

Community Engagement in Clinical Trials
A briefing paper prepared by the Policy Department
Global Alliance for TB Drug Development
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Introduction

Community Advisory Boards (CABs) were originally developed in conjunction with HIV prevention trials to address questions and conflicts between researchers and the HIV community about safety and the issues related to patients enrolled in vaccine trials. Over the past 15 years, CABs have become standard in HIV prevention trials and are now a contractual requirement for grantees participating in the NIH HIV Prevention Trials Network (HPTN). CAB structures vary by site and geographic location. Also, CAB structures used for the HPTN can differ from CAB structures used for other types of clinical trials.

In order to better understand the role of CABs in HIV prevention research and in other clinical trials the Global Alliance for TB Drug Development (TB Alliance) undertook a literature review and a series of interviews with researchers engaged in clinical trials in low income countries.

Methods

A literature review was conducted through a MEDLINE and Pubmed search from March – April 2006, using the following keywords (community advisory board, CAB, community participatory research, clinical trials and community engagement) and relevant references were then identified for further reading. Interviews were conducted with organizations and investigators currently engaged in drug and vaccine trials in low income countries.

Literature Review

There are several different ways that community advisory structures have been developed, and the term “community” has been used to represent a broad cross section of stakeholders, including government officials, clinicians, researchers, religious leaders, policy makers, patient advocates, educators, non-governmental agency staff, local authority figures, individuals from infected patient populations or from a population at risk of infection, such as sex workers and injecting drug users, etc.

As members of CABs are involved on a voluntary basis participants usually have a vested interest in the outcome of the clinical trial, and/or the process by which it is being conducted and want to ensure the safety of the enrolled participants and help educate themselves and rest of their constituency about the clinical trial or the disease in general.

The majority of published articles on CABS describe the NIH sponsored HPTN trials. In summary, these CABS were developed because people living with HIV demanded participation in the NIH clinical trials process. In the early 1990s, a Community Constituency Group was established. Their first policy recommendation was for NIH to require that all clinical trial units establish a Community Advisory Board. From that point forward all grantees have been required to have CABs, and must submit their plans for this structure with their competitive application for sponsorship.

Although NIH requires that each unit have a CAB, they do not give specific instructions as to how these structures should be developed. It remains the responsibility of the clinical trial team, and the community in which the trial is being conducted, to develop this structure. Each CAB structure is different, and defines “community” differently. Success of these CAB structures can be as varied as their design.

Morin, SF, et al discuss experiences with CABs in low income countries and analyze the process of running community advisory structures in 6 research settings participating in the NIH sponsored HPTN trials, including sites in the United States, Thailand, Zimbabwe and Peru. The article concludes that success of a community structure depends on the commitment of members, researchers and trial staff. Morin suggests that those CABs which have developed a specific mission statement may be more successful in function because everyone involved has agreed upon a common goal. Other factors contributing to success include payment of full time staff, support of voluntary members through reimbursements, defining the role and responsibilities of members, and establishing trust between members and research staff. The research concluded that if the CAB function is not well defined, participants tend to experience frustration and confusion around the purpose for their involvement. Other difficulties included: knowledge and language barriers between researchers and non-researchers. In all cases, ensuring that participants understood details about the disease and about the clinical trial process was critical.

Strauss, et al, explain the importance of CABs in ensuring appropriate informed consent for study participants, based on HIV vaccine efficacy trials in the US. The CAB, acting as an advocate for patient rights, can help participants to understand their right to refuse, and their rights to full disclosure of the risks and benefits of the research. The CAB can also sometimes help to develop culturally appropriate materials used to explain the study to participants.

Interviews

Although transparency by the researchers, and community input is critical, a traditional NIH structured CAB may not be the most appropriate way to engage in clinical trials. When there is a large trial that will involve the community for a long period of time, and enroll a large number of patients the impact on community can be greater, and the community needs to be vested in the process. In this case a community advisory structure is necessary to help recruit participants to generate support and establish community “buy-in” into the trial. Researchers interviewed have varying approaches to

community engagement in clinical trials. In summary, there was consensus on a number of issues:

- Clinical trials may be able to take advantage of community advisory structures already established for other research initiatives at that same site.
- Although CAB structures and types of participants may differ, all are committed to bridging the divide between the researchers and the community affected by the clinical trial. CABs are most successful when the site itself decides on the appropriate design for the structure.
- It is important to define the role of the Community Advisory Structure. For example, community advisory structures are not responsible for scientific decisions or ethical protection of subjects, as there are other structures in place to oversee these processes. They can, however, provide input on informed consent and clinical trial-related printed and educational materials. They can also provide input on issues of cultural sensitivity, such as appropriateness of incentives.
- The structure of a CAB may change over time, even at the same site. For example, for one vaccine trial, a formal CAB was set up involving public health program and clinic staff. The CAB met quarterly. This group was then expanded to involve participants from civil society and religious groups and after the trial was up and running with adequate enrollment, the group decided that a once per year meeting would be sufficient.
- It can be difficult to sustain interest or engagement from community members, especially for products that are in early stages of development. Meaningful engagement requires adequate funding for staffing and activities at a trial site. It may also be necessary to reimburse advisory committee members for travel to meetings.
- Although none of the community advisory groups identified included members of the media, in one instance, the CAB had an agreement with a local newspaper's weekly column on public health. The newspaper agreed to accept articles from the CAB at any time to keep the community informed about issues related to the trial.

Most of the organization interviewees see the development of a community engagement structure as the responsibility of the local site coordinator, or local principal investigator, although the global PI may provide input, or assist with materials about the trials.

Aside from the NIH guidelines for the HPTN, no written standard operating procedures (SOPs) for community engagement were identified, however the AIDS Vaccine Advocacy Coalition (AVAC), in conjunction with the Bill and Melinda Gates Foundation and others have been working on the development of a standard for "good participatory practice."

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