THE FIRST 55 STEPS:

A Report of the
Microbicide Development Strategy's
Civil Society Working Group

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Contents

The Microbicide Development Strategy (MDS) was published in 2006 to serve as a prioritisation framework for decision-making by funders, researchers and developers. Unfortunately, few civil society, developing country or advocacy voices were included in its creation. To address this gap, the Global Campaign for Microbicides convened a Civil Society Working Group to craft a comparable framework for civil society involvement in the field.

This report:

- Provides an overview of the status of civil society engagement in each phase of microbicide research, development and introduction and
- Identifies the resources and specific action steps needed to move from the current level of engagement (which is minimal, scatter-shot and under-resourced) to where we need to be (with civil society engaging as a full partner).

Thus, it serves as the missing chapter of the MDS and is understood as such by the MDS' authors.

Executive Summary

BACKGROUND

In 2005–2006, the Microbicide Donors Committee — representing 14 funding agencies and governments currently supporting microbicide research — spearheaded a consultative process to develop a *Microbicide Development Strategy* (MDS). The MDS analyses the field's progress and remaining critical gaps in the areas of:

- Basic and preclinical science,
- Clinical research,
- Manufacturing and formulation, and
- Commercialization and access.

It does not, however, explicitly address progress and gaps regarding civil society engagement as a sometimes integrated, sometimes discrete effort that needs to occur across the entire arc of microbicide research, development, approval, access planning, and monitoring. When this omission was identified, a donor agreed to underwrite the process of exploring how civil society groups can and should be involved in the field now and in the future.

The Global Campaign for Microbicides led this process by convening a Civil Society Working Group in 2006–2007. This tightly focused group explicitly chose not to assemble a "laundry list" of all the complex changes that need to be effected to realize its goal. Like the MDS, it focused on articulating "a strategic framework for action by identifying the gaps where action is urgently needed and by proposing ways to move forward"—but this time from a civil society perspective.

To accomplish this, the Civil Society Working Group:

- Explored the ways in which civil society actors, working hand-in-hand with research institutions, industry, and governments, can contribute to creation of an enabling environment for microbicide research and development,
- Assessed gaps, from a civil society perspective, in the current microbicide research and development process,
- Generated recommendations aimed at promoting stronger civil society engagement and ensuring that critical elements of the enabling environment are supported.

The Working Group defined "civil society" as a wide spectrum of nongovernmental organisations (NGOs) and advocates, inclusive of both of the groups usually identified by clinical trials as "community members," and stakeholders outside the parameters of the geographic locale surrounding a research site. Thus, civil society engagement refers to a broader scope of activities and a wider range of actors than is generally the case for community involvement as it is commonly understood.

The Civil Society Working Group pinpointed dozens of gaps that need attention but chose to focus its analysis specifically on the seven issues that were *both* of greatest concern to civil society *and* that, if addressed with targeted investments of energy and resources, could result in the most immediate benefit to the field. It then articulated seven priority actions needed to address those gaps. To make its recommendations as specific as possible, the Working Group broke down those priority actions into 55 interlocking implementation

steps—concrete activities that, if undertaken, should generate real progress toward the goal of assuring full civil society integration into the field at all levels.

The seven gaps that met the aforementioned Working Group criteria, and the priority actions needed to address them, are:

Highest Priority Gaps	Priority Actions
Insufficient investment in building sustainable research capacity and health care delivery infrastructure in trial communities.	Use microbicide trial site development investments as opportunities to ratchet up local health care infrastructure and expand human capacities for research and health care delivery in ways that provide durable local benefit.
Lack of formal mechanisms and opportunities for civil society engagement and transparent communication with researchers throughout the research process.	Develop mechanisms to increase civil society's engagement across the entire arc of research, development, and product introduction and to improve communication among researchers, sponsors, developers, and civil society.
Inadequate civil society participation in monitoring and accountability across the field.	Create more structural opportunities and build capacity for civil society participation in the monitoring bodies that guide microbicide research and development.
Insufficient investment in science-focused microbicide advocacy.	Invest in initiatives to increase advocacy participation by microbicide scientists and the scientific expertise of microbicide advocates.
Lack of widespread, timely dissemination of results to microbicide stakeholders and the general public.	Improve systems for rapid and user-friendly dissemination of trial results and *their implications* to stakeholder groups and the general public through multiple communications channels.
Lack of civil society involvement in defining plans for acceptability, affordability, sustainable access, and marketing work to maximize microbicide uptake among key populations.	Utilize the existing expertise of civil society actors in current efforts to develop product introduction, distribution and marketing plans.
Lack of effective civil society influence on product regulatory bodies.	Create structural opportunities and build capacity for civil society to have meaningful input into regulatory processes.

The Civil Society Working Group then assessed the role that each of the four sectors within the microbicide field—researchers, donors and trial sponsors, government policymakers, and civil society actors—plays in addressing

these gaps and assigned each of the 55 interlocking action steps to a specific sector. These proposed assignments, together with a picture of how the steps connect with each other, comprise the body of this report.

EXAMPLE. ACTION STEPS BY SPECIFIC SECTOR FOR PRIORITY ACTION #2: Developing mechanisms to increase civil society's engagement

Civil Society	Governments/ Policymakers	Researchers/ Principal Investigators	Funders/Sponsors/ Research Institutions
Work to develop the knowledge base needed to serve on peer review committees, advisory and planning boards, institutional review boards, etc. effectively; request such opportunities.	Increase the number of dedicated civil society seats on national planning and regulatory bodies.	Identify civil society actors who can impact the achievement of research goals and establish transparent opportunities for ongoing communication with them.	Fund mechanisms to facilitate communication between researchers and civil society, including efforts by civil society to build their own science literacy and, thus, capacity for productive participation in the microbicide development and access process.

Each sector is uniquely positioned to take the specific actions assigned to it. Each also benefits in its own way — and the field benefits as a whole — from greater civil society involvement across the entire arc of microbicide research, development, introduction, and access.

Solving the Money Problem

The life blood of civil society engagement is money, capacity, and access. Most civil society entities simply cannot afford to "skill up" and "staff up" to the extent necessary for greater engagement. To maintain their current workloads and follow through on their share of the activities outlined in this report, they need more leaders, more managers, more staff training and development (especially in the area of "research literacy"), and enhanced access to communications technology. Without these, they will fail, even if offered every opportunity for full participation in the microbicide research and development process. They will simply be too over-stretched and under-prepared to take on the additional work.

At present, very limited support is available through foundations and other funders for HIV prevention advocacy, much less for the kind of capacity-building that full civil society integration into the field requires. Large funders have understandable difficulties with making grants to small and medium-sized NGOs. A grants-making window, designed to funnel resources from larger grantmakers to smaller NGOs, is one potential method of efficiently routing much-needed capacity-building money to well-situated civil society entities that are demonstrably committed to increasing their active involvement in this field.

THE ENABLING ENVIRONMENT

In addition to analysing specific gaps and how they can best be addressed, the Working Group focused on (1) defining the enabling environment required for the field to advance as swiftly and ethically as possible and (2) identifying actions needed to create this environment.

An enabling environment is one in which:

- Government policies and regulations facilitate research,
- Science professionals from the relevant disciplines are available in sufficient numbers,
- Adequate clinical research facilities exist,
- A pool of properly trained staff is on hand for recruitment,
- Public awareness of and support for microbicide research and development exists, as does consumer demand, and
- Media coverage of trials is supportive, balanced, and well-informed.

Adequate financial resources, political will, and public support are all essential to creating and maintaining this enabling environment. Civil society entities have the leverage, positioning, and political legitimacy needed to generate these ingredients. But civil society cannot and will not carry out this function fully if it is not appropriately integrated into the field at every other level as well.

This report is a blueprint for bridging the gap between where we are now (with minimal, scatter-shot and under-resourced civil society participation) to where we need to be (with civil society engaging as a full partner). Thus, it serves as the missing chapter of the MDS and is understood as such by the MDS authors.

Introduction

In 2005, the Microbicide Donors Committee initiated a consultative process that resulted in the development of the *Microbicide Development Strategy* (MDS). The goal of the MDS was to "identify the most critical gaps in global effort to develop and deliver microbicides, highlight the main obstacles to resolution of these gaps, and recommend priority actions for overcoming them".[i] The MDS, divided into four chapters, analyses progress and gaps in the areas of basic and preclinical science, clinical research, manufacturing and formulation, and commercialization and access.

At the first review of the draft MDS in late 2005, the Global Campaign for Microbicides, among others, expressed concern about the fact that civil society involvement and advocacy were not addressed in the MDS as a unique and essential component of the field, although the document does recognize that "advocates are becoming increasingly involved in catalysing and monitoring ongoing changes in policy and programmes"[ii]. In response, the donors agreed that a parallel process should be undertaken to analyse how civil society groups can and should be involved as the field moves forward.

The Global Campaign for Microbicides spear-headed this process by assembling an international Civil Society Working Group to map out the roles, added value of, barriers to, and mechanisms for engaging civil society — as well as the associated investments of time, commitment, and funding required to facilitate full engagement of this sector.

From the outset, the Civil Society Working Group[iii] made a clear distinction between civil society engagement and community involvement. Within the context of HIV prevention trials, "community" generally refers to trial participants, their families and partners, other local stakeholders, and service providers/community groups within the geographic parameters of the clinical trial location.

The Joint United Nations Programme on HIV/AIDS (UNAIDS), in collaboration with the AIDS Vaccine Advocacy Coalition (AVAC), recently developed *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials*. In these guidelines, the word community is used to "describe separate and overlapping groups of people who are infected and affected by HIV in various ways"[iv]. Microbicide trial networks generally define community even more specifically. The HIV Prevention Trials Network, for example, defines it for the purposes of their research as "the group of people who will participate in or are likely to be affected by or have an influence on the conduct of the research"[v].

"Civil society", on the other hand, has been described by UNAIDS[vi] as a wide spectrum of nongovernmental organisations (NGOs) and advocates, ranging from those organised and acting at a very local level to those working nationally and/or globally. Civil society includes stakeholders outside the parameters of the geographical locale surrounding a research site.

Civil society engagement, for example, may involve organisations working at the macroscopic scale, such as the International Planned Parenthood Federation using its contraceptive expertise to advise on questions of microbicide formulation or distribution. It can also refer to engagement with local actors, such as a village

women's group informing social scientists about cultural norms that will affect acceptability. Thus, civil society engagement refers to a broader scope of activities and a wider range of actors than is generally the case for community involvement.

As civil society members actively engaged in microbicide advocacy at a variety of levels, the Civil Society Working Group:

- Identified gaps in the field from a civil society perspective,
- Prioritized these gaps, recognizing that the key to making rapid progress is focusing specifically on the issues that are *both* of greatest concern to civil society *and* that, if addressed with targeted investments of energy and resources, could result in the most immediate benefit to the field,
- Considered the roles that each of the four sectors within the microbicide field—researchers, donors and trial sponsors, governmental policymakers, and civil society actors—had to play in addressing these gaps.
- We divided our recommendations into two sections:

1. The first (constituting the bulk of this report) describes the highest-priority gaps and immediate action that each of the four sectors can take, independently or collaboratively, to remedy them. This section also highlights critical benefits to be derived from expanded civil society engagement in each high-priority area.

2. The second section describes the investment that must be made in building the capacity of civil society groups so that this optimal level of engagement can be realized. In almost every country, NGOs are so under-resourced that they cannot become maximally effective partners in the microbicide endeavour without capacity-building support. With such support, however, civil society entities are positioned to provide unique expertise and generate momentum that complements the expertise and momentum provided by research institutions, governments, and trial sponsors. This is the essential "value added" that must be recognized and incorporated into our field-wide strategy before a complete picture of the path forward can emerge.

The scientific and research components detailed in the MDS must be carried out in tandem with a whole set of supportive activities if the field is to advance as swiftly and ethically as possible. These activities create the enabling environment within which research and product development take place.

Like the MDS, this report "provides a strategic framework for action by identifying the gaps where action is urgently needed and by proposing ways to move forward". As a companion piece to the MDS, the report focuses the attention of donors, researchers, governmental policymakers, and civil society on the actions that each needs to take and investments that need to be made. We divided our analysis by sector rather than by developmental stage,[vii] to place emphasis specifically on *who* needs to implement each recommendation. The goal is to prompt substantial progress toward the full integration of civil society into the architecture of the field. This integration will optimize our chances of getting safe, effective, and acceptable microbicides into the hands of all who need them as rapidly as possible.

PRIORITY ACTIONS

1. Use microbicide trial site development investments as opportunities to ratchet up local health care infrastructure and expand human capacities for research and health care delivery in ways that provide durable local benefit.

2. Develop mechanisms to increase civil society's engagement across the entire arc of research, development, and product introduction and to improve communication among researchers, sponsors, developers, and civil society.

3. Create more structural opportunities and build capacity for civil society participation in the monitoring bodies that guide microbicide research and development.

4. Invest in initiatives to increase advocacy participation by microbicide scientists and the scientific expertise of microbicide advocates.

5. Improve systems for rapid and user-friendly dissemination of trial results *and their implications* to stakeholder groups and the general public through multiple communications channels.

6. Fully utilize the existing expertise of civil society actors in current efforts to develop product introduction, distribution, and marketing plans.

7. Create structural opportunities and build capacity for civil society to have meaningful input into regulatory processes.

Part One: Priority Gaps and Actions

PRIORITY GAP #1: INSUFFICIENT INVESTMENT IN BUILDING SUSTAINABLE RESEARCH CAPACITY AND HEALTH CARE DELIVERY INFRASTRUCTURE IN TRIAL COMMUNITIES.

PRIORITY ACTION #1: USE MICROBICIDE TRIAL SITE DEVELOPMENT INVESTMENTS AS OPPORTUNITIES TO RATCHET UP LOCAL HEALTH CARE INFRASTRUCTURE AND EXPAND HUMAN CAPACITIES FOR RESEARCH AND HEALTH CARE DELIVERY IN WAYS THAT PROVIDE DURABLE LOCAL BENEFIT.

Increased investment in building health care infrastructure in trial host communities—by building up both material and human resources for research and health care delivery—facilitates research outcomes and bolsters the health sector generally. It is also an ethical obligation when research is sponsored by institutions located in the Global North but carried out primarily in resource-poor settings in the Global South.

When health care infrastructure is dilapidated, insufficient, or nonexistent; research and health care facilities are drastically under-funded; and insufficient numbers of trained research, clinical, and technical personnel are available; conducting ethical and scientifically valid research is all but impossible. Significant investment in correcting these conditions has the potential to result in:

- Greater efficiency and cost-effectiveness,
- Expanded long-term trial capacity at the site, and
- Ethically appropriate contributions to the community's overall health infrastructure.

Researchers and sponsors entering a community to run a trial can plan proactively for concurrent and post-trial use of facilities such as laboratories and clinics. One trial site, for example, agreed to let a local NGO teach evening literacy classes in its waiting room, thus both enhancing the building's usefulness to the community and de-mystifying the facility to some extent by bringing non-trial participants into it.

The Microbicides Trials Network (MTN) has placed a highly experienced regional physician in Uganda and laboratory coordinators in Zimbabwe and Zambia to support site development and protocol implementation activities at MTN trial sites. These "regional" staff provide advanced training and capacity building assistance, as well as support, to their local counterparts. The regional laboratory coordinators focus particularly on internal and external quality assurance issues to help site staff meet research standards and acquire the knowledge and skills needed for this work.

Some donors, such as the European Commission, require that any capital investments made to mount a trial are transferred to local partners at the conclusion of the trial. Sponsors should have a plan for post-trial use of such facilities or, at minimum, a process for agreeing on such a plan with the host community.

Local personnel can should be hired and trained in the use of technology introduced for the study. In building the community's professional skill base, however, research institutions must also avoid "siphoning off" workers from existing health care facilities by attracting them to better-paying jobs at the trial site. This is a difficult balance to achieve but may be resolvable through transparent conversations with the existing facilities about their staff development needs and how diagnostic, clinical, computer, and research expertise for the whole community can be advanced within the context of trial site preparation and trial conduct. Wherever possible, goods and services should be purchased locally, rather than imported.

The burden of funding and negotiating this needed infrastructure-building must not fall solely on the researchers, however. Study sponsors, policymakers, investigators, and civil society organisations also have roles to play. The following grid identifies high-priority contributions that each sector can make to local capacity-building at trial sites.

#1 PRIORITY ACTION STEPS NEEDED TO:
Use microbicide trial site development investments as opportunities to ratchet up local health care infrastructure and expand human capacities for research and health care delivery in ways that provide durable local benefit.

Civil Society	Governments/ Policymakers	Researchers/ Principal Investigators	Funders/Sponsors/ Research Institutions
1. Engage with donor agencies, trial sponsors, and governments in planning for maximized and sustainable use of human and material resources both during and after the trial; where needed, demand that sponsors enter into such agreements.	2. Create incentives to keep expertise in-country and invest in public health infrastructure. 3. Invest political will and resources as possible in creating post-trial health initiatives, such as new trials or market research, that capitalize on the availability of trained individuals and physical facilities used by the trial.	4. With host community entities, develop formal agreements for the use of human and material resources during and after the trial. 5. Buy/hire locally whenever possible.	6. Consider requiring research institutions to hire and train local staff and, if possible, mitigate the siphoning effect somewhat by simultaneously training local health care institution staff as well. 7. Require that proposals show how the grantee will maximize human and material capacity-building impact during and after the trial. 8. Eliminate requirements for researchers to use or buy products and services from vendors based in the researcher's country.

PRIORITY GAP #2: LACK OF FORMAL MECHANISMS AND OPPORTUNITIES FOR CIVIL SOCIETY ENGAGEMENT AND TRANSPARENT COMMUNICATION WITH RESEARCHERS THROUGHOUT THE RESEARCH PROCESS.

PRIORITY ACTION #2: DEVELOP MECHANISMS TO INCREASE CIVIL SOCIETY'S ENGAGEMENT ACROSS THE ENTIRE ARC OF RESEARCH, DEVELOPMENT, AND PRODUCT INTRODUCTION AND TO IMPROVE COMMUNICATION AMONG RESEARCHERS, SPONSORS, DEVELOPERS, AND CIVIL SOCIETY.

The strongest cross-cutting theme in the Civil Society Working Group's deliberations was the importance of communication among the sectors. The Working Group identified the *timing* of communication, the *capacity of different stakeholders* to engage in effective dialogue, and the *creation and sustaining of mechanisms* to foster communication as key elements needing attention.

Effective communication among scientists, advocates, and other civil society members serves to advance each sector's interests, increase investment in both research and advocacy, build community trust, facilitate local trial recruitment, ensure maintenance of appropriate ethical standards, and assure that the right research questions are being asked. Such communication must occur across the whole research/development/introduction timeline.

1. Setting the scientific agenda

Funders and research sponsors should solicit civil society input through both structured and informal mechanisms when determining what research questions should be pursued. Well-prepared civil society representatives serving on research review committees can articulate the knowledge gaps of greatest concern to their constituencies. They can also weigh in on the types of side effects, acceptability, and cultural context issues that are most likely to affect product uptake. These factors should help shape how funders decide to spend limited resources.

OCAP (ownership, control, access, and possession) is a term coined by the Canadian AIDS Aboriginal Network (CAAN) to speak of their right to self-determination with regard to research. CAAN published a set of principles that embody *OCAP*. With training and technical assistance, CAAN helps communities use these principles to negotiate memoranda of understanding (MOUs) with researchers interested in conducting local trials. The MOUs provide for equitable participation of aboriginal people on research teams and ensure collective decision-making in determining research questions, data collection, interpretation of results, drafting of research reports, and assignment of intellectual property rights.

For more information, see the Canadian Aboriginal AIDS Network website at **www.caan.ca** and the following additional websites:
http://www.linkup-connexion.ca/catalog/prodImages/042805095650_314.pdf.
http://www.cahr-acrv.ca/english/resources/abstracts_2003/abs/abs300P.htm.
http://depts.washington.edu/ccph/pdf_files/Research%20Unit.pdf.

2. As research grant applications are developed

Researchers need to find and talk to "on-the-ground" collaborators, including local and regional social scientists, when developing applications for clinical trial funding. Funders and trial sponsors can facilitate this communication by designing Request for Application (RFA) processes that allow time for meaningful consultations among applicants, local scientists, and civil society stakeholders and requiring reports of such consultations in the application. This process informs protocol development by helping researchers better understand community dynamics and site logistics, as well as local norms, barriers, and acceptability issues that should be reflected in the study design, informed consent, etc. All of these decisions affect trial cost, site selection, post-award community buy-in, and recruitment success.

3. During site preparation and trial launch

Thorough communication with civil society stakeholders well before the trial starts is essential to ensuring that the trial is accurately presented to the host community and involved stakeholders. It also minimizes the risk that rumours and/or sensationalized media coverage regarding the trial will arise. As mentioned in Priority Gap #1, this communication further serves to identify the community's most critical capacity-development needs, explore how these can be collaboratively addressed in trial and post-trial planning, and help researchers establish realistic expectations from the outset about the limit of their ability to fill unmet community needs.

In Botswana, US-based researchers preparing to initiate a microbicide trial spent 15 months on formative research that built gradually from (1) informal, open-ended conversations with a range of civil society stakeholders to (2) more focused discussions of specific questions (where the trial site should be located, what it should be called) to (3) focus groups and structured interviews to document, compare, and assess responses formally. The principal investigator referred to this process as "learning to talk about the topic". Only after this was completed did the trial move to hiring community liaisons, convening a community advisory board (CAB), developing a "reference group" to engage governmental agencies in trial decisions, etc. The strong base of familiarity constructed through this process resulted in a base of support for the trial site across stakeholder groups that has been strong enough to withstand the substantial challenges and changes that have arisen during trial implementation.

Personal interview with Dawn Smith, MD, MS, MPH, August 24, 2007.

4. During the trial

Continuous communication among researchers, trial sponsors, and civil society entities can help avoid or solve problems associated with trial implementation. Experience has shown that the absence of such communication, especially with regard to civil society's pressing concerns, can have negative consequences for the trial itself and the progress of research generally.

In 1995, a protease inhibitor called Indinavir was being tested in Brazil in a three-arm trial that included monotherapy as one of the arms. When evidence emerged suggesting that monotherapy could facilitate antiretroviral (ARV) resistance, civil society advocates approached the trial sponsor to urge them to discontinue the monotherapy arm of the trial for ethical reasons. The sponsor was neither willing to add a second drug to the monotherapy arm nor to provide the results of viral load assays done on the monotherapy volunteers. The advocates then took their case to the public and the media. Ultimately, Brazil's national ethics committee declared that drugs should be added to the monotherapy arm and that the results of the assays must be provided.

For more information, see:
http://www.aids.harvard.edu/conferences_events/Recurrent/vaccine_development/1998/vacdev-9.html
http://www.scielo.br/scielo.php?pid=S0102-311X2001000400020&script=sci_abstract&tlng=

5. When the trial ends

Communication is never more crucial that when a trial is closed or suspended unexpectedly. All stakeholders need full information, in accessible language and formats, to understand what the trial findings mean and what happens next.

In these situations, rumours and speculation tend to fill the void if accurate information is not provided. This dynamic is well-illustrated by contrasting the circumstances surrounding the 2004–2005 closure of oral tenofovir PrEP trials in Cambodia and Cameroon with the aftermath of the cellulose sulfate trial closure in early 2007.

In the former case, a breakdown in communication between researchers and civil society led to governmental decisions to shut down trials, widespread inflammatory media, badly eroded community trust in the research enterprise, and lost opportunities to answer critical HIV prevention questions.

In the latter instance, immediate mobilization of the Microbicides Media and Communications Initiative (MMCI) (see box on page 22) upon the closure of the cellulose sulfate trials helped prevent the circulation of rumours and false information about the outcome. Public confidence in the researchers' conduct before and after the closure was bolstered by the level of transparency displayed by the trial sponsors and their willingness to discuss the issue with civil society entities at all levels. This included holding community meetings in the trial sites, participating in international conference calls and listserv dialogues, and proactive communication with global stakeholders. A call organised by the Global Campaign for Microbicides within two days of the trial closure announcement provided a forum for 45 international advocates to ask questions of two of the Data Monitoring Committee members who had made the recommendation to stop the trials. This discussion formed the basis for a detailed, widely circulated question and answer sheet that went out within a week of the original announcement.

Creating and sustaining mechanisms to foster communication

How civil society actors engage at each stage of the research arc depends, in large part, on the level of transparent, proactive, and productive communication among researchers, sponsors, developers, and civil society. It also depends on all parties having the capacity to communicate with each other effectively. The issue of what is needed to build this capacity among civil society actors is addressed in "Building Organisational Capacity" on page 31.

Creating structural mechanisms that facilitate communication across sectors is also essential. Whether formal or informal, these mechanisms increase interaction and deepen mutual understanding of the specific capacities, perspectives, and priorities that each sector brings to the table. This kind of familiarity and recognition, in turn, engenders the respect that is essential to productive communication.

To date, structural mechanisms of this kind have included:

- Consultations convened by the World Health Organization (WHO), UNAIDS, the US Agency for International Development, and other major funders,
- Community advisory boards or groups, now required by many trial networks, and
- Interaction at various national and international conferences and annual meetings.

But these mechanisms are necessarily limited both by time and the dynamics of who gets to participate. Most civil society actors do not know about these opportunities; cannot get to the places where they are occurring; or are constrained in their participation by limited technical proficiency, limited knowledge of English, etc. Gradually, broader access and opportunities are being generated by creation of alternatives such as:

- Researcher/civil society roundtables and problem-solving sessions at international, national, and regional meetings,
- Researcher/advocate listservs and conference call series dedicated to microbicide topics, and
- More *ad hoc* civil society advisory consultations held by major research funders, such as the Bill and Melinda Gates Foundation, the European Union, and the US National Institutes of Health; or regulatory bodies, such as the European Medicines Agency (EMEA—formerly known as the European Agency for the Evaluation of Medicinal Products) and the US Food and Drug Administration (FDA).

Additional innovative support for such mechanisms is needed.

The International Rectal Microbicides Advocates—an international coalition of nearly 500 advocates in 38 countries—holds bi-monthly global conference calls during which all participants can simultaneously access a PowerPoint presentation on the assigned topic on the group website. The presenter on the call (usually a researcher or developer) walks participants through the presentation, which is followed by question and answer discussions. This process enables participants to build their own scientific knowledge base, make recommendations for further research, and engage in informal information exchange. It successfully disseminates the field's cutting-edge news and generates new questions for researchers and developers to explore.

#2 PRIORITY ACTION STEPS NEEDED TO:
Develop mechanisms to increase civil society's engagement across the entire arc of research, development, and product introduction and to improve communication among researchers, sponsors, developers, and civil society.

Civil Society	Governments/ Policymakers	Researchers/ Principal Investigators	Funders/Sponsors/ Research Institutions
9. Work to develop the knowledge base needed to serve on peer review committees, advisory and planning boards, institutional review boards (IRBs), etc., effectively; request such opportunities. 10. Work with funders, trial sponsors, and research institutions on creating, broadening, and/or staffing communications mechanisms.	11. Broaden existing opportunities for civil society input into national HIV prevention and research planning. Create new opportunities by: increasing the number of dedicated civil society seats on national planning and regulatory bodies, holding more public policy hearings and comment periods, and requiring evidence of civil society input as a condition of approval for research funding and/or permission to conduct in-country trials.	12. Identify civil society actors who can impact the achievement of research goals and establish transparent opportunities for ongoing communication with them. 13. Seek opportunities to work collaboratively with civil society actors on broadening civil society involvement in trial funding proposals, launch, ongoing conduct, evaluation, and reporting of results.	14. Fund mechanisms to facilitate communication between researchers and civil society, including efforts by civil society to build their own science literacy and, thus, capacity for productive participation in the microbicide development and access process. 15. Invite key civil society members to provide input into donor decisions by participating in proposal review processes and briefing donors regarding their perspectives on research, product introduction, and distribution initiatives.

The African Microbicides Advocacy Group (AMAG) is a regional organisation that works toward recognition of the legitimacy of African women's voices and leads coordinated African engagement in setting and moving forward the international microbicide agenda. One of its main mechanisms for communication is a closed email discussion forum on which news of breaking developments in the field is posted. These bulletins generate discussion and questions from participants, to which responses from appropriate experts are solicited and posted. The AMAG e-forum educates participants while simultaneously generating new advocacy ideas and facilitating communication and strategy development across the continent.

PRIORITY GAP #3: INADEQUATE CIVIL SOCIETY PARTICIPATION IN MONITORING AND ACCOUNTABILITY ACROSS THE FIELD.

PRIORITY ACTION #3: CREATE MORE STRUCTURAL OPPORTUNITIES AND BUILD CAPACITY FOR CIVIL SOCIETY PARTICIPATION IN THE MONITORING BODIES THAT GUIDE MICROBICIDE RESEARCH AND DEVELOPMENT.

Civil society has a decisive role to play in monitoring progress across the field and making sure that governments, research institutions, and product sponsors meet stated milestones and fulfil their commitments to trial participants, host communities, and the public at large. Strong motivation for this work derives, in part, from the history of past research abuses in resource-poor settings and the legacy of distrust and suspicion they left behind.[viii] Microbicide trials have been working steadily to address this, but civil society entities continue their vigilant watch over how participants and other community members are treated in trials.

Monitoring and accountability can be carried out at the macro level of national or international policy or at the local level of the clinical trial site. In addition to calling attention to areas where commitments are not being fully realized, civil society members can point out potential new areas for synergy and encourage new investment and attention to important areas where little or no activity is occurring.

At the local and national levels, civil society groups can take the lead in creating independent monitoring entities (such as PEPFAR Watch, a US-based initiative that monitors the expenditures of the US President's Emergency Plan for AIDS Relief) and participate in interdisciplinary monitoring groups established by governmental entities, ethicists, or others. Monitoring of research practices to protect the rights of trial participants is also a function of some, but not all, Community Advisory Boards (CABs).

Knowledgeable civil society monitoring of trial conduct in these settings benefits research institutions by:

- Helping to ensure that trial participants and communities are well-protected,
- Providing an independent information source about the trial that is regarded as credible and unbiased by community and other civil society stakeholders,
- Facilitating engagement between researchers and civil society stakeholders with a level of transparency that helps to overcome historically generated distrust, and
- Gathering input and recommendations that may help reduce trial fatigue and, thus, optimize the possibility of future trial implementation in the community.

The field also needs local civil society groups, especially in the Global South, to track capacity-building commitments in other dimensions—such as the capacity of research institutions to train local scientists, of local industry to participate in commercialization processes, and of governmental bureaucracies to craft and enforce appropriate regulatory mechanisms in a timely fashion. A number of organisations are beginning to function in this role, but efforts need to be expanded further.

#3 PRIORITY ACTION STEPS NEEDED TO:
Create more structural opportunities and build capacity for civil society participation in the monitoring bodies that guide microbicide research and development.

Civil Society	Governments/ Policymakers	Researchers/ Principal Investigators	Funders/Sponsors/ Research Institutions
16. Build the capacity to serve as well-informed monitors and press for opportunities to do so. 17. Insist on visible adherence to specific ethical research standards and access milestones; demand attention to existing gaps.	18. Invite civil society participation in processes for reviewing, approving, and monitoring clinical trial conduct. 19. Give close attention to input from independent civil society monitors.	20. Convene inter-disciplinary working groups to review current trials and determine areas to explore or refine for future trials; create dedicated seats on these bodies for civil society actors.	21. Invite well-informed civil society groups to participate formally in strategic planning and evaluation of microbicide trials. 22. Ensure that civil society is well-represented on national and international ethics review committees and data safety and monitoring boards.

PRIORITY GAP #4: INSUFFICIENT INVESTMENT IN SCIENCE-FOCUSED MICROBICIDE ADVOCACY.

PRIORITY ACTION #4: INVEST IN INITIATIVES TO INCREASE ADVOCACY PARTICIPATION BY MICROBICIDE SCIENTISTS AND THE SCIENTIFIC EXPERTISE OF MICROBICIDE ADVOCATES.

The expert and influential voices of scientists are essential in advocacy for governmental adoption of rational, evidence-based HIV prevention policies. In several countries, a great deal needs to be done to correct current public policies that reflect ideological, rather than public health, reasoning. The research community is an indispensable part of advocacy efforts to reverse such policies.

Microbicide researchers also have an important role to play in advocating for adequate public investment to ensure timely development of a safe and effective microbicide. Under almost any research and development scenario, financing needs are likely to remain considerable in the coming years, as increased support for clinical trials and the strengthening of research and development endeavours to develop novel candidates is needed. The HIV Vaccines and Microbicides Resource Tracking Working Group[ix] generates increasingly accurate and detailed analyses of what has been invested to date and projections of the financial and infrastructure needs for microbicide trials in the future. This work constitutes the basis for current estimates of the funding necessary to develop a safe and effective microbicide.

This section focuses on action needed to engage the research sector in advocacy around both public health policysetting and resource mobilization. Such efforts are generally led by the few microbicide-focused civil society organisations with the support and participation of their NGO partners and allies.

When the UK's Department for International Development (DfID) invited external review and comments on a proposal to fund the Microbicides Development Programme (MDP), advocates and social scientists joined together to advocate for social scientists' involvement in the design and implementation of MDP sponsored trials. As a result, the program was revised to include a strong social science component that is gathering data not only community awareness, opinions and other issues affecting trial recruitment and adherence but also on the role of men and their participation in microbicide research, and community views on anal sex, vaginal cleansing practices and other issues integral to microbicide use. At the Microbicides 2006 conference, the entire MDP program received an award for the contribution of its social science program to the field of microbicide development.

Recommendations for building the capacity of these civil society actors to undertake effective science-focused (as well as needs- and rights-focused) advocacy is detailed in "Building a Common Vocabulary" on page 31.

The action steps listed here, however, suggest how each sector can support efforts to bring the voices of researchers into much-needed advocacy collaborations. As scientists, they bring not only detailed knowledge of the issue and but also their high social and political credibility to the advocacy effort. When scientists and civil society advocates work hand-in-hand, the chances of success are strengthened and all sides potentially benefit.

#4 PRIORITY ACTION STEPS NEEDED TO:
Invest in initiatives to increase advocacy participation by microbicide scientists and the scientific expertise of microbicide advocates.

Civil Society	Governments/ Policymakers	Researchers/ Principal Investigators	Funders/Sponsors/ Research Institutions
23. Work to increase their own scientific knowledge base in preparation for collaboration. 24. Incorporate advocacy initiatives into strategic plans and programme activities, in collaboration with researchers and product developers whenever possible.	25. Create opportunities for public input into policy and funding decisions, such as: • Public hearings, • Comment periods on legislation or regulations, • Participation in task forces, study groups, commissions, etc.	26. Convene cross-training between civil society advocates and scientists (e.g., scientific briefings for advocates and advocacy briefings and skills-building for scientists). 27. Undertake joint and individual advocacy activities with key partners.	28. Fund multi-sectoral advocacy initiatives.

PRIORITY GAP #5: LACK OF WIDESPREAD, TIMELY DISSEMINATION OF RESULTS TO MICROBICIDE STAKEHOLDERS AND THE GENERAL PUBLIC.

PRIORITY ACTION #5: IMPROVE SYSTEMS FOR RAPID AND USER-FRIENDLY DISSEMINATION OF TRIAL RESULTS *AND THEIR IMPLICATIONS* TO STAKEHOLDER GROUPS AND THE GENERAL PUBLIC THROUGH MULTIPLE COMMUNICATIONS CHANNELS.

Clinical trial results—both positive and negative—need to be disseminated more quickly and to a wider audience than is currently occurring. Traditional methods of circulating trial results do not reach all the stakeholders who need to know and understand this information.

Product developers focus on sharing their results with regulatory bodies. Researchers generally focus primarily on communicating results via scientific meetings and publishing them in academic journals. Although critically important steps, these reach limited audiences and present the information in language and formats not easily accessible to civil society and community stakeholders.

The latter two groups await news of trial results. Misinformation and rumours can easily fill the gap when accurate information is not rapidly and widely available following the conclusion or early closure of a trial. The whole field has a stake in preventing the circulation of misinformation that can be detrimental (and potentially ruinous) to future trials or product introduction.

Language differences, lack of general or scientific literacy, lack of resources to attend scientific meetings and subscribe to journals, and intermittent/faulty access to conference calling and the internet all constitute barriers to obtaining public information. Typically, health or science advocacy groups take it upon themselves to learn about new research findings and relay this information to their constituencies. These efforts not only help diverse populations to become well-informed but also contribute substantially to ensuring that the information is perceived as reliable. Whether rightly or wrongly, people tend to perceive information from respected peers as credible.[x,xi] This holds true at every level, whether the communication occurs from researcher to researcher, farmer to farmer, or adolescent to adolescent. We tend to presume that what we learn from "people like ourselves" is more reliable and relevant to our lives than what we learn from people unlike ourselves. The meteoric growth of file-sharing via the Internet is just one example of the power of this dynamic.

Thus, it is critically important that NGOs staffed by people viewed as "peers" by the target population be well-trained, supported, and engaged in serving as their primary source of information about clinical trials. This work must be better resourced and deliberately cultivated if it is to meet the demand for accurate public information as the microbicide research effort continues to expand.

The Joint Civil Society Monitoring Forum in South Africa, comprised of several leading civil society and private-sector organisations, monitors the implementation of South Africa's National Operational Plan to roll out access to HIV/AIDS treatment and prevention. The Forum regularly issues public reports, makes recommendations to government regarding its progress on this challenge, and interacts closely with government on an ongoing basis

Reliance on peer expertise also drives scientific data review processes. In this case, however, a temporal conflict arises between the need for thorough peer review to help ensure scientific validity and the need to make trial results as widely and rapidly available as possible. Although unquestionably necessary, the traditional peer review process prior to publication results in unacceptably long reporting delays.

After submission, the data contained in a manuscript cannot be published elsewhere prior to the journal's publication of it. This prohibition is usually taken very literally, and journals refuse to publish papers if the data in them appear first in newspapers or electronic media. Thus, definitive trial findings may not become publicly available until a year or more after the trial is completed.

To break this deadlock, we need expedited methods of reaping the scientific benefits of peer review without the inordinate delay it sometimes engenders. Experiments in "open peer review" — a process by which information is made available online while it is being reviewed — are being undertaken by some journals.

In 2006, Nature undertook an experiment with "open peer review". Submitting authors could choose to have their manuscripts posted online for public comment while the traditional peer review proceeded in parallel. Any interested scientist could post comments about the online submission. The open peer review period was closed as soon as the traditional review was completed. Journal editors then read all the comments gathered through both processes and made their recommendations to the author for revisions.

The online publication of peer-reviewed journals also speeds up access and, in some cases, removes financial barriers to information by providing "open access" to readers without charging subscription fees. Such innovations may help to provide equitable and expedited access to information for all interested stakeholders.

The Public Library of Science (PLoS) publishes peer-reviewed scientific and medical journals that appear online. With no charge for access, PLoS makes everything they publish freely available for users to read, download, copy, distribute, and use (with attribution) as needed.

Coordinated communications strategies are also critical when trial results are released. Delayed or limited access to information about trial results can create a damaging impression at the community level that information is being deliberately withheld. This, in turn, can lead to sensationalized headlines and local talk show coverage that spreads rumours and makes unfounded accusations against researchers.

When news is disseminated, civil society organisations play a critical mediating role between the scientific community and target populations as well as mass audiences. Communicating the significance and implications of trial results to public and stakeholder groups is at least as important as relaying the results themselves. Thus, civil society actors must be involved in developing messages that interpret results clearly and point to the next steps forward.

The emergence of rumours and misinformation can never be entirely eliminated, but the delivery of well-structured messages by locally credible voices can expand the level of stakeholder awareness and comprehension well beyond that which is otherwise achievable. Dispersal of accessible public information also influences the mainstream media's coverage of new research findings.

The Global Campaign for Microbicides convenes the Microbicides Media and Communications Initiative (MMCI) to help clinical trial staff plan and initiate communication with trial stakeholders, including the media. MMCI meetings bring these staff together with scientist allies and key advocacy network representatives to share news and develop successful collaborative strategies for communicating with trial communities, NGO stakeholders, and government officials, as well as the media.

Finally, multi-sectoral collaboration is required to build durable consensus around the meaning and implications that trial results have for future research programmes. If a microbicide candidate is shown to reduce HIV risk by 40 percent, for example, what does this mean for the next generation of microbicide trials? Dialog among all four sectors is essential to developing coherent, acceptable plans for future research, given that every new level of scientific knowledge raises another host of questions.

The Global Campaign for Microbicides has initiated multi-sectoral consultation work to explore how ethics and logistics issues associated with future clinical trial design will be affected by the emergence of new, partially effective prevention tools such as microbicides, male circumcision, and possibly pre-exposure prophylaxis. The need for creative and thoughtful reflection on this topic is escalating as current trials reach their final stages. The goal of this consultation work is to begin developing some field-wide consensus to inform future planning.

#5 PRIORITY ACTION STEPS NEEDED TO:
Improve systems for rapid and user-friendly dissemination of trial results and their implications to stakeholder groups and the general public through multiple communications channels.

Civil Society	Governments/ Policymakers	Researchers/ Principal Investigators	Funders/Sponsors/ Research Institutions
29. With researchers, develop communications plans for timely dissemination of culturally and linguistically appropriate and accessible messages regarding trial outcomes. 30. Independently, strengthen existing civil society networks to facilitate: • Cross-NGO information-sharing around microbicide issues; • Collective analysis of the implications of new data for their communities. • Effective translation and transmission of this contextualized information to community members and civil society broadly.	31. Public health officials should meet with researchers and civil society groups to craft messages on the potential local public health impact of trial results.	32. Partner with civil society allies to develop and implement concrete communications plans. 33. Build relationships with key reporters, editors, and community leaders who will spread accurate results and "take-home" messages.	34. Engage with academic journals and institutions to explore methods for expediting the publication of peer-reviewed research findings. 35. Support and fund local NGOs (including investment in their communications technologies) to develop and promulgate public education about trials; invest in them as key peer information sources for other NGOs and target communities.

PRIORITY GAP #6: LACK OF CIVIL SOCIETY INVOLVEMENT IN DEFINING PLANS FOR ACCEPTABILITY, AFFORDABILITY, SUSTAINABLE ACCESS, AND MARKETING WORK TO MAXIMIZE MICROBICIDE UPTAKE AMONG KEY POPULATIONS.

PRIORITY ACTION #6: FULLY UTILIZE THE EXISTING EXPERTISE OF CIVIL SOCIETY ACTORS IN CURRENT EFFORTS TO DEVELOP EFFECTIVE PRODUCT INTRODUCTION, DISTRIBUTION, AND MARKETING PLANS.

The MDS notes that "even the most effective and accessible products will fail if consumers choose not to use them. Therefore, understanding of likely consumer preferences, demand, and potential use is crucial to the effective design and evaluation of microbicides"[xii].

The Civil Society Working Group agrees that where, when, and how products come to market conditions their true accessibility. Product uptake and use depends on a number of factors, including easy and affordable access; provider and opinion-leader attitudes; acceptability; and the consonance or dissonance between public perceptions of the product and the local religious, cultural, and social norms that guide sexual conduct and culturally appropriate behaviour.

The MDS describes in detail the complex work needed to address these interlocking access challenges but does not explore the pivotal role that civil society actors—those with the most first-hand experience on the ground—play in accomplishing this work. Here, we describe how the involvement of civil society can and must be integrated into the work of other sectors for maximum effectiveness in this area.

Pre-trial negotiations affecting access

The Civil Society Working Group expressed particular concern about how preferential post-trial access to a successful product can be operationalised in the trial host communities. Different sectors play very different roles in addressing this issue. Developers decide whether, when, and how to pursue product registration. Regulators control whether a product is approved or not.

Research institutions can propose post-trial, pre-introductory studies to trial host governments and funders as a way of gathering vital information while also continuing product access in trial communities prior to registration. These studies generate data that are critical to larger-scale introduction but are not collected during the clinical trial itself. Funders can make commitments to support such research. In some settings, these studies might be dovetailed with the "model programmes" described in the MDS[xiii], thus further strengthening the groundwork for eventual microbicide introduction.

Explicit governmental commitments regarding product introduction are not made in advance of governmental review of the product's effectiveness data, its acceptability to local populations, and the likelihood of international donor support for its introduction. Even before a phase 3 trial produces results, however, it is possible to seek agreements in principle from the relevant governmental bodies that they will review the trial results as soon as they become available and make their introduction decisions in a timely fashion. This requires that a parallel commitment is made by trial sponsors and funders to make fully analysed trial data available to those governmental decision-makers as rapidly as possible.

Agreements in principle can also be supported by engaging government officials, regulators, etc. in informational activities during the trial process, to build their familiarity with new HIV technology and understanding

of its potential utility to their citizens. Governmental willingness to consider new trial data, and their knowledge base for doing so, is enhanced by this kind of engagement early on in the process.

Another important request to make of trial host governments is the inclusion of a phased microbicide introduction plan in national mid- and long-term HIV prevention scenarios. Civil society actors can take the lead in urging such inclusion, as well as in raising public understanding of microbicides and generating audible public demand for them. Without such demand, the steps necessary to assure effective access – including research to shape a region-specific introduction strategy that supports uptake and sustained use – are unlikely to move forward efficiently.

Funding and supply issues

Funding and supply sustainability are other major access hurdles, as illustrated by on-going problems with access to condoms and other reproductive health supplies. Raising community expectations about a product without ensuring sustainable ability to meet the demand for it is unacceptable.[xiv] Before initiating phase 3 trials, most microbicide developers have access agreements in place to provide flexibility in manufacturing and/or pricing.

Tiered pricing, licensing agreements, and other such mechanisms should be in place for all candidate products, to ensure that prices will be low enough to facilitate adoption. If the price is considered exorbitant, some donors and policymakers (especially in middle-income countries likely to pay for the product themselves) may not even consider providing access to them. Access to human papillomavirus vaccine has been hampered in some places by exactly this problem.

Adequate access to essential reproductive health supplies is a critical issue in many developing countries. In 2003, Nigeria's Health Ministry involved relevant actors from the public, private, and civil society sectors in a multi-stakeholder process called Strategic Pathways to Achieve Reproductive Health Commodity Security. Its major outputs to date include:

- Building consensus among the partners about short- and medium-term actions needed,
- Writing a new strategic plan, and
- Securing new funding and commodities-financing from various sources.

While Nigeria continues to confront serious challenges in this area, notable improvement has occurred. A 2005 report documented the availability of most supplies as being "above 75% at all levels. This is in contrast to an assessment in 2001/02, which revealed high stockout levels". The report also noted that "[D]onor behaviour and style of engagement with national stakeholders are critical factors" in this success.

Department for International Development Health Resource Center. Reproductive Health Commodity Security (RHCS) Country Case Studies Synthesis: Cambodia, Nigeria, Uganda and Zambia. Final Report, March 2006; pages 30 and 33. Available at http://www.dfidhealthrc.org/publications/srh/RHCS%20synthesis_Mar06_final.pdf.

The MDS notes, however, that "[t]here is as yet limited detailed information or knowledge about the range of costs for microbicide commercialization and access. The cost forecasts will be important for helping to ensure that products are available and affordable, and for attracting investment from commercial partners. The microbicide field must develop greater clarity about how best to adapt or employ existing and emerging mechanisms for public-sector financing, and about what financing strategies will maximize the public health impact of a microbicide product".

Leadership to accomplish these complex, highly technical tasks is coming from other sectors. Civil society's unique contribution to this effort lies in:

- Advocating with provincial and national policymakers to ensure that the issue of sustainable access, based on accurate demand forecasting, is addressed prior to microbicide introduction and
- Monitoring and advocating for the transparent establishment of public purchase pre-commitments, contracts, multi-lateral funding, and other innovative financing mechanisms to support sustainable microbicide access and distribution

The roll-out of ARVs funded by PEPFAR and Global Fund to Fight AIDS, Tuberculosis and Malaria has already motivated treatment advocates within civil society to develop expertise in these areas. Civil society microbicide advocates are now cultivating partnerships with successful treatment advocacy groups, including the AIDS Vaccine Advocacy Coalition, the European AIDS Treatment Group, the Health Global Access Project, the Médecins Sans Frontières' Drugs for Neglected Diseases Initiative, and the Treatment Action Coalition, among others. The potential for synergy between prevention advocacy and treatment advocacy is enormous, and the expertise, sophistication, and momentum already amassed by the treatment advocacy movement are invaluable to the growth and effectiveness of prevention advocacy efforts.

Shaping provider and opinion-leader attitudes

Provider and opinion-leader attitudes indisputably affect public uptake of HIV prevention tools. Uptake of the female condom, for example, has been sub-optimal due to a number of factors, including negative provider attitudes. The uptake of prevention of mother-to-child transmission (PMTCT) interventions has been similarly affected in some areas.[xvi]

Given their anticipated partial effectiveness, microbicides may meet with resistance among providers uncomfortable with complex prevention messages. Explaining partial efficacy and the risk reduction (but not risk elimination) value of a microbicide is not as straightforward as "just use condoms". Neither is the fact that some products are likely to provide dual protection, while others may reduce HIV risk but not prevent pregnancy. Because microbicide use will be user-dependent rather than provider-dependent (as are vaccines, for example), their successful introduction will require a significant amount of user education.

Preparing providers and opinion leaders for microbicides is a high-priority area of work that can be undertaken effectively by civil society (if adequately resourced) in collaboration with social and behavioural scientists. Specifically, civil society NGOs can help inform and implement behavioural research on current provider attitudes in high HIV-prevalence countries where the first microbicides are likely to be introduced.

Provider education about microbicides must also be folded into current efforts to integrate HIV/AIDS and reproductive health/family planning service provision. WHO, the World Bank, and the European Union all support the integration of family planning and HIV programmes,[xvii] on the grounds that family planning programmes offer optimal entry points for HIV prevention services and reach many women at high risk of infection. Growing support for the financial, practical, and humanitarian benefits of such integration was evident at the AIDS

2006 conference in Toronto. This service delivery trend provides an important opportunity to build microbicide preparedness into the re-structuring and continuing provider education activities that such integration necessitates.

Working with social and behavioural scientists to explore user preferences and the norms influencing use

Clinical research is traditionally envisioned as linear, a view that can obscure the importance of integrating behavioural and social science research into it.[xviii] Chronic under-funding of the field is one of the factors negatively impacting social science and behavioural studies, as these are among the first activities eliminated when research budgets get trimmed. This occurs to the detriment of the whole field, since social science research, especially when incorporated into site development and community-preparedness work, contributes the knowledge base needed for effective product design, trials conduct, and, ultimately, introduction.

Daily community life is the context within which microbicide use will or will not occur. Thus, it must be well-understood if trial participant behaviour (including retention and protocol adherence) is to be maximized and effective social marketing plans are to be made. Well-qualified social scientists must be supported in exploring local religious, cultural, and social norms before developers can understand the full range of variables that can inhibit or promote microbicide acceptability and use in a community. Since conditions in non-trial communities may well vary in many ways from those at trial sites, social science and acceptability research must be done in a range of potential user populations, not just among trial participants.

Service providers, health educators and advocates, community leaders and religious authorities—all members of civil society—are the key informants who provide direction and mediate access to social science data. Thus, the successful conduct of social science and behavioural research depends on collaborative efforts between researchers and civil society.

In Mwanza, Tanzania, researchers used participatory research methods in a microbicide trial feasibility study to facilitate open dialogue and partnership between researchers and study participants. Using an election-based process, they established a city-level community advisory committee with representatives from ten wards. With tools adapted from participatory learning and action techniques, project-related concerns were explored at workshops and community meetings. Among the issues identified were beliefs that blood specimens were being sold for witchcraft purposes, trial specula were not clean, transport allowances were inadequate, and the reporting of laboratory test results to participants was delayed.

The project addressed these issues by inviting community members to directly observe the equipment-cleaning and specimen-preparation procedures in the clinic, raising reimbursement levels, and streamlining the test results-reporting process. By using participatory techniques, this dialogue and collaborative problem-solving effort allowed researchers and community representatives to gain a shared understanding of, and investment in, addressing project-related needs and concerns.

http://www.ncbi.nlm.nih.gov/sites/entrez?Db=pubmed&Cmd=ShowDetailView&TermToSearch=17697333&ordinalpos=2&itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum
Vallely A, Shagi C, Kasindi S, Desmond N, et al.; Microbicides Development Programme.
The benefits of participatory methodologies to develop effective community dialogue in the context of a microbicide trial feasibility study in Mwanza.

Success in this area also depends on increased and streamlined communications channels among researchers, local health care practitioners, community organisations, and the other external stakeholders interested in microbicide development (such as governmental policymakers and activists). Relevant information is overlooked or ignored when those sectors are not talking to one another.

Community-based participatory research (CBPR)[xix] is a methodology uniquely suited to analysing the impact of social, political, and economic systems on health behaviours and outcomes. In CBPR, each sector contributes its perspectives and resources to the collective exploration of a given community problem. The knowledge obtained is then integrated into action to improve the health and well-being of community members. Increased investment in CBPR, as well as other research methods, can substantially enhance the knowledge base required to develop microbicides that will be used consistently.

#6 PRIORITY ACTION STEPS NEEDED TO:
Fully utilize the existing expertise of civil society actors in current efforts to develop product introduction, distribution, and marketing plans.

Civil Society	Governments/ Policymakers	Researchers/ Principal Investigators	Funders/Sponsors/ Research Institutions
36. Advocate for sponsors, governmental agencies, and product developers to seek agreements in principle regarding when and how trial data will be provided and reviewed following trial completion. 37. Advocate for inclusion of phased microbicide introduction plans in host governments' mid- and long-term HIV prevention scenarios and programme planning processes. 38. Develop provider and opinion-leader education programmes; call for their incorporation into provider training and re-training schemes. 39. Advocate for full funding for social science and behavioural research conducted in tandem with clinical trials.	40. With civil society and researchers, make agreements in principle for the expedited regulatory review of successful candidates. 41. Include phased microbicide introduction planning in national mid- and long-term HIV prevention scenarios and programme planning processes. 42. Work with donors, sponsors, and companies with expertise in product distribution to prepare national microbicide introduction plans based on careful assessment of product positioning, subsidy, and distribution strategies.	43. Work with civil society on designing and conducting social and behavioural research on user preferences, product use logistics, provider attitudes, and the impact of entrenched cultural and religious attitudes on eventual microbicide use; use CBPR models for this work when possible.	44. Support post-trial, pre-introduction marketing studies. 45. Develop specific phased access plans based on demand forecasting and other essential data. 46. Work with trial host governments and other heavily impacted governments to develop subsidy purchase and distribution plans prior to final product approval. 47. Provide sufficient funding to support all well-reviewed protocols and the inclusion of all well-designed social science and behavioural research in these clinical trials.

PRIORITY GAP #7: LACK OF EFFECTIVE CIVIL SOCIETY INFLUENCE ON PRODUCT REGULATORY BODIES.

PRIORITY ACTION #7: CREATE STRUCTURAL OPPORTUNITIES AND BUILD CAPACITY FOR CIVIL SOCIETY TO HAVE MEANINGFUL INPUT INTO REGULATORY PROCESSES.

Regulatory bodies set the efficacy and safety standards that microbicides must meet for approval. Thus, they are instrumental in determining when, how, and to whom microbicides will be accessible. The regulatory standards for microbicides, however, are still under development and have yet to be clearly articulated to developers, researchers, or civil society.

Regulators must balance the need to ensure product safety against the urgency with which microbicides are needed. Both post-approval monitoring to help ensure safety *and* the broadest possible access to new prevention tools are essential. This may lead to a double-bind, as the former may necessarily constrain the latter. The situation is further complicated by the fact that regulatory capacity varies substantially by country, as do the nature and intensity of the HIV pandemic and the consequent risk/benefit profile of introducing a partially effective microbicide in a given country.

Historically, many countries without strong regulatory bodies have looked to their western counterparts, such as the EMEA and the FDA, for regulatory guidance. But the potential benefit of introducing a partially effective microbicide in a comparatively low-incidence country in western Europe or North America is very different from that of introducing it into a developing country with double-digit HIV prevalence and minimal treatment availability. Western guidance, therefore, is not readily transferable in this case.

In the 1980s and 1990s, western HIV/AIDS treatment advocates had notable success in influencing national regulators' approach to addressing the urgent needs of people with AIDS. In the United States, for example, they spurred the development of FDA fast-track approval of ARV drugs (and subsequently, additional classes of medication). They also motivated the FDA to consider data from trials that were not placebo-controlled, and successfully advocated for the addition of HIV-related treatments to the WHO essential medicines list.

Groups like the Alliance for Microbicide Development, CONRAD, the Global Campaign for Microbicides, and the International Partnership for Microbicides (IPM) are currently working with WHO and others to identify and address the regulatory hurdles that microbicides are likely to encounter and to design approval protocols that would be appropriate within the microbicide context.

The EMEA, in collaboration with WHO, has designed a process for scientific review of products intended for primary use in developing countries. Even if the EMEA is not willing to approve a product for use in the European Union (due to the region's comparatively low HIV rates, for example), it can provide expert input on the appropriateness of recommending its approval by another country (such as one in which HIV impact is much higher).

Although this review process has been used for evaluation of a few other products, its first application to microbicides will not occur until a novel microbicide is presented for evaluation. It will behoove civil society advocates to mo-nitor the accessibility and functionality of the process when the first microbicides are available for evaluation, to see if it can help meet the needs of countries with less capacity to conduct their own regulatory processes effectively.

Since the FDA is mandated to evaluate products for the US market, it is likely to approve a microbicide only if its effectiveness rate is high enough to warrant potential introduction in the United States. However, much of the world looks to the FDA for guidance on drug approval.

Given this, civil society voices will need to insist that FDA statements regarding candidate products stipulate very clearly whether the agency's decision to withhold approval (or even refusal to review the product) is based

on the risk/benefit ratio the product presents to the US population or on other factors. This is critical, because other countries may perceive local introduction of products not approved for use in the United States as "pharmaceutical dumping". This impression can only be counteracted by clear and definitive FDA statements indicating the product was not rejected because of safety or efficacy concerns, but simply because it was not viewed as suitable for introduction in a country with a comparatively low national HIV rate.

It is the role of civil society to apply pressure for the development of clear criteria and efficient regulatory pathways for the assessment and eventual approval of new microbicides. They can do this by:

- Urging the development of increased linkages among national drug regulatory agencies in countries with comparable HIV epidemics or similar approval criteria (e.g., efficacy standards, safety standards). By facilitating joint reviews of candidate products, such linkages could help expand regulatory capacity, reduce timelines for regulatory review, and ultimately offer greater efficiency than is possible when each country conducts its own technical and safety review. Minimum effectiveness standards will still have to be determined on a country-by-country basis, as mentioned above. Mutual recognition by developing-country agencies of approvals made by other developing countries would also facilitate regulatory efficiency.
- Urging donors to fund the training and technical assistance needed to build developing-country regulators' capacity to make autonomous decisions about candidate microbicides.
- Advocating for the creation of an international advisory group charged with identifying the regulatory hurdles likely to block or delay microbicide access and generating efficient strategies for resolving them. This group should be comprised of developers, regulators, funders, national governments, and civil society stakeholders.
- Seizing opportunities to comment on proposed regulations regarding microbicide approval, serve on regulatory advisory boards, and pressure governments to develop clear standards for in-country microbicide approval.

#7 PRIORITY ACTION STEPS NEEDED TO:
Create structural opportunities and build capacity for civil society to have meaningful input into regulatory processes.

Civil Society	Governments/ Policymakers	Researchers/ Principal Investigators	Funders/Sponsors/ Research Institutions
48. Collaborate with scientists, industry, and regulators on developing national regulatory standards. 49. Comment on proposed regulations through testimony, official comments, advisory committee participation, and commentary in the media. 50. Call for the creation of an international advisory group on regulatory issues; designate well-informed civil society stakeholders to serve on it, when convened.	51. Identify and build effective regional, south-to-south, and south-to-north collaborations to facilitate joint evaluation or advisory assistance (e.g., via the EMEA/WHO process for product evaluation). 52. Adopt regulatory processes that are transparent and open to civil society input during their formative stages; solicit that input through public comment periods, hearings, and via designated seats for civil society representatives on regulatory review panels.	53. Educate regulators about the impact that regulatory requirements have on study feasibility and, where necessary, propose viable alternative regulatory strategies.	54. Convene an international, multi-sectoral advisory group that includes civil society stakeholders to develop efficient strategies for addressing regulatory hurdles. 55. Fund training and technical assistance to build capacity among developing-country regulators.

Part Two: Building the Enabling Environment

INVESTING IN THE BASICS

This above section outlines specific ways in which funders, researchers, governments, and civil society — working together—can accelerate microbicide research, product approval, and access. Full implementation of these recommendations is impossible, however, without attention to the broader structural context within which this work must occur. Civil society integration, as described here, first requires investment in the organisational capacity of the civil society groups.

The National AIDS Research Institute (NARI) of India has established a process for training outreach workers under the supervision of local NGOs. These workers provide peer education to their communities about NARI's vaccine and microbicide trials and to serve as conduits for community feedback about the trials. They receive 60 hours of training and are paid a stipend for their work. The supervising NGOs do not receive funding from NARI but can access technical assistance with fundraising, grant-writing, etc. from them. This has helped to preserve their autonomy as civil society advocates so that they can negotiate transparently with NARI regarding community input into how research is conducted.

This cross-sector collaboration enables NARI to be more responsive to the trial community and the community to be much better informed about the trials than would otherwise be possible. It also builds substantial new capacity among both the NGOs and their staff.

Personal interview with Seema Sahay, PhD, November 13, 2006.

The question of how the financial part of such investment can best be made to myriad relevant NGOs around the world is difficult to answer. One possible mechanism is presented in "Proposing a prevention advocacy funding window" on page 32.

WEAVING CIVIL SOCIETY VOICES INTO THE SOCIAL FABRIC

Fundamental conditions within societies create or inhibit an enabling environment for microbicide research and civil society participation in it. Some of these are broad socio-cultural conditions, such as respect for human rights; active public participation in political discourse; and a rational, accessible process for public policy development. Where these conditions exist, civil society organisations engaged in promoting the social good tend to flourish.

Civil society engagement can also grow where these conditions do not exist— and often do emerge in direct response to oppression, lack of transparency, and public exclusion from governmental decision-making. Their emergence and growth can be supported by outside actors through either "the carrot" of funding or "the stick" of public criticism of exclusionary and/or oppressive governmental policies.

One example of using "the carrot" has been GFATM's requirement that grantee nations explicitly involve civil society stakeholders in creating their national HIV plans. By making this a funding condition, GFATM opens the door for civil society engagement with governmental policymakers in locales where it had not previously occurred.

Whether or not they regard the creation of freer, more equitable societies as one of their primary responsibilities, research institutions, funders, and governmental policymakers are well-positioned to help build capacity among their civil society counterparts. In virtually every country, NGOs need capacity-building assistance to become maximally effective partners in the microbicide endeavour. Investing in this capacity-building is in the best interest of the field overall, as it is a necessary first step in creating the enabling environment described above.

BUILDING A COMMON VOCABULARY

A fundamental step toward any successful collaboration is establishing shared language among the stakeholders. Most people do not know how clinical trials are conducted or why they function as they do. Advocates and other civil society members need sufficient "research scientific literacy" to meaningfully discuss clinical trial conduct, protocol development, and trial results with researchers and explain these processes and the rationale behind them to their constituencies. NGOs need to train their own staff and then provide training to other civil society entities to build their science, research, and regulatory knowledge and vocabularies. Developing scientific literacy at the civil society level is essential to fostering communication and preventing misunderstandings.

Conversely, researchers need to develop their capacity to discuss the nuts and bolts of their work in lay language accessible to a broad range of civil society allies. Priority Gap #4 (on page 18) outlines how scientists can increase their capacity for, and comfort with, advocacy work. Researchers also need to build their "community literacy", to better understand the dynamics shaping communication inside their host communities. Such training improves researchers' capacity to communicate their protocols, goals, and procedures with civil society allies in accessible and relevant language.

Enhancing this community literacy—and concurrently building researchers' willingness to consider input from non-scientists—requires training that experienced advocates, social scientists, and other skilled intermediaries are well-suited to provide. Unfortunately, no such work has been systematically undertaken. As occurred with CABs in the 1980s and 1990s, funder and sponsor mandates may be needed to turn community literacy training, as well as research literacy training, into a field-wide norm.

BUILDING ORGANISATIONAL CAPACITY

One has only to contrast the budget of the average civil society NGO with that of entities in the other sectors (research institutions, funders, and governmental policymakers) to see why truly balanced collaboration among the sectors cannot be achieved without additional investment in NGO capacity-building. Most NGOs simply cannot afford, independently, to "skill up" and "staff up" to the extent necessary to take on the roles they should play in such collaborations.

Civil society NGOs need more leaders, more managers, and more paid staff if they are to maintain their current workloads *and* follow through on the activities mentioned in this report. Without additional personnel and the expanded development and training of existing staff, these NGOs will fail—even if offered all the opportunities for participation outlined above—because they will be too over-stretched and under-prepared to take on the additional work.

Investment in training, technical assistance, and mentorship is also needed, both to increase research literacy and, in some instances, the organisational and management capabilities of staff and volunteers. Special conference tracks along with attendance scholarships can help meet this need; as can local, regional, national, and international training sessions on a range of topics including the role of IRBs; working with the media; good accounting practices; and dissemination of best practice models through websites, webcast, podcast, and twinned organisational partnerships.

Investment is also needed to increase the number of locally trained physicians, nurses, laboratory technicians, health educators, and researchers available to carry out the research. With this investment comes the concomitant need in developing countries for education, training, and professional incentives aimed at reducing "brain drain".

Policysetting, funding decisions, clinical trial implementation, and post-trial product management are all increasingly trans-national processes in which one cannot be fully involved without good international communication capabilities. Access to reliable sources of power, computers, printers, fax machines, and Internet and email access are essential to meaningful participation, no less so for civil society NGOs than for every other sector. Investment in generators, software, cellular telephones, radio air time, and other communications technologies will ultimately pay off in huge dividends by enabling civil society players to maximize communication with their constituencies, scientists, and policymakers.

PROPOSING A PREVENTION ADVOCACY FUNDING WINDOW

At present, very limited support is available through foundations and other funders for HIV prevention advocacy, much less for the kind of capacity-building and foundational work described in this report. Funders are understandably drawing away from giving small grants to small and medium-sized NGOs and moving toward the much more efficient process of making large grants to well-established, highly professionalized organisations.

This results in a functional disconnect. How can smaller groups with the "on-the-ground" expertise and connectedness that qualify them to serve as authentic civil society voices obtain the funding required to do so effectively? This problem is being resolved in other fields by the establishment of intermediary grant-making entities capable of accepting large grants from funders and using them to support a wide range of projects proposed by smaller NGOs. Hivos[xx], one such intermediary, currently supports more than 800 private organisations in 30 countries. Another example, Mama Cash[xxi] funds women's organisations and groups worldwide. Mama Cash issued a total of 2,165,903 euros in grants in 2006, with an average grant size of 10,486 euros.

We propose the creation of a grants-making window dedicated to issuing small grants to the nongovernmental and community-based organisations interested in becoming active in HIV prevention and prevention research. Working through an intermediary experienced in making and monitoring grants of this kind would provide donors with both the efficiency and the accountability they need. It could also ensure a grant application process that is internationally accessible and simple enough to be used by organisations without substantial experience in fundraising.

Finally, it would provide the advantage of separating funding decisions from advocacy partnerships. International advocacy networks such as the Global Campaign for Microbicides and AMAG find it more difficult to work in equal and collaborative partnerships with national NGO colleagues when a grantor/grantee

relationship also exists between them. Providing these smaller NGO partners with access to a grant-making window that is not controlled in any way by the larger advocacy networks would "level the playing field" and facilitate smoother collaboration among partners of various sizes.

One possible strategy for capitalizing the grants-making window would be to ask IPM, the International AIDS Vaccine Initiative, and other product development partnerships to contribute a small percentage of the funding they raise from Canadian, European, and US donors to support civil society work via this grants window. Since these groups benefit enormously from the political mobilization work carried out by advocates, this would be a non-labour-intensive way for them to support that work.

Clearly, the ideal finance mechanism, structure, institutional home, etc. for this proposed funding window has yet to be determined. We propose the concept here simply as one concrete response to the question of how the capacity-building work described above can possibly be supported in today's highly complex funding environment.

EXPLORING NEW MODELS OF ORGANISING

As technology growth revolutionizes societies, new possibilities for international and local civil society collaborations may emerge. An example of this is the rapid proliferation of cellular telephones and other wireless technology throughout Africa and the opportunities thus created for local organising, south-to-south collaboration, and south-to-north collaboration. As technology continues to create new windows of opportunity, innovative ideas that capitalize on access to these new technologies and strengthen civil society capacity should be supported and evaluated.

CONCLUSION

This report lays out concrete, feasible, pragmatic steps toward making civil society a full player in the field of microbicide research, development, and introduction. The Civil Society Working Group identified literally dozens of gaps in the field and potential strategies for addressing them. It then distilled these down to the most critical areas where timely action would have a large impact on success.[xxii] This includes both success in advancing civil society's role in microbicide development and success in reaching the goal of making microbicides an accessible and effective reality in HIV prevention.

These recommendations are not an idealized "pie in the sky" vision, but achievable steps that will have far-reaching impact. Achieving them, however, will require the active engagement and support of researchers and their institutions, donors, and governments, as well as civil society. The recommendations in this report should be revisited, reassessed, and revised as progress is made and needs in the field change.

Civil society involvement is essential to building public awareness, interest in, and support for microbicides. Effective civil society engagement with scientists, researchers, trial sponsors, donors, and governmental authorities will create accountability where it does not currently exist, help avoid pitfalls, mobilize new resources, facilitate communication, and increase researcher/community trust. Everyone benefits. The reality is that — as trial host communities and end users develop greater expectations and make ever greater demands on the research establishment, especially in north-to-south collaborations—researchers' need for civil society to help ensure positive, meaningful, productive collaborations also grows.

The microbicide field can only benefit by involving civil society in the roles it is uniquely positioned and well-qualified to play. It is engagement worth investing in. The dividends will be enormous.

Appendix

MEMBERSHIP OF THE MICROBICIDE DEVELOPMENT STRATEGY CIVIL SOCIETY WORKING GROUP, 2006–2007

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[iii] Membership of the MDS Civil Society Working Group is listed in Appendix 1.

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[xix] CBPR is a collaborative research approach that engages the communities affected by the issue under investigation in all aspects of the research process. It is characterized by processes that enable communities, researchers, and local organizations to work collaboratively and improve health and well-being by taking action, including direct action for social change. For further information, see Viswanathan M, Ammerman A, Eng E, et al. *Community-Based Participatory Research: Assessing the Evidence.* Evidence Report/Technology Assessment No. 99 (prepared by the RTI International-University of North Carolina Evidence-Based Practice Center under Contract No. 290-02-0016). AHRQ Publication 04-E022-2. Rockville, MD: Agency for Healthcare Research and Quality; July 2004.

[xx] See **www.hivos.nl** for more information.

[xxi] See **www.MamaCash.nl** for more information.

[xxii] For a full listing of the gaps and potential strategies identified by the MDS Civil Society Working Group, please see **www.global-campaign.org/mds.htm**.

The Global Campaign for Microbicides (GCM) is an international coalition created in 1998 to serve as an interface between the scientific establishment and citizens whose lives will be influenced by microbicides — as eventual users, trial participants, taxpayers, and/or individuals at risk of, or living with, HIV/AIDS. The GCM agenda is twofold: to accelerate access to safe and effective microbicides, and to transform how science is done. GCM's staff supports microbicide advocacy and civil society engagement in the scientific process, through its direct work and in collaboration with hundreds of nongovernmental organisations worldwide who use GCM's resources to advance their own microbicide advocacy goals. These diverse allies include women's health and rights advocates, gay men's health activists, international development entities, gender equality organisations, and HIV/AIDS service providers. Unlike other actors in the field, GCM does not fund or develop products. Instead, it works to build a sustained political base among civil society groups for microbicide research and access and to empower them to engage productively in the scientific process.

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