

Defining Best Practices for Community Representative Involvement in HIV Clinical Research Networks

A Cross-Network CAB Working Group Meeting

Executive Summary

**Washington Court Hotel
Washington, D.C.
May 6-8, 2005**

**Sponsored by the National Institute of Allergy and Infectious Diseases (NIAID),
Division of AIDS (DAIDS)**

Executive Summary

Community representatives and advocates have, for more than two decades, supported and provided input and advice about HIV research at NIH-funded study sites, and at many stages of research planning, funding, ethical review and implementation. Community voices are heard through a myriad of structures, including community advisory boards (CABs) and organizations representing community interests from specific geographic, population, or HIV-related concerns.¹

However, community involvement and representation in HIV research is fragmented, separated by geography, language, areas of expertise and interest, and the sheer complexity and scope of the HIV research agenda. In late 2004, several individuals working in this field saw a need to initiate new dialogue to bridge this fragmentation, and to improve the standards and support for community involvement.

In early 2005, more than forty individuals were invited to a three-day meeting, held in Washington D.C. in May 2005 and funded by NIAID's Division of AIDS (DAIDS), to discuss experiences, ideas, and proposed "best practice" definitions related to community representation in DAIDS-funded HIV clinical research. Participants had direct experience from four countries (Brazil, South Africa, Zimbabwe, and the U.S.) and with many of the DAIDS-funded clinical trial networks and other research programs.² Participants included CAB members and other community representatives and advocates, community liaison staff supported by trial sites and networks, selected scientific community presenters and DAIDS staff.

The stated goals of the meeting were to define best practices for community involvement in DAIDS-funded HIV clinical research networks, and to explore and propose processes to realize those best practices. The meeting was focused on issues, ideas, and recommendations that could be generically applied to community involvement in HIV clinical research around the world. This meeting was intended as a starting point to better link community representatives across DAIDS-funded research networks, and to spark new interest and unified action toward successful community involvement.

¹ In this report, the term CAB will refer to community advisory boards, and also community constituency groups (CCGs) and community working groups (CWGs).

² The May 2005 meeting included staff and CAB members from the Adult AIDS Clinical Trials Group (AACTG), the Acute Infection Early Disease Research Program (AIEDRP), Community Programs for Clinical Research on AIDS (CPCRA), Evaluation of Subcutaneous Proleukin (ESPRIT), HIV Prevention Trials Network (HPTN), HIV Vaccine Trials Network (HVTN), Multicenter AIDS Cohort Study (MACS), and the Pediatric AIDS Clinical Trials Group (PACTG). A community representative from the Women's Interagency HIV Study (WIHS) was invited but was unable to participate.

At the May 2005 meeting, participants developed recommendations and conclusions in the following areas:

Best practice: Roles, responsibilities, and required competencies

At the May 2005 meeting, participants worked to define the core roles, responsibilities, and required competencies for community representatives working in different facets of community involvement, including community involvement with clinical trial sites, with DAIDS-funded clinical trial networks (i.e. national or global community group), with DAIDS and clinical trial network leadership, and across network CABs.

In defining community representative roles and responsibilities, meeting participants identified work tasks and content, and also who a community representative should interact with. Core competencies included background and experience, abilities, acquired skills and training, and demonstrated interest and commitment.

Best practice: Methods for interacting with researchers and research sponsors

Meeting participants had detailed and lively discussion about models and structures for community representation in HIV clinical research. Participants heard presentations about principles of and alternate models for community representation. Participants agreed on some themes that define ‘functional’ community structures, such as:

- structures should allow broad and evolving participation in decisions and leadership;
- structures should encourage broad, inclusive, and diverse participation from relevant communities;
- structures should facilitate the defined work of community representatives, and enable trust and communication between communities and research networks.

Participants arrived at the following core conclusions and recommendations:

- The requirements for structures for community representation should be understood as going beyond simple questions such as, “Is there a CAB?” to a question of, “Have we integrated community participation into all of our research activities?”
- The current models and structures for community participation are not, and should not be, limited to CABs. There are many examples of useful alternative pathways for community input into the HIV clinical research effort, and this diversity and adaptability of community structures should be acknowledged and appreciated. Community representatives should become familiar with the full range of models, perhaps through on-going research, documentation and sharing of case studies and examples of community participation.
- Although the CAB method is not the only method for structuring the work of community representatives, participants felt that there is sufficient evidence of their importance and their success from clinical trial sites around the world to recommend that a functioning CAB be a minimal standard at every site and network. In this “CAB+” recommendation, participants suggested that

- researchers and communities explicitly recognize when and where CAB models are working, and where other models should be added to augment community participation. Participants recommended on-going research and documentation about CAB success and failures in ensuring broad, inclusive, diverse, and dynamic participation by community representatives in the clinical research process, participation by community and researchers in decisions affecting clinical trials, and trusting engagement between communities and research networks. This documentation should be accompanied by analysis of possible operational factors in success and failure, such as staffing, resources, and timing.
- If community representatives around the world are to understand, adopt and implement this “CAB+” concept, they should be first supported to talk about it at a local level. Their conclusions and recommendations should be incorporated into a larger international discussion.

Regarding structures for community engagement with DAIDS leadership and clinical trial network leadership, participants reviewed the latest information known about the “Managing Partners” and “Community Partners”, groups that will form as part of the DAIDS competitive renewal (currently in progress). At the May 2005 meeting, DAIDS representatives suggested that the group might make recommendations, proposals, or suggestions to DAIDS as to how the Community Partners might be structured. A recommendation was put forward and embraced that meeting participants form a temporary working group to further flesh out recommendations for the composition and function(s) of the Community Partners. Steve Wakefield agreed to provide staff support for this working group.

Best practice: Management and support needs

Participants identified and discussed specific actions and funding needs for supporting community representation in HIV clinical research. These included actions to facilitate participation of new community representatives, and to build and retain the skills and capacity of current community representatives, in their defined roles, responsibilities, required competencies, and structures.

Participants noted inconsistent levels of support for community participation at each DAIDS-funded network and at the many clinical trial sites. Participants recommended a systematic comparison of these network resources be conducted as a possible guide for best practices across all DAIDS-funded networks and research programs.

Training: Participants recommended that the following training topics be funded for community representatives, and that this funding be integrated into network and site budgets:

- Introductory overview to HIV science and clinical research challenges
- Overview of principles and structures for ensuring ethics and human rights, including processes for reviewing research plans and implementation
- Overview of DAIDS-funded clinical research plans, agendas, structures and funding

- Training for researchers about community expectations and perspectives on current HIV clinical research efforts
- History of community representation and participation in HIV clinical research
- Meeting organization and facilitation skills
- Information technology, presentation and communications skills
- Cross-CAB meetings to build informal and formal mentoring (within and across networks)
- Training on specific planned and current HIV clinical protocols, as a way to train community representatives about how to read and evaluate a protocol
- Training on specific planned and current statistical analysis of HIV clinical trial data, as a way to train community representatives about statistics
- Training on monitoring, process and outcomes evaluation, systems research, social science research, and other assessment tools, to help community representatives identify potential areas for monitoring and assessment.

Support: Participants recommended that the following aspects of support be funded for community representatives, and that this funding be integrated into network and site budgets:

- Supplies – including office supplies and printed and other communication materials
- Services – including translation of materials, telephone and internet access, and also support for services inherent to broad community participation needs, such as interpretation, local transportation, child care, etc.
- Travel – including visas and financial support for meeting costs (translation, space, staffing). Financial barriers should be removed (or minimized to the extent possible) to enable community participation.
- Administrative support – including access to office equipment, meeting space and supplies, audiovisual materials, and IT support
- Programmatic support – including staff assigned as point persons in networks and at clinical trial sites.

Language was raised as an important area requiring support. Participants suggested that appropriate communication and trust requires an investment in translating scientific language into locally clear language, and also an investment in developing mechanisms that ensure comprehension. The group recommended funding, organizational contracts and structures, and advance planning for provision of translation, both in terms of printed documents as well as simultaneous interpretation at meetings.

Indicators of success in community representation

Participants identified and discussed specific measurable indicators for evaluating community representation in HIV clinical research. Participants developed a detailed list of possible evaluation indicators for community participation at clinical trial sites and local communities, HIV clinical trial networks, and DAIDS and network leadership.

Because evaluation criteria have rarely been applied to community representative components, participants strongly urged that evaluation criteria be used for identifying the need for support, training and other constructive interventions. It was also recommended that evaluation be conducted by both external review and by self-evaluation.

Discussion of next steps

In a review at the end of the three-day meeting, participants stated that they had:

- gained new appreciation and understanding of the complexities of the topic,
- appreciated the similarities, synergies, competencies, and interest in collaboration among the DAIDS-funded clinical trial networks,
- clarified their expectations and resolve for advancing further dialogue and collaboration for community involvement in HIV clinical research,
- had clear expectations of the next steps for further developing and implementing the recommendations.

Some next steps toward defining best practices for community representation and involvement in HIV clinical research:

June and July 2005: The Cross-CAB Working Group (CCWG) will host a call where interested participants who attended the meeting are invited to participate to discuss this draft report and provide feedback for finalizing the report. Following revisions, an electronic (PDF version) of the final report will be made available to planning committee members, the entire CCWG and all meeting participants for their use in communicating with others in their networks and across networks. A hard copy of the report will not be published. An electronic version of the report will be distributed further per the recommendations of the CCWG.

July-September 2005: A subcommittee of the CCWG will be called to form re: implementation and tracking of the report recommendations. CCWG members from each network will be asked to go back to their networks and ask for a meeting with their CAB and network leadership to discuss report recommendations related to implementation and implications (and provide a written summary of any issues that arose to the aforementioned subcommittee). Participants have particularly emphasized the importance of international input in this process.

October 2005: A small subset of the CCWG subcommittee, preferably including 2 to 3 network staff reps and 2 to 3 community representatives meet with DAIDS leadership to discuss report recommendations, implementations and implications (and provide a written summary of any issues that arose to the subcommittee).

November-December 2005 and throughout 2006: Based on feedback and outcomes of the above activities, a strategy for follow up on the recommendations will be devised, with time lines and assignments.

Throughout the second half of 2005 and early 2006, as decisions are made about the new structures and functions of DAIDS-funded HIV/AIDS clinical trial networks and clinical trial sites, and associated leadership and managing partners group, the CCWG members will provide corresponding recommendations and adaptations of the defined roles/responsibilities, evaluation criteria, and other content in this report.

Defining Best Practices for Community Representative Involvement in HIV Clinical Research Networks

Cross-CAB Working Group Meeting May 6-8, 2005

Meeting Participants

(planning group members indicated with an asterisk)

Participants

Mark Baker (CPCRA)
Deloris Bright (CPCRA)
Gail Broder (HVTN)*
Christopher Camp (MACS)
Allegra Cermak (AACTG staff)*
Shawna Chester (PACTG)
Janet Frohlich (HPTN)
Thomas Gibson (HVTN)
Megan Gottemoeller (Global Campaign for Microbicides)*
Glenda Gray (HVTN investigator)
Reginald Jackson, Jr. (CPCRA)
George Kelly (CPCRA)
James Kublin (Network Coordination)*
Tamara (Samantha) Kuryla (PACTG)
Brenda Lein (Project Inform/ESPRIT)*
Butch McKay (HVTN)
David Metzger (HPTN/HVTN investigator)
Matilda Mogale (HVTN)
David Munroe (CPCRA)*
John Mutsambi (HPTN)
R. Bruce Pain (AIEDRP)
Ljudmila Petrovic (CPCRA staff)*
Hamilton Richardson (HVTN)
Joseph Robinson (AACTG)*
Dorothy Shaw (PACTG)*
William Strain (AACTG)
Jeff Taylor (AMC/AIEDRP)
Rose Todd-Stanford (AACTG)*
Melissa Turner (CPCRA site staff)
Octavio Valente, Jr. (HVTN)
Nalini Visvanathan, Ph.D., M.P.H. (HPTN)
Steve Wakefield (HVTN staff)*
Vita Washington (PACTG staff)
Rhonda White (HPTN staff)*

DAIDS

Brendan Cole (Office of the Director)
Moriane Joseph (Basic Sciences Program, WIHS liaison)
Joanna Katzman, (Vaccine Research Program, HIV Vaccine Communications Campaign)
Chuen-Yen Lau (Vaccine Research Program, HVTN liaison)
Daniel Montoya (Office of the Director)
Matthew Murguia (Office of Program Operations and Scientific Information/ad hoc meeting participant)
Sussan Paydar (Vaccine Research Program/ad hoc meeting participant)
Joan Romaine (International Research Branch, CIPRA liaison)
Rona Siskind (Office of Program Operations and Scientific Information)*
Sue Welsch (Therapeutic Research Program, AACTG/PACTG liaison)

Facilitator

Sam Avrett

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Meeting Agenda

FRIDAY, May 6, 6:00 pm - 9:00 pm

- 5:30 pm – 6:00 p.m.** **Registration**
- 6:00 p.m.-6:30 p.m.** **Reception**
- 6:30p.m.-6:40 p.m.** **Welcome**
Matthew Murguia, Director
Office of Program Operations and Scientific Information.
- 6:40 p.m.-8:00 p.m.** **What Does Success Look Like?**
Steve Wakefield and Gail Broder
- 8:00 p.m.-9:00 p.m.** **What is a Community Representative?**
8:00 p.m.-8:20 p.m. Janet Frohlich
8:20 p.m.-8:40 p.m. Brenda Lein
8:40 p.m.-9:00 p.m. Discussion

SATURDAY, May 7, 9:00 a.m.-6:00 p.m.

(Breakfast on your own)

- 9:00 a.m.-9:10 a.m.** **Welcome and Call to Order**
Rose Todd-Stanford
- 9:10 a.m.-9:30 a.m.** **Introduction/Purpose of Conference**
(format, goals, outcomes and ground rules)
Sam Avrett - Facilitator
- 9:30 a.m.-10:30 a.m.** **International Partners' Presentation**
John Mutsambi, Harare, Zimbabwe
Nalini Visvanathan, Boston, MA, USA
Janet Frohlich, HPTN Int'l Community Working Group Co-Chair
- 10:30 a.m.-10:45 a.m.** **BREAK**
- 10:45 a.m.-12:30 p.m.** **Define the Role(s) and Responsibilities of Community**
in the NIH-sponsored HIV Clinical Research Process
- 10:45 a.m.-11:30 a.m. What do Researchers Want/Need From the Community?

10:45 a.m.-11:00 a.m. 11:00 a.m.-11:30 a.m.	[What does the scientific community see as the role(s) and responsibility(ies) of community?] Presentation Panel (scientists) Dr. David Metzger, HPTN and HVTN PI Mrs. Matilda Mogale representing Dr. Glenda Grey, HVTN PI
11:30 a.m.-12:30 a.m.	What Does the Community See as Role(s) and Responsibility(ies) of the Community? Group Discussion: Define Core Role(s) and Responsibilities
12:30 p.m.-1:00 p.m.	LUNCH (working – ½ hour break to gather food, etc.)
1:00 p.m.-2:15 p.m.	Identify Model(s) to Support Community Fulfilling Roles and Responsibilities
1:00 p.m.-1:15 p.m.	Presentation of Various Models/Processes Megan Gottemoeller
1:15 p.m.-2:15 p.m.	Facilitated Discussion
2:15 p.m.-2:30 p.m.	BREAK
2:30 a.m.-4:00 p.m.	Define Core Competencies of Community “Reps”
4:00 p.m.-4:15 p.m.	BREAK
<u>SATURDAY, May 7, 9:00 a.m.-6:00 p.m. (cont.)</u>	
4:15 p.m.-5:45 p.m.	Define Support and Evaluate Mechanisms to Perform Role(s) and Responsibilities (continued Sunday)
4:15 p.m.-4:30 p.m.	Charges/Instructions to Breakout Groups
4:30 p.m.-5:45 p.m.	Breakout Sessions 1. Training – site level, network level, etc. 2. Support – supplies, structure support (e.g., conference calls, administrative assistant), fiscal support, translation services, web/computer support, etc. 3. Evaluation – based on proposed role(s) and responsibilities, how should individuals and groups (community, scientific leadership) be evaluated to ensure accountability?
5:45 p.m.-6:00 p.m.	Closing Remarks/Adjourn
<i>(Dinner on your own)</i>	

SUNDAY, May 8, 9:00 a.m.-4:00 p.m.

(Breakfast on your own)

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| 9:00 a.m.-9:10 a.m. | Welcome and Call to Order
Rhonda White |
| 9:10 a.m.-10:00 a.m. | Distribute Written Summaries and Review Progress
<i>What is A Community Representative?</i>
<i>Roles and Responsibilities of Community</i>
<i>Recommended Model(s) for Community Input</i>
<i>Core Competencies</i> |
| 10:00 a.m.-11:30 a.m. | Presentation From Support/Evaluate Breakout Sessions |
| 10:00 a.m.-10:15 a.m. | Training |
| 10:15 a.m.-10:30 a.m. | Support |
| 10:30 a.m.-10:45 a.m. | Evaluation |
| 10:45 a.m.-11:30 a.m. | Discussion/Questions |
| 11:30 a.m.-11:45 a.m. | LUNCH (working – break to gather food, etc.) |
| 11:45 – noon | Update on Cross Network Collaboration Activities
Jim Kublin |
| Noon -2:30 p.m. | Additional Discussion/Breakout Sessions
(as needed with working lunch) |
| 2:30 p.m.-3:00 p.m. | Discussion and Next Steps |
| 3:00 p.m.-4:00 p.m. | Discussion: What Does Success Look Like Part II?
Steve Wakefield and Gail Broder |