

First Annual Meeting of the Community Involvement Community of Practice

November 18th–19th, 2008
Cape Town, South Africa

Meeting Report



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Acknowledgments

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Acronyms and Abbreviations

AIDS	acquired immune deficiency syndrome	ICRH	International Centre for Reproductive Health
AMAG	African Microbicide Advocacy Group	IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials group
AMREF	African Medical and Research Foundation	IPM	International Partnership for Microbicides
ART	antiretroviral therapy	LSHTM	London School of Hygiene and Tropical Medicine
ARV	antiretroviral	MDP	Microbicides Development Programme
AVAC	AIDS Vaccine Advocacy Coalition	MMCI	Microbicides Media & Communications Initiative
CAB	community advisory board	MRC	Medical Research Council
CAG	community advisory group	MSM	men who have sex with men
CAPRISA	Centre for the AIDS Programme of Research in South Africa	MTN	Microbicide Trials Network
CDC	US Centers for Disease Control and Prevention	MU/JHU	(Makerere University/Johns Hopkins University)
CEC	community engagement coordinator	MWAMKO	Mwanamke Amua Kuhusu Maisha Yako (translated from Kiswahili to mean “Women decide your life” or “Wake-up”)
CEM	community engagement manager	NGO	nongovernmental organization
CIDRZ	Centre for Infectious Disease Research Zambia	NHVMAS	New HIV Vaccine and Microbicide Advocacy Society
CLO	community liaison officer	NIMR	National Institute for Medical Research
CoP	community of practice	PI	principal investigator
CORPS	community owned resource persons	PrEP	pre-exposure prophylaxis
CRSG	community research support group	SPARTAC	Short Pulse Anti Retroviral Therapy at HIV Seroconversion
CWG	community working group	STI	sexually transmitted infection
DAIDS	Division of Acquired Immune Deficiency Syndrome of the US National Institutes of Health	UNAIDS	Joint United Nations Programme on HIV/AIDS
DoH	department of health	USAID	United States Agency for International Development
FHI	Family Health International	UZ-UCSF	University of Zimbabwe-University of California, San Francisco
GCM	Global Campaign for Microbicides	VOICE	Vaginal and Oral Interventions to Control the Epidemic
GCP	good clinical practice		
GPP	<i>Good participatory practice guidelines for biomedical HIV prevention trials</i>		
HANC	HIV/AIDS Network Coordination		
HIV	human immunodeficiency virus		
HPRU	HIV Prevention Research Unit		
HPTN	HIV Prevention Trials Network		
ICASO	International Council of AIDS Service Organizations		

Introduction and Background

An estimated 33 million people were living with HIV/AIDS in 2007, 67% of them located in sub-Saharan Africa where the majority of HIV prevention research trials take place.¹ A range of microbicide, HIV vaccine, and pre-exposure prophylaxis (PrEP) trials are now underway, with numerous others being planned.

In a field like HIV prevention research—where the mission is urgent but the resources are limited—community preparedness and engagement often fall to the bottom of a long list of competing priorities. However, “the need for community engagement has attracted increased attention in recent years due to the highly vocal demands of HIV activists, the recognition that inclusion and transparency are ethical responsibilities, and the fact that experience has shown that not involving communities in HIV clinical research can threaten the viability of trials.”²

Opening Remarks

Objective: To reach a shared understanding of the history and purpose of the CoP.

The Global Campaign for Microbicides is an international coalition of organizations working to accelerate access to new HIV prevention options. Over the past decade, GCM has focused on mobilizing and sustaining political support, promoting stronger civil society involvement in research, and enabling trials by focusing on building cross-sectoral consensus around ethical and policy challenges (see Box 1).

Recently, GCM has expanded its organizational mission to:

- Re-focus on women’s prevention needs.
- Maintain leadership on microbicides but expand into PrEP and other tools as they affect women.
- Help co-create a larger prevention research field.
- Generate advocacy for access to existing prevention tools and strategies.

Community liaison officers (CLOs), outreach workers, and program managers working on HIV prevention trials are on the frontlines of this vital work. In 2008, the Global Campaign for Microbicides (GCM) established the Community Involvement Community of Practice (CoP) in an effort to support community practitioners in their work and facilitate a culture of collective problem solving and sharing of lessons learned and better practices across research networks and sites.

In November 2008, the CoP held its first face-to-face meeting in Cape Town, South Africa. This report summarizes the discussions that took place during that inaugural meeting. A summary of the conclusions and actions developed during the meeting can be found on page 25.

As part of this work, GCM seeks to support both trial sites and affected communities in conceptualizing and implementing a broader, more comprehensive scope of activities that address the fundamental goals of community involvement.

In 2003, GCM co-convened a dialogue on community involvement with the South African Microbicide Research Initiative. The dialogue (summarized in a meeting report entitled, *Mobilization for Community Involvement in*

Global Campaign for Microbicides’ Stated Mission:

Mobilize and sustain political will: Build citizen demand and governmental support for the timely development, introduction, and use of new HIV prevention technologies, particularly for women.

Promote stronger civil society involvement: Strengthen capacity and expand opportunities for advocates and communities to engage with research and clinical trials productively.

Enable trials: Identify ethical challenges and policy obstacles to the timely implementation of HIV prevention trials and broker the open, well-informed discussion and cross-sectoral consensus-building needed to resolve them.



Pauline Irungu presents on the Global Campaign for Microbicides and the Community of Practice.

Microbicide Trials: Report from a Dialogue in Southern Africa, available at www.global-campaign.org/clientfiles/SA-community-involvement.pdf) is one of the cornerstones of GCM's early community work. As a continuation of this conversation, GCM convened a meeting in November 2007 to further explore issues around community involvement in HIV prevention research and to discuss how GCM could help to move the field forward in both its thinking and practice.

Participants at the 2007 meeting identified three concrete activities that GCM could undertake to further the practice and coordination of community involvement activities at HIV prevention research sites. Those three activities were to:

1. Establish a community of practice around community involvement issues.
2. Launch a web-based resource center for community resources and tools.
3. Convene a larger community involvement meeting to take place in 2008.

Community of Practice

Communities of practice are networks of people bound together by shared expertise and a passion for joint enterprise. Specifically, they:

- Allow for personal connections.
- Create synergies and foster collective strategic planning and/or problem solving.
- Create a level playing field where all experiences and information are valued.

Participants at the meeting in 2007 noted that, while information sharing may occur within individual research networks and sites, there had been little communication on community-related issues across networks, or opportunities for staff at independent research centers to liaise with one another. Research staff at the site level—particularly community staff—seldom have formal mechanisms for sharing their experiences, lessons learned, and better practices. From these observations, the Community Involvement Community of Practice (CoP) was born. In April 2008, GCM officially launched the CoP by convening its first teleconference.

The CoP aims to bring together community staff working at trial sites, community program managers, and others working on community involvement issues to share their experiences and challenges, dialogue on issues related to community engagement, and foster a culture of sharing in the field.

GCM feels strongly that coordinated efforts such as these, aimed at sharing lessons learned and better practices, are vital for the eventual success of HIV prevention research.

GCM does not conduct research—but rather maintains strong relationships with research institutions, communities, civil society organizations, and advocates alike. Thus, it is uniquely positioned to convene the CoP.

Today, the CoP has over 65 members in 14 countries. At a minimum, members represent 4 civil society organizations, 9 research networks/sponsors, and 17 individual trial sites.

The Clearinghouse

In addition to regular teleconferences, CoP members have access to a web-based resource center, the *Community Involvement Clearinghouse for HIV Prevention Research* (or



CoP meeting participants work on creating posters detailing how their community outreach departments are structured.

Clearinghouse as it is commonly called). The Clearinghouse is designed as a communal collection point for sharing resources and tools among CoP members. Currently the site is password protected and can only be accessed by members of the CoP.

Community Consultation

The CoP will also continue to hold annual face-to-face meetings in order to share better practices and lessons learned among CoP members, discuss timely issues related to community engagement, consider ways to move the field forward, and build the capacity of its members.



After the posters about the various community outreach departments were created, they were hung on the walls and participants did a “gallery walk” to learn how their fellow CoP members structure their work.

How Community Outreach Departments Are Structured

Objective: To reach a shared understanding of different community engagement strategies employed by the HIV prevention field.

Over the last several years, the understanding of what constitutes community engagement has evolved substantially—and the need for effective community engagement has become increasingly clear. As a result, it is now common for research networks and individual trial sites to employ dedicated community staff.

How community outreach departments are structured, however, and the duties, roles, and titles of community staff, can vary greatly among institutions. Given this, participants at the CoP meeting spent some time visually sketching out the structure of their trial site or organization’s community department. The goal of this exercise was two-fold:

- To reach a shared understanding of the different community engagement strategies employed in the field.
- To determine how the organizations and trial sites represented in the CoP are organizing their community work.

Participants also were asked to share at least two things that made their site (or organization) unique and at least one challenge they were facing.

A table summarizing each site and organization represented at the CoP meeting is reproduced here (see Table 1). An example of a unique project undertaken by the Microbicide Trials Network is highlighted in Box 2.

The VOICE Community Education Toolkit

In July 2008, the Microbicide Trials Network (MTN) Community Program staff based at Family Health International (FHI) conducted a needs assessment with members of the Vaginal and Oral Interventions to Control the Epidemic (VOICE) Community Working Group (CWG). Facilitators, including CoP member Rhonda White, posed the following question, “What do you need to successfully roll-out the VOICE Study in your communities?” From this assessment, in close collaboration with the CWG, MTN Community Program staff developed the VOICE Community Education Toolkit. The toolkit was presented to the CWG in March 2009 and is comprised of five main components:

The DVD: With the help of MTN staff at the University of Pittsburgh, the network produced a DVD to explain and address concerns about potential HIV drug resistance and ARV-based microbicides. The DVD, entitled HIV Drug Resistance and ARV-Based Prevention, includes a skit performance and a facilitated discussion. As companion pieces, site community educators will also receive a transcript of the DVD and a series of talking points to support them in leading discussions with local community members about HIV drug resistance and ARV-based prevention.

The Resource Notebook and MTN Flash Drive: The toolkit includes a resource notebook with fact sheets and educational resources developed by the Global Campaign for Microbicides, the AIDS Vaccine Advocacy Coalition, and MTN. The resource notebook provides site community educators with easy access to current information about topics relevant to microbicides and PrEP clinical trials that will be useful as they prepare for community meetings and education sessions. A USB electronic drive will also be provided and will include VOICE-related PowerPoint presentations and other resource materials.

The Flipchart: Another component of the toolkit is a custom-built, oversized flipchart developed by the MTN Community Program staff at FHI. The visually rich flipchart will assist site community educators in educating local communities about the VOICE Study, HIV drug resistance, and family planning methods. The flipchart will be produced in English and eight local languages for Malawi, South Africa, Uganda, Zambia, and Zimbabwe.

Talking Points Notebook: Each flipchart will be accompanied by a notebook that includes talking points relevant to each section of the flipchart and the HIV Drug Resistance and ARV-Based Prevention DVD. A copy of the VOICE protocol will also be included as a reference guide. The notebook assists the clinical research site community staff in leading discussions related to the flipchart and DVD during community meetings and education sessions.

Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials Booklet: The toolkit will include a copy of the *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials* booklet. This booklet will be used by community educators and other site staff to guide them in adhering to good community practices as they conduct the VOICE Study and other HIV prevention clinical trials.

Sample Study Products: Also included in the toolkit is a set of sample study products, including images of oral tenofovir and oral Truvada tablets, empty study tablet bottles, empty study gel applicators, and gel applicator cartons. Site community educators will use the sample products as visual aids when educating their communities about the products that will be used by VOICE Study participants.

For more information on the VOICE Community Education Toolkit, please contact Rhonda White at rwhite@fhi.org.

TABLE 1. How community departments are structured: a summary of CoP meeting participants' posters

Trial site, country	Description of community department	What makes it unique?	What are some challenges you are currently facing?
Research networks			
International Partnership for Microbicides (IPM) South Africa	The IPM community department consists of a community engagement manager (CEM) and two community engagement coordinators (CEC) who work with site-level community liaison officers (CLOs). One CEC is the lead on working with the community advisory mechanism, while the other is the lead on working with study populations. The CEM is the lead on community education.	Non-hierarchical structure, team approach.	Moving timelines for study start dates. Various levels of research-centre experience.
Microbicides Development Programme (MDP) UK	MDP's community engagement work is coordinated through the MDP Unit, housed at the Centre for Global Health, Population, Poverty, and Policy at the University of Soton in the United Kingdom. The head of the community department liaises with MDP's six sites in South Africa, Uganda, Zambia, and Tanzania.	<i>(Not completed)</i>	<i>(Not completed)</i>
Microbicide Trials Network (MTN) USA	The MTN community program consists of four full-time staff and the MTN community working group (CWG). One staff member and one community representative or community advisory board (CAB) member from each site serve on the CWG, as well as the CWG Chair, and representatives from GCM, African Microbicide Advocacy Group (AMAG), Division of AIDS (DAIDS) of the US National Institutes of Health, and the ethics field.	MTN conducted trainings on how to review and provide feedback on protocols and held a 2-day consultation on basic bio-statistics, including how to measure effectiveness and confidence intervals.	Ensuring that the CWG has all of the tools and resources they need to effectively prepare their communities for the VOICE Study. This includes coordinating everyone who needs to be involved in developing these tools and ensuring the information and tools provided are accessible and easy to understand.
Research sites			
Centre for Infectious Disease Research Zambia (CIDRZ)/MTN Zambia	The CIDRZ community program is headed by a community educator who works with recruitment nurses, in close collaboration with volunteer outreach workers and the MTN CAB. The community program solicits community input from CAB members and other stakeholders, and through general community meetings.	Well-coordinated and functional CAB sub-committees who work well with the community team on community education.	Preparing communities for PrEP studies.
Partners pre-exposure prophylaxis (PrEP) Study Uganda and Kenya	Partners PrEP community program is headed by the community lead. The community lead works with the outreach team—consisting of a recruitment team and retention team. The community department uses CAB and stakeholder meetings to solicit community input, as well as relationships with partner groups working in HIV prevention and care.	Team work and cross-site sharing. Constant monitoring and evaluation, which allows for flexibility.	Explaining the use of antiretrovirals (ARVs) in HIV prevention. Pushback from the antiretroviral therapy (ART) field, which wishes to reserve ARV drugs for treatment.
Setshaba Research Centre South Africa	The Setshaba Research Centre does not have a dedicated community department. The Centre does however coordinate a CAB and hold CAB, community, and stakeholder meetings.	Research experience. Rapport already established with the community.	Little understanding on community involvement. No organizational support.
Centre for the AIDS Program of Research in South Africa (CAPRISA) South Africa	The community department director at CAPRISA is one of nine directors who work directly under the organization's executive director. The Community Department director supervises a team of CLOs. One CLO is assigned to each of CAPRISA's research studies and/or programs. Each CLO works with field workers and a community research support group (CRSG). CRSG members are drawn from NGOs, local health facilities, and previous and current trial participants. CRSG members can nominate new members to join the group.	<i>(Not completed)</i>	<i>(Not completed)</i>

TABLE 1. How community departments are structured: a summary of CoP meeting participants' posters (cont.)

Trial site, country	Description of community department	What makes it unique?	What are some challenges you are currently facing?
<p>HIV Prevention Research Unit (HPRU), Medical Research Council (MRC) South Africa</p>	<p>The HIV Prevention Research Unit (HPRU) involves the local community in all four aspects of research: treatment, care, prevention, and social research. The principal investigator/director leads the entire research team, followed by the site leaders who manage the individual site teams and community liaison officers. HPRU staff solicit community input from site community stakeholder groups and community working groups.</p>	<p>HPRU implemented good clinical practice (GCP) principles into their community work including training all of their community staff on Human Subjects Protection and GCP. Community involvement is done across all HPRU projects/trials, allowing the community to get feedback on all studies. This site is unique as it works with a wide range of networks including, IPM, MTN, MDP, HIV Prevention Trials Network (HPTN), CDC, Population Council, and the Short Pulse Anti Retroviral Therapy at HIV Serconversion (SPARTAC) study.</p>	<p>Community expectations of social development from researchers in developing countries. Implementation and sustainability of community work. Linking resources and trainings from all networks and groups.</p>
<p>Centers for Disease Control (CDC) Southeast Regional Office CDC Bangkok Tenofovir PrEP Study Thailand</p>	<p>The following programs are run out of the CDC Southeast Regional Office: the Thailand Ministry of Public Health-CDC Collaboration, the International Emerging Infection Program, the Global AIDS Program, and the HIV/AIDS Program (which conducts HIV prevention research).</p>	<p>The CDC site in Bangkok is working with the most at risk populations—including men who have sex with men, intravenous drug users, female and male commercial sex workers, and immigrant communities—while managing the sometimes competing priorities of law, the community, and scientific findings.</p>	<p>Translating scientific findings. Finding a new prevention tool.</p>
<p>MWAMKO/MDP Tanzania</p>	<p>The MWAMKO/MDP site is a collaboration between the African Medical and Research Foundation (AMREF), the National Institute for Medical Research (NIMR), and the London School of Hygiene and Tropical Medicine (LSHTM). The community department is led by the community leader, who works directly with the site's community tracers.</p>	<p>The MWAMKO study solicits community input from two advisory groups and has an active social science component. There is a Stakeholder Advisory Group (which include medical officers, NGOs, town council members, media) and a community advisory committee consisting of 10 ward representatives that represent a total of 78 clusters (geographical areas where participants work—in bars, restaurants, and <i>pombe</i> shops, or as <i>mamilishes</i>).</p>	<p>Measuring participation (do all people get a voice?).</p>
<p>Africa Centre for Health and Population Studies/MDP South Africa</p>	<p>All Africa Centre projects utilize the central Community Liaison Office. The Community Liaison Office relies on a number of stakeholders for community input including the Department of Health (DoH), the local municipality, participant stakeholder groups, the Africa Centre CAB, and the MDP network. Representatives from the municipality, DoH, local NGOs, people living with HIV/AIDS, study participants, and traditional leaders serve on the CAB. In addition, the community surrounding the Africa Centre is organized into 18 separate wards (or <i>izigodi</i>). Each ward also appoints a representative to serve on the CAB.</p>	<p>The Africa Centre has a history of community preparedness and an established Community Liaison Office.</p>	<p>Keeping in contact with trial participants (and disseminating results to them) after their follow-up period ends.</p>
<p>Makerere University/John Hopkins University (MU/JHU)/MTN Uganda</p>	<p>MU/JHU works with three major networks: the International Maternal Pediatric Adolescent AIDS Clinical Trials group (IMPAACT), HPTN, and MTN. One CAB serves all three networks at the Uganda site and MU/JHU staff also participate in Community Partners—a community working group for DAIDS network trials. The MU/JHU site solicits community input through community meetings and consultations with the CAB, Community Partners, and other local stakeholders.</p>	<p>Cross-CAB activities and CAB services.</p>	<p>Incorporating new research strategies such as PrEP. Developing messages for combination prevention strategies.</p>
<p>CDC Botswana-USA (BOTUSA) HIV Prevention and Research Clinic CDC Botswana Tenofovir 2 (TDF2) Study Botswana</p>	<p>The CLO heads the community department and works with retention and recruitment officers. In order to solicit community input, the community department formed both a participant advisory group and a community advisory group, and partner with youth and other organizations dealing with HIV/AIDS related issues in the area.</p>	<p>The community is very receptive. The community department interacts with influential people in the community (chiefs and councilors).</p>	<p>Participants are pushing the study to involve them in recruitment activities. However, the Health Research Development Committee of the Ministry of Health discourages participants from taking on dual roles, arguing that participants cannot act as promoters and at the same time fully participate in the study. Organizational policy dictates that the study is not allowed to recruit at certain places (bars and shabeens—informal bars in the townships). However, this is where the target population is mostly found. Retention of participants (mostly due to competing work and school commitments and the clinic not having weekend hours).</p>

TABLE 1. How community departments are structured: a summary of CoP meeting participants' posters (cont.)

Trial site, country	Description of community department	What makes it unique?	What are some challenges you are currently facing?
Project UBUZIMA / IPM Rwanda	The community outreach manager and the community outreach assistant work with community mobilizers and the community advisory group (CAG). The CAG is involved in most community outreach activities and also serve as liaison between the community and the community outreach department.	There is active participation of and collaboration from local authorities in community mobilization activities. The government has a decentralization policy that has eliminated most of the red tape, allowing for easy access to the community.	Lack of trained personnel to sensitize communities on prevention research in general and microbicides in particular.
MTN Lilongwe Malawi	The community department is headed by the community activities coordinator, who works with a team of community educators. Community educators are assigned to various studies, CABS, and stakeholder groups. Community educators solicit community input through community sensitization activities and stakeholder meetings.	The entire site works as a team, involving local leaders as stakeholders in community meetings. This also helps to meet recruitment and retention targets.	Male involvement in all studies and programs.
University of Zimbabwe- University of California, San Francisco (UZ-UCSF) Collaborative Research Project/ MTN/HPTN Zimbabwe	The UZ-UCSF community department is headed by an international community manager, who works with the community coordinator and CLO. The CLO runs the CAB and works directly with stakeholders.	All community-related issues (for all studies at UZ-UCSF) are handled by the same office.	The site has eleven studies and only two community involvement staff—resulting in the department being overstretched.
International Centre for Reproductive Health (ICRH) Kenya	The ICRH community department is headed by the CLO, who is supervised by the field director. The CLO works with community mobilizers, tracers, field educators, advisory groups, and community owned resource persons (CORPS). CORPS are volunteers, selected for their skills, who work with various organizations on community projects. CORPS volunteers can act as community mobilizers, community health workers, and/or community educators. The community department solicits community input through sensitization and education meetings.	Effective community network systems that function well even with minimal supervision. A good relationship between the site and local administration system that provides support.	Establishing a CAB and sustaining it. Maintaining contact with former participants for inclusion in future studies. Lack of male involvement, which then results in poor involvement of women in programs. Difficult to sustain CORPS volunteers due to the economy in Kenya and the resulting decline of volunteerism.
Civil Society and advocacy organizations			
Aids Vaccine Advocacy Coalition (AVAC) USA	AVAC is an independent advocacy group that promotes biomedical prevention options. AVAC solicits community input by talking to a wide range of stakeholders.	AVAC does not accept funds from government or pharmaceutical companies.	How to measure success in terms of community engagement around HIV prevention trials.
New HIV Vaccine and Microbicides Advocacy Society (NHVMAS) Nigeria	NHVMAS works to sensitize stakeholders on new prevention technologies. NHVMAS works through a number of established committees.	Focus on advocacy and the hosting of consultations and community meetings with stakeholders.	The termination of trials in Nigeria and lack of interest in conducting future trials in Nigeria. Issues around people who screen out of research trials because they do not meet enrollment criteria.

The Values, Mission, and Vision of the Community of Practice

Objectives: To reach a shared understanding of values, mission, and vision and why they are needed. To produce an initial draft set of values that underpin the work that we do, a draft mission statement for the CoP, and key elements of the CoP’s vision for success.

“People believe their efforts can make a difference, and work with greater commitment, when they are guided by vision.”

Recognizing that the CoP is in its formative years, GCM staff felt it important to spend some time at this first annual meeting thinking through the purpose and structure of the CoP and laying the foundation for its continued success.

Values, mission, and vision together guide the actions of individuals, teams, and organizations. They also form an organization’s identity, inform strategy, and inspire commitment. Because of the importance these elements have in solidifying a team or organization, meeting participants spent time discussing the CoP’s values and exploring elements of its mission and vision.

shared understanding of our purpose will be vital to the sustainability of the CoP.

And finally, **Vision** is an image of the mission accomplished—the ideal future state. We need to know where we want to go in order to get there, and vision helps to direct us.

Meeting participants drafted a list of core values that underpin the purpose of the CoP (the resulting list is reproduced in Box 3) and discussed what elements should be included in the CoP’s mission based on the following draft mission statement:

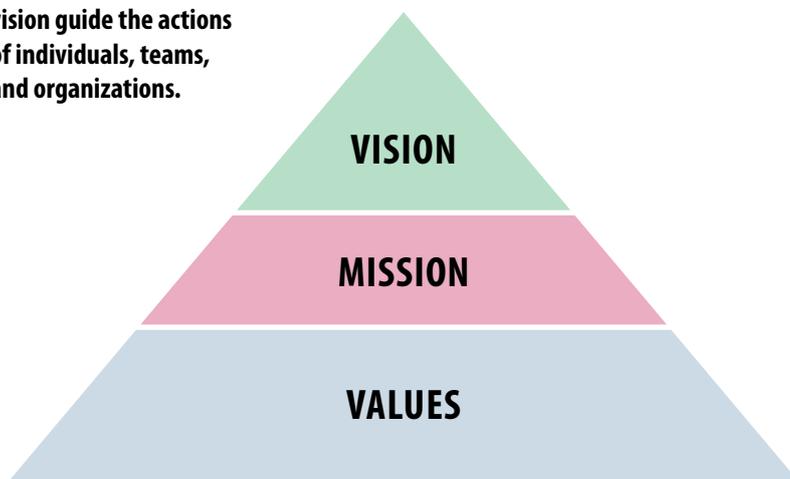
The Community Involvement CoP will help to bring together community staff working at trial sites, community program managers, and others working on community involvement issues, to share their experiences and challenges, discuss important issues and foster a culture of sharing and collective problem solving within the field.

CoP meeting participants discussed the need to avoid duplication and to distinguish the CoP from other community groups working in the field—specifically Community Partners, coordinated by HIV/AIDS Network Coordination (HANC) and the Community Working Group (CWG), coordinated by MTN.

However, it’s important to recognize that, while groups like Community Partners and the CWG do serve some of the same functions as the CoP, they are network-specific. Community Partners serves only those trials under the DAIDS network, and the CWG is exclusive to those trials under the authority of the MTN. The CoP, on the other hand, seeks to bring together community practitioners from all HIV prevention research sites and organizations to stimulate sharing across networks, trial sites, and disciplines.

Meeting participants also discussed ways

FIGURE 1. Values, mission, and vision guide the actions of individuals, teams, and organizations.



Values are beliefs or judgments about what is worthy, important, or desirable. They are reflected in individual and organizational behavior and form the foundation of a team or organization (see Figure 1). Identifying shared values enables us to understand why we are committed to working together and what makes us feel connected.

Mission is the task, purpose, or calling of an individual, team, or organization. Reaching a



The First Annual CoP Meeting took place at the iKhaya Lodge, Cape Town, South Africa.

BOX 3

Core Values of the CoP

- Communication (including two-way communication)
- Community
- Sharing (experiences, best practices, knowledge, and resources)
- Accountability (particularly to the community)
- Transparency
- Mutual respect
- Active participation
- Sustainability
- Community engagement as a normative standard
- Diversity
- Supportive
- Integrity

the CoP could help to broaden community engagement beyond CLOs to include decision-makers and help to normalize and strengthen community engagement.

Most agreed that the CoP should go beyond simply being a forum for discussion, but how far was debated. Some felt that the CoP is in a unique position to advocate for greater community involvement in HIV prevention research and the needs of community practitioners. Specifically, members asserted that the CoP could advocate for the inclusion of community work in research budgets and protocols, and/or develop tools for and spearhead field-wide efforts to monitor and evaluate community involvement work.

Some participants expressed optimism about the possibility that the CoP could take on collaborative projects, while others were hesitant about the group taking on too much. Ultimately, meeting participants came to the consensus that, if the CoP does take on future projects, those projects will need to be clearly defined, not duplicative of existing efforts, and immediately useful. Participants expressed the greatest interest in developing materials and resources that could be adapted for individual trials and trial sites.

Overall, however, most participants felt that the main aims of the CoP should be to:

- Share better practices and lessons learned.

- Promote two-way communication and dialogue (as opposed to research entities dictating to communities).
- Identify gaps and challenges.
- Provide capacity building efforts for members.
- Contextualize issues and help bridge misunderstandings and/or miscommunications between communities and researchers.
- Problem solve.

Generally, participants concluded that the CoP mission statement needs to be shortened and should more clearly emphasize the main aims (outlined above). The group discussed the need for principal investigators (PI) and other decision-makers to recognize community engagement and the CoP's contribution as priorities—and be vested in the process—in order for either to be successful. Participants also put forward the need for CoP members to have ways to share back what they learn from the CoP (specifically what they gain from attending meetings) to other site level staff, and to show the value added of their participation.

Discussions about how the CoP can reach out to network and site level leadership and help to support mechanisms for sharing resources and knowledge with other site-level staff will continue and is the responsibility of all CoP members.

Functioning of the CoP

“We cannot assume that everyone has the same access and knowledge base about technology. We don’t all know what Skype is, what different modes of technology are. Let’s bring it back to the level of the sites.”

– MODESTA CHILISHE

Objective: To draft a plan for how the CoP will operate.

In addition to clarity around values, mission, and vision, efficient communication and operation of the CoP is also vital to its success. The CoP does have funding restrictions—the CoP’s current funding is limited to a set amount that GCM receives from the United States Agency for International Development (USAID). That funding provides for the basic operation of the group and one in-person meeting per year. It may be possible, however, to seek out additional funding for future activities, if needed. While considering these immediate funding limitations, meeting participants brainstormed tools that could help to make the CoP successful.

Participants noted that telecommunications—particularly in Africa—can be a very challenging way to communicate. People are often dropped from calls or have difficulty dialing in or hearing the discussion. Discussion via internet is also challenging as many CoP members do not have reliable internet access and/or do not have daily access to a computer (since they are often working in the field with local communities).

One CoP member suggested that the member profiles on the Clearinghouse’s CoP Members page be expanded to include each member’s areas of interest and expertise in order to facilitate member communication. Another member suggested that the CoP Coordinator use SMS messages to send CoP members notices when new resources or discussions are posted to the Clearinghouse or important email messages are sent.

Overall, meeting participants concluded that the CoP will need to use a variety of ways to communicate to ensure that all members are able to participate. The CoP will continue to explore options for creative and accessible ways to communicate and welcomes suggestions from its members. Participants decided that the CoP will continue to hold monthly conference calls while exploring options for how to best facilitate them. The CoP Coordinator will reorganize the Clearinghouse and send an email to the entire CoP asking members to complete a member profile. In addition, the coordinator will establish an SMS system for CoP alerts and messages.

Current and Future Projects in the Field of Community Involvement

Objective: To reach a shared understanding of the initiative currently underway in the field and the types of collaborative projects the CoP could work on.

In addition to the establishment of the CoP, there are many other examples of community work underway in the field of HIV prevention research. As the field of HIV prevention research and community engagement in HIV prevention research grows, a number of resources, tools, and guidance documents on effective and appropriate engagement have emerged. There

are, however, distinctions among the kinds of resources and documents that have emerged.

As Figure 2 shows, normative guidance documents are generally aspirational in nature. An example of a normative guidance is the *Good participatory practice guidelines for biomedical HIV prevention trials* (GPP). The GPP seeks to establish clear, global standards

for community participation and input into HIV prevention trials. This document, published by AIDS Vaccine Advocacy Coalition and the Joint United Nations Programme on HIV/AIDS (UNAIDS), outlines what community participation should include but does not have the authority of a sponsoring institution behind it. Nor does it aim to tell the reader how to achieve the aspirations it champions.

Institutional or internal guidances lay out specific guidelines for their staff or grantees to follow. These documents typically take the form of network or sponsor guidelines or policies such as the HPTN CAB Guidelines.

Resources or how-to documents tend to be more practical in nature, setting out specific tools or steps that one can follow to achieve an aim but may or may not outline why you should do it. These documents can take the form of site-level standard operating procedures or other kinds of toolkits or manuals.

Some examples of projects underway in the field are outlined in Box 4.

FIGURE 2. Normative guidance, institutional guidelines, and operational tools.

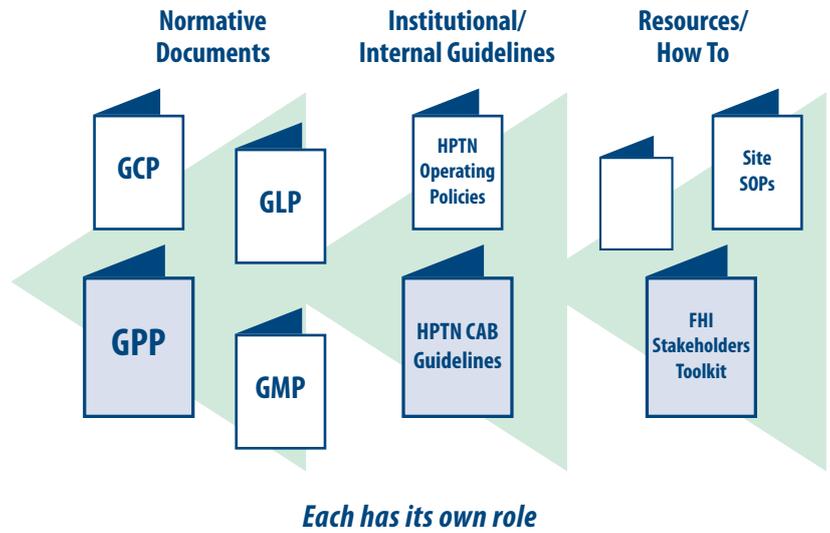
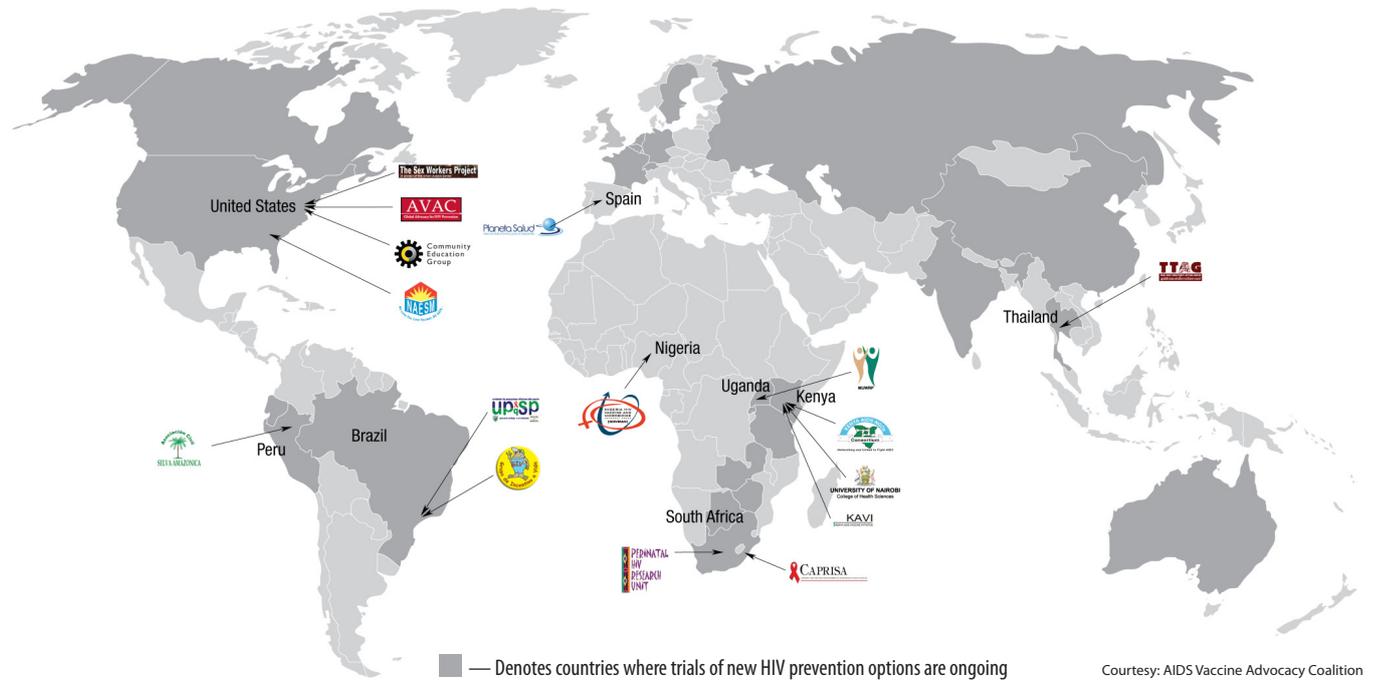


FIGURE 3. GPP Community Consultation Grantees.



Sample of Community Involvement Initiatives

The Microbicide Development Strategy was published in 2006 to analyze the microbicide field's progress and outline gaps in the areas of basic and preclinical science, clinical research, manufacturing and formulation, and commercialization and access. In response to what they felt was a distinct lack of community and civil society voice, a civil society working group was formed to draft what they felt was the missing chapter on gaps in civil society engagement. The report is available at www.global-campaign.org/mds.htm.

In an effort to document first-hand community experiences, the International Council of AIDS Service Organizations (ICASO) set out on a **Community Voices** project to capture stories from microbicide trial participants across a number of settings. Out of the project, ICASO plans to develop two global documents based on country reports from India and Nigeria. The documents will include key advocacy issues and anecdotal experiences from trial participants, researchers, and advocates.

The Microbicide Essentials course is designed to build the capacity of clinical trial staff, advocates, policymakers, and other stakeholders to be able to speak knowledgeably and answer questions regarding the complexities of microbicides development. GCM will be developing CD-ROM versions of the course for those with limited internet access. GCM also has some funding to conduct trainings at trials sites and will consider adding the course to the *Prevention Research E-Learning Centre*. The *Microbicide Essentials* course can be accessed at www.hivpreventionresearch.org.

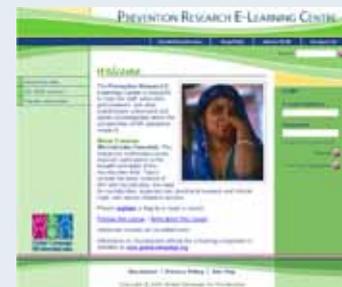
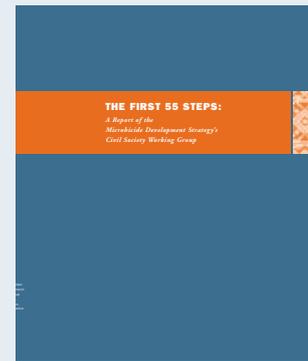
GCM is discussing the possibility of hosting **digital storytelling workshops** with (former and/or current) trial participants and clinical trial staff to help create a space for them to tell their own stories about why they are involved in HIV prevention research. The hope is that a series of digital stories will allow for participants' voices to be part of ongoing discussions about the ethics and utility of clinical trial research. For example:

The Blessing: www.youtube.com/watch?v=ill6yVla8CQ&eurl=http://www.justassociates.org/digitalstories.htm

Robbed of Motherhood: www.youtube.com/watch?v=htIrb8mj5mE&eurl=http://www.justassociates.org/digitalstories.htm

AVAC and UNAIDS developed the **Good participatory practice guidelines for biomedical HIV prevention trials (GPP)** guidelines in 2007 in response to the need expressed by a wide range of stakeholders for a tool to both plan and evaluate community engagement. Specifically, the GPP guidelines seek to establish ways to develop and objectively measure how trial sponsors and implementers are communicating and partnering with communities in the process of conducting HIV prevention trials. The GPP guidelines are published in six languages (English, Spanish, French, Portuguese, Chinese, and Arabic). In addition, AVAC has published a companion piece to the GPP, entitled the GPP Facilitator's Guide. Published in a broad range of languages including isiZulu, Kiswahili, Sesotho, Russian, and Thai, the guide aims to make the GPP more accessible to a wider range of stakeholders and includes discussion tools to help facilitators conduct community consultations. In addition, AVAC launched a grants program to conduct community consultations and solicit feedback on the guidelines. A total of 16 organizations were awarded grants: four in the United States, three in Kenya, two each in Brazil and South Africa, and one each in Peru, Spain, Thailand, Nigeria, and Uganda. For more information on the GPP or the community consultation process, or to offer comments on the document, contact Lori Miller at lori@avac.org. Both the GPP guidelines and the Facilitator's Guide are available at www.avac.org/gpp.htm.

The FHI Stakeholder Toolkit—an ongoing project by Family Health International—seeks to lay out practical steps for engaging a wide range of stakeholders including: study participants and their families, local communities, policy makers and advocates, the research enterprise (including funders), and health service providers. The toolkit is organized into three phases—conceptual, experimental, and application. To learn more about the *FHI Stakeholder Toolkit* or to offer feedback on parts of the document, please contact Tom Milroy at tommilroy@mindspring.com.



Measuring Success

Objective: To reach a shared understanding of what we mean by ‘success’ for community engagement in HIV prevention clinical research.

A question that often emerges and has yet to find a successful answer is, “how do we, as a field, recognize successful community engagement?” Box 5 summarizes the results of the group discussion on this point. Some

CoP members put forth the idea of the CoP holding a future workshop with the specific aim of developing measures, indicators, and tools, as well as training staff on how to use these tools.

Measuring Success in Community Engagement

What are the components necessary for successful community engagement?

- Consultative approach (mutual understanding between researchers and community).
- Active community advisory board (CAB) and/or stakeholders in the community that can communicate effectively.
- Established community partners where everyone is aware of the research.
- A structured community program, with organized activities that are monitored and evaluated.
- Implementation of indicators for success.
- A dedicated budget for community engagement.
- Stakeholder consultations at all levels (women’s groups, traditional healers, etc.).
- Two-way communication with the broader community.
- Management of community expectations (people need to trust you but also have realistic expectations).
- Implementation of mechanisms for community feedback and “feed-forwarding” [proactively seeking input from community].
- Improving male [partner] involvement.

What is the goal of community engagement?

- Sustainability.
- Successful implementation of a clinical trial, including reaching recruitment and retention targets.
- Accountability to the community.

What are some ways to evaluate whether we’re meeting our goals and measures of success?

- Qualitative research (interviews with participants and community at large).
- Recruitment and retention levels.
- Use of CAB meeting notes to determine targets for measuring goals.
- The existence of fewer myths and misconceptions in the community.
- Support for study protocol within the broader host community.
- Assess male/partner involvement at the site (could be achieved through partner/community events and discussion groups).
- Sub-studies and surveys measuring community involvement.
- Participatory research.
- Social science tools (to evaluate effectiveness of messages).

Case Study: Addressing Rumors

A number of meeting participants reported that their sites have dealt with various rumors around the collection of blood. CoP meeting participants agreed that research staff should not ignore these rumors but rather be transparent and address them upfront. Some CoP members shared strategies they had used at their individual trial sites to combat such rumors:

- The Microbicides Development Programme site in Mwanza, Tanzania, invited community representatives to take a tour of the site's laboratory to see first-hand how blood is collected and handled. The site also invited community representatives to witness the destruction of blood samples that were no longer needed for the study.
- At some Family Health International sites, staff members volunteered to have their own blood drawn to demonstrate that it is safe.
- Other sites have creatively used community theatre to address community rumors.



“At the MDP site in Tanzania, we measure reduction in rumors and concerns, through participatory research and interviews with participants. Through using these methods, we have been able to measure a reduction in misconceptions about contaminated blood at our site.”

– SHELLEY LEES

Community Engagement Strategies: Advisory Structures and Other Mechanisms

Objectives: To reach a shared understanding of some of the various strategies being employed in the field to solicit community input and assess their strengths and limitations.

Community liaison officers and outreach workers employ a number of creative strategies to solicit community input. Some of the strategies identified during

the meeting, as well as the strengths and limitations of each, are summarized below (see Table 2).

The Challenges We Face

Objectives: To demonstrate the concept of sharing and collective problem solving as a function of the CoP. To discuss challenges we face in community engagement at HIV prevention trials.

There are many challenges one faces when attempting to implement effective community engagement. Meeting participants engaged in a group brainstorm of some of the common challenges they face in doing their work (see Box 6). Four of these challenges emerged as the most pressing and were discussed in-depth.

It should be noted that all of the challenges listed in the brainstorm were relevant and important and will serve as a list of future discussion topics for monthly CoP teleconferences (the full list can be found in Box 7).

TABLE 2. Evaluation of various community engagement strategies

Strategy	Strength	Limitation
Stakeholders meetings	Can gather a lot of information easily. Two-way communication. Face-to-face interaction. Can solicit input from specific constituencies (women, partners, etc.).	Cannot include/invite everyone. Can be costly. One person can overtake/direct agenda.
Participatory methodology	Brings in different perspectives. Can simultaneously disseminate information and respond to concerns of community. Can get input on protocols.	Time consuming. Requires staff and financial resources. Raises ethical issues.
Participatory community mapping	If acceptable, enhances ownership. Provides visual output.	Can produce stigma—tagging certain groups or venues as “high risk.”
Training community ambassadors <i>(such as barbers and other locals who interact widely with community)</i>	Can track whether correct messages are reaching the community. Potential for correcting myths and misconceptions. Reaches peers and solicits uncensored input.	Resource- and time-intensive. Can have limited effectiveness, with ambassadors quickly going through their networks. High turnover. Training of ambassadors required.
Internet polls	Anonymous. Far-reaching. Allows you to focus on your target population (i.e., men who have sex with men [MSM] through websites attracting MSM).	Not feasible in communities with limited to no Internet access.
Community advisory board (CAB)	Inexpensive and easy to manage. A way to build research literacy of liaisons to community.	Sometimes do not represent communities. CAB members can become “professionalized.” Issues related to power dynamics.
Call-in radio shows	Wide coverage/far-reaching. Real-time interaction and opportunity for rapid response to clarify misconceptions. Opportunity for anonymous input.	Can be costly (if you have to pay for air time, produce the show, etc.).
Qualitative and social science <i>(formative research, community monitoring survey, sub-study, focus groups)</i>	Immediate and direct feedback. Eliminates bias due to large sampling. Confidential. Provides good cross-section.	Time consuming. Expensive. Cannot follow-up or clarify due to confidentiality restrictions.
Participant events	Increases understanding and support of research. Opportunity to invite partners, stakeholders, and/or other research sites. Ability to reach a lot of people and partners.	Raises issues of confidentiality. Logistically challenging.
Participatory community theatre	Community ownership. Affordable. Accessible. Fun.	Information can be oversimplified. Requires good facilitation skills. Difficult to reflect reality.
Mock study visits	Helps inform the process for study sites. Exposes community stakeholders to the clinical trial process.	<i>(No limitations recorded)</i>
Suggestion box	Can get anonymous input and feedback from participants.	<i>(No limitations recorded)</i>



Vuyelwa Mtimkulu of the Setshaba Research Centre in South Africa.

Describing Trial Results

When communicating trial results to local communities, it is important to use language that is easy to understand. The use of clear messages in local languages is vital—as are tools for disseminating the messages (such as community theatre). One participant suggested adapting the simplified language found in informed consent materials to aid in the development of results dissemination materials. CoP members, however, cautioned that if messages are developed in English and then translated into local language, it is necessary to first test them in local community contexts before using them broadly to ensure that the messages are perceived as they were intended.

Participants also observed that, in order to explain the meaning of trial results and complex concepts such as partial efficacy, trial staff should be trained on the “technical jargon” and have an understanding of the results, what they mean, and how to explain them to others. Building on this, the group suggested that staff should be trained to understand the design of the study, including the power, sample size, level of efficacy, and stopping rules early on—arguing that staff cannot explain these concepts to the community if they do not fully have a grasp of these concepts themselves.

Lastly, participants recommended that study staff prepare for a variety of trial outcomes. They urged that study staff should do scenario-planning for all possible outcomes

based on individual protocols. These outcomes could include: effective, some effect (partial efficacy), no effect, futility, and harm.

Care for Seroconverters

Loss to follow-up is also a major challenge, particularly the difficulty of keeping track of women after they have completed their participation in a study. Compounding factors include:

- The timing of when a study is closed and how the close-out is approached.
- The number and type of staff that remain at the site after the study closes (to help answer questions, disseminate trial results, and act as support for former trial participants—including those who have seroconverted or may seroconvert during the close-out period).

Participants discussed the importance of involving male partners from the beginning of a study. They noted many reasons for this including the benefits of couples counseling, and the ability to facilitate support and assist with disclosure of HIV status to partners when study participants seroconvert.

Participants also discussed the differences in the quality of care at research centers versus public facilities. They noted that trial participants who seroconvert represent increased workload to service providers, often in settings where service delivery deficits already exist. They also noted the need for standard operating procedures for women who screen out and formal memoranda of understanding between research groups and service providers. Participants recommended that research institutions ensure that both male and female condoms are provided and accessible to study participants.

Male Involvement

Partner involvement improves adherence to study products, retains women in the study, and helps women feel comfortable disclosing their sexually transmitted infection (STI) and HIV status. If studies do not include men from the start, it can often lead to

disgruntled partners and misunderstandings among partners and the community at-large.

In light of this, participants noted that there are many challenges and little funding to do male involvement activities. One of the challenges of involving men in HIV prevention trials—at least in microbicide trials—is that clinics are seen as a women’s space and many men do not feel comfortable or welcome in them. Providing STI treatment to male partners, couples counseling, and activities targeted to men (such as soccer matches) can help facilitate men’s desire and willingness to get involved.

Participants also discussed the idea of building a pool of progressive men that can reach out to male partners and act as role models. They felt that these men would be able to gain access to male-dominated spaces, ensure that activities are culturally appropriate, and help link the study to men’s organizations. Participants did not have concrete examples of this approach being implemented but offered it as a possible strategy.

Sustaining Community Advisory Boards

Many studies face a high turnover of CAB members and struggle with decisions around how much incentive is appropriate to offer to CAB members to maintain the stability of the group.

Some of the CoP members reported that there is a general lack of understanding regarding the roles of CABs and CAB members, noting that recruiting CAB members is typically far easier than retaining them over a long period of time.

The group discussed the issue of power dynamics and whether or not CAB members can truly represent a community if they are perceived to work for the trial and/or are receiving some form of compensation from the trial. They also discussed the difficulty of negotiating with certain organizations about who will serve on a CAB and whether the stakeholder organization or the study should decide who will represent the organization on the advisory board.

Some in the group suggested the idea of formalizing the role of CABs through

constitutions. At the same time, however, they countered that this idea raises many questions, including:

- Who would write the constitution?
- Should constitutions be standardized or adapted to individual studies and sites?
- And at the end of the day, how can the effectiveness of CABs be evaluated?

Future CoP Discussion Topics

- Involving broader civil society in HIV prevention research
- *Good participatory practice guidelines for biomedical HIV prevention trials: enthusiasm and concerns*
- Understanding methodology (results, social science, etc.)
- Professionalization of community advisory boards (to what extent are they representative?)
- Power dynamics
- How to monitor impact
- Media coaching/skills development
- Regulatory authorities and ethics committees
- Conflicting messages around HIV prevention
- Participant/community expectations
- Relationships with principal investigators
- Discontinuation of trials: maintaining participant and community momentum
- Advantages and disadvantages of community input into protocols
- Working with NGOs/community-based organizations
- Participant retention
- Evaluation: measuring impact
- Adherence
- New HIV prevention technologies

Dissemination of Trial Results

Objective: To reach a shared understanding of what we need to consider when planning for result dissemination and the role of community departments in the dissemination process.

“I learned from experience how best to disseminate the results to participants. The first time I did a meeting, I unblinded the women first and then I told them the results, and asked about their experience. I noticed that the women in the Carraguard arm were more disappointed than those in the placebo arm. The next time I did a group meeting, I asked all the women about their experience first and THEN unblinded them to tell them which arm they were in. This time the reactions were totally even between the groups.”

– MALEBO RATLHANGANA

In recent years, a number of HIV prevention research trials have closed—both prematurely and on schedule. These closures have prompted the field to pay increased attention to identifying effective ways to disseminate trial results to participants, communities, and other local and international stakeholders.

When a study comes to an end, international and local research staff face a number of challenges, including the need to prepare for a variety of possible trial outcomes and draft messages for each in coordination with a range of stakeholders.

Community liaison officers working at research sites play a large role in disseminating results—particularly to trial participants, CABs, and local stakeholders.

Given their role in the dissemination process, it is essential that community liaison officers be properly trained on how to interpret and accurately communicate trial results. It is also essential for research sites to retain an adequate number of community staff at a study’s end, in order to conduct proper dissemination.

A vast majority of CoP members identified trial results dissemination as a key issue affecting their sites. In response, staff from the Microbicides Development Programme (MDP) and the Population Council’s Carraguard® study were invited to share their experiences.

MDP Network: Planning for Dissemination

In preparation of the trial’s end, MDP established a network-wide Dissemination Working Group coordinated by the clinical trials unit of the Medical Research Council. The working group, includes external partners, site dissemination teams, and

representatives from the drug manufacturer. Its aim is to:

- Identify a budget for the working group.
- Develop key messages around a variety of possible scenarios.
- Ascertain an overall results timeline.
- Identify issues that could impact dissemination.
- Develop a dissemination strategy.

Since both the HPTN and MDP studies used PRO2000 as their study product (the HPTN study tested both PRO2000 and BufferGel, and released their results in February 2009, before the closure of the MDP trial), HPTN and MDP have been in close communication about the dissemination of results, how to coordinate the release of information, and how the results from the HPTN trial may affect the MDP study.

A concern, echoed by many meeting participants, was the need for research sites to ensure that they will have sufficient staff available during the entire dissemination process, including the retention of staff after official trial closure.

To supplement the work group’s efforts, MDP sites share information and better practices with each other by sharing templates used during past closures as well as lessons learned from sites with trial closure experience. It was noted that, in addition to sites within one’s network, important lessons can be learned from other organizations and networks that have experience in the countries where trials are located.

Dissemination of Carraguard Trial Results in South Africa

The MRC in Durban and Setshaba in Soshanguve were both research sites for the Population Council’s Carraguard® study.

Enrollment into the study began in April 2004 and was completed in June 2006. Follow-up was completed by March 2007, and the results of the study were officially released in February 2008. Former trial staff presenting the Carraguard® case study emphasized the importance of preparing for trial dissemination and the need to use timelines. They underscored that preparing for dissemination takes serious time and commitment. It took those working on the Carraguard® study over a year of phone calls and preparation before they agreed on the process that would be used for dissemination.

It is essential to disseminate study results to former study participants first, and timing considerations need to be taken into account to do this effectively (for instance, you cannot have results released over December holidays).

Some of the challenges identified by MRC staff included the outsourcing of media communications. The use of an outside company can work well in certain situations but, in the case of the trial site in Durban, it did not. Instead, it resulted in an unknown company making media calls on behalf of the local PI, who already had established relationships with local news entities and reporters.

The surrounding community at the Setshaba Research Center, another of the Carraguard study sites, is comprised of research teams at nearby trial sites, study participants, local community members, academic institutions, and the study's community advisory group (CAG). Other stakeholders include non-governmental organizations, faith-based organizations, and traditional healers.

By the time the results were released, the site had lost most of its staff. As a result the site's community liaison officer, Malebo Ratlhanga, was charged with disseminating trial results to this wide definition of community.

In order to share the results, Malebo invited members of the CAG to attend "results feedback" meetings at the site or at various community venues. In addition, the results were disseminated at local meetings, including ward council meetings

and meetings of traditional leaders. Former trial participants were informed about the availability of results by SMS, through a toll-free line set up by the study, and at various meetings.

An outline of the lessons learned from the dissemination of the Carraguard® results can be found in Box 8.

Other CoP members also shared their experiences with result dissemination and the preparations their sites are making in anticipation of results being released. Modesta Chileshe from the HPTN 035 site in Zambia shared that staff at her site have started talking with participants, preparing them for the results that will be released in February 2009. The Zambia site also organized a media sensitization training to precede the release of the results. Stella Kirkendale of FHI highlighted a fact sheet developed by AVAC on the role of data safety monitoring boards as an important resource to help communities understand how trial results work. This fact sheet is available at: www.avac.org/pdf/AVAC-DSMB-fact-sheet-apr-2007.pdf.

Lessons Learned: Dissemination of Trial Results from the Carraguard Study

- Ask up front about the design of the study and what the potential outcomes may be. From that, develop a strategy around dissemination.
- Engage and train media on HIV clinical trials and regulatory processes.
- Conduct scenario planning of possible outcomes.
- Communicate with regulatory bodies at all levels.
- Tell the community what the scenarios are before the results are announced. This will help to prepare them and to test whether or not the messages developed are on point.
- Make sure to have adequate staff to disseminate results.
- Acknowledge when mistakes are made.
- Trial results must include explanations on ethical considerations and community input.
- Maintain communication well after results are available. Keep asking communities if they have received the results and if they have any questions.
- Target your audience: prepare separate presentations/messages for different audiences.
- Practice answering tough questions.

Conclusions and Action Items for the Community Involvement Community of Practice

Conclusions

At this first annual meeting of the Community Involvement CoP, it was concluded that the CoP should:

- Avoid duplication and distinguish itself from other community groups working in the field.
- Help to engage principal investigators, study sponsors, and other decision-makers in discussions and activities around community engagement.
- Help PIs and decision-makers recognize community engagement and CoP members' participation in the CoP as a priority.
- Develop materials and resources that can be adapted for individual trials and trial sites.
- Shorten the CoP mission statement to more clearly emphasize its main aims (CoP aims are outlined on page 13).
- Identify ways for CoP members to share back what they learn from the CoP with other site level staff.

Action Items

Throughout 2009, the CoP will:

- Discuss how the CoP can reach out to network and site-level leadership and help to support mechanisms for the sharing of resources and knowledge with other site-level staff.
- Explore options for creative and accessible ways to communicate.
- Continue to hold monthly conference calls.
- Reorganize the Clearinghouse to make it more user-friendly.
- Complete and post all CoP member profiles (please send member bios and photos to kwest@path.org).
- Establish an SMS system for CoP alerts and messages.
- Receive updates from Tom Milroy on the FHI Stakeholders Toolkit.
- Explore the idea of holding a workshop with the specific aim of developing measures, indicators, and tools (and training staff on how to use these tools) to measure the impact of community engagement efforts.
- Use the list of challenges developed at the meeting to serve as a list for future CoP call discussion topics (see Box 7).

The Role of the Microbicides Media & Communication Initiative in Dissemination

The Microbicides Media & Communications Initiative (MMCI), a community of practice that brings together communications staff working in HIV prevention research and advocacy, was established in 2005 in order to respond to the special communication challenges of large-scale microbicide studies. The group facilitates coordination among individual trial sponsors and networks.

The MMCI supports trials preparing for results dissemination by helping with the development and review of materials, the preparation and coordination of messages, and the preparation of media strategies. The

MMCI has held confidential pre-embargo briefings of trial results to assist with coordination in the field and has assisted with the dissemination of results from the following studies:

- Savvy
- Cellulose Sulfate
- MIRA
- Carraguard
- STEP/Phambili

The MMCI also provides media and journalist trainings, coordinates a series of collaborative working groups, and hosts a Rapid Response Committee to help respond to any sudden trial closures or changes. For more information about the MMCI, please contact Deborah Baron at deborah.baron@gmail.com.

Conclusion and Action Items

Coordinated efforts to share lessons learned and better practices are vital for successful HIV prevention research, as are questions of how to evaluate such strategies and measure their success. While information sharing occurs within different research networks, there has been little communication on community-related issues across networks and independent research centers, and across the microbicide, vaccine, and pre-exposure and prophylaxis fields prior to the establishment of the Community of Practice (CoP).

Working collaboratively as a field to share proven strategies, lessons learned, and better practices can reduce the burden on network sponsors and individual research staff by providing proven means to carry out effective and meaningful community engagement and education. The sharing of resources and knowledge between colleagues and across research networks—and prevention fields—not only fosters a collaborative culture but also helps to ensure that networks and individual trial sites are engaging in the most effective community engagement possible and safeguarding the smooth functioning of their trials.

The Community Involvement CoP will work toward this collaborative culture by continuing to dialogue on a regular basis, identify needs and challenges within the field, and share strategies for effective community engagement and education. Box 9 outlines the main conclusions from this first annual meeting of the Community Involvement CoP in terms of how the CoP will function and its goals for the next year.

The following box, Box 10, outlines key conclusions reached by CoP members at the meeting in terms of the practice of community preparedness and engagement at HIV prevention research trials.

For more information on this meeting or the CoP, please contact Katie West Slevin at kwest@path.org.



Above: Shelley Lees, Grace Mtolela, and Charles Shagi of the Microbicides Development Programme's site in Mwanza, Tanzania, sketch out how their community department is organized.

Below: Pauline Irungu (Global Campaign for Microbicides) and Marie-Michele Umulisa (Project Ubuzima) on the last day of the meeting.

Conclusions on Community Preparedness and Engagement from the Community Involvement CoP

At this first annual meeting of the Community Involvement CoP, participants made the following collective observations in regard to community preparedness and engagement:

Trial Results Dissemination

- When communicating trial results to local communities, it is important to use clear messages in local languages.
- If messages are developed in English and then translated into local language, it is important to first test them in local community contexts before using them broadly to ensure the messages are perceived the way they were intended.
- Trial staff should be trained to understand the design of the study (including the power, sample size, level of efficacy, and stopping rules) early on in order to explain these concepts to the community.
- Staff should prepare and conduct scenario-planning for all possible outcomes based on individual protocols.
- Sites must ensure that they will have sufficient staff available during the entire dissemination process.
- It is essential for researchers to disseminate study results to participants first.
- Researchers should inform the community of all possible scenarios before the results are announced. This will help both to prepare the community and to test whether developed messages are on point.

(Additional lessons learned related to results dissemination can be found in Box 8)

Partner Involvement

- Male partners should be involved from the beginning of a study (this can improve adherence to study products, help keep women in the study, and aid in the disclosure of STI and HIV status).
- Providing STI treatment to male partners, couples counseling, and activities targeted to men can help facilitate men's desire and willingness to get involved.

Standards of Care

- Studies should develop standard operating procedures for women who screen out. Formal memorandums of understanding between research groups and service providers should be drafted to outline how care and treatment services will be provided.
- Research institutions should ensure that both male and female condoms are provided and accessible to study participants.

Community Advisory Boards

- The roles of CABs and CAB members need to be clearly defined.

Participant List

The Global Campaign for Microbicides hosted the First Annual Meeting of the Community Involvement Community of Practice (CoP) on November 18–19, 2008, at the iKhaya Lodge, Dunkley Square, Cape Town, South Africa. A cross-section of community liaison officers, educators, outreach workers, program managers, advocates, and other community engagement practitioners—all of whom are members of the CoP—were invited to participate. A full list of meeting attendees is included below.

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Endnotes

1. Joint United Nations Programme on HIV/AIDS (UNAIDS). *2008 Report on the global AIDS epidemic: Executive Summary*. Geneva: WHO; 2008.
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