

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

A Cross-CAB Working Group Meeting

**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)**

**National Institute of Allergy and Infectious Diseases (NIAID)
Division of AIDS (DAIDS)**

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in HIV Clinical Research Networks**

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1. Meeting genesis and goals

HIV clinical research now encompasses the work of hundreds of research sites throughout the world, seeking to answer questions related to treatment and clinical management of HIV infection and AIDS, prevention of maternal-child transmission, and development of new prevention interventions including microbicides and vaccines. In major cities of the United States and elsewhere, there are often several study sites, each recruiting people living with HIV/AIDS or at risk for HIV/AIDS for multiple trials. In many cases, HIV study sites conduct research in communities where vulnerability to HIV is compounded by vulnerability due to gender, youth, poverty, incarceration, drug use, sexuality, and many other factors.

The U.S. government, through several agencies, networks and partners, is the world's largest public sponsor of HIV research. Among these U.S. agencies, NIAID's Division of AIDS provides the largest investment of funding and effort, seeking to support clinical research in the full range of HIV-related scientific challenges and priorities.

Community input and involvement into HIV clinical research efforts has been recognized as essential for nearly two decades. 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

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. Community representatives have worked with the NIH and researchers during the past fifteen years in many ways to reduce this fragmentation, and to link experiences and best practices across sites and areas of research.

This most recent effort by a Cross-CAB Working Group (CCWG) was sparked by the development of the DAIDS clinical trial network request for applications (RFA) in late 2004. In developing this RFA, DAIDS solicited input from network CAB members. Through this regular communication, network CAB members and network staff identified a need to initiate new dialogue about best practices in community representation in HIV research. With DAIDS support, the network CAB members and network staff of the CCWG began planning a meeting on best practices in November 2004.²

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 fourteen members of the CCWG meeting planning group were Gail Broder(HVTN), Allegra Cermak (AACTG), Megan Gottemoeller (Global Campaign for Microbicides), Stella Kirkendale (HPTN), James Kublin (Network Coordination), Brenda Lein (Project Inform/ESPRIT), David Munroe (CPCRA), Ljudmila Petrovic (CPCRA), Joseph Robinson (AACTG), Dorothy Shaw (PACTG), Rona Siskind (DAIDS), Rose Todd-Stanford (AACTG), Steve Wakefield (HVTN), and Rhonda White (HPTN).

The three-day meeting was held in Washington D.C. in May 2005 and funded by NIAID's Division of AIDS (DAIDS). More than forty individuals were invited 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.³ 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.

2. Meeting report

The May 2005 meeting succeeded in providing initial consensus recommendations from participants across DAIDS-funded clinical trial networks. 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 fleshing out and implementing the recommendations.

In addition, the following were summary recommendations and discussions of the meeting:

2.1 Definitions of community representatives

Participants agreed that the term and concept of "community representative" can include a broad range of definitions. Participants noted that the term "community representative" is currently defined in different ways, depending on trial site location and

³ The May 2005 meeting included staff and CAB members from the Adult AIDS Clinical Trials Group (AACTG), the Acture 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.

history. Participants discussed the term as it is currently being applied, and as it might ideally be defined.

Participants described their core definitions for the term, including who “community representatives” are, their relationship to communities, their relationship to clinical research infrastructures and funding, and their individual backgrounds, values, and goals. Discussion included:

- community representatives as individuals who are ‘representing’, ‘representative’, and/or ‘consultative’ of one or more populations or affinity groups,
- community representatives as stakeholders, opinion leaders, organizers, advocates, and trial participants,
- community representatives as committed, passionate, present, vocal, honest, offering outside perspectives, and experienced in, and guided by, community-based HIV priorities and needs, and
- community representatives as those who serve as a platform and channel for information and voices of community and research, who communicate ideas and concepts between community and researchers, and who hold people and processes accountable.

The meeting participants raised several important questions:

- Are there consistent definitions and measures of who is a community representative, across all HIV research areas, populations, and trial site locations? If so, what is the process for agreeing on these? If not, who decides at a local level, and how?
- When can ‘community representatives’ be appropriately paid by a clinical trial site or network? How can independence be ensured where community representatives are reliant on researchers for information and compensation for their efforts?
- It was noted that becoming a community representative in clinical trial planning, funding, ethical review and implementation often requires autonomy, courage, support, and a way to start. Therefore, how does the definition of ‘community representative’ need to inherently accommodate those who might be marginalized or less powerful in a society, such as people living with HIV/AIDS (PLWHA), women, ethnic and cultural minorities, immigrants, people with limited education, people with histories of poverty, incarceration and drug use, people marginalized due to sexuality or gender identities, and/or adolescents and young adults? Where people have less ability and power to advocate for themselves, do clinical trial researchers and outside community advocates have a responsibility for or role in ‘pushing’ or ‘pulling’ individuals into this role?
- How can HIV clinical research networks ‘share’ the limited number and time of community representatives? How can community representatives be supported to work across multiple HIV research and other HIV topics?

The goal was not to come up with a unified and agreed upon consensus definition of “community representative.” Rather, the goal of this discussion was to come to an understanding and appreciation of the breadth of each of our definitions, to highlight that

this term means different things to different people. By recognizing the diversity of our definitions we might better form best practice recommendations that take into consideration the breadth and depth of these differing definitions.

2.2 Roles, responsibilities, and required competencies

During the three-day meeting, participants arrived at much agreement about core roles, responsibilities, and required competencies of community representatives in clinical trial research:

At every clinical trial site, community representatives should be tasked with:

- Facilitating research toward effective prevention, treatment, and/or a cure for AIDS
- Sharing information and advising the site's research team about:
 - The research needs and concerns of the local community
 - The changing epidemic
 - How to best reach the local target population(s)
 - Identifying linkages with the local target population(s)
 - Trial recruitment, retention, and implementation issues
- Sharing information, reporting back to and educating the community about:
 - Research opportunities at the local site
 - About the value of the research to/in the community
- In addition to educating the research staff about the research needs of their community and educating the community about the value of the research, it is also the responsibility of community advisors to educate *one another* about the communities they represent.
- Assure that ethical issues are being identified and addressed appropriately on:
 - Research projects being proposed
 - Obtaining Informed Consent (document and/or procedures)
 - The value and risk of proposed research to the community

Core competencies for this work would include:

- Individual experience and background that allow knowledge and cultural understanding of the relevant and diverse communities, and authenticity and legitimacy within those communities.
- Ability to communicate easily, to work in an inclusive and participatory way, to openly communicate criticism and critique, to be accountable to communities, and to be a leader.
- Capacity to listen and learn from both community and researchers, to gain understanding about the local HIV epidemic, community concerns and priorities, clinical research plans and protocols, and ethical concepts and issues.
- A 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.

Participants raised several questions related to the role of community at clinical trial sites:

- How can study sites and local community representatives better document the impact and outcomes of community involvement in clinical research such that community involvement in research processes can be better studied and evaluated?
- How can study sites and community representatives better measure and document needs and progress related to building community trust in research?
- How can study sites and community representatives better address language and other communication barriers?
- How can study sites and community representatives better handle access to sensitive or complicated information, such as scientific protocols?
- How can community representatives evaluate themselves and/or allow themselves to be evaluated in their work?

At the highest level within each of the DAIDS-funded clinical trials networks (i.e. national or global community group), community representatives should be responsible for:

- Facilitating research toward effective prevention, treatment, and/or a cure for AIDS
- Sharing information and advising the network investigators about:
 - The research priorities, needs and concerns of the community
 - The research priorities of the network
- Providing input, review, comment and feedback on:
 - The research agenda/priorities of the network overall
 - Recruitment and retention plans for studies
 - Every concept proposal and protocol
- Sharing information, reporting back to and educating the community:
 - About research priorities of the network and research opportunities generated by the network
 - About the value of the research to/in the community (and to site community representatives)
 - Assure materials are being made available to site community advisors
 - Foster site-level collaboration (where possible and appropriate)
- Assure that ethical issues are being identified and addressed appropriately on:
 - Research projects being proposed
 - Obtaining Informed Consent (document and/or procedures)
 - Participant compensation and incentives, and other aspects of research design and implementation that will affect community trust and welfare
 - The value and risk of proposed research to the community
- In addition to educating the research staff about the research needs of their community and educating the community about the value of the research, it is also the responsibility of community advisors to educate *one another* about the communities they represent.
- Other: Identify community training and support needs and community needs across many trial sites, such as for translated materials.

Core competencies for this work would include the same competencies needed for work at DAIDS-funded clinical trial sites, but would also require greater understanding of scientific language and the research environment, and a greater ability to translate the science to language that is appropriate for non-scientists as well as the ability to translate the language of the lay person to the scientist (*bi-directional translation* of issues, priorities and concerns).

In involvement with DAIDS and clinical trial network leadership, community representatives should be tasked with:

- Facilitating research toward effective prevention, treatment, and/or a cure for AIDS
- Sharing information and advising the network leadership about:
 - The research priorities, needs and concerns of the community across the spectrum of scientific areas of concern
 - The research agenda and priorities of the networks overall
 - Cross-CAB activities
- Sharing information, reporting back to and educating the community:
 - About the overarching research priorities of the networks and leadership level issues, discussions and outcomes.
 - Articulate the value of the research to/in the community (and to network community representatives)

Core competencies for this work would include the same competencies as required for work at a network-dimension, but would also require greater understanding of scientific language and the research environment.

It was recommended that this area be fleshed out further when more detailed information is available about the roles, responsibilities, structure and function(s) of the network leadership body (i.e. the “Managing Partners Committee”).

At the dimension of cross-network CAB communication and collaboration, community representatives should be tasked with:

- Identify and define/refine community training and support needs across all dimensions (site, network and leadership) of community involvement in HIV research.
- Educate one another about community research needs and priorities
- Education one another about the scientific agendas of respective networks (and how these might differ from the community research needs and priorities noted above.)
- Identify common research (and other) priorities and articulate areas of divergence to the scientific community
- Educate *one another* about the communities they represent.

Core competencies for this work would include the same competencies as required for work at a network dimension. The group’s discussion reflected concern that people should not be required to walk into new roles with fully developed skills, but that training

and accommodation should be provided (as discussed in this report section 2.4). This included a sentiment that researchers at clinical trial sites, networks, and in leadership positions should be able to access training to gain new abilities and sensitivities for working with community representatives.

Language was identified as an important issue. HIV clinical research now involves populations speaking multiple languages, at varying levels of literacy. Populations ‘hear’ and apply different meanings to the same words and concepts. In-person contact was identified as essential for communication across these challenges of language, terminology and meaning. Participants suggested that appropriate communication and trust requires an investment in translating scientific language into simple language, and also an investment in translating this again into messages and 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.

Recruitment and retention was also identified as an important issue. DAIDS does not have a formal policy on the role (and legal liability) of unpaid community representatives related to trial recruitment, and DAIDS representatives encouraged the Cross-CAB Working Group to discuss possible roles. Participants agreed that community representatives should not recruit for clinical trials, although it was agreed that CAB members and other community representatives can play an important role in facilitating, supporting, and ensuring a trusting environment in which clinical trial recruitment can take place.

2.3 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 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 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 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 ideas for “Managing Partners” and “Community Partners”:

- A Managing Partners Committee (MPC), yet to be formed, is described in the DAIDS Network RFA. It is assumed that the MPC may include PIs, DAIDS representatives, and community representatives. The Managing Partners would begin operating in March or April 2006. The above discussion on the “Network Leadership” dimension of community representation is relevant to the role of the community representatives serving on the MPC.
- A Community Partners Committee (CPC), yet to be formed, is also described in the DAIDS Network RFA. The Community Partners could comprise persons from the newly-established clinical research networks—perhaps many CAB members—and possibly other community representatives as well. Community Partners representation could be by network (as awarded) or by research content areas, or both. One or more Community Partners members may also serve as a member of the Managing Partners. 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. The meeting participants cautioned against developing a hierarchical model. They also recognized that resources could limit the number of non-network groups that could be asked to join. The above discussion on the “Cross-network CAB” dimension is relevant to the role of community representatives serving on the CPC.

- *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 Committee. Steve Wakefield agreed to provide staff support for this working group.*

2.4 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. For example, the HVTN, HPTN and AACTG fund full-time staff members to support CAB activities and to travel to clinical trial sites for provision of training and technical assistance, while the PACTG and CPCRA do not.

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.

2.5 Indicators of success in community representation

Participants identified and discussed specific measurable indicators for evaluating community representation in HIV clinical research. Participants discussed evaluation indicators for community participation at clinical trial sites and local communities, HIV clinical trial networks, and DAIDS and network leadership. First and foremost, it is critical to state that discussions of evaluation are not intended to be punitive in nature. It was acknowledged that many fear evaluation as punishment. The purpose of having evaluation criteria is to have mechanisms to identify when support, training or other resources are needed, and not to penalize, punish or admonish. Because evaluation criteria have rarely been applied to community representative components, it is strongly urged that they be used for identifying the need for support, training or *constructive* intervention.

It was also determined that evaluation should be conducted by both external review and by self-evaluation.

Site Dimension Evaluation Criteria:

It was noted that community involvement should be part of a site's evaluation.

- How often did the CAB meet?
- How often did the site principle investigator (PI) and/or other research staff attend the CAB meeting? Do they meet the stated expectation?
- Attendance – How many CAB members attend meetings or other planned events?
- Turnover/retention of CAB members
- Does the CAB reflect the demographics and/or otherwise represent the target population for the research?
- Are funds being used effectively at a site level with regard to community activities (e.g. if a brochure is produced, are there funds to distribute it to the target audience)?

- *Recommendation: Further define evaluation mechanisms to assess (1) if the community is making an impact, and (2) if the relationship between the community and the PI and other site staff is productive and meaningful.*

Network Dimension Evaluation Criteria

- How many community representatives attend network meetings?
- Are community representatives on all protocol development teams and other science committees?
- Are community representatives attending meetings, conference calls and providing input and feedback to investigators?
- Is there evidence that networking and collaboration was fostered between sites (e.g. documented conference calls, training sessions, exchange programs)?
- Did each community group representing a network produce a document outlining community research priorities and other concerns?
- Is there evidence that the community's priorities/concerns were incorporated into the network's research agenda?
- Do the PI's, leadership and Executive Committees know what the top ten priorities of the community are?
- Did the site community representatives learn about the network's priorities and the community priorities document and did they receive feedback from community network representatives? (i.e., does information from the network get disseminated back to local communities, and vice versa?)

Leadership Dimension Evaluation Criteria:

- Are the community representatives attending and participating in the meetings/conference calls?
- Is there evidence that community priorities and concerns have been incorporated into leadership dimension activities?
- Do members of the leadership group know what the top ten community priorities and concerns are from the Cross-network CAB level?
- *Action Item: It is recommended that the roles/responsibilities and perhaps evaluation criteria for community representatives be further defined once the structure and function of the Managing Partner's Committee is further described.*

Cross-network CAB Dimension Evaluation Criteria

- Was there participation from all networks' community representatives in meetings and conference calls?
- Were training materials identified and/or developed and/or delivered?
- Were support needs identified, documented, and met?
- Were evaluation criteria developed for and reviewed by community representatives at various dimensions (i.e. site, network or leadership community reps)?
- Did the group produce a document articulating and recording its priorities and concerns?
- Is there evidence that these priorities/concerns were incorporated into network and leadership level priorities and activities?

Each DAIDS-funded network has, or should develop, expertise in evaluation and indicators of success related to community representative involvement in clinical research. To harness and complement this expertise, participants raised several important observations and questions:

- Should a working group be formed to create a document about evaluation research opportunities within the DAIDS-funded networks? Such a working group would share a draft outline with CABs, trial site PIs, and network leadership to first ensure that any evaluation plans are broadly supported and methodologically rigorous, and secondly to advance development and funding of resultant evaluation plans.
- Because the intended outcome of this evaluation research would be training and support within the DAIDS-funded networks, how might a working group ensure funding of the follow-up to the evaluation recommendations (such as structural changes at sites or training and support for researchers and community representatives), and perhaps even a second phase of evaluation for this training and support?
- How might efforts on documentation and evaluation cover the work of community representatives who do not work through trial site CABs, yet who still have an interest and ability to advocate about the HIV clinical research agenda,

3. Discussion of next steps

This report has been drafted as a guide and first step toward defining best practices for community representation and involvement in HIV clinical research. The following are some of the intended timeline and follow-up steps for this document:

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 no fewer than 3 network staff representatives and no fewer than 3 community representatives meet with DAIDS leadership to discuss report recommendations,

implementation 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.

Attachments

- A. Participant list
- B. Meeting agenda
- C. List of resource materials
- D. Meeting proceedings

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)
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Shawna Chester (PACTG)
Janet Frohlich (HPTN)
Thomas Gibson (HVTN)
Megan Gottemoeller (Global Campaign for
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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)
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David Munroe (CPCRA)*
John Mutsambi (HPTN)
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Ljudmila Petrovic (CPCRA staff)*
Hamilton Richardson (HVTN)
Joseph Robinson (AACTG)*
Dorothy Shaw (PACTG)*
William Strain (AACTG)
Jeff Taylor (AMC/AIEDRP)
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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
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Moriane Joseph (Basic Sciences
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Joanna Katzman, (Vaccine Research
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Chuen-Yen Lau (Vaccine Research
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Daniel Montoya (Office of the
Director)

Matthew Murguia (Office of
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Sussan Paydar (Vaccine Research
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Program, AACTG/PACTG liaison)

Facilitator

Sam Avrett

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

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

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. | <i>BREAK</i> |
| 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? [What does the scientific community see as the role(s) and responsibility(ies) of community?]
10:45 a.m.-11:00 a.m.	Presentation
11:00 a.m.-11:30 a.m.	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)

- | | |
|------------------------------|--|
| 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 |

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

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

Background materials distributed before and at the meeting

AACTG, *Community Involvement* (one page overview)

A Costello and A Zumla, “*Moving to research partnerships in developing countries*”
BMJ, 2000;321: 827-829.

J Bolitho and A Garrow, “*Reflections on being a community representative*”
Stronger Families Learning Exchange Bulletin, 2003;3: 9-10.

J Boote, R Telford, C Cooper. “*Consumer involvement in health research: a review and
research agenda*” Health Policy, 2002;61: 213-236.

L Cox, JR Rouff, KH Svendsen, M Markowitz, DI Abrams “*Community advisory
boards: their role in AIDS clinical trials*” Health and Social Work, 1998;23;4: 290-297.

CPCRA, *CPCRA Community Constituency Group (CCG)* (one page overview)

DAIDS, *History of Cross-CAB (NCAB/CCG) Activities*, July 2004.

DAIDS, *Selected Clinical Research Programs*, May 2005.

FHI HPTN, *Community Indicators Survey*, September 2004.

DW Fitzgerald, JW Pape, JN Wasserheit, GW Counts, L Corey, “*Provision of treatment
in HIV-1 vaccine trials in developing countries*” Lancet, 2003;362: 993-994.

LW Green and SL Mercer, “*Can public health researchers and agencies reconcile the
push from funding bodies and the pull from communities?*” AJPH, 2001;91;12:
1926-1929.

HPTN, *Structure of the HPTN Community Programme* (one page overview), and
distribution of a information packet containing 22 background documents

HVTN, *Getting to Know the HIV Vaccine Trials Network* (ten page overview)

DL Katz, “*Representing your community in community-based participatory research:
differences made and measured*” Preventing Chronic Disease, 2004;1;1

B Lo and R Bayer, “*Establishing ethical trials for treatment and prevention of AIDS in developing countries*” *BMJ* 2003;327:337-339.

KM MacQueen, E McLellan, DS Metzger, S Kegeles, RP Strauss, R Scotti, L Blanchard, RT Trotter, “*What is community? An evidence-based definition for participatory public health*” *AJPH*, 2001;91;12: 1929-1938.

PACTG, *Community Involvement in the PACTG* (four page overview)

SF Morin, A Maiorana, KA Koester, NM Sheon, T Anne Richards, “Community consultation in HIV prevention research: A study of Community Advisory Boards at six research sites” *JAIDS*, 2003;33: 513-520.

B Snow. “Community Advisory Boards” *Bay Area Reporter*, October 1998. Copied from AVAC’s “HIV Vaccine Handbook” at www.avac.org

RP Strauss, S Sengupta, SC Quinn, et al. “The role of Community Advisory Boards: involving communities in the informed consent process” *AJPH*; December 2001;91(12): 1938-1943.

SL Syme, “*Social determinants of health: the community as an empowered partner*” *Preventing Chronic Disease*, 2004;1;1

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

Cross-CAB Working Group Meeting

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

Meeting Proceedings (reported by Don Cunningham)

Friday Evening, May 6, 2005

Welcome

Matthew Murguia, Director of the Office of Program of Operations and Scientific Information at DAIDS, welcomed the participants. He expressed gratitude for this convening of representatives of communities, and he emphasized the need to bring research into the communities. In all of its programs, DAIDS works with the understanding that the role of community members is crucial. The results of this meeting of the Cross-CAB Working Group (CCWG) would therefore serve to guide the NIAID as it proceeds to fund new research.

As Brenda Lein's arrival was delayed, Steven Wakefield offered some thoughts regarding the role of individuals from communities to offer new perspectives and solutions to the HIV/AIDS research effort. He charged this meeting's participants to develop a definition of "community" and consider ways in which the network community leadership could plan for the future. The main goal of the meeting would be to define best practices. The participants would return to their respective Community Advisory Boards (CABs) to share the results.

Sam Avrett, the meeting's facilitator, cited the breadth of issues to be discussed. He asked the meeting participants to be open to new ideas, to consider all possible approaches to community involvement, and to use practical examples.

What Does Success Look Like?

In a warm-up exercise, the meeting participants divided into pairs to answer individually questions about defining success. They regrouped and offered their answers, as follows:

- *What does creativity look like?* Working outside the box; selling one's ideas to the powers that be.
- *What does communication look like?* A colorful mosaic representing diversity; open dialogue, consensus-building, discussions of differences.
- *What does competence look like?* Knowing when to seek help; identifying training needs; balancing social issues and scientific research.
- *What does commitment look like?* Experiencing passion 24/7.
- *What does collaboration look like?* Experiencing a sense of mutual benefit/value; identifying pieces that are missing.
- *What does context look like?* Diversity of opinion, perspective, and experience; the target audiences.
- *What does cultural sensitivity look like?* Showing respect for values; putting principles before personalities.
- *What do consequences look like?* Creating buy-in across populations/groups.

The participants provided additional responses, claiming the importance of literacy, building trust, increasing awareness, and increasing the community's appreciation of the process. They also focused on the role and consequences of the CABs themselves. Can the CAB be a problem in the community? Should it play a role in explaining broader issues, such as the recent revelation of AIDS drugs being provided, during the 1990s to children without proper protections? Success can mean different things to different persons within the same community. The CABs could learn lessons from other groups who perform such community work.

What Is a Community Representative?

Dr.. Janet Frohlich, International Co-Chair of the HPTN , cited a description of the community representative's role given by the AIDS Action Foundation: "Representatives of relevant local communities should be full participants in planning, implementing, overseeing..." A question remained: Should a representative be a stakeholder or a person drawn from a stakeholder group? Stakeholders are persons or organizations who are affected by outcomes and who can affect outcomes. There are primary and secondary stakeholders, and there are levels of representation (policymakers, service providers, community, study participant and researcher). Dr. Frohlich noted the types of partnerships that occur with representatives, including consultative, contractual, collaborative, collegiate, and collective.

The participants made a number of points and suggestions:

- Do not encourage an idea of levels that imply different powers.
- Focus on the roles of community representatives.
- Consider how to create synergy when different interests are present.
- Define "community representative" for the sake of developing best practices.
- Define stakeholders in terms of driving an agenda.

- Do not be prescriptive; develop guidelines.

Saturday, May 7, 2005

Introduction

Mr. Avrett set the stage for the second day by asking the participants to consider ways to work together to design and implement clinical research. Another goal would be to define community representatives—what they do, what they look like, who they are. He cited technologies for communication as an important large topic, the first of a number of topics brought up at the meeting and worthy of further discussion at the end.

[Parking Lot Topic: technology for communication]

International Partners' Presentation

John Mutsambi, of Harare, Zimbabwe, presented details of the University of Zimbabwe-University of California, San Francisco Collaborative Research Program, which currently features 4 HPTN protocols and 11 non-HPTN studies. The site has three CABs, with an average membership of 15, composed of health officials, traditional healers, ethicists, and study participants. The community education team provides training, technical assistance and other support. Among the challenges to the program, Mr. Mutsambi listed suspicions, fear of disempowerment (on the part of community leaders), hidden agendas (among the community advisors, such as hopes for formal employment), and the need to keep up high spirits among advisors. Answers to the challenges include education, partnerships and establishing a positive image.

Dr Nalini Visvanathan, of the Fenway Community Health Center in Boston, US, reviewed the history of AIDS treatment and mortality and described the center, at which clinical trials are being conducted. The Fenway CAB has 15 members and has been focusing on diverse perspectives, the review of informed consent forms, recruitment

literature and educational materials. A key recommendation for the future is to be involved in protocol review. She listed lessons learned from the CAB's work in the areas of communication, recruitment and structures. Community involvement challenged the traditional model of top-down communication between scientists/researchers and community participants. Recruitment experience showed that high-profile gay men were effective in creating interest in the trials, while African-American and young men seemed resistant to recruitment. The CAB needed to be re-imagined to counter complacency and increase commitment. Non-Western methods of community involvement present relevant models for disadvantaged and ethnic minorities in the US. This reimagining of the CAB is the most important lesson learned..

Dr. Frohlich described the cross cutting themes that had emerged from the HPTN regional working groups and site community working groups: (HIV/AIDS Research in Africa, America's and Euroasia, Community Representation – CABS, CAB Training, Communication, Community vulnerability, Building community capacity, Community involvement in science, Sustainability, Moving beyond “CAB”). She cited the challenge to **move from having a “CAB” in place with “advisory” role as the measure of community involvement TO integrating participatory methodologies that lead to concrete partnerships.** To sustain the community involvement would require training community representatives, staff and creating partnerships as well as innovative ideas and resources to sustain CAB and community activities ie transport, telephones and funds for meetings. Community involvement programs should use proven models and transformative models.

In discussion, the meeting participants noted common needs—for sites to support each other (partner), for financial support, for an awareness of results, for access to target populations, and for reducing disparities in participating groups (gender, race). Brenda Lein proposed that a plan for community involvement be one criterion for DAIDS review processes.

[Parking Lot Topic: Disparities in program participation]

[Parking Lot Topic: Resources]

[Parking Lot Topic: Media communications]

Define the Roles and Responsibilities of Community in the NIH-Sponsored HIV Clinical Research Process

Dr. David Metzger, a HPTN and HVTN Principle Investigator (PI) working at the University of Pennsylvania, described what researchers need from the community. He remarked that networks are complex and research often can be slowed. His program in the Philadelphia area has enrolled about 2,000 participants and has attempted to embed itself in the relevant communities. This has required targeting, identifying linkages, and obtaining good feedback from the communities. CAB members meet with researchers to tell them how they are perceived by the communities. CAB members are not permitted to engage in recruitment, yet they play roles in support of recruitment and they can provide input to protocol development teams. Dr. Metzger emphasized the importance of an immediate public relations campaign when developing a CAB.

Mrs. Matilda Mogale, of the Perinatal HIV Research Unit of Chris Hani Baragwanath Hospital, in South Africa, spoke on behalf of Dr. Glenda Gray, HVTN Principal Investigator. She cited the need for community engagement, systematic processes, and a theoretical model. Researchers need to define the communities and inform and empower the communities. They should perform geographic mapping, institute regular meetings, disseminate results, and review strategies. Mrs. Mogale also cited delays as a major problem for trials.

The meeting participants presented additional specific and practical recommendations based on their experiences:

- Value all dimensions of work (e.g. at clinical trial sites, within clinical trial networks, with DAIDS and clinical trial leadership, and across network CABs).

- Persons in a single area can have different feelings about the process of community consultation.
- Within a CAB, there can be “members” and “visitors.”
- The CAB should be involved in the science from the start (protocol development).
- Define the value that the community brings to the science and network.
- The CAB could monitor and provide feedback on recruitment strategies.
- There is a need to examine the issue of trust (e.g., in data gathering).
- There is a need to study the effects of compensation to study participants.
- The networks should work to decrease language barriers and increase access to translated materials (e.g., protocols). Determine funding for translations.
- Evaluate the education of the community.
- Determine the legal liabilities of CAB members.
- Define the roles of leadership (a work in progress).

[Parking Lot Topic: the roles of leadership]

Evolution in Community Involvement: Adapting to Environmental Change

Megan Gottemoeller, of the Global Campaign for Microbicides, based in Washington, D.C., described her group’s participatory research in Africa and India. Some characteristics of her research (donor-led, little chance of immediate benefit) have led to a reduced sense of community and have marginalized individuals. Ms. Gottemoeller called on researchers to respond to such challenges by pulling-in the community—sharing information, partnering in decision-making, protecting participants, encouraging access, and addressing ethics. We must institutionalize community involvement. Two efforts are crucial: adapting involvement to the setting and expanding paradigms to reflect changing needs.

Ms. Gottemoeller’s presentation led the participants to raise a number of questions and ideas:

- What groups help to set an agenda?
- When hiring persons to help with administering consent forms, such as translators, how is confidentiality respected?
- Consider requiring a plan for community involvement.
- Continue using the CAB structure outside the United States (with additions from other models as needed).
- Consider mechanisms that work other than the CAB structure.
- Consider alternative models for special populations (e.g., youth).
- Share ideas among CABs.
- Work to increase representation in the membership.
- Increase the voice of CAB within DAIDS.

Mr. Avrett summed up by listing three recommendations:

- Define current models and structures and analyze them.
- Disseminate those models and structures.
- Implement them with appropriate resources.

Defining Core Competencies

Mr. Avrett asked the group to consider core competencies for CAB members in areas such as background, abilities, training, and experience. The participants proposed and discussed the following core competencies:

(At the site domain)

- Honesty, openness, empathy
- Authenticity (legitimate representation)
- Cultural understanding
- Ethical reasoning
- Knowledge of the affected community

- Ability to communicate
- A strong interest, enthusiasm
- Knowledge and history of basic science and the research
- An ability to self-evaluate

At the leadership domain:

- A sensitivity to others' views

At the network domain:

- Understanding scientific language and the research environment

At the cross-network CAB domain:

- Understanding the structures and terms of the various networks and their community programs.

The participants added that a person need not have all the competencies. Perhaps a range of skills would be sufficient, especially if it included partnering skills. Also, persons who are not familiar with the science can play important roles. Mentoring programs could be used to bring members up to speed.

At the end of Saturday's session, the participants broke into three groups to discuss three topics—training, support, and evaluation.

Sunday, May 8, 2005

Written Summaries and the Review Process

The third day of the meeting began with summary discussions of four topics.

(1) What is a community representative? (presented by Steve Wakefield) A traditional way to address this question is to consider geography. However, representatives may be

opinion leaders, persons with organizational experience, and others who have a passion to represent the community and support the clinical research. Although the best representatives would be persons directly affected (target population), a CAB might require other connected individuals to create a full complement to advance its goals.

(2) What are the roles and responsibilities? Brenda Lein provided an extensive list of roles and responsibilities, including, in the site dimension, identifying target communities, identifying linkages, providing feedback, supporting recruitment efforts, staying in touch with the local epidemic, reviewing informed consent documents, educating, and addressing ethical issues.

In the network dimension, roles would include identifying target communities, fostering site-level communication, providing input and feedback on protocol development and the research agenda, articulating research needs and community concerns, making materials available, translating scientific issues, and educating representatives and the community about the work of the network and researchers.

In the leadership dimension, roles would include providing input to the research agenda and conveying cross-network activities. In the cross-CAB dimension, roles would include identifying training and support needs, shaping common issues, and educating about the scientific agenda.

Additional roles and responsibilities would involve the following:

- Advisory committees
- Legal issues (brought up in training)
- Sharing research findings and obtaining community comments
- Revising informed consent forms and materials for local relevance and cultural appropriateness
- Obtaining input from the investigators and study participants
- Promoting minimal acceptable standards.

(3) *What are the recommended structures and models?* Gail Broder listed issues and actions in this area:

- Educate community members about alternative models.
- Recognize when CAB models are working.
- Engage multiple community groups to address the different research agendas and target populations.
- Develop data on current models (e.g., success, staffing, resources).
- Supplement current models with alternative models.

(4) *What are the core competencies?* (Gail Broder) In addition to the list of competencies developed the previous day, the group added the following:

- For scientists, an ability to work with community members and understand the community's needs and issues
- For representatives, knowledge of the basic science of HIV and HIV research
- An ability to translate science into lay language that is culturally relevant.

Define Support and Evaluate Mechanisms To Perform Roles and Responsibilities: Results from the Breakout Sessions

Representatives of the subgroups presented recommendations from the previous day's breakout sessions.

Training. (Allegra Cermak) This breakout group recommended the following topics for training, distributed variously for the domains/dimensions (e.g. at clinical trial sites, within clinical trial networks, with DAIDS and clinical trial leadership, and across network CABs):

- Introduction to HIV

- Clinical research concepts, scientific agendas of each network
- Ethics, human rights, social harms
- Community expectations and perspectives
- History of community representatives and participation
- Meeting skills
- Technology and communications skills
- Federal and network structures
- Mentoring
- Reading protocols
- Statistics and how to interpret them
- Evaluation

Support. (Gail Broder) This breakout group recommended the following areas for support:

- Supplies (office equipment, Internet access, textual materials)
- Translations of materials
- Travel (costs of translation, instruction, meetings, visas)
- Administrative support (meeting planning, IT personnel, food at meetings, audiovisual materials)
- Programmatic support (staffing structures and various staffs themselves)

Evaluation. (Brenda Lein) This breakout group recommended the following items for evaluation:

- How often the CAB meets
- How often the PIs attend the meetings (do they meet the stated expectation?)
- The turnover of CAB members
- Whether membership reflects the demographics of the epidemic and/or the demographics of populations being targeted by the research

- Relationships
- Community involvement
- Whether funds are used effectively
- How many CAB members attend meetings.

Additional aspects that could be evaluated include the involvement of community representatives in protocol development and committees, fostering networking, creating a document about research needs (and incorporating it into the research agenda), the PIs' knowledge of research needs viewed as important by the community, identifying support needs, developing training materials, and evaluating the support and training.

The meeting participants noted that some representatives are not members of a local CAB and do not have site-level input, yet are aware of the research agenda. They considered a need for widening the evaluation process, perhaps using independent evaluators.

Update on Cross-Network Collaboration Activities

Dr. James Kublin, of the Fred Hutchinson Cancer Research Center, in Seattle, Washington, reviewed trends in the AIDS pandemic and the efforts to defeat it. He stated that the good response in recent years has resulted from a synergy of effects including therapy, prevention, and efficiencies (e.g., networks). The number of persons living with HIV continues to rise.

We are making strides in coordination of the following:

- Global laboratory activities
- Clinical trial logistics
- Training
- Data management
- Evaluation

- Career development
- Community engagement.

Dr. Kublin presented a draft chart of the Cross-Network Coordination of Community Engagement, which illuminated the major functions, including guideline development and maintenance, work of the various program participants, training, protocol operations, reviews of recommendations, support, and evaluation.

Roles that span the networks could act to cause a harmonization on the network level. When the program is fully functional, some members of the Cross-CAB Working Group attending this meeting could serve on the new Community Partner's Group.

Parking Lot Issues

The group members agreed that most of the parking lot topics cited had been addressed in the various discussions and presentations. A few topics required further discussion.

Gender and representation

The idea of representation splits into (1) the role played by persons who are actual members of the target population (therefore *representative* of the population), and (2) the role played by persons who can act on behalf of the interests of the target population (thereby *representing* the population). The meeting participants agreed that the former type is preferable to serve as member of a CAB. However, as a practical matter, CABs often must rely on the latter. The former type can represent acutely the interests of the target population and can ensure accountability. The participants agreed that enlisting these true representatives of the population should be a goal, yet CABs should be free to

enlist all persons with capabilities and passion who can work to represent the interests of the target population. The decision should belong to the community.

Language

The participants agreed on a need to address communication problems resulting from the use of different languages. Funding mechanisms often bring together people who use different languages. Some sites serve populations with multiple languages. The group made a number of suggestions to address this issue:

- Clarify terms used in reports.
- Assemble a glossary of terms (a global recommendation).
- Have translators present (including street language).
- Conduct training for sensitivity to languages.
- Distribute topic briefs prior to phone conversations.
- Avoid using slang and idioms that others might not understand.
- During phone calls, stop periodically to ensure that all understand.
- Conduct meetings face-to-face when possible.
- During phone calls, ensure that person from outside the US have an opportunity to speak; culturally, they often wait to be called upon (rather than US habit of just speaking up)

Leadership – Managing Partners

The Managing Partners, a group yet to be formed, would include PIs, DAIDS representatives, community managers, and members of the Community Partners Group. The Managing Partners would begin operating in March or April, 2006. The Community Partners, another new group, would comprise persons from the networks—perhaps many CAB members—and perhaps representatives of other groups (e.g., other diseases). Some also would serve on the Managing Partners group. DAIDS suggested that the group might make recommendations, proposals, or suggestions to DAIDS as to how the Community

Partners might be structured. That group's members would represent the networks (as awarded) rather than content areas. The meeting participants cautioned against developing a hierarchical model. They also recognized that resources could limit the number of non-network groups that could be asked to join.

Mr. Wakefield proposed that the participants form a temporary working group to develop recommendations for the makeup of the Community Partners group.

Recruitment

The participants again stressed that the CABs should not recruit directly but could support the efforts by site personnel to recruit. DAIDS does not have a formal policy, and it encouraged the Cross-CAB Working Group to discuss possible roles. Ms. Broder suggested that the CABs propose strategies, techniques, and methodologies for recruitment. Retention is a related issue that the cross-CAB group could consider.

[The group members agreed to discuss media issues in upcoming scheduled conference calls.]

Next Steps

Brenda Lein listed the following next steps:

- Write a summary of this meeting (contract writer).
- Develop a full report in draft form (planning committee).
- Discuss the draft report in a CCWG members conference call.
- Produce an electronic version of the report (no hard copies).
- Share the report with all CCWG members and meeting participants, who would communicate the findings with their networks.
- Form a subcommittee to track implementation of recommendations.
- Work with DAIDS on follow-up.

- Devise a future strategy regarding recommendations and timelines.

The planning committee would distribute the final electronic report to DAIDS staff, senior leadership at DAIDS, leadership in the networks, and elsewhere. In an effort to be transparent and make the public aware of this meeting and its outcomes, the report would be distributed through listservs, the AIDS community press, and organizations working in HIV prevention, treatment, and care. The following remaining issues were noted:

- Distributing a press release
- Translating the report into Spanish, Portuguese and French
- Creating timelines for implementation
- Identifying additional forms of communication
- Distributing the report at conferences
- Ensuring accountability for the implementation of recommendations.

What Does Success Look Like?

The participants ended the meeting by returning to the issue of success, adding final thoughts about success and key points that the meeting produced. They offered the following reactions and summary thoughts:

- Surprise at the great amount of collaboration and interest in synergy expressed in this meeting.
- A clear sense of expectations.
- A sense of commitment and ownership.
- A sense of competence within the program.
- A better idea of the complexities.
- A belief that some goals are lofty.
- A sense that this work would affect efforts by others.
- A need to obtain additional international input.

- A need to include an introduction in the final report, providing overview information about DAIDS-funded clinical research, community representative involvement in that research, and background about why and how this meeting was organized.

Mr. Avrett adjourned the meeting.