the potential impact of study results</li> </ul>
<i>Information Sharing</i>	<ul style="list-style-type: none"> <li>▪ Provide feedback to the broader community about:               <ul style="list-style-type: none"> <li>○ why the study was conducted</li> <li>○ findings of the study</li> <li>○ key messages</li> <li>○ impact on clinical care and/or prevention strategies and future research</li> </ul> </li> <li>▪ Work with CTU/CRS, as appropriate, to share information via newsletters, radio, or other media outlets</li> </ul>	<ul style="list-style-type: none"> <li>▪ Disseminate information about research progress/findings to the CAB and others in the community in a forum that allows for questions and answers that address:               <ul style="list-style-type: none"> <li>○ actual results and impact on clinical care</li> <li>○ whether additional studies will be needed to address specific questions that were not answered by this study</li> <li>○ whether product is unsafe or ineffective and, therefore, not to be studied further</li> <li>○ implications of results for other populations, such as children, adolescents, pregnant women, or men who have sex with men</li> <li>○ next steps</li> </ul> </li> </ul>
<i>Consult</i>	<ul style="list-style-type: none"> <li>▪ Consult key stakeholders on specific target audiences to reach with results, how best to link with local target populations, and how best to relay information about the trial results</li> <li>▪ Ensure communication materials are written in clear, understandable lay language and/or are translated as needed</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ensure that CAB members are involved in creating and conveying the key messages</li> </ul>

<b>Role</b>	<b>Responsibilities of Site CAB</b>	<b>Responsibilities of Research Staff</b>
<i>Advocate</i>	<ul style="list-style-type: none"> <li>Ensure that CAB members understand the study results so that they can advocate for additional research or policy changes</li> </ul>	<ul style="list-style-type: none"> <li>Outline key issues for community awareness and policy considerations</li> <li>Work with network leadership and DAIDS to facilitate timely release and dissemination of study findings</li> </ul>

## 2.2 Network CAB, Research Network, and DAIDS

<b>Role</b>	<b>Responsibilities of Network CAB</b>	<b>Responsibilities of Network Leadership</b>	<b>Responsibilities of DAIDS</b>
<i>Inform Other Networks</i>	<ul style="list-style-type: none"> <li>Inform/educate Community Partners about research findings</li> </ul>	<ul style="list-style-type: none"> <li>Inform other networks of research results</li> </ul>	<ul style="list-style-type: none"> <li>Plan for possibility of early trial termination as a result of favorable interim results, harm, efficacy, or lack of feasibility</li> <li>Inform collaborators, partners, relevant government agencies, and international ministries of health and other key stakeholders of study results</li> </ul>
<i>Share Information</i>	<ul style="list-style-type: none"> <li>Work with community educators and/or network staff to review communication materials to ensure appropriateness for target population(s)</li> <li>Work with network staff to identify/develop other mechanisms for sharing information such as forums, workshops, op-eds</li> </ul>	<ul style="list-style-type: none"> <li>Develop appropriate communications materials to disseminate findings</li> <li>Post appropriate communications materials on network-specific Web sites</li> <li>Issue letters to clinicians and study participants if indicated by results</li> </ul>	<ul style="list-style-type: none"> <li>Develop communications materials (press releases, Questions and Answers) to share with media outlets and others to broadly disseminate information</li> <li>Post materials on NIAID Web sites</li> </ul>

### **3. Training**

The following types of training could be offered for both local and network CABs. Community liaison staff may also benefit from some of these training programs.

- Listening skills training
- Communications skills training
- Specific trainings on HIV treatment and/or prevention (relevant to the research at the specific site)
- Basic training in adult learning and education to enhance communication strategy development

The depth and nature of the trainings may vary depending upon the skills and responsibilities of the members at each level of the network enterprise. Site and network community liaison staff may also benefit from some of these training programs depending on their level of experience and expertise in these areas.

### **4. Indicators of Success**

It would be beneficial for each site and network CAB to document the methods used to disseminate research results to specific target communities and the community at large. This would not only facilitate evaluation, but would help in documenting different approaches/activities that could then be shared with other CABs.

Specific evaluation criteria may include:

- CAB meetings held with researchers and research staff to discuss research results
- Coverage of research results in local press, newsletters, and/or media discussing research results

#### **4.1 Communicating Research Results Checklist**

- CAB meeting with researchers and research staff to discuss status of ongoing studies and timelines for study completion
- Target communities identified
- Meeting planned to discuss research results
- Ways to disseminate targeted information identified
- Conference call/meeting held with researchers and research staff to review results and key messages
- Materials for trial participants are developed
- Materials for media (e.g., press release, Q and A, Web content, talking points) are developed
- Community-specific materials distributed
- Targeted newspapers and magazines
- Community Forums

- Flyers
- Contact made with any of the following target audiences:
  - Clinics
  - Private providers
  - Church-based groups
  - National HIV/AIDS organizations, advocacy organizations, etc.

## Setting CAB Scientific Priorities

The identification of the network CAB's scientific priorities can help CAB members influence which scientific questions their network addresses. Within each network, CAB members may participate in scientific or network leadership committees. At the cross-network level of Community Partners, representatives participate in the Network Leadership Organizing Group (NLOG), which consists of the Principal Investigators of each network; and the Strategic Working Group (SWG), which includes experts who advise NIAID and DAIDS in addition to the network leadership. These Community Partners representatives serve as a resource on each of these groups, providing the community's perspective as to the relative importance of the proposed studies and initiatives. This input is considered as decisions are made about which studies should proceed and in defining the scientific agenda and how it is implemented. Identifying the network CAB's scientific priorities provides a foundation for CAB representatives when they are asked if they are in support or opposition to the proposed studies or initiatives being discussed.

Specifically, the value of identifying network CAB priorities is that they enable the network CAB and Community Partners to:

- Clearly articulate to DAIDS, the network leadership, and network investigators, areas of potential research of importance to the community
- Identify gaps within the existing research portfolio relative to perceived community needs

### Process for Identifying Scientific Priorities:

A potential approach for the identification of scientific priorities is described below.

- Distribute an overview of the network's research plan to ensure that CAB members have a clear understanding of the scope of the network's research, including current and planned studies
- Explore the current research plan with CAB members, addressing their questions or concerns; these suggestions and concerns will help to identify potential gaps in research
- Involve local and network CAB members in identifying issues and potential gaps in research that may impact priorities
- Determine which community issues and/or gaps in research should be of highest priority
- Ensure that network leadership receives and understands the community scientific priorities
- Share network priorities with Community Partners
- Community Partners can then set priorities taking all network CAB priorities into consideration

To facilitate the CAB's ability to set priorities, researchers and research staff should:

- Present current research information in a format and language that is accessible to a community audience and easily shared



- Acknowledge and take network CAB scientific priorities into consideration for decision making

### **Considerations for Developing Research Priorities:**

The following issues might be considered when trying to establish research priorities:

- **Potential Impact** as measured by the size of the targeted population that would potentially benefit from the therapeutic intervention or preventive strategy
- **Likelihood of Achieving the Potential Impact**, including how persuasive are the proof-of-concept data regarding the likelihood that the drug, treatment strategy, or biologic/behavioral intervention will effectively impact the targeted patient population or transmission pathway
- **Feasibility, Affordability, and Practicality** for the intervention to be widely implemented so that the potential favorable effect is realized
- **Strength of Scientific Proposal**, including availability of supporting evidence from prior studies
- **Efficiency of the Research Proposal**, so that multiple questions can be answered in one trial
- **Consistency with Network Strengths**, core competencies, and mission including the uniqueness of the network's scientific and site resources for trial design, conduct, and analysis
- **Likelihood of the Scientific Question Being Addressed Elsewhere**, either by pharmaceutical companies, well funded non-governmental organizations (NGOs), or other government-sponsored trials networks
- **Timeliness or Urgency of the Research Proposal**; for example, sometimes a lower priority issue must be addressed in order to tackle a more important priority

## Part II. Stories from the Frontlines: Case Narratives of Community-Researcher Partnerships

*Nalini Visvanathan, Editor*

### Introduction

To illustrate how communities and NIAID/DAIDS-funded researchers have partnered over the years and what some of the outcomes have been for both communities and researchers, the Recommendations Working Group asked a number of community participants and the researchers and staff who work with them to share and reflect on their experiences. The case narratives explore community contributions to treatment and prevention research and the impact of communities' increased knowledge of scientific research, disease concepts, treatment regimens, and health outcomes. Community contributions to scientific research and the advancement of knowledge about the prevention and treatment of HIV infection are also explored.

Specifically, the case narratives address the following issues:

- What initiatives have CABs/community members taken to support the clinical trials?
- What examples are there of community/CAB leadership in the clinical trials partnership?
- What examples are there of the community/CAB's initiating partnerships with the researchers and staff to serve common goals?
- What distinctive ethical perspectives do local communities and/or their representatives bring to the conduct of the clinical trials?
- What are the stories and narratives of incidents regarding community members involved in the trials that will inspire others in the community to give their support?

The case narratives are based on the observations and experiences of the writers working in various roles within DAIDS' clinical trials networks. Although the authors are based at sites in seven countries on four continents, they cannot be considered representative of all sites in the networks. Coordinators of the Recommendations Working Group sent out appeals to the larger community group for contributions to the case narratives. To incorporate a broad range of topics and include international experiences, two of the sites featured in the HPTN's "Lessons Learned" document were specifically solicited as well as others without a publishing history. The writing process was iterative and went through multiple revisions using interactive and consultative processes to incorporate the comments and interpretations of CAB members and colleagues. Undoubtedly, this collaborative approach has enriched the accounts and ensured an authentic reflection of community experience.

## Participatory Author Discussion<sup>4</sup>

The case narratives included here reflect many of the priorities and concerns that bring community participants into HIV clinical trials and sustain their partnership with researchers. CABs based in the United States have evolved over almost two decades and draw on the remarkable history of HIV/AIDS activism led by gay men that brought communities into the research process as partners. In “Clinical Trials Directories,” we learn that HIV/AIDS activists in the 1980s and 1990s secured a place at the table for government-sponsored HIV research, and then went on to monitor the clinical trials for therapeutic treatments through their vigilance in tracking disease symptoms and treatment side effects. By creating and maintaining directories for HIV clinical trials, they disseminated critical information in a timely manner to those seeking treatment, facilitated enrollment, and tracked scientific progress for the lay public.

More recently, CABs outside the United States were created to support clinical trials at local sites and meet the requirements established by DAIDS. Many of the sites are located in post-colonial societies where a history of political and social oppression raises questions about the benefits of clinical trials involvement to the community. At the same time, the epidemic’s deadly impact has infused a sense of urgency and responsiveness in these communities that were once apparent in the United States before antiretrovirals transformed a terminal disease into a chronic condition. To some extent, this shift can be attributed to the changing composition of the U.S. CABs, now attracting fewer activists and more advocates and professionals. This so-called “professionalization” trend stands in contrast to the large and diverse body of representatives found in the newly emergent CABs at international sites. In the United States, the increasingly complex therapeutic and vaccine products in trials dominate the attention of the lay CAB members and change the dynamics of interaction with scientists.

“Evolution of the Substance Abuse CAB of the CTU in Chiang Mai (Thailand)” shows that, by enlarging its organizational structure to incorporate a subgroup knowledgeable and experienced in substance abuse, the CAB could bring the affected community and the police (law enforcement) to the same table. It underscores the value of bringing highly informed community members into the CAB. We have learned that CABs can respond to the needs that arise rather than abide within rigid structures. Also noteworthy is the plea to the sponsor for giving trial participants continued access to the drug on grounds of compassionate treatment. This approach is a reminder that in the Buddhist cultural environment, it is compassion that creates the high ground for ethical treatment and not the liberal notion of (human) rights or entitlement that sets the moral compass in western societies.

CPCRA’s “Physician–Patient–Researcher Partnership” exemplifies how vital it was for the community to understand the study and the research design in order to spot the gaps in Medicare coverage that would, otherwise, have had negative repercussions. It is a testimony to the CAB’s grounding in the real world outside the laboratory and its ability to apply that knowledge to the conduct of trials. It underscores the role of experience and expertise of individual CAB members that must be recognized and harnessed.

Community members initiated the Participants’ Bill of Rights and Responsibilities (PBORR), <http://www.hvtm.org/community/rights.html>, and sustained their development efforts over an

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<sup>4</sup> All cases were reviewed by the authors and their comments integrated to constitute the body of the discussion. The editor also participated as a commentator and the feedback from all were synthesized by the coordinator, Michael Petillo, who set up an online survey to elicit greater participation among the writers.

extended period in order for the Bill to gain acceptance and approval from sponsors and staff. A small group of committed members stayed the course for 12 years to get this Bill approved for the conduct of vaccine trials. Because it was developed by many different stakeholders, the PBORR is a powerful tool that can increase community involvement in the vaccine trials. The Bill has yet to resolve issues of injury compensation where a consensus has not been reached by all the stakeholders. Language and structural barriers highlight the challenges faced in articulating and communicating a universal statement of individual rights that apply to varied local public health issues and systems. The Bill continues to evolve in its quest for accessible language and appropriate responses to the ethical issues that arise over time.

The “IMPAACT Community Directs Research Responsive to Families’ Needs” case is an inspiring account of the community’s assuming leadership in response to secondary (mental health) effects in children on a new drug regimen. Parents and caregivers articulated their concerns to their research staff, and, finding the providers and researchers unresponsive, they took the matter to NIH agencies where their observations were validated. At the end, they set the agenda for conducting a scientific study to assess the mental health effects of the drug on the children. It can be argued that their ability to define the problem, based on their collective observations, is a reflection of the community’s grasp of scientific literacy and basic research skills. The community’s commitment to this scientific inquiry forced them to consult with mental health researchers and, later, to work with their research partners to design and implement a follow-up study. Community-driven research priorities, when shared with scientific groups and funding agencies, should create better cooperative efforts to meet community needs.

The Brazilian case, “Community Involvement in HIV/AIDS Research,” demonstrates how the political environment of the CTU location (Brazil has given human rights a central place in its revised Constitution) can influence the positions taken by the community. Here, we clearly see the CAB playing a protective role in safeguarding the interests of the trial participants. CAB members raise exemplary questions about protocols, which are also relevant to many protocols in other contexts. Community committees for research provide a critical structure for community involvement, particularly when they are multidisciplinary and bring varied perspectives to bear on the protocols reviewed. Differences in local laws and cultures play an important role in international research; consequently, full consideration must be given to ethical concerns that are locally grounded. Such concerns are often outside the scope of centrally located scientific research committees. This case also gives us a compelling model of how government policies can shape the oversight for clinical trials.

As stated earlier, “Clinical Trials Directories” gives us a window into the early history of therapeutic development in the epidemic and the role of activism in opening the door to community participation. Community members learned the science, functioned as watch dogs of experimental research, and engaged in translating new-found knowledge for the lay public. This historical narrative is instructive and inspirational for communities involved in trials in the United States and elsewhere.

In the Indian narrative “Transparency and Equity as Ethical Issues,” the researchers felt the imperative to maintain open communications with the communities from which they recruited participants in the trials. Transparency is a highly significant issue in countries where information to the public has generally been controlled by authorities and there is mistrust of government intentions. By educating communities about their rights before recruiting participants and administering the informed consent, the NARI staff established the transparency needed to build trust. The mobilization of civil society organizations as partners also helped their

outreach. To ensure that treatment was available to participants after the trials, an equity issue of major concern to the CAB, the research staff and the ethics committees worked with them to devise a strategy that was feasible and acceptable to all. It is strategic to involve the non-governmental organization (NGO) in reaching community groups that are difficult to reach and to educate those groups on the ethical foundations for the trial. At this site, the emphasis on transparency and equity are grounded in local realities and constitute an ethical response to the needs of the community. The creation of a Trust to fund post-trial treatment is a potential model for groups at other sites that struggle to address this critical need.

Cultural changes, especially involving gender roles, can be both slow and challenging. In the South African narrative “Women’s Leadership and Gender Dynamics,” the women in the Hlabisa CAB took over the leadership at their own pace and through their customary practices. Gender roles and relations are social sensitivities best addressed by insiders who are well grounded in the situation. By accepting a gradual change in process, the women allowed the men to continue to be involved and to lend their full support; consequently, they diffused what could have been great resistance.

In “Male Involvement in Mother-to-Child Transmission Trials,” the CAB considered the unique constraints women face when they enroll in a clinical trial. Community members recognized how gender, cultural, and social dynamics affected communication between spouses/partners locally, and the staff introduced changes that facilitated men’s access to the clinics. The involvement of their spouses helped women in their decision making and in circumventing potential barriers to their continued participation in the trials. As in all partnerships that work, the staff played a critical role in the process. Community insights and initiatives, especially in resource-constrained settings, can lead to productive outcomes only when the site staff members recognize the potential value of the CAB’s insights and respond promptly.

These case narratives provide snapshots of community actions and initiatives at varied time periods in the growth and evolution of local CABs. Readers should individually interpret the experiences recorded and elicit the lessons that they perceive would be of relevance to their CABs and local sites. Group discussions could enrich the scope of interpretation and provide more ideas for adaptation.

## Reflections on the Need for Community Participation in the Research Process from One of the Earliest HIV Treatment Trials

*Steve Morin, co-chair of HPTN's Community Working Group, (as of this writing) relates a story about an event that contributed to the paradigm shift in scientific research and opened the door to community involvement in clinical trials.*<sup>5</sup>

### AZT Story

“An early example of the need for community consultation goes back to controversy over a highly politicized randomized, controlled trial of azidothymidine (AZT), which was the first drug to demonstrate efficacy in treating HIV. In community meetings with activists, the study (ACTG 019) was seen as the first major hope for people facing a near-certain early death. The study generated a sense of urgency to find answers and the community was optimistic that the drug would work. Interestingly, some of the advocates were participants in the trial and reported that it was obvious from side-effects who was receiving drug and who was not. Should the decision of who was going to live and who was going to die be based on randomization? Could the study be done without a placebo? Why was so little information given to those taking part in the study? Some trial members, presumed to be on the study drug, reported splitting their pills with other trial participants presumed to be on placebo. The rationale was that they were unwilling to have their lives extended at the expense of their friends in the study. Others raised concerns that splitting drugs would compromise the methodology of the study and could cause harm to the larger group of people facing death who were not part of the trial. Ultimately, the University managing the trial was alerted, and the lead researchers called a community meeting to begin listening to the concerns of the advocates and participants in their study—the beginning of community consultation in HIV research, which is now an expected standard. The first meetings were quite tense. Researchers had not previously had such confrontational meetings with trial participants. People living with AIDS were literally dying between scheduled meetings. The combination of advocacy and urgency proved to be powerful. Research has not been quite the same since then.” –Steve Morin

In a period of high HIV mortality, when there was no therapy for those who were infected, a randomized control trial (RCT) used a placebo in the absence of a “standard of care treatment.” Now that there are many HIV treatment regimens and standards of care, this would no longer be considered ethical, but at the time there was no available treatment and the use of placebos was an accepted practice that was necessary to maintain the rigor of scientific studies and ensure the

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<sup>5</sup> “Yes. I would be pleased to try to reconstruct what happened all those many years ago. I think it reflects the kind of activism from the early days of the epidemic. I got involved at the request of Congresswoman Nancy Pelosi. I was her Principal Assistant at the time and we had a monthly meeting with people living with AIDS where this issue of pill sharing of AZT came up. She then had me meet with I think it was the Dean of UCSF School of Medicine to follow up. As I recall, Mark Cloutier, who was then a legislative assistant to Congresswoman Barbara Boxer but is now the ED of the SF AIDS Foundation, joined the meeting to represent Mrs. Boxer. The follow-up to the meeting with the Dean was the convening of a meeting of involved AIDS researchers at SFGH and community activists to discuss the AZT trial. I believe Donald Abrams was part of the research group and has also written up his memories of the events. Mark and I attended the first meeting as I recall and both sides decided it was best to keep the conversation going through subsequent meetings ultimately leading to a CAB. Tony Fauci also became involved and flew out to SFGH for one of the early meetings. Hopefully, we could jointly try to remember some of the details.” (E-mail communication from Steve Morin, Ph.D., Director, Center for AIDS Prevention Studies, University of California, San Francisco. November 13, 2006. At the time of the early AZT trial, Professor Morin was Principal Legislative Assistant to Rep. Nancy Pelosi)

validity of their findings. However, the trial participants, who shared their pills with their friends, seized the high moral ground and challenged this long-established scientific research tradition. Their ethical stand arose from a community with shared values facing a deadly threat.

This story is a powerful account of the community highlighting an ethical dilemma and a humanitarian response that could have potentially subverted an important clinical trial. In effect though, it forced researchers to recognize the importance of community participation in the HIV research process and to take steps to include community representatives in research discussions. Together with NIAID, these researchers and the affected community forged new ground as they began discussions that led to a paradigm shift not just in HIV/AIDS research but for all clinical research. Their partnership paved new directions for research advocacy and opened the research process to community involvement.

## Case Narratives

### **Evolution of the Substance Abuse Community Advisory Board (S.A.CAB) for HIV Prevention Trials among Drug Users at Chiang Mai, Thailand**

*Apinun Aramrattana, MD, PhD<sup>6</sup>, Nantapol Chuenchooklin<sup>7</sup>, Madeleine O'Hare<sup>8</sup>*

The history of community involvement at the Chiang Mai site started when the Research Institute for Health Sciences (RIHES), at Chiang Mai University prepared for an HIV vaccine trial study in 1999. This was the first time that key persons from various sectors, including community leaders, were invited to discuss the trial. The first CAB was then established, and shortly after that, the CAB admitted more community representatives, including people living with HIV infection. The CAB guided the community activities, increasing their understanding of HIV vaccine trials. It was a learning process for both CAB members and the Institute. Through continuing communication and meetings, the relationship between investigators and CAB members has been strengthened. The CAB has learned more about research ideas and operations and is making more contributions. However, most of the interactions have occurred during regular meetings held every other month to discuss the protocols and consent forms that have already been approved by the international protocol teams.

In 2002, the Institute participated in the development of the protocol for HPTN 037, an HIV prevention trial among injecting drug users. The then-CAB could not contribute to the study due to the lack of direct knowledge about injection drug use, so it suggested the creation of a sub-CAB directly involving people who had injection drug use experiences. The first sub-CAB members were the study investigators, research staff, and drug treatment center staff and patients, led by the then-director of the drug treatment center who was also listed as a study investigator. In 2003, the Thai Drug User Network was established, and it soon gained significant ground for protecting their rights, especially for access to antiretroviral drugs. A key member of the Thai Drug User Network was invited to join the sub-CAB together with other non-governmental organization (NGO) representatives and local administrators. The expanded sub-CAB met regularly every two months. It was named the Substance Abuse CAB and operated independently of the first HIV CAB. Its members included people who had direct experiences with both injection and non-injection drug use. During the meetings, the focus was on investigator-driven activities. Studies among both injection and non-injection drug users were discussed and progress was reported.

In 2004, the CAB invited a police general, who had lengthy experience dealing with drug problems and had also been a strong advocate for drug treatment, to join as a consultant. Since then, there have been police and drug user representatives at every meeting. However, this did not lead to more active involvement by drug user representatives who were too small a group within the CAB. The Institute then created two separate working groups for injection drug users and non-injection drug users. Each consisted of current drug users, their relatives, and local community leaders including health center staff. These smaller groups are better focused on the

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<sup>6</sup> Deputy Chair of the Substance Abuse CAB

<sup>7</sup> SA-CAB Member from Thai Drug User Network

<sup>8</sup> Member of Injection Drug User Working Group Research Institute for Health Sciences, Chiang Mai University, Chiang Mai, Thailand, 21 May 2007



issues relevant to the study activities in their specific areas and have therefore increased member participation. Their suggestions have led to productive community education activities directly responsive to their needs as well as community development activities indirectly related to the study.

The biggest community input into protocol development occurred when the site participated in HPTN 058 development. It is a trial of opioid substitution therapy against HIV transmission using a drug new to Thailand called Suboxone<sup>®</sup>. Community input into the early phase of protocol development was suggested. An open community forum was organized at the site in October 2005. The Substance Abuse CAB members, media, and relevant officials were invited to two half-day forums. The study ideas were described to the forums by the protocol chair. Questions relevant to various aspects of the study were raised and discussed. One of those questions was what the study and its sponsor would do for participants when the study ended. It was suggested that the study drug should be provided free-of-charge to participants who needed it after the study ended (compassionate treatment). This idea was also separately raised by members of Thai Drug Users in Bangkok. It was later included in the protocol and agreed to by the drug company (Reckitt Benckiser).<sup>9</sup>

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<sup>9</sup> Although the drug user involvement in HIV research at the site has been increasing and has become more meaningful, two studies of CAB activities by Steve Morin, conducted three years apart, suggested that the community involvement at the site was still lacking active participation by the study population and there was more room for improvement. Key members of drug user representatives and investigators agree that more active involvement can be gained if the working groups are driven more by drug user agendas and not the agendas set by the study staff. This change has been recently implemented. The structure of the Substance Abuse CAB and drug user working groups have been revised to ensure more efficient flow of communication from drug users to the working group and from the working group to CAB members and study investigators. These changes have brought in better participation by drug users and related persons. (Apinun Aramrattana, July 17, 2008)

## **CPCRA/INSIGHT: A Physician–Patient–Researcher Partnership**

*Claire Rappoport*

The INSIGHT Network was born out of the merger of the DAIDS-funded Terry Beirn CPCRA and the Evaluation of Subcutaneous Proleukin<sup>®</sup> in a Randomized International Trial (ESPRIT) networks. The CPCRA CCG had developed an effective model of community representation that has become the basis for the INSIGHT CAB. This is illustrated with an issue that the community identified and brought to the attention of network leadership and then worked jointly to resolve.

The CPCRA designed a study called Strategies for the Management of Anti-Retroviral Therapy, or SMART. The SMART study utilized a two-armed management strategy. In the viral suppression (VS) strategy arm, study participants were treated according to current U.S. Department of Health and Human Services (DHHS) clinical care guidelines, while in the discontinuation arm (DC) study participants were treated according to a pre-established CD4 pattern of cells' rise and fall. Since the SMART study was a drug management study, the provider and patient sought the antiretroviral (ARV) regimen in whatever way was available to the patient. This, of course, would vary from patient to patient with some having medical third party insurance or another payer, and some using state programs.

During the design of SMART, the community realized that those study participants who receive their ARV drugs through the state AIDS Drug Assistance Program (ADAP) might be penalized or dropped from their approved status if their treatment interruption was CD4 cell-driven rather than for a pre-prescribed time period. This was because many ADAP programs had criteria in place that required prescriptions to be filled on a consistent basis and/or strict periodic renewal criteria that would have penalized study participants in this arm of the study. Study participants therefore could be dropped from their state's ADAP roll and/or moved to the end of a waiting list because they agreed to discontinue their medication by participating in the DC arm of the SMART study. The SMART study team discussed this issue and felt that the clinician might be able to make arrangements for some of his/her individual patients, but that overall, it would be better to try to derail this issue.

Shortly thereafter, another issue arose with the restructuring of Medicare Part D. Medicare Part D is the U.S.-based government program that was crafted to contain drug costs for persons qualified for Medicare (federal assistance program for health and medical care.) Unfortunately the program debuted with a large gap in coverage referred to as the 'doughnut hole' (up to \$3,600 in out-of-pocket expenses in 2006 and growing each year) for persons with incomes below 150% of the Federal Poverty Level (FPL). Every state was given the latitude to decide how their ADAP was going to interface with Medicare Part D. Across the United States, ADAPs varied greatly with regard to income guidelines and medication formularies. This meant that in addition to the ADAP issue, study participants in SMART who were receiving Medicare Part D and receiving their study medication through ADAP might not receive any help with payment for their medications, and might also be disqualified for ADAP. The community members quickly recognized that this would create difficulty for themselves and for other study participants, and might mean that they would not be able to obtain their medications in a study-prescribed manner.

One of the CPCRA community members was very well versed in both the ADAP and Medicare rules. He was responsible for bringing this potential situation to the group's attention and helped the CCG strategize a proactive plan. The Chair of the CCG of the CPCRA, along with a knowledgeable CCG member, informed the Principal Investigator in charge of the network. The

CCG member was able to explain the situation and, consequently, the CCG members were able to mobilize and educate themselves, their clinicians, and their local legislators about the devastating impact that this legislation could have on numerous Persons Living with HIV and AIDS (PLWHAs), as well as on the SMART study retention. With the help of the Network leadership, the CPCRA was able to obtain cooperative agreements through the NIH and National Alliance of States and Territorial AIDS Directors (NASTAD) that would protect and support patients on the DC arm of SMART. As a result, no patients were inconvenienced or lost to follow-up from the study.

The partnership model set by both CPCRA and INSIGHT is reflected in the INSIGHT organizational structure, where active community participation is expected at each level of decision making.

## **Participant's Bill of Rights and Responsibilities**

*John Bunting, Tom Gibson, and Butch McKay*

The Participant's Bill of Rights and Responsibilities (PBORR), <http://www.hvtn.org/community/rights.html>, which was approved by the HVTN in 2003, is a living document that has been evolving for over a decade of vaccine trials beginning with the HIV Network for Prevention Trials (HIVNET), the precursor to HVTN, and the AIDS Vaccine Evaluation Group (AVEG).

Community activists who worked on the earliest draft of PBORR advocated for its adoption with the network leadership. When HVTN was formed, they joined the new Global CAB and helped ensure that this group, with combined AVEG and HIVNET representatives, would move the PBORR forward. They handed over the draft to staff at HVTN and DAIDS, thereby including lawyers and ethicists among the reviewers.

At the very first HVTN full group meeting, the PBORR found a place on the agenda and raised consciousness across the network, leading to the creation of the Ethics Working Group (EWG) in 2002, a working group of the Global CAB. A task force was created to include investigators, clinic coordinators, educators, recruiters from the U.S and international sites, and DAIDS staff, so that all constituent groups would be involved in the adoption of the final document.

Today, the PBORR is a two-page document listing the rights of participants in HIV vaccine trials and the responsibilities they bear. It covers, succinctly, most of what the Informed Consent Form (ICF) covers in depth. In its original form, the PBORR was a set of crisp bulleted statements, without the technical language that bogs down lay readers. When lawyers and regulatory experts joined the drafting team, they raised issues of risk management that could only be addressed by legal language in more extended statements. Institutional Review Boards (IRBs) at clinical trial sites have responded to the Bill with varying levels of concern and approval. Advocates for the PBORR have never expected it to supplant the ICF or challenge the IRB's authority. In fact, the PBORR underscores the rights stated in the ICF and equally emphasizes the responsibilities vested in the participant.

The PBORR has many proponents who recognize its community-driven origins and its potential for allaying the fears of groups that may have been adversely affected by past research. The PBORR is a highly effective tool for educating the community about the trials, recruiting participants, and engaging with the public to enhance the image of scientific conduct.

An early objective was for the network to accept the principles of the PBORR. While network staff acknowledged the necessity and utility of the PBORR, negotiating its language was difficult. A U.S. government-funded network had to consider both wording and intent, which had to be filtered through the federal prism. While DAIDS at NIAID embraced the development of the PBORR, language again proved to be a formidable adversary.

Over the past several years, many questions regarding barriers to codifying the rights of participants, especially the right to care for injury due to trial participation, were considered. *What kind of injury should be covered? Who would determine the cause and/or source of injury? What kind of compensation? What health care needs should be considered? How should lost wages be addressed? Should care for dependent children be provided?*

The stumbling block was the extent of coverage for study-related injuries. Legal and regulatory departments were consulted, and a search began for ways to ensure promises made could be met,

including the possibility of an insurance carrier. Congressional offices were contacted and federal legislation was considered. However, despite the efforts of the HVTN leadership and DAIDS specialists, the search did not meet its goal.

The diversity of locations where HVTN trials are conducted, particularly in resource-poor regions of the world, has raised complex issues for the proponents of PBORR's universal adoption in HVTN. One of the rights states that participants injured in the conduct of trials would receive medical treatment. In countries where insurance policies determine treatment or where treatments are scarce and rationed, the network is not in a position to enforce such entitlement. Another issue was that translations in indigenous languages with limited terminology tended to undermine the scope of the Bill. And in the United States, African American community members in Baltimore wanted coverage for the wages lost through participation or its impact.

Since its official adoption by the HVTN, the PBORR is likely to be used in the informed consent process or made available to participants in other contexts at all HVTN sites once it has received local IRB approval. The Bill continues to evolve, responsive to emerging issues and incorporating new community interests. A revised version was adopted by the network in April 2007.

## **International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Community Directs Research Responsive to Families' Needs**

*Claire Schuster and Dorothy Shaw*

The NIAID-funded IMPAACT network includes the former PACTG and HPTN Perinatal Working Group. Both networks' communities consist of potential trial participants including pregnant women, parents and caregivers of HIV-infected children and adolescents, and adolescents themselves. These stakeholders partner with HIV/AIDS researchers to develop studies that address their needs and those of the children. The partnership has evolved from limited community participation to full involvement on network leadership, scientific committees, and study teams. In addition to representing their own experiences, community members bring the voices of their local sites to the global research network. This is a narrative about how community members identified a health issue affecting their children, advocated for its inclusion on the scientific research agenda, and eventually partnered with researchers to develop a study to address their concerns and to find funding for it.

Starting in the late 1990s, families began to voice their concerns about psychiatric issues (including, psychiatric hospitalizations; mood disorders—severe depression, anxiety, bipolar, ADD/ADHD, aggressive or out-of-control behavior; learning problems; neurological difficulties; and substance abuse) among their HIV-positive children and adolescents. They questioned if these issues resulted from neurological, mental, behavioral, cognitive, or environmental causes, or possibly HIV infection and/or antiretroviral therapy. They hoped answers to these questions would ultimately improve their children's quality of life, allowing them to function socially and behaviorally. Families at research sites brought these concerns to their site CABs where CCG members began to recognize a widespread concern among families.

The CCG (now IMPAACT CAB or ICAB) comprises members who are primarily parents/caregivers or others affected by HIV/AIDS. The ICAB functions at the network level to ensure that the voice of the community is represented in the network's scientific agenda, protocol designs, and other network activities.

When individual parents and caregivers compared notes about how the pediatricians had responded to their concerns, they found they had been frequently told “children with terminal/chronic illnesses have grown up being treated specially and frequently have not learned to control their behaviors;” or “it's related to parental depression or parental substance abuse;” or “ADHD is so prevalent in our society;” or “we didn't expect the children to live this long.” The physicians did not seem to be concerned about the high incidence of these issues, nor did they consider them to be of significance. Their focus was on keeping the child alive longer rather than on quality of life.

When the CCG brought these concerns to network investigators, the investigators felt there was no scientific basis to pursue research. Community members later learned the PACTG investigators had created a list of commonly prescribed psychiatric medications and their interactions with ARVs, indicating some awareness of these psychiatric issues and concerns, but lacking an awareness of the scope.

Recognizing that the PACTG researchers might not have the necessary expertise in mental health related research, the CCG leadership tried to convince PACTG leadership to have a day-long interactive session with representatives from several different NIH institutes (National Institute of Mental Health or NIMH, National Institute of Drug Abuse or NIDA, National Cancer Institute

or NCI, National Institute of Child Health and Human Development or NICHD, National Institute of Allergy and Infectious Disease or NIAID), pharmaceutical companies, and the community to discuss how to collaborate on a mental health research study for HIV-infected children. The CCG learned that these institutes were already developing mental health research related to HIV/AIDS. While working on this proposal, the CCG leadership developed key contacts within the institutes. Ultimately, the PACTG leadership denied the request for the interactive session.

In February of 2002, members of the CCG met to list and rank their scientific priorities. Psychiatric issues ranked among the top three. The CCG formally presented their priorities to the PACTG leadership and Research Agenda Committee chairs. The presentation included a timeline stating when the community expected the PACTG leadership to address each of their major priority areas. For months after those meetings, CCG leadership continued to advocate with PACTG leadership for the community priorities and timeline.

Finally, the PACTG leadership invited CCG leadership to attend a conference call to discuss the community's mental health priorities. The PACTG leadership disclosed that some of the institutes had begun to talk about the issue, as suggested by the CCG months earlier. The PACTG leadership, using the key contacts the CCG had developed, pursued the idea of collaboration with NIMH. The NIMH collaborated with PACTG on the study design and financially supported the study. Discussions have already begun for further studies utilizing this partnership.

This community-driven partnership resulted in a high-priority study among families living with HIV/AIDS. A CCG member served on the study team and provided valuable community feedback throughout the development of the protocol. In 2005, the study enrolled 582 participants at 29 sites across the United States. The study marks a successful partnership between the community, researchers, and also a notable and new partnership between NIMH and NIAID.

## **Community Involvement in HIV/AIDS Research in Brazil**

*Julio Barros<sup>10</sup>*

UNAIDS data show that the impact of the HIV epidemic is devastating. Most new infections occur in underdeveloped and developing countries, affecting over 40 million people in their productive and reproductive years. In Brazil, there are over 600,000 cases of HIV infection. Currently, the epidemic has a very low socio-economic-cultural profile, thus making prevention actions and AIDS treatment compliance difficult. Additionally, prejudice, discrimination, and stigmatization make research difficult.

The 1999 Brazilian establishment of Community Committees for Research Follow-Up (CCRF) led to Brazil's participation in research within the frameworks of the HVTN, HPTN, ACTG, and IMPAACT networks. Previously, some AIDS NGOs in Brazil were closely monitoring ethical issues in research protocols sponsored by the pharmaceutical industry with the advent of antiretroviral drugs.

Today, six Community Committees are following research in the cities of Belo Horizonte, Porto Alegre, Rio de Janeiro, and São Paulo. These Community Committees share a few features: multi- or cross-disciplinary membership, volunteer members from the community with many having previous experience as activists in HIV/AIDS and sexually transmitted diseases (STDs) community prevention actions, and human rights and health promotion in general. They also share the same goals of ensuring voluntary participation in research, respect for ethics, and guarantee for the rights of volunteers and the community at all research levels. In addition, they serve as a communication channel between researchers and the community, focusing on community education.

Every research study involving human beings in Brazil is required to follow the rules and guidelines set forth in Resolution 196/96 by the National Health Council based on the principal international documents that generated declarations and guidelines for research involving humans. Resolution 196/96 also established the Committees of Ethics in Research (CEPs) and the National Board of Ethics in Research (CONEP), made up of experts in various fields and community representatives that follow all research work.

For the CCRF members, Resolution 196/96 and complementary resolutions, the CEPs, and CONEP play a key and exemplary role in assessing scientific, methodological, and ethical issues regarding research. Research protocols within the framework of HVTN, HPTN, ACTG, and IMPAACT networks have been approved by these organizations.

The Porto Alegre CAB is currently following protocols HPTN 040/052/057 and ACTG 5175. Our biggest challenge has been to understand and critically assess a protocol, its significance, and impact on the community. Even if these protocols have been approved at all ethical and scientific levels, it is worth mentioning our experience with protocol HPTN 052.

In our reading and assessment meetings, more than 25 questions were raised about issues related to ethics and volunteer rights. We asked for a meeting with the Principal Investigator and his staff to seek clarifications. One of the most controversial and debated issues was the use or non-use of post-exposure prophylaxis (PEP). For us as CAB members, this was an ethical issue, since in Brazil the use of PEP is guaranteed by the Ministry of Health, and this had not been included

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<sup>10</sup> CAB Member, Community Committee For HIV/AIDS Research Follow-Up, Porto Alegre, Brazil



in the research protocol. We were told that PEP would be used in case of exposure. The same discussion took place at the Rio de Janeiro CAB.

Representative questions raised at CAB meetings for consideration by the PI include:

- What are the research benefits at the local level, considering that the financial supporter is not from Brazil?
- What impact will the research have at the public health level?
- Will the PI be committed to the community after the research results change public health policies?
- Who will guarantee treatment maintenance after the end of the study?
- Why are drug users not included in the study?
- Who will provide drugs if the research site decides to use a different drug?
- What kind of contraceptive will be used during the study? Male only or female as well? Will a lubricant be included? <sup>11</sup>
- The Brazilian Ministry of Health strongly recommends that HIV-positive women not breastfeed. In a particular study, such women, when using ARVs, may breastfeed. This goes against an implemented and widespread policy in Brazil. How can this situation be resolved? <sup>12</sup>
- In Brazil, payment for study participation is forbidden. How much will volunteers be offered for transport and food? <sup>ibid.</sup>
- How will informed consent be applied to illiterate volunteers? <sup>ibid.</sup>

Community participation is essential for the success of any clinical trial. The establishment of CABS in Brazil has added another level of social control to research projects of public interest, thus making sure that citizenship, human rights, and ethics are respected.

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<sup>11</sup> CAB members were reassured that both male and female condoms would be provided.

<sup>12</sup> The author considers these major ethical issues. The CAB is concerned that while Brazilians are guaranteed treatment, trial participants in other countries do not have that assurance. After discussions with the PI, it was agreed that local CAB members would be present when illiterate participants were consented.

**References:** abia.org.br; Resolution 196/96 CNS; Boletim de Vacinas – GI; Desenvolvendo Vacinas; para prevenir o Hiv/ICASO 2000; Boletim Epidemiológico-Ministério da Saúde

## Clinical Trials Directories: A Window into Community Initiatives in HIV Research

*Richard Jefferys*

The evidence of progress in AIDS research lies not only in the scientific literature, but also in the community-produced clinical trials directories that have tracked experimental protocols as they opened and closed over the years. A variety of non-profit and community-based AIDS organizations have produced such directories since the 1980s. AmFAR (the American Foundation for AIDS Research) produced the *HIV/AIDS Treatment Directory*; the San Francisco AIDS Foundation published trial information in their *BETA* (Bulletin of Experimental Treatments for AIDS) newsletter; and AIDS Treatment Resources produced a New York State directory which subsequently became the *Experimental Treatment Guide* (produced by the AIDS Treatment Data Network) and now continues as the *ACRIA HIV/AIDS Clinical Trials Directory* ([www.acria.org/clinical\\_trials/](http://www.acria.org/clinical_trials/)). When tracked over time, the directories can be seen to reflect the effects of greater community involvement in designing research protocols, such as increased study of opportunistic infection treatments, less restrictive entry criteria, and more attention to protecting the interests of trial participants.

The historical arc the directories trace goes back to the formation of the U.S. government-sponsored clinical trials network, the ACTG, in 1987. The goal of the ACTG was to coordinate the study of potential new treatments for HIV and AIDS in the U.S. through formal linkages between academic research centers and investigators. However, the ACTG's initial plan failed to take into account the importance of the communities most affected by HIV/AIDS in the planning and design of research; the network's original structure provided no seats at the table for any community members. This oversight rapidly became controversial, because while the ACTG focused almost exclusively on studying experimental anti-HIV drugs such as AZT, community activists—led by ACT UP—were clamoring for studies of approved drugs (like Bactrim and pentamidine) that might prevent and treat the opportunistic infections that were causing the deaths of people with AIDS.

This dispute culminated in 1990 when ACT UP held a massive protest on the campus of the ACTG's overseer and source of funding, the National Institutes of Health (NIH) in Bethesda, Maryland. This protest led directly to negotiations between the community and the ACTG's leadership and ultimately the formation of the ACTG's CCG. The CCG included more than 20 community activists who distributed themselves across each of the various committees of the ACTG, including the Executive Committee.

The clinical trials directories from that era provide compelling evidence of the importance of the influx of community participants into the ACTG system. For example, there were 13 ACTG trials of opportunistic infection treatments in the New York State directory published by AIDS Treatment Resources in the winter of 1990. By winter 1993, the number had expanded to 21. Community advocates also played a key role in drawing attention to the manifestations of AIDS that were specific to women, and by 1993 two trials were specifically studying treatments for opportunistic infections in women. The studies included ACTG 200, which evaluated 5-FU as a treatment for high-grade cervical dysplasia, and a trial run by the Terry Beirn CPCRA which

looked at the efficacy of fluconazole for preventing recurrent thrush (candidiasis) in women. Historical listings of completed ACTG and CPCRA trials are available online.<sup>13</sup>

Over the subsequent years, the voices of CCG members continued to help shape clinical research in AIDS. The community encouraged the study of interventions that might help ameliorate common side effects of antiretroviral drugs, such as neuropathy. CCG members have also collaborated to generate their own research agenda to share with ACTG researchers, highlighting community concerns such as the impact of hepatitis C co-infection on the health of individuals with HIV.

In 2007, this legacy of activism continued with the current CCG and equivalent community advisory bodies for the other HIV/AIDS-related clinical trials networks.

Community members have a unique and critical role to play in guiding the future of HIV research. Looking back at the history of clinical trials, the impact of community advocacy can be an inspiration for those seeking to become involved with the CCG and other community advisory boards today.

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<sup>13</sup> CPCRA: [http://www.cpcra.org/pubs\\_prot.htm](http://www.cpcra.org/pubs_prot.htm)  
ACTG: [https://www.actgnetwork.org/protocols/allprotocols\\_paging.aspx](https://www.actgnetwork.org/protocols/allprotocols_paging.aspx) has a complete listing of ACTG trials, but access to the report is password protected. If you do not have a password and would like this information, you can contact the ACTG Community Coordinator at [acermak@s-3.com](mailto:acermak@s-3.com). The ACTG public Web site is located at <http://www.aactg.org/>.

## **India's National AIDS Research Institute (NARI) and Local Communities Collaborate for Transparency and Equity**

*Dr. Seema Sahay and Dr. S. M. Mehendale*

### **Community Involvement: An effort towards transparency**

The National AIDS Research Institute (NARI), Pune, India, has been collaborating with Johns Hopkins University, USA since the early 1990s. The location of NARI in the Pimpri Chinchwad Municipal Corporation (PCMC) industrial area has been a challenge, especially for conducting recruitment for clinical trials and biomedical research, because it is very far from populous Pune city.

NARI considered the factors influencing the community's participation and involvement in the research. To increase accessibility, it established seven study clinics in Pune city and one in the PCMC area, in addition to the one on NARI's main campus. When NARI made a transition from clinic-based cohort studies to community-based clinical trials in 2002, the Institute implemented a Community Involvement Plan to create awareness about HIV/AIDS and its research activities.

The CAB was formed as a requirement for NIH-sponsored studies. Stakeholders, both direct and indirect, were invited to become members of the CAB to advise and provide input on the conduct of NIH-sponsored trials on the backdrop of Indian cultural context. Invitations were sent to over 50 stakeholders who were nongovernmental (NGO) representatives, PLHA self-help groups, ethicists, student bodies, lawyers' organizations, academicians, and philanthropists, etc. thought to be interested in working for the community. Initially, 19 members accepted the invitation and were given orientation training. Eventually, some of them attended training at the national and international levels. NARI has gradually extended the benefits of community involvement through the CAB to non-NIH funded studies as well.

As a result of repeated trainings and discussions, the contributions of the CAB became increasingly useful to researchers, thereby increasing the visibility and acceptance of the Institute's work in the community. Consequently, voluntary membership in NARI's CAB increased, and the CAB created a plan to reach the grassroots of the community through NGOs and community-level workers. CAB members, holding key decision-making positions in local NGOs, helped to build linkages between the Institute and the NGOs.

At two exploratory meetings involving nearly 20-25 local NGOs, NGO directors participated in discussions on the need for community involvement in biomedical research. It was explained that the research was being funded by international and national funding agencies, and that CAB's role was to bridge the gap between the scientists and the community through NGOs. These discussions resulted in increased support of the Institute's goals, with six NGOs joining the partnership and signing memorandums of understanding with NARI in the year 2003. Next, the partner NGOs facilitated selection of peer educators who were trained by a NARI research team to impart information regarding biomedical research versus treatment, communication skills, and clinical studies and trials to their respective communities. In January 2007, the addition of two more NGOs culminated in an all-encompassing network of NGO peers throughout the city. Now, NARI has a team of over 130 who educate the community about the ongoing research at the

Institute and their rights<sup>14</sup> as study participants, and it is an initiation into a multi-stage informed consent process. Today, dissemination of technical information about clinical trials is considered a collective responsibility of the CAB, peers, and the NARI scientists. This program helps maintain transparency in the community and in facilitating the expanded informed consent process.

### **Equity and Access to Care**

Post-trial access to treatment has always been an issue in clinical trials settings especially in third world countries where affordability and poverty-related issues are serious problems and the treatment offered through research is not necessarily available as part of the standard of care through the Government-supported health care. Researchers explained to the CAB that sponsors cannot commit to indefinite post-trial care; there are ethical issues, and cost is a major limitation.<sup>15</sup> The institutions are bound by rules of spending as per the federal norms. Formation of trust involving this public/private relationship was considered to be a strategy to provide flexibility and additional care and support in the post-trial phase.

CAB members believe there is disparity between the facilities provided to the research participants and the local resources otherwise available. As the voice of the community, they reminded the researchers of their ethical obligations to provide care to the research study participants after the trials are over. The CAB members raised pertinent issues such as care for inter-current HIV infection for the HPTN study participants and also for HIV vaccine trial participants. Access to ART was always an issue in the CAB meetings. NARI leadership and researchers convinced the National AIDS Control Organization (NACO) of the Government of India (GOI) to establish an ART link center at NARI in December, 2006.

The CAB and NARI Ethics Committee (EC) both had concerns about expensive tests or unforeseeable events that could occur beyond the purview of study protocols, including ART. They discussed with the researchers the need to develop mechanisms that could help to provide sustained services to beneficiaries. Both the EC and the CAB supported the idea of establishing an independent body that may have funds to support the needs of study participants. NARI held consultations with the CAB and public and private agencies for HIV-related services and ART sustainability for inter-current HIV infection. The idea then emerged of establishing an independent "Trust" and raising funds through contributions from Government, non-Government sectors, and civil society organizations. Today, this Trust has been registered and is ready to function. Some CAB members are members of this Trust to ensure transparency and facilitate two-way communications with the communities they represent.

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<sup>14</sup> These rights state: (1) You can question any of the trial team and you can ask more questions till you are satisfied; (2) You have the right to get an answer; (3) You have right to your privacy; and (4) You have the right to withdraw from the study.

<sup>15</sup> "ART for how long?" is a complex issue, because even if the researchers manage to give ART for life, this might be considered as "inducement" for some participants.

## Medical Research Council, HIV Prevention Research Unit, Durban

### Women's Leadership and Gender Dynamics within a Rural-based Community Working Group (CWG), Kwazulu Natal

*Neetha S Morar<sup>16</sup> and Sibusiso Nhleko<sup>17</sup>*

The rural Hlabisa area's socio-cultural norms include male-dominated political and community leadership, including the community decision-making processes. However, women are now participating more in the decision-making process of community events. Between 1999 and 2000, when the Hlabisa Community Working Group (CWG) was formed, the membership was 90 percent men. The chairperson and the executive committee were male stakeholders from the community. At this time, the Hlabisa CWG was referred to as a CAB. The HIV prevention research efforts of the Medical Research Council (MRC) were also politicized within the community in terms of political party affiliations, as a few members perceived the MRC to be aligned to specific political parties. The dominant role of men as leaders and decision makers, coupled with the socio-cultural issues, partially impacted gender dynamics, interaction, and decision making among members of the CWG. Men were often selected to attend and present at public meetings and training sessions with limited opportunities being given to the women members. CWG male members always attended the international and local meetings, trainings, and conferences.

MRC staff experienced challenges in terms of getting community women involved in HIV education and awareness. Women on the committee sometimes experienced confusion about their role, at times acting in more traditional roles such as secretaries, rather than in more modern roles such as educators. Women who were part of the CWG did not freely verbalize their views and opinions on issues. They also adhered to the cultural norms of respect that women must accord to men in traditional settings.

During 2004/5, the HIV Prevention Research Unit's (HPRU) community management staff suggested that the CWG be constituted to represent the research participants, who were women participating in vaginal microbicide trials. After months of discussions and input from MRC, a respected and well-known woman, who is the head of a VCT clinic in Hlabisa and a member of the traditional rural royal family, was elected as chairperson. In the past few years, the CWG has gained more women members including research participants. The members initiated HIV awareness and education programs in the community, which included male education sessions on HIV prevention and treatment. Participants in the study volunteered to share their trial participation and product-use experiences at community meetings with the aim of making the community aware of the research program. Generally, the women have been effective at community sensitization, whether they are doing outreach on their own or participating in events arranged by the MRC community staff.

The men continue to be part of the CWG, and their community involvement has increased. In keeping with cultural traditions, the topic of gender dynamics has not been discussed openly. From the start, women challenged men in culturally accepted ways; however, the process of reversing leadership roles was slow and cumulative. When elections gave women the principal roles, the men were accommodating and there were good partnerships and no hostility. Men have continued to contribute to outreach and education and serve under women's leadership.

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<sup>16</sup> Senior Scientist

<sup>17</sup> Community Liaison Officer

Currently, the chairwoman is supported by a male deputy chairperson who is a teacher by profession. Six of the ten executive members are women. Recently, the CWG has been represented by women at all national and international meetings. CWG members include health care workers, educators, priests, administrators, politicians, HIV-positive individuals, and trial participants. They represent the community from which participants are recruited and help with the recruitment processes. Members are active in clearing community misconceptions about the research and engendering trust in the researchers and their work.

## **Challenges in Involving Ugandan Men in Prevention of Mother-to-Child Transmission (PMTCT)**

*Teopista Nakyanzi*<sup>18</sup>

Makerere University-Johns Hopkins University (MU-JHU) Care Ltd. Research Collaboration is located at upper Mulago Hill Road in Mulago Hospital in Kampala city, which has a population of 1.5–2 million people. Most of the participants in MU-JHU studies and programs are of low socio-economic status. While results from the recently released Uganda HIV Sero-Behavioral Survey (UHSBS) revealed an adult HIV prevalence of 6.4%, among pregnant women at Mulago Hospital, the seroprevalence is 10%.

When the recruitment activities began at Mulago Hospital for MU-JHU studies, the majority of the people in the communities did not know MU-JHU and were not aware of the PMTCT HIV clinical trials taking place. Prior to the site's community education events, people heard about research mostly from the pregnant women attending hospital-based routine counseling and voluntary HIV testing in the antenatal clinic (ANC) in Mulago National referral hospital. At one time, rumors spread in the community that testing at the ANC was without consent. Rumors and the stigma in the community raised fears among pregnant women and their spouses and reduced attendance at the clinic.

During HIVNET 012; a Phase IIB trial to determine the efficacy of oral AZT and Nevirapine (NVP) for the prevention of vertical transmission of HIV-1 infection in pregnant Ugandan women and their neonate, pregnant women were asked to consent for HIV testing. NVP is given to pregnant women at the onset of labor, and a dose is given to the baby after delivery.

At CAB meetings, the topic of male disengagement from ante-natal testing and counseling was discussed by community members and the researchers. It was important for men to be part of this process, because they wielded tremendous influence over the women's decision making. Women attending the ANC asked health workers to send invitations to their husbands to come to the clinic, because they could not directly tell their husbands to accompany them. For their part, men complained that the women did not inform them, and the health workers did not invite them. The CAB noted that the women's positive response in the ANC emphasized the need for male involvement in maternal and pediatric HIV prevention research. The CAB recommended that men be involved in discussions about research studies. Based on this input, male involvement in subsequent trials, such as HPTN 027, was strongly encouraged, which enhanced recruitment, retention, and adherence to study procedures.

CAB members noted that the ANC was not friendly to men and suggested that research staff design a package to increase men's interest in the ANC. At the clinic, the men were welcomed, and those who waited for their wives outside were invited in as well. Couples were served quickly to enable the men to get to work. Still, involving the men in the ANC remained a challenge, and few men came in. The staff responded by starting a male access clinic from 5 pm–9 pm every Thursday, when men would be able to attend after work hours. The interactive sessions enabled men to ask questions, a brochure was designed for them, and they could watch sports programs on TV and be served a soda. This added value to the clinic and the numbers started increasing.

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<sup>18</sup> ICAB Member



The PI and CAB together held a series of meetings about PTMCT challenges. Some of the questions raised during the meetings were: “How do we mobilize the men? How can we involve men in PMTCT?” After the opening of the evening clinic, more men began to accompany their wives or partners. Women were pleased with this change in traditional behavior that helped them to share responsibilities with their spouses. This innovative approach soon spread, and other hospital sites in Kampala adopted the idea of an evening clinic to get men involved in care and treatment for their wives and children.

### **Significance of male involvement in the PMTCT regimen**

According to the UHSBS, 40% of HIV-infected adults have an HIV-negative spouse. As long as couples are healthy, the majority prefer not to seek an HIV test and do not know their HIV sero-status. PMTCT programs are now offering the pregnant mothers the opportunity to be tested, and they have been able to increase the number of childbearing women who are tested. Male involvement means that men will attend the ANC together with their pregnant wives and participate actively in the reproductive health awareness talks as well as HIV counseling and testing, and PMTCT intervention services. The presence of the man at the ANC accelerates decision making for the woman for HIV testing, PMTCT services, infant feeding and care, and treatment after delivery. Informed couples are more likely to seek further HIV care and treatment for their child and self and will be healthier. Absence of men leads to low PMTCT uptake, a breastfeeding dilemma for HIV-positive mothers, delay in accessing available HIV care and treatment, sicker babies, and continued HIV re-infection or transmission to other sexual partners. Couples, especially the mothers who have to take sick children to the hospital, suffer emotionally and psychologically.

### **Impact of male involvement on the community**

Women whose husbands have participated in the ANC express great relief regarding the assurance of support from their spouse. They are open about their sero-status and able to discuss and plan care for their child or children and themselves. These couples have served as models in the community for other men inclined to participate. As a result of male involvement, some of the men have joined HIV psychosocial support groups and meet regularly to support one another. In the past, men were neither required to participate in the ANC nor be present during labor. Men view their gender role to include feeding for the family and providing economic support, but not accompanying their wives to the ANC. Some men felt it was “being showy” to go to ANC with their pregnant wives. Others said they lacked money for transportation, and others felt it was not their domain to participate in the ANC and wanted to know what services would be provided to the men. Although a group of men have now embraced the concept of male involvement in the ANC, it will take some time and resources to change attitudes and reverse practices.

## PART III. APPENDIX

### GLOSSARY

**AIDS Clinical Trials Group (ACTG):** The ACTG plays a major role in setting standards of care for HIV infection and opportunistic diseases related to HIV/AIDS in the United States and the developed world. The ACTG is composed of, and directed by, scientists in HIV/AIDS therapeutics research. For more information, visit [www.aactg.org/](http://www.aactg.org/).

**Clinical Research Site (CRS):** A CRS or site may be affiliated with one or more clinical trials unit and may conduct clinical trials associated with one or more network's clinical research plan.

**Clinical Trials Unit (CTU):** A CTU is a research entity comprising an administrative component and one or more clinical research sites. A CTU is a member of one or more clinical trials networks.

**Community Advisory Board (CAB):** A CAB is an active group of community members at a clinical trials unit or clinical research site that represents the local population(s) impacted by HIV/AIDS. Ideally, CAB members work in close collaboration with network, CTU, and/or CRS researchers and staff; they provide the community's perspective in design and implementation of, and the communication about, HIV/AIDS clinical research within a network or site. (Network Community Advisory Board refers to the CAB that works at the network level of the research enterprise; local CABs work with the clinical trials site and/or unit).

**Concept:** A concept is the general idea for a research study. It is usually generated as a result of previous research findings, pre-existing clinical practice and observation, or from the existing public health needs/concerns of a community/society. Local, national, and international research priorities and public health challenges also impact the development of research concepts.

**Data and Safety Monitoring Board (DSMB):** A DSMB is an independent panel of experts established by NIAID and charged with the responsibility of monitoring the progress of trials, the safety of participants, and the efficacy of treatments or prevention methods being tested. A DSMB also makes recommendations to NIAID concerning continuation, termination, or modification of each study based on observed beneficial or adverse effects of the intervention being studied. DSMBs are funded by NIAID separately from the research networks.

**Division of AIDS (DAIDS):** The Division within NIAID that has primary responsibility for basic and clinical prevention and therapeutic research on HIV/AIDS within the National Institutes of Health.

**Good Clinical Practices (GCP):** An international standard established to guide the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. It is designed to provide assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected.

**HIV Prevention Trials Network (HPTN):** The HPTN is an international collaborative clinical trials network that develops and tests the safety and efficacy of non-vaccine interventions designed to prevent or reduce the transmission of HIV. For more information, visit [www.hptn.org/](http://www.hptn.org/).

**HIV Vaccine Trials Network (HVTN):** The HVTN is an international collaboration of scientists and educators searching for a safe and effective HIV vaccine. The HVTN's mission is

to facilitate the process of testing preventive vaccines against HIV/AIDS. It conducts all phases of clinical trials, from evaluating experimental vaccines for safety and the ability to stimulate immune responses to testing vaccine efficacy. For more information, visit [www.hvtn.org](http://www.hvtn.org).

**International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT):** IMPAACT is a merger of the former Pediatric AIDS Clinical Trials Group and the Perinatal Scientific Working Group, which was part of the HPTN. IMPAACT develops and evaluates safe and effective approaches to interrupting mother-to-child transmission of HIV; evaluates treatments for HIV-infected children, adolescents, and pregnant women, including prevention and treatment of co-infections; and evaluates vaccines for the prevention of HIV transmission to and among adolescents. For more information, visit <http://pactg.s-3.com/>.

**Informed Consent:** A process by which a participant voluntarily confirms his or her willingness to participate in a particular study after having been informed of all aspects of the study that are believed by the researcher to be relevant to the participant's decision to participate.

**International Network For Strategic Initiatives In Global HIV Trials (INSIGHT):** INSIGHT is a merger of two existing clinical trials research groups, ESPRIT (Evaluation of Subcutaneous Proleukin® in a Randomized Clinical Trial) and the CPCRA (Terry Beirn Community Programs for Clinical Research on AIDS). INSIGHT's mission is to develop strategies for the optimization of treatment (antiretroviral and immunomodulatory therapies as well as interventions to prevent and treat complications of HIV and antiretroviral therapies) to prolong disease-free survival in a demographically, geographically, and socioeconomically diverse population of individuals infected with HIV. For more information, visit <http://www.insight-trials.org/index.php>.

**Microbicide Trials Network (MTN):** The MTN is a worldwide collaborative clinical trials network that evaluates the safety and efficacy of microbicides designed to prevent HIV transmission. The MTN conducts scientifically rigorous and ethically sound clinical trials that will support licensure of topical microbicide products and will carry out its mission through a strong network of expert scientists and investigators from domestic and international sites. For more information, visit: <http://www.mtnstopshiv.org>.

**National Institute of Allergy and Infectious Diseases (NIAID):** NIAID conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 50 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world. NIAID is a component of the U.S. Department of Health and Human Services, National Institutes of Health (NIH).

**Network:** A cooperative of institutions conducting clinical trials under a common research agenda. A network comprises the CORE Operations Center, Statistical and Data Management Center (SDMC), Network Laboratory, and the Clinical Trial Units and Clinical Research Sites.

**Protocol:** A descriptive document that presents a synopsis of the science supporting the study, details the scientific objectives, and describes the methods to achieve these objectives. A protocol outlines the specific requirements for the trial in a concise, organized, and comprehensive manner.

**Study Design:** The study design describes in detail how the research question will be answered, including the methods that will be used to collect data, where the study will be conducted, the

number and type of people required for the study, how the study will be implemented, and when the research will be conducted.