Community Consultation in HIV Prevention Research: A Study of Community Advisory Boards at 6 Research Sites

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Objective: To better understand how community advisory boards (CABs) can be used to improve the quality of HIV prevention trials.

Design: Data collected included descriptive and epidemiologic reports, ethnographic observations, and face-to-face semistructured qualitative interviews with 67 CAB and research team members. Interviews were coded for themes related to community-based consultation.

Setting: The study was conducted at 6 sites of the HIV Prevention Trials Network—Los Angeles, California; Birmingham, Alabama; Philadelphia, Pennsylvania; Harare, Zimbabwe; Lima, Peru; and Chiang Mai, Thailand.

Participants: Thirty-six CAB members and 31 research team members, identified with the assistance of research staff at each site, were recruited for interviews across the 6 sites.

Results: Both “broad community” and “population-specific” models were identified as strategies for CABs to represent potential participants in HIV prevention trials. CABs viewed their role as a bridge between the research team and trial participants. CABs improved prevention clinical trials by assisting in protocol development, recruitment, and retention. In addition, CABs both identified and helped resolve ethical issues in clinical trials.

Conclusions: When given time to develop, CABs appear to be a good strategy for building partnerships between researchers and communities for collaborative research projects. This approach has the potential to build sustainable capacity to identify and address ethical issues in research as well as community needs.

Key Words: community advisory boards, HIV Prevention Trials Network, community consultation, community partnerships, research ethics

Many of the ethical and practical issues raised by research require a partnership between researchers and potential participants or their representatives. Community-based participatory research, also referred to as community-centered research, is a model for promoting active involvement of community representatives in all stages of the research process. This approach is not a research method but rather an orientation to research that stresses community partnership and action for social change. Such an orientation is particularly important in socially sensitive areas such as HIV prevention and in international research sponsored by the United States. One approach to community-based participatory research has been the establishment of community advisory boards (CABs) to provide consultation and to articulate community needs.

The objective of the study was to better understand how CABs contribute to improving HIV prevention tri-
als. Although ultimately our goal is to be able to assess the outcome of CAB involvement in general and measure the relative effectiveness of different CABs, we believe that it is important to first understand the process of engagement between CABs and HIV research team members. Thus, we gathered qualitative data at 6 HIV prevention research sites to assess the views of CAB and research team members about the roles and responsibilities of CABs and the process of structuring a CAB. Although CABs have been a common component of HIV research for >1 decade, no one, to our knowledge, has examined how these groups function or the barriers they face in fulfilling their role.

From the beginning, the AIDS epidemic has led to conflicts between researchers and community groups.6 An early example involved the controversy over a highly politicized randomized, controlled trial of azidothymidine, which was the first drug to demonstrate efficacy against HIV.7 Much of the dispute centered on the justification for placebo-controlled trials. Although the controversy was largely resolved through the actions of a special data safety monitoring board, it also became clear that participants at some research sites were compromising the methodological goals of the trial. In particular, participants who believed they were receiving azidothymidine reported sharing their doses with participants who believed they were receiving the placebo. Such dose sharing defeated the purpose of a double-blinded, placebo controlled trial. Importantly, however, this incident shed light on the need for participants in research to be more involved in a partnership to answer scientific questions.1

In May 1990, frustrated by conflicts with researchers over various trials for the treatment of AIDS-related opportunistic infections, >1000 activists marched on the National Institutes of Health campus to demand a seat at the table.8 This resulted in the subsequent establishment of the Community Constituency Group within the National Institute of Allergy and Infectious Diseases, composed of community representatives from research sites across the United States. The group debated issues of clinical trial design, equity in access to trials, and the need to make results of trials known rapidly to patients and providers. One of the first policy recommendations made by the group was for the National Institute of Allergy and Infectious Diseases to require each of their clinical trial units to establish a CAB that included people living with HIV infection.

Subsequently the National Institute of Allergy and Infectious Diseases, but not other parts of the National Institutes of Health, issued a policy guidance requiring that each grantee establish a CAB, and document in their competitive applications how the group would contribute to the overall scientific success of the unit. This policy was then used as the National Institute of Allergy and Infectious Diseases funded both domestic and international sites applying to be part of an HIV vaccine trials network, thus extending these concepts and strategies of community consultation to international sites. These CABs emerged from activist roots9–11 but have now become institutionalized in HIV-related clinical trials.

Research on CABs is limited. A survey of CABs at 17 AIDS-related research units found that 12 of the 17 had a mission statement. The existence of these mission statements was associated with better attendance and more active participation.5 Respondents in this survey indicated that CABs were minimally involved in daily operations but were involved in expressing community preferences concerning research, educating community members about HIV, and evaluating study-specific education materials. In research to support HIV vaccine trials, qualitative interviews with prospective participants resulted in a common definition of community as “a group of people with diverse characteristics who are linked by social ties, share common perspectives and engage in joint action in geographic locations or settings.”12 Experience in preparing for vaccine trials has led some to suggest that CABs be used to provide advice about the informed consent process and the design of research protocols.13

In 1999, the National Institutes of Health established the HIV Prevention Trials Network (HPTN), a worldwide collaborative clinical trials network composed of 25 domestic and international research sites to evaluate the safety and efficacy of nonvaccine HIV prevention interventions. HPTN research focuses on behavioral and substance abuse interventions as well as microbicides, treatment of sexually transmitted diseases, prevention of mother-to-child transmission, and the use of antiretroviral drugs for prevention of sexual transmission. Each site is required to establish, support, maintain, and monitor community participation through a CAB. These activities are monitored by HPTN’s Community Working Group, which developed the concept for this study.

Sites are not given specific instructions on developing CABs. Rather, sites propose CAB plans that are then reviewed as part of the competitive scientific review process.

Although CABs developed for clinical trials of treatments for HIV infection are composed of mostly HIV-infected individuals, prevention trials, which involve the recruitment of HIV-uninfected individuals, have the challenge of developing CABs representing the concerns of groups or communities at increased risk of HIV in-
fection. Thus, we would expect to observe different dynamics in CABs for prevention trials than treatment trials.

The use of CABs is one strategy for promoting community-based participatory research. However, a number of questions remain. Who speaks for the community in prevention trials—i.e., how is representation determined? What is the role of the CAB in prevention research—i.e., what contributions do CABs make to improve the quality of HIV prevention trials? This study set out to find preliminary answers to these questions.

**METHODS**

We selected 6 research sites from the 25 network research units of the HPTN: Philadelphia, Pennsylvania; Birmingham, Alabama; and Los Angeles, California; as well as sites from Africa (Harare, Zimbabwe), Asia (Chiang Mai, Thailand), and South America (Lima, Peru). Sites were selected in consultation with the HPTN Community Working Group to reflect different geographic regions as well as diversity in primary research focus (behavioral, microbiologic, sexually transmitted disease, injection drug use, and mother-to-child transmission). Our goal was to select diverse sites that would help us understand the process of community consultation. We then contacted the principal investigators at each research site to seek the site’s participation in the study. All sites agreed to participate.

**Data Collection**

We used a rapid assessment model of data collection to develop a preliminary qualitative understanding of how CABs function. This type of qualitative inquiry was especially suited to our research questions, since much of our research focused on the process of CAB formation and the interaction between CAB members and research team members. Understanding the process by which events and actions take place is a hallmark of qualitative research. Rapid assessment first received attention as a tool for understanding rural development processes. This approach is particularly appropriate when the process cannot be identified in advance. Consistent with this approach, field teams visited each research unit for 5 consecutive days. The University of California at San Francisco Institutional Review Board approved the study protocol. Institutional review board approval was also required at one site in the United States and at other international sites.

Triangulation of data, or using multiple sources of data, is an important component of rapid assessment techniques to ensure reliability and validity. Three sources of data were collected to allow for triangulation of findins. First, prior to fieldwork, we gathered secondary data in the form of research site reports prepared for the HPTN describing each research unit, the population it studied, and the site’s capacity in terms of the types of research (e.g., microbiode trials) being planned. Second, site observations were written as field notes capturing the site environment, such as descriptions of drug treatment facilities where prevention trials were being conducted. Finally, we conducted 100 face-to-face semistructured interviews with a purposeful selection of CAB members, research team members, and potential prevention trial participants. Data are presented here on the 67 interviews with CAB and research team members conducted in space provided by each research site we visited. The sampling strategy was designed to select

<table>
<thead>
<tr>
<th>Site</th>
<th>Researchers</th>
<th>CAB</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birmingham, PA</td>
<td>5</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Philadelphia, PA</td>
<td>5</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Los Angeles, CA</td>
<td>4</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Chiang Mai, Thailand</td>
<td>7</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>Harare, Zimbabwe</td>
<td>5</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Lima, Peru</td>
<td>5</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
<td>36</td>
<td>67</td>
</tr>
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</table>

**RESULTS**

Two of the 6 CABs in the study were long-standing, established groups. The other 4 CABs had been in exist
tence for ≤6 months at the time of our site visit and thus were newly emerging. One of the emerging CABs included members with extensive prior CAB experience. Site characteristics are outlined in Table 2.

Representing Communities

We identified two different CAB models. A “broad community” model involved representation from a cross section of the larger community, including government officials, educators, religious leaders, nongovernmental organization officials, and people living with HIV infection. This model, found in Thailand and Zimbabwe, entailed a long-term view of the CAB’s mission to respond to potential future research projects. Such CABs desired sustainability, sought independence in funding and accountability, and promoted community-initiated research.

A “population-specific” model reflected the needs of a particular group at risk for HIV infection, such as African Americans, women, or injection drug users. Representation was from a limited population of the community at large. These CABs tended to be driven by an existing protocol. The Philadelphia CAB was composed primarily of current or former injection drug users who advised on several protocols involving HIV prevention among injection drug users. This was also the case in Birmingham, where the site was conducting early testing of microbicides and the CAB was formed to represent women who may be participants in the trials. Similarly, two other CABs in Los Angeles and Peru, where specific protocols were not established at the time of the site visit, were focused on preparedness and building site capacity for future research. The Los Angeles CAB focused on preparedness among African Americans, and the Peru CAB focused primarily on preparedness among men who have sex with men. The membership of these CABs reflected the target population of future trials.

Recruiting and Retaining Members

Concern about the impact of HIV/AIDS on their community was the dominant reason reported as to why people were willing to serve on CABs.

The commitment to fighting HIV/AIDS often flowed from a personal experience with AIDS, such as losing a loved one. CAB members who were living with HIV infection often brought personal urgency to the discussions of the need to prevent new infections. Among representatives from agencies or organizations, the opportunity to know about the practices of other agencies and researchers and to learn more about HIV, as well as to influence policy, were primary themes. Other personal motivations among members included reimbursements, lunch, tokens, travel, and stipends. Another motivation was legitimacy—a sense of self-worth and having something meaningful to contribute to their community:

“You know, just being part of something. Just being a part of something that means something. Sometimes when you’re a drug user or ex-drug user or whatever, you know, being a part of something that’s good and right means something.”—CAB member

A primary retention barrier among CABs appeared to be a knowledge gap between researchers and members of

<table>
<thead>
<tr>
<th>Site</th>
<th>Year formed</th>
<th>Frequency of meetings</th>
<th>Reimbursement</th>
<th>Number of members</th>
<th>Composition</th>
<th>Site research focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birmingham, AL</td>
<td>2001</td>
<td>Monthly</td>
<td>None</td>
<td>TBD</td>
<td>Prior study participants; community health and social</td>
<td>Microbicides</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>service organization representatives</td>
<td></td>
</tr>
<tr>
<td>Philadelphia, PA</td>
<td>1993</td>
<td>Monthly</td>
<td>$10, lunch</td>
<td>24</td>
<td>Prior study participants</td>
<td>IDU</td>
</tr>
<tr>
<td>Los Angeles, CA</td>
<td>2001</td>
<td>Monthly</td>
<td>None, food</td>
<td>TBD</td>
<td>African American focus</td>
<td>Prepared STD</td>
</tr>
<tr>
<td>Chiang Mai, Thailand</td>
<td>2001</td>
<td>Monthly</td>
<td>None</td>
<td>19</td>
<td>Health and social service agency representatives; NGO</td>
<td>IDU and behavioral</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>representatives; elected officials; government</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>representatives; religious leaders; people with HIV</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>infection</td>
<td></td>
</tr>
<tr>
<td>Harare, Zimbabwe</td>
<td>1996</td>
<td>Bi-monthly</td>
<td>None, food, transportation stipend</td>
<td>17</td>
<td>Local politicians; educators; health workers; church leaders; traditional healer; youth organization representatives; people with HIV infection</td>
<td>Microbicides and MTCT</td>
</tr>
<tr>
<td>Lima, Peru</td>
<td>2001</td>
<td>Monthly</td>
<td>None</td>
<td>9</td>
<td>HIV-related NGO representatives; MSM focus</td>
<td>Prepared STD</td>
</tr>
</tbody>
</table>

IDU, injection drug use; MSM, men who have sex with men; MTCT, Mother-to-child transmission; NGO, Non-governmental organization; STD, sexually transmitted disease; TBD, To be determined.
the community. Informants repeatedly expressed frustration with the use of technical terms by researchers:

“... it’s frustrating when you got to keep interrupting to tell them, could you explain that? Or could you talk in laymen’s terms? They start to make you feel stupid.”—CAB member

CAB participation placed demands on nonsalaried volunteer CAB members. Time, child care, and travel demands were reported as practical barriers. Other practical issues identified were lack of access to phones and computers in resource-poor settings. HIV-infected members also posed a retention challenge due to illness or death.

**Meeting Expectations of Partnership**

We found that research team members, particularly at sites with established CABs, reported that CABs could provide constructive criticism and feedback to help improve the quality of research protocols. Researchers identified the ability of CABs to advise them on recruitment and retention strategies. In particular, community participation was viewed as facilitating the researcher’s ability to move into new communities—either geographic or different populations. CABs were seen as playing a role in communicating to community members the risks and benefits of participating in the research project.

CAB members wanted certain returns for their work. Chief among them was validation or respect for their expertise by the research team and to see their recommendations implemented. CAB members wanted to become resources for information in their communities. They indicated a desire for training to increase their knowledge about HIV, research in general, and ways to communicate in nontechnical language. CAB members repeatedly requested that prevention information and research results be shared with the community as soon as possible. In general, CAB members were impatient for HIV education and advocacy even in the absence of research findings.

**Defining Role**

CABs understood their role as a bridge between the research team and trial participants. CAB members used terms such as “link,” “go-between,” and “liaison.” A CAB member illustrated the tension inherent in this role:

“To whom is the CAB accountable to? Is it to the community? Is it the local municipal authorities? Or is it to the research programs? That is a gray area. And that is an area we are struggling with.”—CAB member

Researchers reported concerns about conducting the best possible clinical trials. To do this, they discussed the need to attend to issues of recruitment, retention, and protecting participants.

To serve as this bridge, CAB members viewed their role as advisors not only regarding existing protocols but also influencing the development of future protocols. They saw their role as legitimizing research in their communities. For example, they could respond to misinformation about research and also serve as gatekeepers, providing access to potential research participants. The other major function identified was to serve as a “clearinghouse” for ethical issues.

**Identifying Ethical Issues**

Ethical concerns were implicit in CAB member discussions pertaining to community representation and protection of potential trial participants. They felt compelled to provide as much information as possible to the community regarding research activities. There were 3 consistent ethical themes: care and treatment, benefits to community resulting from research, and issues of social harm.

Across all sites, concerns were raised about providing treatment and social support to people diagnosed with HIV infection. This was a particular concern in that this research network was organized around randomized, controlled trials of HIV prevention interventions with seroconversion as an end point. Thus, the trials recruited for negative participants. As one of the informants indicated, these trials open “Pandora’s box.” People were screened, and if diagnosed with HIV infection, they were not eligible to participate in the prevention trial. The dilemma then became what could reasonably be provided to those persons who were diagnosed but would not be part of the ongoing research project. In resource-constrained countries, the options for referrals were limited.

At the sites in Peru, Thailand, and Zimbabwe, CAB members were particularly concerned that research should reflect the needs of the host country. As one informant indicated, “Historically researchers came in, drew blood and left to write their papers.” CAB members at these sites pointed to the need for the research project to leave something behind to provide a lasting benefit to their countries.

CABs saw protecting participants as part of their function. As representatives of vulnerable populations, CAB
members raised concerns about confidentiality. Participating in research was viewed as a potential form of public disclosure regarding HIV status or membership in a stigmatized group. As one CAB member stated, “People must know what the consequences and advantages are before going into the study.”

We found the term “guinea pig” used at 4 sites to reflect concern about the distributive justice of research projects. As one informant put it, “Are we being killed to develop a better product?” Others questioned why a particular locale had been selected for research. Relating back to prior experience with a vaccine trial, one informant asked, “Why is a vaccine study being conducted in Peru since they might not see benefit from it?”

**Responding to Ethical Issues**

The Philadelphia site offered an example of a CAB successfully resolving an ethical issue. Researchers at that site had tested participants in prior trials who had given general consent to test banked blood specimens for CCR-5, a genetic variation affecting susceptibility to HIV infection and disease progression in infected persons. The practical concern at the site was whether to expend the resources and effort to call people back for unplanned and unscheduled visits to give them the results of this test. The research team framed this as a debatable question for the CAB. A research team member then briefed the CAB about the test in lay language, and after answering questions, the CAB was asked to debate and resolve the issue. The CAB raised many practical reasons not to give results: eg, the potential for misunderstanding the results and the effect of that information on risky behavior. However, in the end, the CAB decided that ethical considerations trumped practical considerations and that participants had a right to know:

“The issue wasn’t about can we predict how people are gonna react, but do people have a right to know . . . if you’re testing something from their bodies . . . these are not just people who are here for you to draw specimens from.”

This example also illustrated the importance of structuring CAB meetings in ways that produce useful results.

**DISCUSSION**

The focus of this study was on the process of community consultation. Our rapid assessment provided a snapshot of an otherwise lengthy process of CAB formation. At the time of our site visits, 4 of the sites were newly formed, and CAB members had not yet discussed specific protocols. In future work, we hope to look more closely at the product of community consultation in terms of scientific outcomes. In the meantime, a number of important findings emerged from this qualitative study.

**Structural Issues**

In establishing a CAB, 2 central questions needed to be answered. First, how was community defined? Second, who spoke for the community? For a broad community model, the primary issue appeared to be sustainability and how best to promote the capacity of the CAB to improve the welfare of the community. One reason for this was that members of the CAB were drawn from existing positions of leadership who brought to the table their knowledge and concerns about various community needs. These members wanted to build something of lasting value to their community. Partnership with the research team gave CAB members this opportunity. Research teams need to work with CABs to provide an evidence base for prevention programs so that community groups will have a stronger position when advocating for government support. With regard to sustainability, CABs may need to be linked to nongovernmental organizations to follow up on long-term goals.

For a population-specific model, community building and leadership training were needed as part of the process of CAB development. Unlike in the broad community model, affected populations frequently lacked recognized leaders. Because HIV disproportionately affects poor and stigmatized groups, strategies for identifying and training individuals from these populations were needed. As this capacity was built, effective representation of these populations improved the potential of the CAB to meet its goals.

Sites needed to decide on a model—either the broad community model or the population-specific model—and recruit members accordingly. In the broad community model, finding community leaders with the time to commit to the project was challenging. In the population-specific model, the challenge was identifying and retaining representatives from marginalized populations, such as commercial sex workers and injection drug users.

In the case of either model, it took time for CABs to establish themselves and for a clear understanding of roles and responsibilities to evolve. Newly emerging CABs were struggling with membership, attendance, bylaws, and defining responsibilities. Our findings suggest that the underlying components of these struggles, particularly among the domestic sites, could be attributed to the development of mutual trust between the CAB and
the research team, which is a basic dynamic of group process.22

Advising Versus Partnership

CABs were organized along advisory or partnership lines. In CABs that were essentially advisory, members offered information and views that the research team considered and either accepted or rejected, as it deemed necessary. In CABs that were in partnership with researchers, issues and concerns were discussed and resolved in a mutually satisfactory manner before work proceeded. The process was collaborative and based on a mutually respectful relationship between the CAB and researchers who shared knowledge and authority more equitably. Each member of the partnership was recognized and valued for their individual expertise. This partnership differed from the approach taken by activists in earlier treatment trials who saw themselves as outsiders whose role was to criticize methods, timetables, ethics, and usefulness of research.

Maximizing Community Consultation

We found that one of the primary barriers to retention of CAB members was a knowledge gap between researchers and members of the community. Continuous formal and informal training for both CAB members and research staff may be needed across sites to respond to disparities in knowledge. CAB members were interested in cross-site training, skills building, and information sharing. CAB members wanted regular updates on research activities and plans as well as training to talk about the research without reliance on technical terms. Both CABs and research teams need to plan for timely feedback of research findings to the communities that have participated in research. Models for such feedback need to be described more systematically and shared across sites. In addition, CAB members suggested that researchers be trained in methods to communicate and work effectively with their community.

For CABs to be more productive, meetings need to be structured. Debatable issues should be brought to the table to initiate discussions. Research participants should be encouraged to periodically participate in CAB meetings to share their experience in the research and to offer feedback.

One issue that affects the relationship between CABs and researchers was the question of compensation for CAB members that is consistent with their responsibilities. However, this consideration must be balanced with the concern that compensation often results in less vigorous criticism and oversight by CAB members who tend to view themselves, at least in part, as employees of the research team. Time, travel, and other demands were frequently cited as barriers to retention of CAB members. Ideally, researchers should address practical needs for services such as transportation and child care without necessarily providing direct compensation.

Responding to Ethical Concerns

Three basic principles that guide ethical research—respect for persons, beneficence, and justice—were reflected in interviews with CAB members.23 Beyond identifying issues, CABs contributed to protecting human participants by suggesting options for research staff to consider. This was seen in discussions of such practical issues as the need for referrals for people diagnosed with HIV infection.

One of the ethical problems uncovered in this study was how to assure genuine informed consent. CABs viewed themselves as having a legitimate role in protecting vulnerable people who may be participants in research. Research teams relied on informed consent forms to meet this goal. However, reliance on these forms failed to recognize that true informed consent must be a process that engages people in a deeper understanding of the nature, opportunities, limitations, and requirements of the research. CABs should help identify ways of meeting the goals of informed consent that are culturally relevant and acceptable.

The concept of community consultation was introduced into discussions of research ethics in the mid-1970s23 in response to concerns about the vulnerability of research participants who were often at a significant disadvantage in terms of information when interacting with researchers. One way to make the informed consent process more meaningful was to assemble groups of potential participants to discuss proposed research where members of the group could provide support for one another in seeking explanations. These meetings also offered the opportunity for researchers to demonstrate respect for the concerns of potential participants. Such considerations were one of the essential reasons why CABs were created in the first place.

CONCLUSIONS

Representation on CABs in HIV prevention trials can be accomplished with either broad community or population-specific models. CABs see their role as a bridge between research projects and community members. CABs can improve the quality of HIV prevention trials.
through improving recruitment, retention, and the protection of research participants. CABs can both identify and help resolve ethical issues in HIV prevention research. The policy of requiring a CAB at research sites appears to have increased partnerships between researchers and the communities represented by the CAB members. However, before CABs can be effective, they need time to develop an understanding of their role that balances community needs and those of the research process.

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