



Mobilization

*For Community Involvement
in Microbicide Trials*



Global Campaign
FOR Microbicides

**Report from a Dialogue
in Southern Africa**



Global Campaign for Microbicides

c/o PATH

1800 K Street NW, Suite 800

Washington DC 20006 USA

www.global-campaign.org



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About the Organizations



Global Campaign FOR Microbicides

The Global Campaign for Microbicides is a broad-based, international effort to build support among policymakers, opinion leaders, and the general public for increased investment into microbicides and other user-controlled prevention methods. Through advocacy, policy analysis, and social science research, the Campaign works to accelerate product development, facilitate widespread access and use, and protect the needs and interests of users, especially women.

Specifically, the goals of the Campaign are to:

- Raise awareness and mobilize political support for increased funding for microbicide research, female condoms, and cervical barrier methods.
- Create a supportive policy environment for the timely development, introduction, and use of new prevention technologies.
- Ensure that as science proceeds, the public interest is protected and the rights and interests of trial participants, users, and communities are fully represented and respected.

The Global Campaign has project initiatives in community mobilization, capacity-building for advocates, policy analysis and influence, ethics of clinical trials, and community involvement. It works through partner organizations and local sites, with a small secretariat based at PATH in Washington DC.



The South African Microbicide Research Initiative (SAMRI) is a national prevention initiative coordinated by the Medical Research

Council (MRC)'s HIV

Prevention Research Unit. Launched in December 2002, the initiative focuses on accelerated testing of safe and effective microbicides. SAMRI's mission is to **accelerate testing of prevention technologies to curb the spread of HIV among women and men in South Africa.**

SAMRI's objectives are to:

- Maintain a database of microbicides and other barrier-method research scientists in South Africa.
- Create a forum for discussion of issues pertaining to microbicide and other female-controlled method trials in the country, for example, ethics, community issues, etc.
- Support other groups such as the International Partnerships on Microbicides, the International Working Group on Microbicides, and the Global Campaign for Microbicides.
- Offer expertise and training to other African countries working in microbicide research.
- Strengthen HIV prevention education among participating communities through partnerships with local and international initiatives.





Executive Summary

By promoting community involvement in clinical trials, AIDS movement organizations have contributed significantly to medical research. Community involvement represents on-the-ground implementation of science's accountability to society, at the local as well as global level. It is also a key factor in appropriate quality research, especially in the highly charged, sensitive field of HIV and AIDS programming. Almost all public funders of HIV research now require community involvement in trials.

particularly the focus on a community advisory board (CAB) as the locus of community involvement. In today's HIV prevention trials, environment, society, politics, the nature of the research, and developments in the pandemic present new challenges and opportunities for community involvement. The committed teams working at trial sites need a variety of tools, mechanisms, and strategies at their disposal in order to maximize authentic partnership between communities and research institutions.

While the institutionalization of community involvement signals a recognition of its value in clinical research, it can also place constraints on what should be a dynamic and evolving process. More than a decade of experience has established models that work well in certain contexts, but that may not be appropriate in others. An "institutionalized" approach to community involvement has evolved in transnational research networks and clinical trials with several sites. This approach needs to be critically examined,

Research institutions have dedicated staff working to build relationships in the communities where clinical trials are happening. The teams from eight trial sites in four southern African countries met in Johannesburg in July 2003 to discuss challenges, share strategies, and identify opportunities for community involvement, specifically in microbicide trials. This *Dialogue on Community Involvement in Microbicide Clinical Trials* was co-hosted by the Global Campaign for Microbicides (the Global Campaign) and the South African Microbicide



What Are Microbicides?

Microbicides are topical substances that can help prevent HIV when applied vaginally. They offer women a method they can use themselves to reduce their risk of infection. Several potential microbicides are being tested in different countries to see whether they are safe and effective in reducing sexual transmission of HIV or other STDs. Microbicides are not yet available, but with successful research and investment, they could be widely available in five to seven years.

Research Initiative (SAMRI). This meeting report describes some of the challenges and strategies discussed during this event.

Several observations and recommendations emerged from the three-day meeting. First of all, Dialogue participants emphasized the unique challenges of microbicides research that contribute to both the importance and the difficulty of community involvement. Secondly, through focused discussions, it became clear that CABs are **not** always the only or the best mechanism for involving communities in microbicides research. Teams are already trying a number of strategies, and are anxious to expand their repertoire and learn from each other.

In addition, two major themes emerged from the Dialogue: ***research institutions and communities are committed to genuine partnership, and there are overall benefits to communities who host prevention trials.***

Partnership and benefit concerns are becoming increasingly part of the microbicides and HIV prevention research discourse. Participants in various ethics and advocacy consultations¹ have raised these questions, sometimes in discussions of providing anti-retroviral treatment (ART) to trial participants, and sometimes as part of a broader discussion of research ethics. As research institutions struggle to design protocols that are scientifically achievable and also acceptable to a rising bar of ethical review, the quality and sustainability of community involvement becomes increasingly important.

In response to the growing emphasis on the quality of community relationships, and based on an assessment of techniques sites are already exploring, the Global Campaign developed a framework that posits community involvement not only as an outcome but also as a process. Based on a Community Mobilization approach, this framework outlines ways to achieve the necessary tasks associated with implementing ethical clinical trials in communities, while simultaneously building sustainable capacity and authentic partnerships. We believe this framework has multiple benefits for many actors—for institutions seeking to do good research in an ethical way, for community members dedicating time and energy to assisting trial staff, and to all contributors in the microbicides' field.

This report serves several purposes. It captures the discussion and the information shared by participants, and can serve as a tool they can use at their sites. It presents recommendations for community liaison staff, research institutions, and funders to consider as they make decisions about implementing trials and research network activities. It also represents what we hope is the beginning of a dynamic and broad-reaching discourse among all stakeholders in HIV prevention research who are working toward genuine partnership between communities and researchers to help curb the HIV epidemic and maximize social justice and positive change.



¹These consultations include: Global Campaign for Microbicides Ethics Consultation, Washington DC, October 2003; WHO/UNAIDS Ethics of Prevention Trials Meeting, Geneva, July 2003; Global Campaign for Microbicides and International AIDS Vaccine Initiative consultation on ART in HIV prevention trials, Washington DC, February 2003; Gender AIDS Forum Workshop on Marginalization and Vulnerability, South Africa, August 2003; Reproductive Health Priorities Conference, South Africa October 2002; HPTN Ethics Working Group, HPTN Community Working Group.





Part I: Background

The HIV pandemic has devastated lives and gutted social infrastructures. It has also fostered an historic shift in the role of civil society in medical research. Traditionally, clinical research has been the exclusive realm of elite scientific experts. Scientists, funders, and pharmaceutical company executives made decisions about what research to pursue and how, with little input from outside. Then in response to the AIDS crisis, treatment activists mobilized to confront scientists and demand a role for themselves in influencing not only what research would be done but also how it should be done. This pioneering effort to democratize science took root and grew. Today in HIV and AIDS research, we expect communities affected by research to be actively involved in its conceptualization and implementation.

Most network and institution staffs conducting microbicides and other publicly-funded HIV prevention research in the United States (U.S.) and the United Kingdom (U.K.) have incorporated an explicit community component. However, the definitions, goals, and methods of “community involvement” vary from network to network, and even within networks the interpretation and commitment to community involvement is inconsistent.

Though history and experience motivated concern for community involvement, the challenges have shifted since its origins in early treatment activism in the industrialized world. Now most large-scale prevention trials

take place in resource-poor countries, in communities that have borne the brunt not only of AIDS but also a host of health, social, and economic injustices. Rather than accommodating educated, self-mobilizing activists “pushing” for their own inclusion, researchers must now “pull” untrained, overburdened, and often marginalized individuals into an active partnership with Western-educated researchers, in the researchers’ own highly technical terrain.

The nature of the research is different as well. Questions of ethics and justice are even more significant for transnational research sponsored by wealthy countries and conducted in poor ones. As opposed to treatment research done with HIV-positive individuals who have the potential to benefit directly from participating in the study, prevention research enrolls at-risk but currently healthy people, some of whom will seroconvert over the course of the study. And microbicides—new products that women will use proactively and possibly independently of their partners to reduce their risk of HIV—raise additional challenges in settings where gender norms may not support women’s control over their own sexuality. These factors have unique implications for defining the appropriate goals and strategies for community involvement in microbicide research.

The Global Campaign

The Global Campaign for Microbicides (Global Campaign) promotes a community-

oriented approach to accelerating research, development, and access to microbicides and HIV prevention options for women. In addition to the goals of raising awareness, mobilizing resources, and informing policy,

the Global Campaign works to ensure that as microbicide research proceeds, the public interest is protected and the rights and perspectives of users are fully represented and respected. The Global Campaign is a

TABLE 1: Selected Research Networks and Entities Working on HIV Prevention Technologies²

Network	Funder	Types of Trials	Countries
Family Health International	U.S. government through USAID	Microbicides	Ghana, Nigeria
Global Microbicides Project	Private donors, U.S. government- through USAID	Microbicides, contraceptive barrier methods for disease prevention	Belgium, Benin, Burkina Faso, Dominican Republic, India, Kenya, South Africa, U.S.
HIV Prevention Trials Network (HPTN)	U.S. government through National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID)	Non-vaccine HIV prevention interventions, including PMTCT, STD treatment, ARV, substance abuse, and behavioral interventions	Brazil, China, India, Malawi, Peru, Russia, South Africa*, Tanzania, Thailand, Uganda, U.S., Zambia, Zimbabwe* ³
HIV Vaccine Trials Network (HVTN)	U.S. government through NIAID	Vaccines	Botswana, Brazil, China, Dominica Republic, Haiti, India, Malawi, Peru, Puerto Rico, South Africa, Thailand, Trinidad & Tobago, U.S.
International AIDS Vaccine Initiative (IAVI)	Governments and private donors	Vaccines	India, Kenya, Netherlands, South Africa, Uganda, UK, U.S.
International Partnership for Microbicides	Governments and private donors	Microbicides	Global
Microbicides Development Program (MDP)	UK-DfID through the British Medical Research Council	Microbicides	South Africa*, Tanzania, Uganda, Zambia*, UK
Population Council	Private donors, USAID	Microbicides	South Africa*, Thailand,
U.S. Centers for Disease Control and Prevention (CDC)	U.S. government through Department of Health and Human Services	Microbicides	U.S., Botswana*, Thailand

*Site represented at the Dialogue

² This table does not represent the full spectrum of groups engaged in HIV prevention research, but seeks to highlight those that are either engaged in microbicide research, or developing specific community involvement programs, or both.

³ All HPTN sites are listed; not all are actively engaged in microbicide trials.





coalition of 200 organizations that collaborates with research and advocacy entities on a collective agenda, based on the perspectives of the women, men, and communities most affected by the HIV and sexually transmitted disease (STD) epidemics.

In 2002, with support from the United States Agency for International Development (USAID), the Global Campaign began an Initiative on Community Involvement in Microbicide Research. The goal of the Initiative is to support researchers and communities in building effective partnerships in microbicides research. Activities include advancing the dialogue and debate on approaches to community involvement, providing tools and capacity-building, and capturing the evolution of community involvement through appropriate documentation and evaluation. As a non-governmental organization (NGO) coalition, the Global Campaign is unaffiliated with any particular research network or trial site, and serves as a resource for the field as a whole.

The Dialogue

As part of its Community Involvement Initiative, the Global Campaign worked with the South African Microbicide Research Initiative (SAMRI) to convene the *Dialogue on Community Involvement in Microbicide Clinical Trials* in Johannesburg, South Africa, in July 2003. The Dialogue brought together community outreach staff from eight research sites in four countries in southern Africa, marking the first time that community involvement in microbicide trials has been specifically considered across various networks. Thirty-five participants shared experiences and challenges from ongoing community involvement operations in their sites. Together they developed responses to some of the more challenging issues, and discussed various approaches to community involvement in microbicide research. Structured first of all as an exchange of experiences to-date, the Dialogue also involved extensive discussion of emerging practices, unresolved questions, and future directions for community involvement in microbicide trials.



Part II: Why Community Involvement?

“Community involvement”—efforts to engage a wide range of stakeholders in decision-making about the research and its implementation— is crucial for practical and ethical implementation of clinical research. Research and donor institutions recognize both the **benefits** of partnership with the affected community, and the **costs** of not involving them. Supporting a community voice in the research process improves the likelihood that the research will be accurate, acceptable, and ethical. Institutional motivations for investing in community involvement include:

- Facilitating the research.
- Improving the scientific and ethical integrity of trials.
- Protecting “vulnerable populations”.

Beyond an institutional mandate however, community involvement also acknowledges the significance of clinical research for host communities. Research focuses attention on issues of great concern to the community. Given the profound and devastating impact of HIV/AIDS, any study related to AIDS attracts high levels of concern, expectations, and hopes. Though not in disagreement with the researchers’ goals above, community members’ perspectives on research involvement may be articulated in a slightly different way. The motivations for communities to actively participate in research include:

- Increasing the relevance, transparency, and accountability of the research to the community.

- Maximizing the benefits and decrease the risks of the research to the community.
- Potentially leveraging additional benefits to the community not directly associated with the research.

Understanding and integrating these related but different orientations toward research is a fundamental part of moving toward meaningful community involvement and partnership.

Who Is “the Community”?

What does “community” in community involvement mean? Who are the appropriate people who should be involved in the research process at a microbicide trial site?

The Dialogue focused on the “shared characteristics” that could define a community. This characteristic could be geographic proximity, or it could be a common identity or interest, or a shared risk. Participants recognized that individuals defined by outsiders as part of a community may not see themselves that way at all. A first impulse might be to define the “community” for microbicide trials as the women living in a certain area where the research is located. Defining women as the relevant community would be narrow, however. As one attendee noted:

“Once you have women, already you’ve got men because women sleep with men, and that is also part of your community... And the minute you talk about the stigmas and what not, we are



talking about the cultural issues within that community. We are talking about their social interactions within their community.”

Alternatively, the community could be considered **interest-based**, including those who are concerned about reducing HIV rates in the town or nation where the trial site is located, regardless of where individuals live. Or it could be **functional**, including all sex workers, truck drivers, health care workers, etc.

While a geographic definition of community is generally the most common one, Dialogue participants thought it useful to borrow from all constructs, and to think of a shifting and multi-faceted definition of community.⁴

Community Involvement as Partnership

Fundamentally, community involvement represents a relationship between researchers and the communities where trials occur. Members of the HIV Prevention Trials Network (HPTN) and others have conceptualized the researcher-community relationship on a continuum from “Advisory/Consultative” to “Collaboration/ Partnership” (Mutsambi and HPTN, 2002). Currently, microbicide research teams are in a process of evolving along this

continuum, and most are interested in pushing further towards authentic collaboration and partnership. The idea of collaboration also implies a sense of **shared ownership**. After the Dialogue, one participant wrote to the Global Campaign to share the following thoughts:

“Since [the Dialogue] I have been driven towards thinking about promoting our research/trial projects as ‘partnerships’, rather than as ‘our projects’ that need the community’s involvement. What I mean is, can we go out there and start by saying this is the community’s project in which everybody has a role to play, rather than going out there and start by pleading with them for their involvement!”

Mobilization: the Next Step

Dialogue participants described a number of questions and challenges that could be addressed by expanding the concept of community involvement in clinical trials to a broader social and community mobilization effort. Sites currently employ several mobilization theories and tactics. These could be expanded and strengthened by explicitly applying a **mobilization framework**.



Terminology defined

“Community Involvement” is distinguished here from two other activities of clinical trials.

1. **Trial participation:** eligible volunteers from the community enroll and participate directly in the trial as study subjects.
2. **Community education or outreach:** the research team’s communication and relationship-building efforts in the trial community, in order to raise awareness and gain acceptance of the trial, and to facilitate recruitment of advisors and participants.

Community Involvement: activities in which communities work collaboratively with the research team in decision-making, problem-solving, and project implementation.



⁴ For more discussion of defining and understanding “community” in relation to clinical trials, see MacQueen et al, 2001.

Advisory	Collaborative	Mobilization
Community representatives provide input into specific areas of the study as requested by the research team.	Community representatives and research team cooperate in developing and implementing research process.	Engagement in the research process strengthens community capacity to analyze and address its own health and development priorities.

Community mobilization describes a process by which communities develop the capacity and mechanisms to articulate their needs, decide on their priorities, and design and implement actions to address health, development, or other social needs. The key element is that action is based in the **community's self-identified interests**. However, community mobilization can legitimately be initiated by outside organizations or institutions when the goal is "not only a problem solved, but the increased capacity to successfully address other community needs and desires as well" (Health Communications Partnership, 2003).

Mobilization is an accepted strategy to increase community ownership of a program, as well as to improve program design, implementation, results, and sustainability. Many community involvement programs at trial sites already employ some community mobilization strategies, as described by the Johns Hopkins Health Communications Partnership curriculum on community mobilization (Health Communications Partnership, 2003). These include:

- Creating or strengthening community organizations.
- Developing ongoing dialogue with community members.
- Working in partnership with community

members in all phases of a project to create locally appropriate responses to health needs.

However, other community mobilization strategies are not yet an explicit part of the community involvement agenda within research institutions. These tend to be the ones having more to do with empowerment and sustainability beyond the trial, such as:

- Assisting in creating an environment in which individuals can empower themselves to address their own and their community's health needs.
- Identifying and supporting the creative potential of communities to develop a variety of strategies and approaches to improve health.
- Assisting in linking communities with external resources.

What is the **"value added"** of a community mobilization framework to existing community involvement efforts in microbicide research?

This is a valid question, particularly given the nature of a clinical trial as a time-limited enterprise operating with limited resources. The benefits of employing mobilization strategies extend well beyond the scope of the clinical trial.





One reason to focus on mobilization and empowerment as an explicit goal in community involvement is the notion of “giving back” to the community. Unlike treatment research, where individuals enrolled in the trial can at least hope for some immediate benefit to themselves, prevention research relies on the voluntarism of individuals who are primarily motivated by contributing to future generations. Much of the current ethical debate around HIV prevention trials involves **benefit**, usually conceptualized as the overall package that trial sponsors offer to participants and communities that represents reasonable compensation but not undue inducement. In settings often characterized by severe deprivation and injustice, researchers cannot begin to address all existing needs, nor should they. However, by including the skills, training, and experience involved in mobilization among the benefits they do provide, institutions can strengthen community members’ ability to address critical social needs.

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A second reason to focus on building capacity and sustainability is the convergence of various HIV and health-related efforts being rolled out in various communities. As new interventions are introduced (particularly ART programs), the benefits of having informed, mobilized communities able to articulate and represent their needs and priorities is crucial. By moving beyond the specific needs of their own trial, microbicide researchers can contribute to the introduction of appropriate, responsive services and programs in the communities where they are working. Ultimately, this benefits the research by addressing needs for support and referral services, voluntary counseling and testing

(VCT), behavior change communication (BCC), and other interventions, both during the research and beyond.

Every researcher and advocate knows that the best microbicide in the world will do no good unless it is available to people who know they are at risk, can afford the product, and know how to use it correctly. The job does not end when the last piece of data is analyzed—in fact, it’s just beginning. Mobilization strategies prepare community members to become knowledgeable, effective advocates for microbicides and other HIV prevention methods. Mobilized communities and organizations can help community “partners” articulate demand, pressure governments and ministries, raise awareness, and address issues of accessibility. One community liaison officer at the Dialogue described how community members could become future microbicide advocates:

“Even though we don’t have money, we don’t have Congress or something to devote funds to [the cause], but in the communities where we’re doing the microbicide trials, I feel ... that we should be mobilizing ourselves ‘cause we’re affected so why shouldn’t we? If we got people jumping up and down overseas why shouldn’t we also be jumping up and down [here]? Of course not on day one people would jump up and down, but we’re raising people to a certain level of empowerment and [they should be] also talking about their own rights and thinking about their own rights.”



Part III: Goals, Tasks and Mechanisms

Goals for Community Involvement

Participants from the eight research sites attending the Dialogue each presented the goals and objectives of their community involvement programs (see Appendix 1). Throughout the discussion, the groups refined and added additional goals. These can be grouped in four general categories: gain entrée to the community and trial start-up, promote an ongoing exchange of knowledge and information, maintain the scientific validity and ethical integrity of the trial, and contribute to overall community mobilization capacity and development.

- Helps make the language of research materials and messages culturally relevant and comprehensible.
- Gives input into certain trial components, notably informed consent (Strauss et al, 2001) and the “compensation” or “benefits” that trial participants and the broader community receive.
- Serves as a vehicle through which the community can learn about and provide input to the trial as it moves forward.

Current Mechanisms: Community Liaison Officers and CABs

Currently, trial site staff rely primarily on two interacting mechanisms: community liaison officers or educators hired by the research institution, and community advisory boards (CABs)⁵ composed of interested community members. The community liaison officer and his or her team recruit and train CAB members, provide administrative support, and help facilitate meetings. They may also try to guide decision-making and ensure input of different voices and perspectives in the process.

As generally conceptualized, the CAB:

- Serves as the community voice, “representing” the community perspective.
- Acts as a “go-between” or bridge between researchers and the community.

History of the CAB model

The CAB evolved from AIDS treatment activism in the U.S. Activists from the communities most affected by HIV and AIDS began to demand a role in decision-making about treatment trials and the AIDS research agenda. In 1989, members of the AIDS activist organization ACT UP New York “crashed” the meeting of the AIDS Clinical Trials Group (ACTG), which had been formed in 1987 at the National Institute of Allergy and Infectious Diseases (NIAID). Recognizing perhaps both the seriousness of the activists as well as the research benefits of better interaction with affected communities, the ACTG responded. By May 1990, a Patient Constituency Group (later the Community Constituency Group, or CCG) was formed and invited to observe executive and scientific meetings of the ACTG. By 1996, mechanisms to promote community involvement in HIV clinical trials had become a requirement in NIAID-funded research (Snow, 1998).



⁵ Many sites reported adapting the traditional term “Community Advisory Board” to better reflect the work and identity of the group at their sites. For example, in Gugulethu and Ga-Rankua, South Africa, people perceive the word “board” as alienating, and prefer “Community Advisory Group,” or CAG. In Hlabisa, Kwa Zulu-Natal, the “Community Working Group” has deliberately removed the word “Advisory” from the description of its role. While welcoming these variations, the authors use “CAB” throughout the rest of this paper for simplicity.



TABLE 2: Goals for Community Involvement

Goal	Tasks
<i>Gain entrée to the community; trial start-up</i>	<ul style="list-style-type: none">● Introduce the research institution.● Create awareness about the study.● Obtain permission and support from official leaders and community figures (Ndunas, NGOs, health care providers, teachers, etc.).● Build trust and relationships.
<i>Promote an ongoing exchange of knowledge and information</i>	<ul style="list-style-type: none">● Gather information about the community (demographic, cultural, social).● Maintain ongoing two-way communication between research team and community members.● Manage rumors and expectations.● Increase transparency.● Disseminate results of research to the community.
<i>Maintain the scientific validity and ethical integrity of the trial</i>	<ul style="list-style-type: none">● Design services (referral and support) and benefits packages.● Enhance recruitment and retention.● Ensure community and participant comprehension of materials and messages.● Promote joint decision-making in research planning and implementation process.● Monitor impact of research on the community.● Provide mechanisms for accountability.● Reduce real and perceived power imbalances.
<i>Contribute to overall community capacity and development</i>	<ul style="list-style-type: none">● Build sustainable partnerships between and among research institutions and NGOs.● Train selected community representatives to participate in research design and ethics and support their participation in decision-making.● Prepare community organizations to help translate research findings into government or donor policy.● Plan skills development and capacity-building that can apply to future research, HIV interventions, and broader community development.● Assist community organizations in accessing resources and influencing decision-making that affects the community.

Recruiting a group of representatives from the affected community to guide and assist the research team (a CAB) became standard practice, both for trials conducted in the U.S. and elsewhere. However, HIV research has evolved, challenging the assumption that the CAB model can meet the diverse and complex challenges of community involvement. The membership of early AIDS treatment CABs tended to be educated individuals with high degrees of self-efficacy (activist-orientation) and self-motivation (directly affected by HIV in the short term). Today, HIV prevention trials often draw CAB membership from people who have little formal education, few resources, little political power, and significant competing priorities. Early treatment-research CABs tended to represent a self-defined community—people with HIV or AIDS, often men who have sex with men. Prevention-trial CABs now try to represent a much broader, nebulous and shifting community, with all of the associated challenges (Snow, 1998).

Challenges of the CAB model

CABs face multiple challenges. Like any consensus-oriented institution, CAB deliberations can move slowly, and political agendas can divert the mission. The amount of work may challenge members who have pressing income-generating obligations and other priorities. While CABs are advisory bodies of volunteers, frequently community liaison officers look to CAB members to manage the hands-on activities of ongoing outreach, education, and other tasks. Retention is a core concern, with dropout rates high at many sites:

"People dropped out because they found jobs, lost interest, were overwhelmed by the amount of work to be done, especially for something new, that you are not sure of... all this new language."

Another concern raised about CABs was the question of representation. For CABs to fulfill their expected role in promoting community involvement, they need to "represent" the community. Yet site staff questioned whether they could guarantee this characteristic of CABs.

"It really worries me because they have set themselves up as representatives of NGO's, have set themselves up as concerned individuals from the community, but they have come forward pretty much on their own steam... We don't really have a mechanism for them to go back to anyone and so... what are the communities that we think we are representing when we put together a CAB and where do those people come from and do they in fact represent anyone?"

Further discussion revealed a lack of consensus about what representation means. One participant noted that by deliberately seeking out individuals from different sectors, populations, and interest groups in the community, one could assemble a "representative" group. Yet this approach does not guarantee representation in an **active** sense, which requires accountability and two-way communication between community members and the individuals who "represent" their interests. Currently, many CABs do not have explicit mechanisms that allow them to function as active representatives of their communities.

In the southern Africa research sites with CABs, community liaison staff recruit and train CAB members, convene meetings, and essentially manage the work of the CAB through its' early stages. Dialogue participants discussed their concerns about two possible outcomes of this dynamic. One was the issue of "**desired response**," (i.e., would a group convened and compensated by the





research institution be effective in offering opinions that conflict with the institution's interests, or would they see their role as confirming what the institution expected of them?) Since a key concern in clinical trials is that volunteers will provide answers to study questions based on what they perceive researchers want to hear rather than on their actual beliefs or behavior, community liaison staff were highly attuned to the phenomenon, and keen to prevent it. Dialogue participants also raised concerns about the "**arbitrary power**" that the institution can convey on CABs formed for the purpose of guiding research. Without the assurance of diversity, inclusion, and shared authority, CABs run the risk of becoming a vehicle for one group or individual to manifest their own agenda.

Developing Comprehensive Community Involvement Mechanisms

By focusing on a CAB as the primary mechanism for implementing community involvement, the whole enterprise is subject to the success or failure of one strategy. CABs that are truly representative, that function independently and effectively, whose members remain engaged, and who are identified by the broader community as information resources who can help neighbors interact with the trial staff, may indeed achieve a meaningful level of community involvement. Sites that have highly functioning CABs, such as the Zimbabwe HPTN site, have been cultivating the group for several years. But discussions at the Dialogue revealed that sites have begun to use other mechanisms to help educate, respond to, protect, collaborate with, and seek ongoing input from communities.



Part IV: Mobilization Framework for Community Involvement

By breaking out the goals and tasks of the community involvement process and considering them separately from the objectives of a CAB, Dialogue participants were able to identify many different mechanisms and strategies for achieving them. A tentative four-part framework for a robust community/researcher partnership emerged from the Dialogue. This framework can serve as the basis for a **Community Involvement Plan**, which some sites are discovering is a more useful way of approaching the community involvement enterprise. The framework provides a menu of strategies for accomplishing the various goals and tasks of each stage of community involvement. Liaison staff, working together with communities, can develop a plan that employs the most appropriate and sustainable strategies to accomplish the broader goals of partnership and mobilization.

A. Community Entrée and Trial Start-up

The communities where trials are taking place vary widely in terms of their familiarity with the sponsoring institution, with research, and with microbicides specifically. Some have a long relationship with the research institution, while others are “research-naïve.” Although the exact configuration of tasks to gain entrée to the community varies from site to site, they include (from Table 2):

- Introducing the research institution.
- Creating awareness about the study.

- Obtaining permission and support from official leaders (*ndunas*, district officials) and community figures (NGOs, health care providers, teachers, etc.).
- Building trust and relationships.

Through site reports and discussion, participants identified the following strategies for achieving the goal of community entrée and trial start-up:

1) **Develop a strategic plan together with community representatives**

Some of the best resources on community involvement are already in the community. Rather than developing a plan to involve the community, why not involve the community in making the plan? A few key representatives identified through initial outreach can inform and assist next steps. People are more likely to endorse something they help create than something they are presented and expected to respond to.

2) **Broad initial outreach**

Sites’ staff said they were extending beyond targeting “official” leadership to also reach out to a broad range of stakeholders such as NGOs, women’s clubs, men’s clubs, and other formal and informal groups. Site representatives say that galvanizing broad community awareness is helping them establish trust, better understand the community, and engage a broader range of people.



3) *Collaborate with non-governmental and community-based organizations*

In many communities, NGO and CBOs' staff are already trusted. These organizations offer communication, research, and other technical capacity that is relevant and useful to the community involvement goals of the trial. NGO and CBO staffs can also help coordinate referrals and assist in community health mobilization. An early strategy should be to thoroughly scan a community's existing institutions for possible areas of synergy and collaboration. Research institutions should then be prepared to support NGO and CBO efforts that can help implement parts of the community involvement agenda.

4) *Comprehensive health and community education*

In trial settings in southern Africa, many people lack basic knowledge of HIV transmission and interventions. Myths and misconceptions fuel stigma and discrimination. In addition, the social and gender context of health disparities and vulnerability is not always part of the popular dialogue around HIV. Several participants reported overcoming barriers to community involvement by going "back to the beginning" in their community education. When placed within a broader analysis of health and social issues affecting the community, specific information about microbicides and the clinical trial seems more relevant, enhancing the community's interest in the discussion. Access to information also benefits community members beyond the scope of the trial. Participants noted, however, that this approach requires some tradeoffs given current resources and staff time available to do broad health education, and the implications in very underserved communities of raising awareness without having adequate services and support in place.

5) *Piggyback on advisory groups at local AIDS organizations or other community health initiatives*

One multi-study center is taking this approach:

"In many of our sites there are mobilized groups, and should we then be creating a separate group or should we be working through these existing groups, and so we are working with existing structures, because it seemed the best thing to do, and to avoid conflict and obstacles."

This will be especially important as other HIV interventions (ART, PMTCT, vaccine trials) are rolled out in communities..

B. Communication: Promoting the Exchange of Knowledge and Information

Dialogue attendees highlighted the fact that open, two-way communication between researcher and community is the most essential piece of community involvement. Community liaison teams are searching for mechanisms to foster ongoing communication that researchers and the community **both** control, in order to:

- Gather information about the community (demographic, cultural, social).
- Maintain ongoing two-way communication between research teams and community members.
- Manage rumors and expectations.
- Increase transparency.
- Disseminate research results to the community.

Some strategies include:

1) Using participatory action research

Some sites are using participatory research techniques to gain knowledge and insight into communities. At one multi-study site, project staff conducted initial situation analyses to understand the social and political landscape, prior to rolling out a new study. Another site involved dozens of community residents in a mapping exercise that identified existing community resources relevant to the research project.

2) Seeking community input in translating scientific concepts into lay language

Scientific language is a barrier to communication and comprehension between researchers and community members. Sites reported enlisting the help of advisory bodies and others in translating scientific concepts into language that makes sense to most people. Liaison staff have found that the word “experiment” rather than “research” is better understood as conveying the unknown outcome, or that describing randomization as a “lottery” improves comprehension of that process. All the representatives at the Dialogue were anxious to learn from each other, and to create a shared vocabulary or lexicon for explaining research concepts more simply.

3) Developing feedback mechanisms

The existence of a CAB does not guarantee appropriate communication between the CAB and the community. Dialogue participants believe mechanisms need to be established to ensure feedback and two-way communication between community members and those representing them in the research. Suggestions included:

- Holding open meetings or consultations to disseminate information and solicit broader input.

- Employing qualitative and participatory research techniques to elicit community viewpoints.
- Creating mechanisms for private or confidential input to be given.

One of the most intriguing suggestions was to have a specific community advocate, or “ombudsperson,” who would have a role similar to that of an ombudsman at a newspaper. It would be this person’s job to seek input from the community, analyze it in the context of his or her knowledge, and present it back to both the research institution and the broader community in ways that can be either critical or supportive. (This suggestion will be developed further in future sections.)

4) Developing multiple advisory groups

This strategy is underway in two sites. One site is developing two separate advisory groups: a CAB, which will represent the broader community’s interests in the research, and a Participant Advisory Group, which specifically represents the needs of participants enrolled in the study. This approach recognizes that there are multiple stakeholders with different needs for information, feedback, and support, and that a single body cannot represent all those needs. Staff at a second site is launching both a CAB, which will address trial-related issues, and a microbicide advisory group to raise general awareness on microbicides apart from the specific trial that is underway.

5) Communicating results to the community

A significant concern from even relatively recent experience with research is the failure to communicate results to the community in a timely and understandable way. This is often due to funding constraints, particularly at the end of the project, as well as to copyright restrictions of the academic journals where results are published. Dia-





logue participants acknowledged that neither of these are valid excuses for not delivering the results of research back to the community, and research networks are addressing the problem creatively. For example, HPTN sites have begun to share the results of trials before they are published under a confidentiality agreement with the community. This practice recognizes the community's right to participate in the scientific process from beginning to end. Another possibility is to build upon local NGOs' capacity in information, education, and communication (IEC) and peer education techniques to help disseminate the results of the research, along with related health promotion messages.

C. Maintaining the Scientific Validity and Ethical Integrity of the Trial

Ethical guidelines have evolved over several decades to protect the individuals and communities involved in clinical research. All Western codifications of biomedical ethics are founded on three basic ethical principles: *respect for persons*, *beneficence*, and *justice*.

Ensuring scientific rigor in the study is also part of an ethical mandate. It is a violation of the **principle of beneficence** (potential good outweighs potential harm) to conduct research that cannot generate conclusive results. Compromising the scientific rigor of a trial can result in insufficient data and uninterpretable results—essentially a waste of resources and, most importantly, participants' time and effort. Of course, maintaining ethical integrity always trumps scientific rigor when the two are in direct conflict. However, the goal is to develop research protocols that maximize both.

Community involvement is essential in achieving this goal. As researchers strive to design protocols that meet ethical principles,

they seek the community's help in applying these principles in the real world.

Participants in the Dialogue gave examples of ways communities contribute to the design and implementation of ethically and scientifically sound protocols:

1) Decision-making about benefits

Community representatives give input into the compensation package and standard of care that participants receive, to ensure that it is appropriate for the situation and does not represent an undue inducement to enroll in the trial.

2) Informed consent procedures

Design and pre-testing of informed consent procedures supports the principle of respect for persons. Community input into comprehensible, culturally appropriate informed consent (or, alternatively, "informed decision-making") increases the likelihood that women fully understand the aspects of the trial protocol that impact them, and that they enroll voluntarily, without pressure from researchers, community, family or partners.

3) Retention of volunteers

Being able to follow volunteers throughout the course of the trial is crucial for obtaining good data, and community involvement is important in retention. Although volunteers are free to leave the trial at any time, they are less likely to do so if they feel that they have the support of their families, peers, and community members. Rumors about the trial, real or perceived breaches of trust between research staff and participants, or inadequate recognition of or compensation for the burden women face in participating can discourage women from continuing with the trial. Key activities in community involvement are promoting a supportive environment for participants and responding appropriately to

challenges as they emerge. Staff at Population Council sites talked about creating messages of support for trial participants, acknowledging that they are the heroines and the “bright stars” on the front lines of the fight against AIDS.

There are times, however, when community input may contradict standard ethical principles. In one example from the Dialogue, CAB members at a particular site advised researchers to obtain consent not only from women, but from their male sexual partners as well.⁶ According to one attendee, this demand, which conflicts with the principle of autonomy and respect for persons, was rooted in the cultural belief that men own their wives’ bodies, in particular their wives’ sexual organs. This is a troubling example of a clash between community norms and ethical principles. *Ultimately, community involvement is necessary though not sufficient for clinical trials to be done in an ethical manner.* Combining community input with thorough ethical training and discussion should increase the chance that the outcomes protect the rights and integrity of participants as well as respect cultural norms.

Dialogue participants suggested the following ways to involve the community in applying ethical principles to research:

4) Training and experience for community representatives in ethical reasoning

It is not enough to have a community member interact with a formal ethics committee or institutional review board (IRB) unless they have the knowledge, experience, and ability to engage in discussions with the trained professionals who make up those committees. The selected community representa-

tives need sufficient training and support, not only to understand the principles assumed by professional committee members, but also to apply those principles to impact research in their community.

5) A local, trained ombudsperson directly accountable to the community

Attendees reported that community members frequently express concern over whether studies are operating ethically in their communities, but they do not know how to “find out.” In a key recommendation, attendees suggested that there should be an ombudsperson, selected by and from the community, who would receive special in-depth training in ethical reasoning, research, and the trial protocol. This ombudsperson could then serve as an informed and trusted resource person for any concerned community members—both helping to explain issues the community is worried about and to take those issues to the research institution or the ethics committee to be addressed.

6) Ongoing community-researcher communication

Aspects of trial design or procedure, such as standard of care and informed consent, may only be judged as ethical or unethical with time, as ramifications become evident to the community. Ongoing evaluation and dialogue provide programmers an opportunity for mid-course corrections as needed.

7) Reduce real or perceived power imbalances between community, participants, and research institutions

Community liaison staff noted that power dynamics affect their ability to promote meaningful community involvement at their



⁶ The issue of “partner consent” is a hot topic in microbicide research. One argument is that if men are likely to be exposed to an unproven product through their partner, they should give their explicit informed consent. Another argument holds that the rationale for women-controlled methods is the lack of partner cooperation when women try to protect themselves, and so expecting women to obtain that consent is unrealistic, in addition to compromising women’s ability to decide for themselves whether or not to participate in the trial. Currently, candidate microbicides are evaluated in separate “penile safety” studies to ensure that they will not harm men whose partners use them in large scale effectiveness trials. For more information on partner consent in microbicide trials, see reports from the Global Campaign for Microbicides Ethics Consultation, October 2003, www.global-campaign.org.



sites. Sometimes the higher educational level, social status, resources, expertise, and authority associated with researchers and their institutions create a perception of greater power. Decades of community members' personal experiences have ingrained the perception of this power imbalance, even though research staff try to be highly sensitive to this dynamic. Scientists may inadvertently reinforce the power gap, for instance, by talking either "above" or "below" community members. This has a direct impact on the degree to which community members feel free to engage directly and on equal footing with the research team.

Power imbalances are a factor in the many myths and rumors that arise in study communities about research teams and their intentions. More than one site reported that the international affiliation of the research institution contributed to rumors that the study was "collecting blood to sell to foreigners." In another research site (in a company-run town), community members thought study team members were spies for the local employer. The politically charged environment of one community led to questions about the research team's political affiliation.

Power imbalances may also exist within research teams. Most community outreach staff who attended the dialogue emphasized that an entrenched hierarchy places them—non-technical staff dealing with "soft" social issues rather than "hard" clinical science—at the bottom rung. This internal power differential not only affects the vigor with which the team approaches community involvement; it can also convey a message that technical expertise has greater currency than community knowledge.

However, one participant offered a caveat to this idea of power imbalances that resonated

with many. She reminded research staff as well as community members to question the presumption of a power imbalance:

"We are too protective of the community. If they are poor and vulnerable it has nothing to do with our research, except narrowly. They can think. They live their lives. We knock on their doors and all of a sudden we have all the power and they have none? That's crazy. They have the power! The onus is with us. We are [creating the power imbalance]."

D. Contributing to Community Capacity and Development

An important concern at the Dialogue, as in the field of HIV prevention research in general, was how the community benefits from the research project. While researchers are obliged to protect subjects from harm and to maximize possible benefit, "benefit" generally refers either to the individual participant, or to society as a whole (in the sense of public benefit from the products of successful research). The social unit that falls in between—and through the cracks of traditional ethical debate—is the community where the research takes place.

Yet host communities do take on risks or burdens, particularly in high-HIV incidence, low-resource settings. Studies may place demands on a community's overstretched resources. For example, women who test HIV-positive and are excluded at screening are often referred to local NGOs or other community-based organizations for counseling and care, creating an additional caseload that these groups may not be prepared for. Study sites may hire health care professionals away from local NGOs or clinics. Research also consumes community leaders, activists, and others' time, taking their attention away from other important community priorities.

Researchers and communities can work to determine what kinds of benefits would offset these community-level burdens in appropriate and acceptable ways, that would not be undue inducement to resource-poor communities, and that are consistent with the research institution's abilities and resources. Discussion at the Dialogue also suggested that community benefit is not merely a matter of *quid pro quo*; the research team should not seek to provide benefit to the community only to the extent that the community has been burdened. Rather, institutions and communities can use the opportunities provided by the research to find practical and creative ways to address a range of development needs they have. If true distributive justice is impossible, securing other benefits for the community offers a way of applying the justice principle to the contexts where research is carried out. Community benefits can therefore be understood as a way to **maximize justice in an unjust environment**.

Several suggestions for how research institution activities can enhance community capacity and development, in addition to meeting the specific needs of the trial, include:

1) Training select community representatives to participate in research design and ethics, and support their participation in decision-making

Community training and participation facilitate trial implementation, but they also help build capacity. Community members acquire skills such as management and meeting facilitation, negotiation with outside professionals and officials, application of theory to their everyday reality, documentation, and communication. They also expand their knowledge of research, HIV, and social issues

such as gender that can enhance their participation in future research, HIV and health interventions, and community development.

2) Share resources and expand available community services

Research institutions often have to invest in the physical infrastructure or expand the services available in a community in order to conduct research there. This investment can have wider benefits if, for example, people can access meeting rooms or other spaces for community activities, if local health personnel receive training and skills that will stay in the community, or if services for trial participants are made more widely available.

3) Prepare community organizations to help translate research findings into government or donor policy

Evidence-based advocacy is highly effective in informing and changing policy, but it requires the convergence of knowledge and action. Research staff can help ensure that their efforts provide the potential for real life impact by collaborating with community organizations to develop sound policy recommendations based on locally-relevant data. They can also help build skills of local organizations' staff to interpret and use data effectively in advocating for change.

4) Build sustainable partnerships between and among research institutions and NGOs

Microbicide research falls at the juncture of several relevant issues and movements. As an emerging HIV prevention technology that also addresses issues of women's vulnerability and empowerment, it fits into the agendas of AIDS activism, women's rights, reproductive health, fair access to essential technologies, human rights, and bioethics.





Microbicide research and advocacy offer the opportunity for synergy across these diverse movements, a cross-fertilization that, until recently, has largely been absent. To the extent that community involvement efforts in microbicide clinical trials engage local organizations and stakeholders, they can help bring these groups into contact and cooperation with each other. The convergence of agendas on microbicides and other issues has the potential to strengthen community organizations and networks.

5) *Assist community organizations in accessing resources and influencing decision-making that affects the community*

In many of the countries where trials are taking place, international donors and

national governments are also active in scaling up funding for HIV-related projects. Though these agencies may not fund research, they do fund community-based programs that raise awareness, deliver services, reduce stigma, and promote human rights. Staff at research institutions may have more information and access to these potential donors. In addition, they have experience planning programs, writing proposals, and networking with donors and decision-makers at national and international levels and can support the community in implementing projects on their own. A research presence can be attractive to donors, who may recognize a chance for multiplying the impact of their investment by collaborating with the ongoing activities associated with the research.



Part V: Special Issues for Community Involvement in Microbicides Trials

Why My Community?

At the initial stages of a research project many community members may be suspicious and defensive about being the subjects of research. This is a common and logical reaction. Dialogue participants began to refer to this as the “Why us?” Question (i.e., “Why have you chosen our community to do this research?”) Nearly every site reported encountering some level of suspicion and skepticism from the community, despite outward support for the research. Community liaison staff understood the question as a rational response to several factors:

- **Fear of exploitation.** A shameful history of past exploitation of disadvantaged communities has left many people suspicious of research in general. People are concerned that their community has been chosen because it is cheaper to do research there, or because they are seen as easily influenced or expendable.
- **Fear of harm.** The concept of vaginal gels is unfamiliar in many of the regions that currently host microbicide research. As with any novel product, it is met with suspicion and fear that it could harm women.

A separate concern revolves around the research protocol. Like any HIV preventive protocol, a microbicide research protocol can imply that investigators are “trying to find” new HIV infections, possibly contributing to a belief that research either directly exposes women to HIV, or that

researchers “hope” to see HIV spread in the community. This interpretation reflects a real challenge facing the communication efforts of research projects. It is hard to effectively communicate the distinction between an epidemiologically based expectation that new HIV cases will occur and the goal of the study.

- **Lack of direct benefit.** People have heard about research that generated knowledge or interventions that never reached the host community. They wonder whether they are being used to generate data that will result in profits and prestige for foreign corporations and no benefits for them or their community.
- **HIV stigma.** Hosting an HIV study can exacerbate a community’s reputation as a “high AIDS” area.

Dialogue attendees understood the rational basis behind these concerns, and brainstormed ways to better communicate the reasons for selecting particular communities for research. They saw information about who funds and conducts microbicide research as helpful in allaying fears about exploitation. Sponsors of microbicides research are generally non-profit, publicly-funded entities, not major pharmaceutical corporations seeking to increase their profits and market share. The microbicides field has a strong advocacy arm and is committed to making microbicides affordable and accessible. Participants also noted that emphasizing the difference between research—and its



potential benefits in the future—and direct health and social interventions that presumably have immediate impact helps set boundaries for community expectations and avoids disappointment.

Staff of one site described how they responded to the community concern that participating in the trial would put women at greater risk of HIV. They graphically illustrated data from previous trials showing that HIV incidence generally goes down for all women in the trial, regardless of whether they are receiving the active gel or the placebo. (This is due to the fact that participants are simultaneously receiving STD diagnosis and treatment, state of the art condom counseling and support, and may be bringing their partners in for consultation with the study team.) The site staff also described the impact of simply describing the study differently; rather than saying the data would compare how many women sero-converted in each arm of the trial, they emphasized how it would show “how many infections were prevented when women used the microbicide.”

A challenge for trial site staff is how to manage media and other public communications about the research. Dialogue participants recommended framing public messages in the contexts of a community’s assets rather than risk factors, emphasizing a community’s interest and capacity to participate in research, rather than its demographics, HIV or STD incidence, behavioral patterns, etc., and how this influenced its selection as a site.

Working Within Cultural Traditions and Gender Dynamics

Microbicides and microbicide trials can challenge certain cultural traditions related to sex, sexuality, and male-hierarchical gender

norms. Discussion around the following topics was quite lively.

- **Virginity Testing.** In some regions where microbicide studies are underway, “virginity testing” of young women is practiced. These communities highly value young women’s virginity, and any effort to recruit younger women into microbicide trials is seen as a violation of that community norm since such recruitment efforts imply that young women in the community are sexually active.
- **Dry sex.** While the prevalence and contextual meaning of “dry sex” is unclear, the practice is often cited as a barrier to microbicide use. “Wet sex,” in which the vagina is lubricated, is disfavored because it suggests the woman is unclean or unfaithful. Vaginal gels like microbicides add lubrication.
- **“Woman-controlled” methods.** Researchers and community members are increasingly hesitant to call microbicides a “woman-controlled method.” The term, and the concept of female control over aspects of sexuality, can be threatening to traditional beliefs of male sexual dominance.

“Once you say something is “female controlled,” my wife is given the right [sexually] to say no, not today, maybe tomorrow.”

These challenges represent real contradictions between research and community cultures, and have concrete repercussions. Some sites report difficulties with enrollment and retention specifically resulting from pressure on the women from male partners unhappy with the implications of the research. Some communities have actively opposed recruitment of younger women. Also, women who enroll in trials may face ostracism or be overtly disrespected.

Community liaison staff, advocates and researchers are often frustrated and wish to challenge these cultural norms. In the field, however, Dialogue participants walk the line between challenging and working within these constraints, while taking care not to overtly legitimize men's exclusive power over sexual decision-making. The foremost strategic approach is to launch comprehensive communication and outreach strategies that **include men**. Sites have encouraged men to become actively involved in the research. Men are encouraged to accompany their enrolled partners to clinic visits, creating an opportunity to assuage fears and educate them about microbicides, sexual health and partnerships. Men have joined CABs, and while some attendees felt CABs should contain more women than men, most supported broad CAB membership without any kind of gender-based quota.

These efforts at involving men in ways that acknowledge, without necessarily condoning, gender norms have had positive results. Participants reported that some men who previously opposed the research now actively support microbicide studies and have become spokespeople for the effort, educating other men in their community. Another approach is to involve local organizations that have a gender-based analysis in designing communications that can be enlightening without alienating key community allies.

“Therapeutic Misconception,” or Expectation of Protection

One of the greatest challenges faced by trial site workers is familiar to all clinical researchers: combating the unrealistic hope for personal benefit among trial participants. Some study participants actively express hope that they have received the candidate microbicide and not the placebo, which

demonstrates a belief, despite education to the contrary, that the gel “works.” Others, noting an improvement in sexual or overall health since enrolling in the study, may (falsely) attribute these changes to the gel rather than to other study interventions, such as routine treatment for bacterial STDs. Despite diligent efforts to help trial volunteers understand that neither the gel nor the placebo is known to work- including several sessions of education, feedback, and evaluation of comprehension- therapeutic misconception lingers among some participants.

*“Most of the participants who completed [our] study were women who said, ‘since I started using this gel our sexual life has improved at home, so this is the real one [i.e., the candidate microbicide]. Look at my hair, my complexion, I have gained weight,’ and you listen and she is convinced it's the gel. **It is motivating her to use it and to come regularly for their visits.**” [emphasis added]*

Therapeutic misconception is hard to prevent. Unrealistic beliefs are common in any therapeutic or preventive study, whether people are poor or wealthy, community members, or researchers (Applebaum et al, 1987). Misconceptions can evolve over the course of the trial, even when people fully understand information presented at the beginning. Dialogue attendees felt strongly that they had a responsibility to correct these beliefs.

Several strategies to counter therapeutic misconception emerged from the discussion:

1) Emphasizing the experimental nature of research and “biological plausibility.”

Community liaison staff must find the right balance of information for research participants. Some Dialogue attendees emphasized the need to educate trial participants on



important research terms like randomization, blinding, placebo, etc. Others remarked that too much or too technical information could be overwhelming to participants and could actually undermine comprehension. They focused on two concepts as key to minimizing therapeutic misconception: 1) the **experimental nature** of research, i.e.—no one can know whether the gel works or not until the end, and 2) “**biological plausibility**” i.e.—based on the gel’s intended purpose and mechanism of action, what effects can reasonably be attributed to gel use and what cannot.

2) **An ongoing informed consent process.**

Participants from all sites described informed consent as a process that continues throughout a volunteer’s participation in the trial. Providing time for potential participants to consider information before enrolling, assessing comprehension, and periodic refreshers of key concepts are fairly standard procedures for informed consent. Nevertheless, several participants were concerned about what they perceived as a gap between the information they provide and participants’ interpretation. According to one attendee:

“A lot of the way we do informed consent is giving information and then doing either verbally or in some other method a quick assessment of did they get the facts, whatever the facts are that you represent. And I think what that misses is really trying to work with women to understand how they are using the information in their thought processes.”

The Population Council has developed a video to help explain the research concepts to potential participants. Other sites are exploring creative communication methods as well. More qualitative research at sites, possibly using ethnographic interview tech-

niques, could help staff understand how the information (as understood by participants) influences their behavior and decision-making.

3) **Direct contradiction of erroneous beliefs.**

Counselors can proactively confront erroneous beliefs about gel efficacy. By asking participants if they have heard their peers claim they are using “the good gel,” or telling stories about *other* women who believed they had “the gel that worked” but were mistaken, counselors not only help correct the misconception but may also enlist participants’ help in refuting these beliefs among their peers.

4) **Reinforce safe behaviors.**

Reinforcing what does work (e.g., reducing one’s number of partners, using male and female condoms consistently, and seeking prompt treatment of STD symptoms) can help counter the effects of therapeutic misconception and increase participants’ safety.

Structuring Messages About Effectiveness

Microbicides will possibly reduce the risk of transmission of HIV, but they will probably not be 100 percent effective. Communicating “partial effectiveness” is a crucial part of raising awareness about microbicides. Dialogue attendees discussed the challenges involved in “messaging” about microbicide effectiveness, and how to shape advice and expectations about microbicides.

Discussion of microbicides has traditionally taken a “heirarchical” approach. This is a two- or three-tiered message such as:

- 1) A microbicide used with a condom will provide additional protection.
- 2) A male or female condom alone will be the next most effective option.

3) A microbicide alone will be better than nothing.

Even when talking about microbicides in the abstract, it is important to explain partial effectiveness and not to imply that they will be a substitute for condoms. However, research staff reported that a common reaction from community members is, “How can we support something that is not 100 percent effective?” or “Why bother if it will never be as good as a condom?”

Participants offered several ways to respond to these concerns:

- Analogies to other preventive public health measures like tooth-brushing and wearing seatbelts. Tooth brushing is not 100 percent effective and yet people do it since it helps prevent disease.
- Mathematical modeling that has demonstrated the potential impact of partially effective microbicides on the overall epidemic.
- Citing local or national data about how infrequently women are actually able to negotiate male or female condom use, particularly with their primary partner.

Managing Expectations: Staging Information?

It is the nature of research that not everything turns out as expected. Microbicide research is a process that can be stopped, interrupted, or diverted at any time. Products that look promising in Phase 1 trials may not show good results in Phase 2. Researchers may prepare for a Phase 3 trial by conducting a feasibility study in a community, only to discover that the site is not appropriate for the trial after all. This is not always bad news. For example, a Phase 3 trial may not go forward as planned because the incidence of HIV in the community is too low for data

to show an effect of a microbicide, which is good for the community. This process helps protect communities from harmful, superfluous, or inappropriate research. But such changes can be disappointing to a community and damaging to the relationship with the research team. Some Dialogue participants who had similar experiences reported that communities complained that their involvement had been in vain, and felt a breach of trust had occurred.

An important insight offered at the Dialogue was that the community involvement efforts themselves may be partly to blame. The emerging standard is to engage communities early on, and broadly educate them about microbicides and the proposed research as soon as possible. This approach however, may be “too much, too soon.” Seeking to build a dynamic a partnership with communities, community outreach workers and researchers may end up raising expectations and setting the stage for frustration and ill will.

A suggestion offered to address this problem was to “stage” community involvement efforts in a manner that better matches the timing of information outflow and the level of community engagement.

Two variants of this idea were offered:

- 1) **More effectively target who gets the information**, providing information on an “as-needed” basis. Research participants would receive more information and education than would regular community members.
- 2) **Slow down the dissemination of information**, “phasing in” information gradually, as the research enters each new phase. In the feasibility phase, researchers would convey basic



information about HIV, research methods and participant rights, saving specific details about protocols and microbicides until the trial is closer to implementation.

In extensive discussion, however, attendees said these ideas raised several red flags. Generally, they were concerned that a staging process lacked transparency and compromised respect for the community.

Specific concerns were:

- Providing information on an “as-needed” basis ignores the natural communication patterns in communities, in which information is quickly circulated through informal networks.
- Gradually “phasing in” information could make it hard to explain the ultimate goals of research. One person noted that there is value in providing a fairly thorough explanation of the entire process even at an early feasibility phase, otherwise the sense of goals (“feasibility for what?”) is lost.
- Explaining later phases up front in the feasibility phase also shows respect to participants, who are being asked sensitive questions about their sexual behavior.
- Erring on the side of more information helps correct the power imbalance between researchers and communities. As another attendee noted, *“I think we need to be sharing the information because half the time we have an agenda when we go to the communities.”*

Attendees also underscored the importance of comprehensive communication, despite its difficulties and risks:

“In one of the community meetings...once we gave the explanation as to what is feasibility

and why do we need a feasibility study, they really understood it... It is very important for us as community educators not to undermine the people’s understanding [by leaving information out]. We need to give them information.”

Another advantage of providing full information to communities is that these efforts can set the groundwork for community mobilization for microbicide advocacy.

An early awareness phase: comprehensive education and linkages

Dialogue attendees did express support for the idea of a preliminary, pre-research phase of general awareness-raising about microbicides, AIDS and research, that would occur even prior to a feasibility study. In this pre-trial phase, the research team would work closely with existing NGOs and other partners to articulate the impact of HIV in the community, discuss how research can help address the problem of HIV and AIDS, and identify existing resources to help support the community. In addition, it could be an opportunity to begin to publicly distinguish research from service delivery and intervention programs, and explain who the research team is and who they represent, including making the distinction between public and privately-funded research. This may also be the time to promote a gender-based perspective on HIV that looks at women’s vulnerabilities and men’s involvement in confronting the epidemic, and introduce the possibility of female-oriented prevention methods such as microbicides. Some multi-study centers that conduct a range of HIV prevention research and have greater financial flexibility have begun to implement this approach.



Part Six: Recommendations

Based on discussions at the Dialogue and with research sites, the following recommendations for achieving meaningful community involvement in clinical trials are offered.

1) Integrate multiple strategies into a Community Involvement Plan rather than a single mechanism

In the dynamic and complex world of international research collaborations, a one-size-fits-all approach is insufficient for mobilizing effective partnerships between researchers and community. Instead, research institutions and communities can borrow strategies from several disciplines and areas of expertise to fulfill the goals and tasks of community involvement in research. A comprehensive Community Involvement Plan, ideally developed in collaboration with the community itself and drawing from the community's existing strengths, should form the foundation of today's community involvement efforts.

Elements of this plan could include a CAB or other structured advisory group, a funded position for a community advocate or ombudsperson, or small grants to local NGOs.

2) Expand training for community liaison staff and community members

In order to better implement a multi-strategy community involvement plan, programs must invest in building the capacity of site staff, as well as those community members involved with the outreach, advisory structures or other aspects of research implementation.

Training areas recommended for community involvement staff include:

- Community mobilization and advocacy.
- Skills for facilitating Participatory Action Research.

Training areas recommended for both staff and community members include:

- Contextual knowledge and analysis of HIV and AIDS, particularly how it affects development and the community, including the effects of stigma or fear.
- Gender analysis of health, HIV and AIDS, and community development.
- Ethical principles and reasoning, particularly in terms of application to decision-making in research settings.

Dialogue participants emphasized creative ways to access such training and focused on exchanges between research institutions and community organizations. For example, local NGOs with expertise in gender issues could facilitate a training for both the research staff and the CAB or broader community. In exchange, they might receive technical assistance for integrating HIV prevention into their regular program.

3) Leverage and integrate resources for community involvement activities and outcomes

A frequent concern cited in discussions about expanding community involvement and related activities is the potential for



additional cost in already tight budgets, or the implied commitment to supporting activities or infrastructure not directly related to the needs of the trial. While advocates support increased discretionary spending for community involvement within research budgets, all recognize that research institutions cannot support every initiative the community envisions. In fact, such an expectation would conflict with broader goals of mobilization, empowerment, and sustainability.

Research teams can, however, work with communities to identify possibilities for integrating funding or leveraging additional funding. Collaborating with other institutions or services, especially in introducing facilities required for scaling up other programs (for example, education and communication, VCT, STD diagnosis and treatment, care and support for HIV positive individuals) is one way. Together researchers and communities can pressure national and local governments to uphold commitments to ensure access to basic services. And international advocates working together with research teams and mobilized community organizations can look to bi-lateral and multi-lateral donors, including the Global Fund to fight AIDS, Tuberculosis and Malaria, to prioritize areas where research is taking place in their grant-making and programming.

4) Develop indicators and expand evaluation efforts

Finding ways to evaluate, document, and assess the impact of involvement on both the research outcomes and community development will allow staff to fine-tune and adapt new and emerging models and strategies. It will also help mobilize greater political will, participation, and resources.

There is general consensus about the need for specific indicators to evaluate community involvement. Debate continues, however, on what those indicators should measure, and how data should be collected. HPTN has a designated working group on indicators (see resources), and many organizations and networks are working on evaluating their own programs.

Some indicators, culled from several sources include:

Scientific and ethical indicators:

- Rates of volunteer retention.
- Long-term comprehension of research concepts and protocol.
- Levels of compliance with research protocol (both self-reported and independently validated).
- Effective management of rumors.
- Number of volunteers screened who feel free not to enroll in the trial.

Partnership and mobilization indicators:

- Number of community members or organizations receiving training or capacity-building.
- Times when community input went against research policy.
- Times when such advice was implemented, i.e., policy changed or adapted to reflect community concerns.
- Acceptability of disagreement and debate within structures.
- Reduction in HIV-related stigma over the course of the research project.

- Sustainability of infrastructure or services set up or expanded by the research institution.
- Times when structures established by research team have taken on other projects.
- Resources leveraged through partnership between research institutions and community bodies.

Methods for evaluating community involvement may include participatory action research, surveys, review of notes from CAB and research staff meetings, and in-depth interviews of key stakeholders.

5) *Advocate with research institutions and donors to support a mobilization framework for community involvement*

For better or for worse, research programs are currently donor-driven. In order to implement more mobilization-oriented,

sustainable programs, donors need to provide the mandates and sufficient resources to support community involvement. Local and national governments have a key role to play as research gatekeepers.

6) *Develop mechanisms for sites to share experiences, outputs, and lessons learned with each other*

Participants at the Dialogue identified common needs for information and resources that could be shared among them. These include:

- A lexicon of research terms conveyed in lay language.
- Materials on microbicide trials produced for community outreach or participant education.
- Opportunities for continued exchange with and learning from other sites.





Conclusion

As HIV infections among women increase, it is imperative that the international research and advocacy communities use every tool at their disposal to expand prevention options. Microbicides clinical trials are underway in many countries in Africa and around the world, and more will be launched in the near future. The quality of community involvement in these trials will undoubtedly have an impact on their success, and thereby on the timely discovery of a safe and effective microbicide. Community involvement can enhance the scientific validity of the data collected by minimizing the misunderstandings and barriers to participation, adherence, and follow-up. Working in meaningful ways with communities

can ensure that ethical principles are applied to the real world research settings, in ways that are understandable and agreeable to all stakeholders, and that will stand up to the test of time. Mobilizing communities around HIV research and microbicides in general can ease the way for proven safe and effective products by creating networks of informed local advocates and experts. Finally, community involvement done through a mobilization framework can help build a base of skills and experience that contributes to health, well-being and social change in communities. Researchers, institutions, donors, governments, and advocates must meet the opportunities head on, with time, resources, and the spirit of genuine partnership.



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Resources and Links

AIDS Vaccine Advocacy Coalition
www.avac.org

Centers for Disease Control and Prevention: Microbicides Research Program www.cdc.gov/hiv/PUBS/microbicides.htm

Global Campaign for Microbicides
www.global-campaign.org

Health Communications Partnership
www.hcpartnership.org

HIV Prevention Trials Network
www.hptn.org

HIV Vaccine Trials Network
www.hvtn.org

International AIDS Vaccine Initiative
www.iavi.org

International Partnership for Microbicides www.ipm-microbicides.org

Microbicides 2004 Conference
www.microbicides2004.org.uk

Medical Research Council UK
www.mrc.ac.uk

Medical Research Council South Africa
www.mrc.ac.za

Population Council www.popcouncil.org

Reproductive Health Research Unit
www.rhru.co.za

South African AIDS Vaccine Initiative (SAAVI) www.saavi.org.za



Appendix 1: Outline for Site Presentations

Dialogue on Community Involvement in Microbicide Clinical Trials *Proposed Framework for Site Presentations*

We are asking each site to prepare an overview of current community involvement activities and programs to present at the meeting. These questions are meant to serve as an outline for site presentations. Not every site will have answers to all these questions, and you may wish to include additional information outside of this outline. You can use this outline for discussion with the research team and community groups to guide your presentation for the Dialogue meeting. Presentations should be about 20-30 minutes long. Please contact Megan Gottemoeller with any questions. Mgottemoeller@path-dc.org

1. Short description of the community you work in (two or three slides):

- Demographics – urban/rural/peri-urban
- Mix of employment types
- Previous experience with research (see below)
- Level of social organization (presence of existing community groups, NGOs, extension services, etc).
- Migration patterns – how mobile is your community?
- Level of general knowledge about HIV and HIV transmission

- Level of stigma
- Any other distinguishing/important features

2. Description of your current microbicide work and research set up (one or two slides)

- Description of the research institution to which your project is attached
- Is this one of many research projects your institution is managing locally or is your group convened specifically for microbicide work?
- Purpose of current microbicide project
- Description of individuals being recruited (how and from where)
- Description of site set up (clinic maintained by research staff? VCT center? Public STD clinic?)
- Description of current study staffing structure (e.g., are there specific community liaison officers, are these the same people who recruit individuals for the study, etc.)

3. Description of past research projects the site has been involved with (one slide):

- Purpose of research (e.g., earlier microbicide work, vaccine, MTCT, adolescent health)
- Did the same researchers as those conducting the microbicide work lead these projects?



4. Describe the history of community involvement activities at your site (two - three slides):

- What were the initial goals and motivations for engaging with the community?
- Did you develop a specific plan for community involvement at first?
- How did you first go about it?
 - What, if any thing, was done to gain entry and acceptance by the community for current or past research?
 - How did community members/leaders respond?
 - What issues arose in the early days of community engagement?

5. Community working groups/advisory boards (two - three slides):

- Have any formal structures been convened to facilitate community engagement?
- Are these specific to microbicide trials or do they serve a variety of research projects?
- How have these been organized and managed?
- What was the original impetus for creating these structures?
- What challenges have you faced in conceptualizing and maintaining these groups (the more detail you can give her the better!)

- What do you perceive as the primary function(s) of such groups? (e.g., building political support, giving input on protocols, etc.)
- What issues have arisen for you and your site from efforts to organize and maintain such groups (e.g., how to sustain interest, how to define membership, etc.)
- How does the research staff relate to the community structure (in terms of roles, responsibilities, etc.)?

6. Community-related issues and concerns (one - two slides):

- What are the primary community issues/concerns that have come to your attention through the above mechanisms?
- How have these been managed?

7. Overall reflections:

- How would you describe your current goals and objectives in community involvement activities?
- Has your approach evolved or changed over time?
- What did you learn from initial experiences that informed these changes?
- What uncertainties/worries are you still grappling with?

What additional opportunities/resources would help you do your job better?



Appendix 2: Participants

Dudu Biyela

Africa Centre
PO Box 198
Mtubatuba 3935
South Africa
Tel. +27 35 550 7513
Fax +27 35 550 7565
biyelad@mrc.ac.za

Kelly Blanchard

Associate
Ibis Reproductive Health
PO Box 1985 , Parklands
Johannesburg, South Africa
Tel. +27 11 646 7264
Fax +27 11 486 1501
Mob. +27 82 453 4549
kblanchard@ibisreproductivehealth.org

Kata Chillag

Investigator (Social Science)
Centers For Disease Control and Prevention
(CDC)
8 Corporate Building
MSE –B 45
Atlanta, GA 30329
Tel. +1 404 639 0948
Fax +1 404 639 6127
Centers for Diseases Control/ HIV Epi Branch
kjc7@cdc.gov

Brendon Christian

Gender AIDS Forum
Suite 108, 1st floor
Sangro House, 417
Smith Street, Durban
Tel +27 31 307 1253
Fax +27 31 307 1254
genderaids@mweb.co.za

Alana de Kock

Research Coordinator
Department of Public Health and Family
Medicine Health
Sciences Faculty; University of Cape Town
Anzoi Road Observatory 7925
Cape Town, South Africa
Tel. +2711 406 6716
Fax +2711 406 6713
dekock@cormack.uct.ac.za

Kim Dickson

Director: Regional Development
Reproductive Health Research Unit
Chris Hani Baragwanath Hospital
Department of Obstetrics and Gynaecology,
University of Witswatersrand;
P O Bertsham 2013
Johannesburg Soweto
South Africa
Tel. +2711 933 1228
Fax +2711 989 9298
kimdt@rhrujhb.co.za

Michelle Folsom

Africa Regional Coordinator
PATH
A.C.S. Plaza, 4th floor,
Lenana and Galana Road,
P.O. Box 76634
Nairobi 00508 KENYA
Tel. 254 2 577 177
Fax 254 2 577 172
mfolsom@path.org



Megan Gottemoeller

International Programs Coordinator
 Global Campaign for Microbicides
 C/o PATH
 1800 K Street NW, Suite 800
 Washington, DC 20006 USA
 Tel. +1 202 822 0033
 Fax +1 202 457 1466
 mgottemoeller@path-dc.org

Julie Hantman

Public Health Policy Analyst/Writer
 6339 31st Street NW
 Washington DC USA 20015
 Tel. +1 202 364 4743
 Fax +1 202 318 7788
 juliehantman@yahoo.com

Lori Heise

Director
 Global Campaign for Microbicides
 1800 K Street NW, Suite 800
 Washington DC, 20006
 Tel +1 202 454 5028
 lheise@path-dc.org

Vinen Kubeka

Community Liaison Officer
 Reproductive Health Research Unit
 Chris Hani Baragwanath Hospital
 Department of Obstetrics and Gynaecology,
 University of Witwatersrand;
 P O Bertsham 2013
 Johannesburg Soweto
 South Africa
 Tel. +2711 933 1228
 Fax +2711 989 9298
 v.kubeka@rhrujh.co.za

Connie Lefowane

Youth Volunteer Peer Educator
 Youth Health Organization/BOTUSA
 P O Box 90
 Gaborone, Botswana
 Tel. +267 722 7511
 Fax +267 393 3537
 sconu@yahoo.com

Mabitso Marumo

Senior HIV/AIDS Councillor
 Population Council/MEDUNSA
 Department of Psychology,
 P O Box 182 Medunsa 0104
 Pretoria, South Africa
 Tel. +27 12 521 4404
 Fax +27 12 521 5906
 bitso@medunsa.ac.za

Margaret Mlingo

Project Coordinator
 UZ-UCSF
 15 Phillips Avenue, Belgravia,
 Harare Zimbabwe.
 Tel. 2634704890/920
 Fax 2634704 897
 Mob 091 236 338
 margaret@uz-ucsf.co.zw

Dimakatso Molete

Community Liaison Officer
 Population Council/MEDUNSA
 Department of Psychology,
 P O Box 182 Medunsa 0104
 Pretoria, South Africa
 Tel. +27 12 521 4404
 Fax +27 12 521 5906
 Pop Council MEDUNSA
 tsitso2002@yahoo.com

Neetha S Morar

Senior Scientist
MRC Durban, HPRU
491 Ridge Road
Overport 4092
Durban, South Africa
Tel. +2731 203 4745
Fax +2731 403 4702
moram@mrc.ac.za

Kennedy Mundia

Community Liaison Officer
MDP Zambia,
P O Box 670555
Mazabuka Zambia
Tel./Fax +260 032 30868
Kenlove4@lycos.com

Richard Mutemwa

Social Scientist/ Community Involvement
Coordinator
Microbicides Development Project
University of Southampton
Dept. of Social Stats
Highfield, UK S017 1BJ
Tel. +44 23 805 97988
Rim1@socsci.soton.ac.uk

John Mutsambi

Community Liaison Officer
UZ-UCSF
15 Phillips Avenue, Belgravia,
Harare, Zimbabwe
Tel. 2634704890/920
Fax 2634704 897
Mob. 091259661
john@u2-ucsf.co.zw

Oliver Mweemba

Social Scientist
MDP Zambia,
P O Box 670555
Mazabuka Zambia
Tel./Fax +260 032 30868
mweebao@lycos.com

Catherine Ndinda

Social Scientist
Africa Centre
PO Box 198
Mtubatuba 3935
South Africa
Tel. +27 35 550 7513
Fax +27 35 550 7565
Catherine.ndinda@mrc.ac.za

Paul Ngcobo

Community Liaison Officer
MRC Durban, HPRU
491 Ridge Road
Overport 4092
Durban, South Africa
Tel +27 31 203 4745
Fax +27 31 203 4703
pngcobo@mrc.ac.za

Veronica Ngcozela

Community Liaison Officer
Department of Public Health and Family
Medicine Health
Sciences Faculty; University of Capetown
Anzoi Road Observatory 7925
Cape Town, South Africa
Tel. +2711 406 6716
Fax +2711 406 6713
ngcozela@cormack.uct.ac.za

Sbusiso Nhleko

Community Liaison Officer
MRC Durban/Hlabisa
PO Box 685
Hlabisa, 3937
Tel. +27 35 838 1139
Tel. +27 83 335 5235
snhleko@mrc.ac.za



Busi Nkala

Project Coordinator
Reproductive Health Research Unit
Chris Hani Baragwanath Hospital
Department of Obstetrics and Gynaecology,
University of Witwatersrand;
P O Bertsham 2013
Johannesburg Soweto
South Africa
Tel. +2711 933 1228
Fax +2711 989 9298
b.nkala@rhrujh.co.za

Smangaliso Ntshela

Community Mobile Project Leader
MRC Durban, HPRU
491 Ridge Road
Overport 4092
Durban, South Africa
Tel +27 31 203 4745
Fax +27 31 203 4703
sntshela@mrc.ac.za

Annalie Pistorias

Head of Behavioral Division on Microbicides
Population Council/MEDUNSA
Department of Psychology,
P O Box 182 Medunsa 0104
Pretoria, South Africa
Tel. +27 12 521 4364
Fax +27 12 521 5906
annalie@medunsa.ac.za

Ethel Qwana

Project Coordinator
Reproductive Health Research Unit
Chris Hani Baragwanath Hospital
Department of Obstetrics and Gynaecology,
University of Witwatersrand;
P O Bertsham 2013
Johannesburg Soweto
South Africa
Tel. +2711 933 1228
Fax +2711 989 9298
e.qwana@rhrujh.co.za

Malebo Rathlagana

Recruitment Officer
Population Council/MEDUNSA
Department of Psychology,
P O Box 182 Medunsa 0104
Pretoria, South Africa
Tel. +27 12 521 4404
Fax +27 12 521 5906
Mrathlagana2002@yahoo.com

Dawn Smith

Assoc. Director for Microbicides Research
BOTUSA Project
Box 90
Gaborone, Botswana
Tel. +267 3901 696 x 157
Fax +267 3973 118
Mob. +267 7131 5084
dsmith1@cdc.gov

Vicci Tallis

Health and Development Networks
Gender AIDS Forum
33 Fairfield Road
Hillaru, 4093
Durban, South Africa
Tel. +27 31 464 3929
Fax +27 31 464 5323
vicci@mweb.co.za
genderaids@mweb.co.za

Victoria Xolo

Community & Service Liaison Officer
Africa Centre
PO Box 198
Mtubatuba 3935
South Africa
Tel. +27 35 550 7513
Fax +27 35 550 7565
xolov@mrc.ac.za

