



ICASO
INTERNATIONAL COUNCIL OF
AIDS SERVICE ORGANIZATIONS



A Community-led Advocacy Agenda for Microbicides



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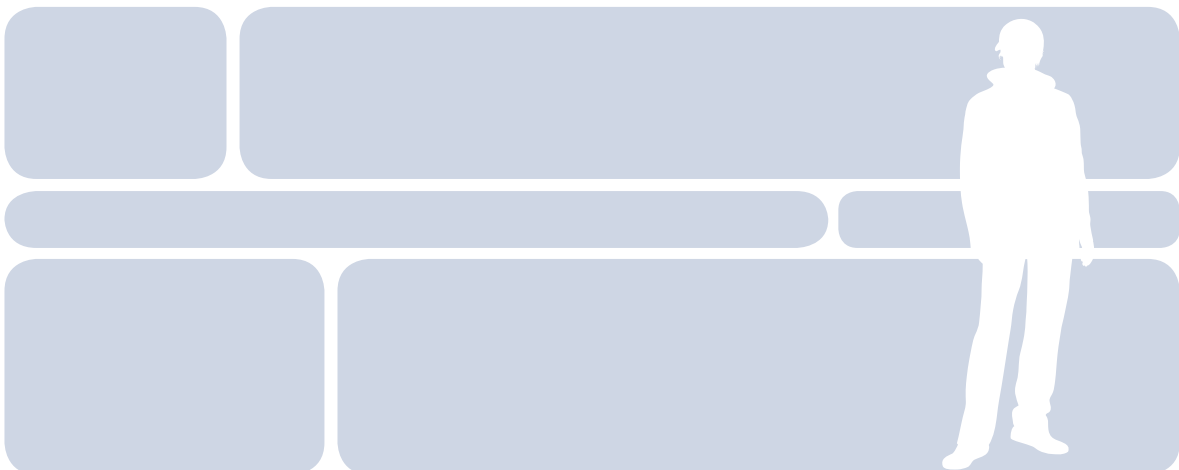
This document is dedicated to the memory of Steve Harvey, a tireless Jamaican AIDS advocate who was murdered in 2005.

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Executive Summary

Vaginal and rectal microbicides are biomedical prevention interventions, currently in clinical trials, which could substantially reduce new HIV infections among women and men who have sex with men (MSM). However, despite many years of clinical trials, no microbicide candidate to date has demonstrated sufficient efficacy to proceed to regulatory approval and the HIV field faces many scientific, operational, financial and ethical hurdles in bringing a prospective candidate from pre-clinical evaluation to a licensed and effective new prevention tool in the field.*

The community sector has an important role to play in promoting microbicides awareness, advocating for the ethical design and conduct of microbicide trials, collaborating with the research community to disseminate trial results and working with normative agencies, manufacturers and policymakers to prepare for the delivery of a safe and effective microbicide. In order to identify both the challenges and opportunities facing the community sector regarding their involvement in microbicides research and development (R&D) ICASO undertook a community-based research project in five focus countries: India, Nigeria, Kenya (all of which have experience with microbicide trials), Jamaica and Belize (in which community advocates are working to raise awareness about microbicides, including microbicides research.)

ICASO's research included focus groups, key informant interviews, and case studies based on the experiences of trial participants, researchers, community representatives and microbicide advocates, all of which were collected and analyzed in four country-level reports (with Jamaica and Belize included in a single joint report). This advocacy brief is based on the information and lessons learned from those documents and it includes three broad recommendations:

- 1. Strengthen Community Involvement in Microbicides Research & Development.**
- 2. Build Community-Sector Research Literacy.**
- 3. Increase Investments in Microbicides Research and Advocacy.**

A number of activities and examples from the research are included within each of the above recommendations, and are intended to provide guidance and good practice examples that will help the community sector become more informed and involved in microbicides research and advocacy. Ultimately the goal of greater engagement by the community sector is to accelerate the development of safe and effective microbicides as part of a comprehensive package of evidence-based HIV prevention interventions.

* The term 'efficacy' or 'efficacious' is used to describe the impact of an intervention on desired outcomes in a clinical trial (e.g., whether a topical gel microbicide reduces HIV infection); effectiveness is a term used to describe the impact of the intervention outside of the unique context of a clinical trial, where there are factors (such as regular counselling and free condom provision for trial participants) which may be different than in general community settings.

A Community-led Advocacy Agenda for Microbicides

Introduction

Despite a number of proven HIV prevention interventions and more than 25 years experience with the HIV epidemic, almost 7,400 new infections occur worldwide every day – an estimated 2.7 million in 2008 alone.¹

The limitations of existing prevention efforts in halting the spread of HIV have redoubled interest in evaluating vaginal and rectal microbicides as potentially powerful new biomedical tools that would complement existing HIV prevention interventions (including behavioural, biomedical and structural interventions) in the response to AIDS. The need for a female-controlled prevention intervention in a context of gender inequality, where many women have limited agency in sexual decision-making, has amplified interest in the potential of microbicides to reduce HIV transmission. The potential impact of an effective microbicide on the epidemic may be particularly significant among high-burden countries in sub-Saharan Africa, where women (15 years of age and older) account for approximately 60% of people living with HIV (PLHIV), and rates of infection among young, sexually active women (15 – 24 years of age) are particularly high compared to their male counterparts.²

Rectal microbicides hold promise for both heterosexual transmission and for men who have sex with men (MSM), a population which globally tends to have much higher HIV prevalence and incidence than the heterosexual population in both concentrated and generalized epidemics.³ However, the microbicide field faces daunting scientific, operational, ethical and financial challenges in moving potential candidates from pre-clinical evaluation to a safe and effective new intervention in the field.

How Microbicides Work

Opportunities and Challenges

Microbicides can potentially prevent or reduce HIV transmission through a variety of potential mechanisms, for example by interfering with viral attachment to target cells in the mucous membrane (or ‘mucosa’) of the vagina or rectum or by disrupting viral replication within cells.

The active compound within a microbicide can be formulated and delivered in a number of different ways via: gels, creams, suppositories, films, sponges, diaphragms and vaginal ‘rings’ or other cervical barriers that release drugs slowly over time. A number of different compounds, formulations and delivery systems are currently in pre-clinical (laboratory or in vitro) testing or Phase I, II or III clinical trials (in vivo testing in human volunteers) to evaluate their acceptability, safety, tolerability and efficacy in reducing HIV transmission. Rectal microbicides face additional challenges: rectal mucosa are thinner and contain a greater concentration of CD4+ cells (a primary target of HIV) compared to vaginal mucosa, so unprotected anal intercourse is a more effective route of HIV transmission for the receptive partner than vaginal intercourse.⁴ As a result, a microbicide that has demonstrated efficacy in clinical trials as a vaginal microbicide will not necessarily be an efficacious rectal microbicide, and will require separate testing in clinical trials.

Detailed information on the research and development (R&D) process for microbicides, the status of current microbicides pre-clinical and clinical trials, and related issues are available online at the Global Campaign for Microbicides (GCM) at <http://www.global-campaign.org>, AVAC Global Advocacy for HIV prevention at <http://www.avac.org>, the International Partnership for Microbicides (IPM) at <http://www.ipmglobal.org> and International Rectal Microbicide Advocates (IRMA) at <http://www.rectalmicrobicides.org>

The Rationale for a Community-led Advocacy Agenda

The community sector has a potentially powerful role to play in promoting microbicides awareness, advocating for the ethical design and conduct of microbicide trials, collaborating with the research community to disseminate trial results and working with normative agencies, manufacturers and policymakers to prepare for the delivery of a safe and effective microbicide.

The key message of the International Council of AIDS Service Organizations (ICASO) brief on community involvement in vaccine research is equally relevant for microbicides: inclusion of communities in research activities not only leads to better science (as it is likely to impact the enrolment, retention and trial practices), but it can also play an important role in ensuring that research findings are translated rapidly into accepted and effective programmes. History also demonstrates that when medical and public health research is planned and conducted without considering the cultural context of such work, or without regard for human rights, the individuals who participate in research activities, along with the communities they belong to, can be harmed.⁵

Working through our regional and country-level networks, in partnership with international leaders in microbicides development and advocacy, ICASO aims to expand and strengthen the community-sector microbicides advocacy movement that builds on existing work and strengthens links among community organizations (including national and international non-governmental organizations), trial participants, researchers, donors and policymakers to accelerate the pace of microbicides R&D.

Research to Inform an Advocacy Agenda

Although a number of biomedical prevention advocacy organizations have been involved in supporting community dialogue and engagement in microbicides research, there have been few transnational efforts to systematically collect information from the perspective of trial participants.

This includes the issues and challenges they face and how effective, long-term partnerships can be forged among the community sector, investigators and other stakeholders that will best prepare communities for microbicide trials and the implementation of an efficacious product.

As a result, ICASO undertook a community-based research project with two aims:

- to identify, document and share community experiences in microbicides trials;
- to improve the understanding of community issues and challenges in participating in microbicide trials and advocate for appropriate support mechanisms.

Capturing information on how communities have been involved in planning for and implementing microbicide trials, including the perspectives of investigators, will help identify the key challenges and opportunities in moving forward as microbicide research expands and prospective candidates move from clinical trials to potential regulatory approval. The voices of community members, advocates, trial participants and investigators will inform ICASO's global advocacy on microbicides and other new biomedical prevention technologies.



“The potential impact of an effective microbicide on the epidemic may be particularly significant among high-burden countries...”

Method

Questionnaires were developed and focus groups and one-on-one interviews were conducted with advocates, community members and researchers in three focus countries with experience in implementing microbicide trials: Nigeria, Kenya and India.

Questions focused on the type of information provided to prospective trial participants, the level of knowledge among community organizations and trial participants about microbicides development (and, in some cases, specific microbicide candidates), and what efforts have been made in capacity-building, policy development and advocacy by local, national and international community organizations and non-governmental organizations (NGOs).

Focus groups and interviews were also conducted in two focus countries (Jamaica and Belize) which have not yet hosted microbicide trials, and in which community organizations are working to prepare for microbicide trials and/or a potentially successful microbicide candidate. The International Rectal Microbicide Advocate (IRMA) provided a briefing paper on rectal microbicides, supplemented with interviews from participants in a Phase I rectal microbicide trial sponsored by the University of California in Los Angeles (UCLA) to help document the unique issues faced by rectal microbicides research, which is at a much earlier stage of development than vaginal microbicides.

Information from interviews and focus groups were collected as a series of case studies. Consistent issues were then identified and included as lessons learned and recommendations in four country-level summary reports - one each from India, Kenya and Nigeria and a fourth joint report from Jamaica and Belize. Although the level of community involvement in microbicides research, development and advocacy varied widely among the focus countries, three broad themes emerged across the reports, irrespective of their stage of development, in addition to country-specific recommendations. The first two themes are operational in focus, while the third addresses the need for an enabling policy environment and the financial support required to support a community-led microbicide advocacy agenda and the expansion of microbicide R&D. Case studies selected from each of the five focus countries and the IRMA update on rectal microbicides are appended to provide additional detail in support of these recommendations and to provide practical guidance on community involvement in microbicides R&D. (See Case Studies.)

Key Recommendations

Throughout the interviews and focus group discussions contextual issues in all five focus countries emerged related to gender inequality, the challenges of condom negotiation in a context of economic dependency (particularly for women), homophobia and the social stigma faced by populations with high rates of HIV infection and even potential stigma related to participation in HIV biomedical prevention clinical trials.

The need to establish a shared understanding of the sexual and reproductive health issues facing women and how they impact on sexual decision-making and prospective participation in microbicide trials emerged as a particularly strong theme. Research on rectal microbicides faces a unique set of financial, social, cultural and sometimes statutory barriers: the association of anal sex with gay and other men who have sex with men (MSM) populations in countries where same-sex intercourse is highly stigmatized and often illegal is a substantial barrier for testing prospective candidates. In Jamaica, for example, the case study noted that violence against MSM (including the murder of a leading gay rights advocate who was working on microbicides advocacy) reflected virulent widespread homophobia that made preparing for rectal microbicides particularly challenging. Although anal sex is relatively common among heterosexual couples, it remains taboo in many cultures and community-sector advocates and the research community face formidable challenges in preparing communities for rectal microbicide trials.

Interviewees and focus group participants stressed the need to ensure these contextual issues inform how community sector organizations, donors, investigators and trial sites need to work collaboratively to prepare for research into new prevention technologies and the potential delivery of an efficacious product (see Box 1: The Tenofovir Trials).

The experiences of community members, advocates and investigators in the case studies collected as part of the ICASO research project highlight the importance of a community-led advocacy agenda in ensuring that these contextual issues inform the design and conduct of microbicide trials. Early and effective communications among the research team, sponsor(s) and community representatives are fundamental to all three of the recommendations below, and should be considered a prerequisite for community involvement in the design, ethical approval, conduct and post-trial dissemination of research findings.

The Tenofovir Trials: Why Collaboration among Researchers, Sponsors and the Community Sector is Critical for Success

BOX 1

The cancellation of several clinical trials in 2004 and 2005 evaluating tenofovir (a drug approved for treating HIV infection) as a potential preventive agent among prospective cohorts of sex workers (in Cambodia) and sexually active heterosexual women (in Nigeria, Cameroon and Malawi) was referenced in some reports as a cautionary tale of what can happen when clear, consistent and accurate communications among stakeholders are not established early in the clinical trial planning process about important issues, including the rationale for selecting particular populations within which to evaluate a candidate microbicide, the risks and benefits of trial participation and counselling, care and treatment standards for trial participants (including post-trial care). The dynamics of these and other trials are further complicated by the fact that the majority of research is funded and driven by research granting agencies in high-income countries but conducted among communities (often vulnerable populations which face pre-existing stigma and discrimination) in resource-poor settings. Accusations of using marginalized populations as ‘guinea pigs’ and a lack of responsiveness to community concerns were levelled at researchers, while the researchers in turn accused local and international activists for grossly misrepresenting the trial protocol in their advocacy campaign. The Global Campaign for Microbicides (GCM) recently released two case reports analyzing why the trials in Cameroon and Cambodia failed, identifying a number of lessons learned which are consistent with the key recommendations in this advocacy briefing. The Global Campaign for Microbicides (GCM) case reports are available online at <http://www.global-campaign.org/ethics-resources.htm>

The three overall recommendations are consistent with guidance outlined in the Good Participatory Practice Guidelines for Biomedical Prevention Trials, released jointly by UNAIDS and AVAC in 2007.⁶ The Guidelines aim to provide systematic guidance on the roles and responsibilities of entities funding and conducting biomedical HIV prevention trials towards participants and their communities; additional guidance and discussion on biomedical HIV prevention research is available in Ethical Considerations in Biomedical HIV Prevention Trials.⁷

The three recommendations are:

- 1. Strengthen Community Involvement in Microbicides Research & Development.**
- 2. Build Community-sector Research Literacy.**
- 3. Increase Investments in Microbicides Research and Advocacy.**

Recommendation 1 **Strengthen Community Involvement in Microbicides R&D**

One of the strongest themes that emerged throughout the case studies and reports was the need to expand and strengthen community involvement in microbicides research and development: to prepare communities – particularly populations at high risk for HIV, such as sex workers, sexually active young heterosexual women and gay and other men who have sex with men (MSM) – for informed participation in the design, ethical approval and conduct of vaginal and rectal microbicide trials, and to ensure that trial results are widely disseminated (see Box 2: Increasing Microbicides Awareness Among the Community Sector). Advocates and community members were consistently enthusiastic about becoming involved in microbicides research and understood the potential impact of an effective microbicide at both an individual and population level. However, community engagement in various aspects of the research process was often described as inadequate or inconsistent. Even the establishment of a Community Advisory Board (CAB) or Community Advisory Group (CAG) was not always sufficient to ensure what community advocates felt was an appropriate and effective voice for community issues.

Increasing Microbicides Awareness Among the Community Sector

BOX 2

The Kenya AIDS NGOs Consortium (KANCO) worked with GCM and the International AIDS Vaccine Initiative (IAVI) on increasing awareness of vaccines, microbicides and other new prevention technologies among a range of Kenyan NGOs. A 2003 joint project between KANCO and IAVI created a Vaccine Support Network comprised of a range of civil society organizations that have included increasing basic biomedical research literacy and awareness and advocating for increased research into new prevention technologies. A 2008 partnership between KANCO and AfriCASO focused on raising awareness about microbicides and the need to increase investments in new prevention technologies through national advocacy forums, newsletters and other community media.

Interviews with community advocates and the Principal Investigator (PI) of a Kenyan Phase I microbicide trial, for example, revealed differences in perception regarding whether the CAG was representative of the community, susceptible to pressure from trial investigators or had the required expertise (particularly related to women’s sexual and reproductive health issues) to ensure it was adequately representing community issues. Some CAB members of an Indian trial reported that researchers did not communicate with either study participants or the CAB about study results once the trial had concluded.

Although CABs have been widely accepted as the standard mechanism for community input into clinical research, their effectiveness is dependent on the technical expertise, accountability and diversity of individuals serving on them, on having a clearly-defined operational authority in monitoring and providing input into the design and conduct of a trial, and on the research team supporting and communicating with the CAB throughout the trial. CABs have also proven insufficient to address all of the potential issues related to community involvement in a trial which may arise at each stage in the research process, and additional mechanisms such as participant forums have proven useful to address concerns among participants and community advocates throughout the clinical trial process. The need for trial sponsors, investigators and local trial sites to establish ongoing relationships with national and local community-sector organizations and advocates early in the process of protocol development was reiterated throughout the case studies and country-level reports (see Box 3: Involving Communities in the Research Process).

Involving Communities in the Research Process

BOX 3

The Phase III cellulose sulphate microbicide trial in two Nigerian sites (Lagos and Port Harcourt) included a full year of planning to ensure communities were appropriately prepared and guidelines regulating research in human subjects followed rigorously. Both Nigerian trial sites recruited ‘participant advocates’, independent of the trial, to ensure any concerns raised by trial participants would be addressed and participant forums were held regularly to share information and address emerging concerns. The Nigerian HIV Vaccines and Microbicides Advocacy Group (NHVMAG) trained outreach workers before active recruitment began, helping to establish strong relationships between the research team and community representatives. The Port Harcourt site recruited community-based field workers from local NGOs working in the area of sexual and reproductive rights and health, who in turn developed relationships with prospective trial participants that helped build trust in the research process. NHVMAG also trained institutional review board (IRB) chairs to help ensure an appropriate ethical review, and additional trainings were held for several local IRBs.

Ongoing relationships require due diligence on the part of both community-sector organizations (the staff of which often do not have the technical knowledge required for informed participation in biomedical research discussions) and of the research community (which often has limited knowledge of community issues and has sometimes been content with desultory attempts at engaging community-sector organizations in trial design and implementation).

Key activities to ensure effective community participation in clinical trials include:

- Establish **formal relationships** among clinical trial staff and national and local community-sector organizations early in the clinical trial planning process.
- Establish **formal mechanisms** (e.g., by establishing a CAB, trial participant forums and other mechanisms) in advance of ethical review and recruitment that establishes clear communication channels and messages, accountability mechanisms and roles/responsibilities of key stakeholders throughout the research process, including post-trial dissemination of trial results.
- Ensure the **CAB composition** reflects the community in which the trial is situated and includes relevant key populations (such as sex workers, MSM and PLHIV).
- Establish clear CAB Terms of Reference that ensures a **shared understanding** among the research team and community representatives regarding the role, responsibilities, composition and operational authority of the CAB.
- Ensure **community input** into the ethical review of the trial protocol.
- Establish and communicate processes for trial participants to **contact community-sector** representatives before, during and after the trial.
- Establish a **shared understanding** of the social, cultural, economic and statutory issues related to the study population (e.g., gender inequity, women's sexual and reproductive health issues, homophobia) and how they will inform the trial protocol, communications (including recruitment efforts), counselling, care and treatment standards and dissemination of trial results.
- In advance of trial recruitment, **establish agreement** between the CAB (and/or other community input mechanisms), research team and relevant treatment programmes on counselling, care and treatment standards for trial participants, including individuals who screen out of the trial at enrolment or during the trial.
- Develop strategies for improving **enrolment and community engagement** in the research process, such as educating male partners regarding microbicides, in collaboration with community-sector organizations serving study populations.
- Establish consensus on the how to **communicate trial findings** (including unexpected results such as increased HIV incidence in the intervention arm) to study participants and community-sector organizations.

Recommendation 2

Build Community-Sector Research Literacy

One of the most consistent issues that emerged from the case studies was the need to improve biomedical research literacy within communities and among local and national community-sector organizations.

The biomedical research field is operationally complex and has unique ethical issues that require a solid understanding of clinical trial design and conduct, as well as the science underpinning microbicides R&D. Building research literacy among community organizations, vulnerable populations and trial participants related to new prevention technologies and the research process is key to ensuring that the risks and benefits of trial participation are accurately assessed, that appropriate standards of counselling, care and treatment (including length of post-trial care) are established in advance of recruitment efforts and that trial results are available to participants and community representatives after the trial concludes.

There needs to be a stronger and more consistent understanding of the biomedical research process (e.g., why investigators need very large trial cohorts among high-prevalence populations in order to demonstrate efficacy and the role of the Data Safety and Monitoring Board in evaluating interim trial data). Without this understanding, community representatives on CABs and other community-input mechanisms will be hampered in their ability to understand their role and how best to represent vulnerable communities and trial participants in the research process. Information on specific trial protocols should be supplemented with training and resources developed by multilateral agencies and international and regional microbicide advocacy organizations to ensure the impartiality of the information source.

Understanding what informed consent means in a low-income setting where, for example, trial participants may have access to much higher standards of health care (e.g., regular counselling, testing and treatment for HIV and other STIs) than is available to other community members and how this may affect recruitment, retention and post-trial standards of care, is particularly important in informing ethical reviews and informed consent procedures (see Box 4: Informed Consent.) Ethical guidance in this field recognizes that vulnerable populations which are already socially or economically disadvantaged may be particularly susceptible to coercion or influence. This is reflected in the Declaration of Helsinki⁸, Ethical Considerations for Biomedical HIV Prevention Trials and Good Participatory Practice Guidelines. Knowledge of the research process and potential misconceptions about the efficacy of the candidate under study must be addressed regularly. This applies to both specific studies and more broadly to work undertaken by community-sector organizations in preparing communities for the

delivery of an efficacious microbicide; managing expectations among trial participants and community members must be done with accurate, current information about specific microbicide candidates.

Informed Consent

BOX 4

In one trial site at the National AIDS Research Institute in India, a two-step informed consent process was employed: Participants were initially screened for eligibility and then for actual enrolment consent. The enrolment consent procedure was supplemented with a “test of comprehension”, which has proven to be a useful tool in assessing participant’s knowledge. The Principal Investigator indicated that they had introduced this over the last 2-3 years to ensure that the participants’ understanding about the study procedures is very clear.

Specific activities to increase biomedical research and science literacy may include:

- Train national, state and local **community-sector advocates** on the fundamentals of HIV biomedical science and research using resources developed by UNAIDS, AVAC and GCM, including the Good Participatory Practice Guidelines for Biomedical Prevention Trials.
- Establish an **understanding of the research ethics** guiding biomedical researchers, including Ethical considerations in biomedical HIV prevention trials and the Declaration of Helsinki.
- Establish processes for **community input on the trial protocol**, including informed consent procedures, Institutional or Ethical Review Board approval, standards of care for trial participants and mechanisms for disseminating research findings after study conclusion.

Recommendation 3

Increase Investments in Microbicides Research and Advocacy

Establishing an enabling policy environment and increasing financial support for microbicides R&D are key to accelerating the pace of microbicides research and expanding the number of countries prepared to host microbicide clinical trials.

All of the country reports from the five focus countries underscored that substantial preparatory work is required to strengthen the technical capacity, infrastructure and policy framework required to conduct well-designed clinical trials that include community-sector input throughout the research process. Analysis of the country reports revealed that countries in which community-sector organizations have been funded to build their technical capacity and engage in policy development and advocacy activities with academic research centres and national AIDS authorities have been more successful in attracting microbicides R&D than those in which microbicides advocacy has been limited (see Box 5: Placing Microbicides on the National AIDS Agenda).

There are formidable challenges to placing microbicides – particularly rectal microbicides – on the agenda of policymakers. The country reports from Jamaica and Nigeria, for example, noted that – as a result of the virulent homophobia prevalent in these settings - raising awareness about rectal microbicides needed to be carefully managed by working with community-sector organizations serving gay/MSM populations and that community mobilization efforts also needed to include heterosexual populations.

Placing Microbicides on the National AIDS Agenda

BOX 5

In Nigeria, a number of community sector organizations including NHVMWG, the Network of People Living with HIV/AIDS in Nigeria (NEPWHAN), Microbicide Advocacy Network and Gender Concerns (MANAG) and Alliance Right (which advocates on behalf of MSM communities in Nigeria) have been actively engaged in working with GCM, key populations and policymakers for several years and have been successful in advocating with the National Action Committee on AIDS to include promotion of research into new prevention technologies in the National Strategic Framework (the Nigerian National AIDS Plan). They are currently advocating for the adoption of a standard of care consensus statement for new prevention technologies with the federal government.

Advocacy with national regulators and policymakers should include plans for accessing a microbicide that has demonstrated efficacy in clinical trials as part of a comprehensive approach to HIV prevention. Country-level reports underscored the need to work with policymakers and key population communities for the potential introduction of an efficacious microbicide as part of a package of evidence-based HIV prevention interventions.

In 2007, the total global investment in microbicide R&D was approximately US\$226.5 million, a 2% increase over 2006 funding levels; of this amount, approximately 90% was provided by the public sector, 8% by philanthropic foundations and 2% by the commercial sector.⁹ Unlike treatment for HIV, there is limited commercial interest among the pharmaceutical and biotechnology firms in microbicides R&D. As a result, the vast majority of funding for microbicides R&D must – at least initially - come from public sector and philanthropic foundations. Additional investments are needed to expand the range of candidate products and delivery mechanisms in development. Investment in rectal microbicides clinical research received little attention or funding until 2004, when the US National Institute of Allergy and Infectious Disease (NIAID) began to allocate funding for research into rectal microbicides.¹⁰ The world's first (Phase I) clinical trial of a rectal microbicide was not launched until early 2007, although there are promising signs that increased attention from NIAID and other donors will result in a robust pipeline of candidates, including research to assess vaginal microbicides (e.g., the PRO2000 vaginal gel) for its efficacy as a rectal microbicide.

Activities to develop an enabling policy environment and increased investments in microbicides R&D may include:

- **Expand existing collaborations** among local, national, regional and international community-sector organizations and multilateral agencies on microbicides advocacy.
- **Advocate for increased investment** to support community-sector training and capacity-building on vaginal and rectal microbicides research and policy development as an integral component of microbicides research funding.
- Collaborate with academic research centres, UN agency offices, the media and other stakeholders to advocate for **the inclusion** of vaginal and rectal **microbicides R&D investments** (for infrastructure, training and public awareness) as a component of national AIDS plans.
- Advocate for the **inclusion of funds** to prepare for the licensing, purchase and distribution of an efficacious microbicide candidate in national AIDS plans.



2007 – 2% increase in global investment in microbicide R&D

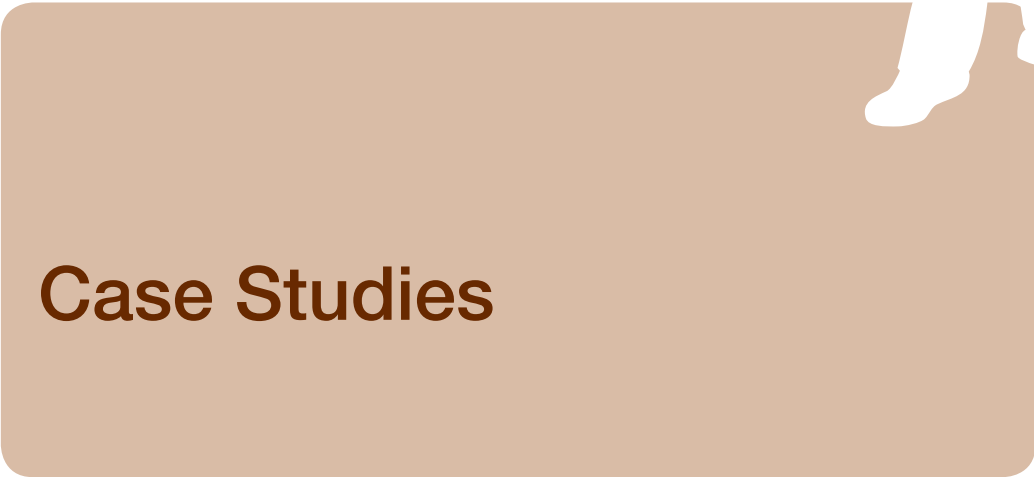
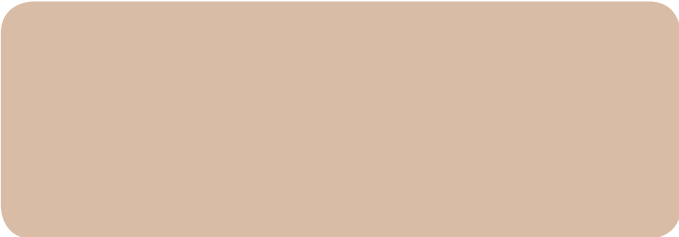
Conclusion

Microbicides have the potential to prevent the spread of HIV and may be particularly effective at reducing infections among women and MSM, groups which continue to face formidable challenges in implementing existing evidence-based prevention interventions.

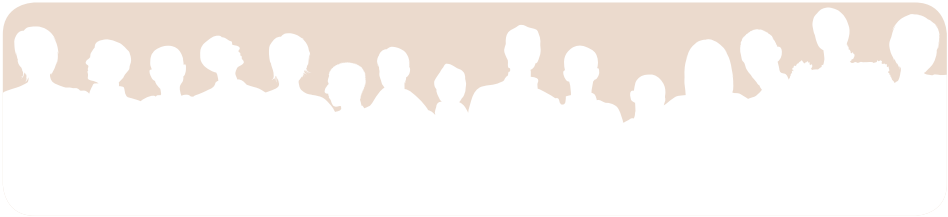
This advocacy brief identifies three broad recommendations and specific activities related to each recommendation that will help advance a community-led microbicides advocacy agenda. Implementing these recommendations will better equip the community sector to move forward on a coordinated approach to microbicides advocacy at the local, national and international level, in partnership with the research community, sponsors and policymakers.

Ultimately, the promise of microbicides will only be realized when all stakeholders— from donors and researchers, to advocates and trial participants— play a role in research and development. The involvement of communities, in particular, is crucial because they are both the subjects of research trials and the true beneficiaries when a successful product is discovered. They will help determine not only whether this new prevention technology is efficacious in clinical trials, but whether it will be effective when used by the women and men who need it most. In the end, the success of the microbicides movement will be determined not just by technological breakthroughs, but by whether women and men from the most vulnerable communities have the means and tools to protect themselves.





Case Studies



Community Involvement in Nigeria: Perspectives from Microbicides Researchers

Introduction

Since the late 1990s, Nigeria has hosted multiple microbicide trials, including two Phase 3 trials of the most promising microbicides. The Phase 3 Cellulose Sulfate trial, which occurred in Lagos and Port Harcourt, represents a pioneering example of community involvement and interaction between researchers, community members, advocates and policy-makers. It was halted in 2007 due to safety concerns,* but the trial process itself presents a model for future research.

Pre-trial preparations

Effective Partnerships

Scheduled to last three years beginning in March 2004, the trial included one full year of participant recruitment and pre-trial preparation to ensure communities were appropriately prepared and regulatory guidelines rigorously followed. Ethical approval was obtained from the study centres and from the National Agency for Food and Drug Administration and Control “NAFDAC”. Both sites recruited advocates independent of the trial to ensure volunteer concerns were addressed. In addition, the Lagos site held advocacy visits and community sensitization programmes. Effective partnerships were forged with community groups, and outreach workers were trained by the Nigeria HIV Vaccine and Microbicides Advocacy Group (NHVMAG) before active community education and engagement. Extensive outreach was undertaken to sensitize the community and to encourage them to participate in trial efforts. This process was described by field workers as follows:

“We have to become their friends... We go to motor parks and other places where people take part in risky behaviour. Most times we visit with them... and they tell us things about their everyday life. Through our interaction with them, we even get to know the possible reaction of some of their male friends, at least the steady partner to their participation in the study.”

* While no risk of increased HIV infection was found in Nigeria, results from a sister trial simultaneously taking place in Benin, showed significantly more HIV infections in the microbicide group than the placebo group. The trial was also stopped in Nigeria as a precautionary measure.

In Port Harcourt, community-based field workers were recruited from local NGOs working in the area of sexual and reproductive rights and health. The advantage of this approach became apparent in the course of the trial: they had a clear understanding of the community, and the frequency of interaction with potential trial participants facilitated the building of trust. Furthermore, the training received by the study staff built the capacity of local workers, enriching the resource pool of local civil society organisations.

The Trial

A Comprehensive Approach

During the study, participants received condoms and HIV prevention counselling. Treatment was available to HIV positive volunteers and participants who sero-converted, with referral to national or international ART programs (PEPFAR for the Lagos site, and the national ART program for the Port Harcourt Site). Additionally, participants were referred to a local branch of the Network of People Living with HIV and AIDS in Nigeria (NEPWHAN) to receive additional care and social support.

This trial was unique in that the research team actively solicited participant feedback to assess their interpersonal approach and their recruitment and retention strategies. According to Dr. Obunge, the enthusiasm, personal commitment and openness of the field staff enabled them to have an on-going dialogue with the participants culminating in joint meetings coined “participants’ forums”. These meetings were steered by the participants themselves, with outreach workers in attendance. The meetings fostered a sense of ownership of the trial, and participants began to consider themselves as partners in the trial process.

Finally, the health and well-being of participants was taken into consideration after the trial ended. One post-trial activity will actively trace all sero-converted and screened participants beyond the study protocol. In this way, local civil society organizations groups such as NEPWHAN can continue to provide services to volunteers long after the research has ended.

Lessons Learned

- **Actively involving civil society organizations** is a critical component of trial effectiveness. Researchers increased the success of their work by involving civil society organisations in a variety of ways: hiring members of local NGOs, tapping into the expertise of national level advocacy groups such as NHVMAG, and utilizing the services of NEPWHAN.
- **Involving local staff** familiar with key populations facilitates community access and increases community capacity in the longer term. Local staff trained by the research team had a clear understanding of community needs, and became a valuable resource for community based organizations in the future.
- Participants' forums keep volunteers engaged and informed. **Open dialogue** gives participants a place to make their concerns heard, increasing their interest and personal investment in the trial process and outcome.
- **Providing treatment to research participants** is an important component of trust building. Partnerships with national and international drug therapy programmes helped participants feel as if they would be taken care of during the trial and beyond.

“Involve civil society organizations, involve local staff and ensure open dialogue.”



Selling Hope: Microbicides Advocacy in Jamaica

Introduction

The Caribbean region is ranked third in terms of world-wide rates of HIV infection and has one of the highest rates of infection in women outside of Africa.¹¹ Sexual intercourse is the main means of transmission, particularly unprotected sex with multiple partners. High rates of transactional sex and an early age of sexual debut contribute to the spread of the disease, behaviours that occur in a context of poverty, violence, and gender inequalities in which women have little sexual decision-making power.

Jamaica is a Caribbean country that has actively addressed the AIDS epidemic for two decades. In 1988, the Jamaican government established a National HIV/Sexually Transmitted Disease Prevention and Control Programme, an integrated disease prevention and health promotion initiative directed towards behavioural change. The goal of the current 2007 – 2011 multi-sectoral plan is universal access to prevention, treatment, care and support. Despite its active AIDS movement, however, Jamaica (like the rest of the Caribbean) has hosted no microbicides trials. The microbicides advocacy movement is in its infancy, with only a small group of committed supporters based in Jamaica AIDS Support for Life (JASL), the oldest AIDS support organization in the Caribbean.

The experience of JASL illustrates the tenacity of microbicides advocates in hostile conditions, and its readiness to play a role in advancing microbicide research.

Jamaica AIDS Support for Life (JASL)

A Pioneer in the Region

Founded in 1991 by a group of men assisting a friend dying of AIDS-related complications, JASL is the oldest HIV and AIDS organization in the Caribbean. It is dedicated to preserving the dignity and rights of persons living with HIV and those affected by AIDS, with a particular focus on marginalized communities. The main focus of its work is delivering education and support services and community empowerment.

JASL is the base of microbicide advocacy in the Caribbean, hosting four microbicide advocacy working groups, including one devoted to rectal microbicides. Working group members come from a wide variety of professions and backgrounds including:

- nurses
- doctors
- the community coordinator of JASL
- clergy
- the Red Cross and the Parish Aids Council
- the Ministry of Health
- HIV community organizers
- the Mandeville MSM community
- people living with HIV

The advocacy work of JASL is undertaken in a country in which homophobia is rampant and discussions of anal sex remain taboo. In 2005 its work suffered a major setback following the hate-based murder of prominent AIDS activist Steve Harvey. In recent years, however, microbicides advocacy has gained new impetus. Five goals have been identified as central to the microbicide advocacy groups and to preparing communities for the advent of microbicides. These goals are to improve the understanding of: science literacy (the science behind HIV and AIDS) and research literacy; to support rectal microbicide advocacy; to develop advocacy tools for advocates and to strengthen public presentation skills (through training.)

According to Tonya, a JASL coordinator of support services for people living with HIV, advocacy around microbicides in Jamaica “makes women believe a solution is possible.” Ultimately what she and her fellow advocates are doing is “selling hope.” Tonya says:

“I talk about it in my work all the time, every day. I see women who say my partner does not want to use a condom and I tell them about microbicides, and they all want to know where that product is. Even though it is not available, I give them the Global Campaign for Microbicides address to check it on-line. I use every opportunity to do this. I have to say I am biased, I talk only to women about this, not men. This gives women hope, and hope is important because you know that someone is thinking about fixing a problem that is so difficult for you.”

Lessons Learned

- **Involving individuals** from a wide variety of professions and backgrounds gives the microbicide working groups legitimacy and increases their effectiveness.
- **Education** in HIV science and prevention research bioethics is required to ensure effective community-sector advocacy and community preparedness.
- Offering advocates user-friendly **tools and training** in communications and public presentation empowers them in their role of developing public awareness.
- **Integrating rectal microbicides** into all microbicides advocacy work is key to strengthening consensus for the cause.
- Getting **women excited about the potential of microbicides** is a vital component of movement building.

“Involve individuals, offer tools and training, and create advocacy opportunities.”



Bridging the Gap: Connecting Researchers and Local Communities in Kenya

Introduction

Approximately 1.1 million adults are currently living with HIV in Kenya. While overall prevalence rates are falling, significant gender disparities remain. Twice as many Kenyan women as men are living with HIV and young women aged 15 to 24 are 5.5 times more likely to become infected with HIV than young men of the same age. Despite issues of gender around HIV and AIDS being national news and Kenya hosting the first international conference focused on women and HIV in 2007, many Kenyans have no knowledge of microbicides. Indeed, there is not a single mention of microbicides or other new prevention technologies in either the 2005-2010 Kenya National HIV/AIDS strategic plan or the 2008 country progress report for UNGASS.

While the Global Campaign for Microbicides (GCM) works in partnership with local organizations to spearhead microbicides campaigns, only a few have been involved to date and most of these are Kenyan branches of international NGOs or national research institutes collaborating with international/regional partners. One exception is the Kenya AIDS NGO Consortium (KANCO) which coordinates networks of NGOs, community-based organizations (CBOs), faith-based organizations (FBOs) around HIV and AIDS issues, including microbicides.

Advocacy Issues

Meaningful Involvement of Communities

The work of Kenyan microbicides advocates is focused on involving communities in microbicides research. They are a bridge between researchers, trial participants, and community members. As the microbicides advocacy movement in Kenya matures, they increasingly serve as watchdogs, ensuring that trials follow ethical guidelines and that communities are thoroughly informed.

The Kenyan microbicides advocacy movement is, however, in its infancy, and many advocacy groups have yet to mobilize their members around clinical trials. In fact, 7 out of 10 respondents who were queried about microbicide trials were not prepared to participate due to lack of information. This may be due to the limited data available on the ongoing trials, as well as a lack of collaboration between clinical trial institutions and civil organizations. Key civil society organizations, especially in the areas of gender, sexual and reproductive health, have been conspicuously absent from involvement in

clinical trials. Finally some advocates have expressed the view that community advisory boards or groups are being manipulated by trial staff who seem more concerned with completing research than with representing the local community.

Approach

Partnerships between Civil Society Organizations and Research Agencies

Despite the fledgling status of microbicides research in Kenya, the work of community advocates appears to be making a difference. During the course of a trial that involved testing a female vaginal ring, KANCO itself participated in the research process by working with the principal investigator and the Ethics Committee to develop research tools, such as an in-depth interview guide, to help trial staff comply with research ethics.

Research agencies themselves have undertaken a number of activities to better inform communities and ensure they have a voice in the microbicides movement. These include:

- workshops and seminars on microbicides
- involvement in key HIV events such as World AIDS day
- participation in community events where they share information regarding the trials
- developing simplified educational materials such as fliers and fact sheets and distributing them to community members.

Advocates noted that information sharing is critical to community involvement. Communities should be knowledgeable about the objectives, goals and outcomes of the trials in which they participate, notified of their rights and available compensation in the event of adverse effects, and kept up to date on the progress of the studies. It is also vital to manage the expectations of volunteers. They must understand their role in testing products that are not yet available to the public. According to one advocate,

“Whether people are illiterate or semi-literate, strategies should be devised to ensure that all communities in Kenya understand issues surrounding microbicides.”

Reaching vulnerable communities is of particular concern. Despite such groups being most affected by HIV and AIDS, they often have little say in the policies and programmes that affect their lives. Some national and international groups have recently begun work with key populations groups. For example, the Bar Hostess Empowerment and Support Program (BHESP) works with sex workers and bar hostesses in three provinces in Kenya. In an effort to inform and empower women, BHESP has organized

seminars on microbicides for their constituents, and has met with researchers to gain up-to-date information on the state of microbicides research. The GCM has also been working in this area. A staff member who was interviewed stated:

“The Campaign is also working with MSM mainly through our membership to IRMA (International Rectal Microbicides Advocates). In Kenya and other African countries we are in the process of cultivating links with vulnerable communities, however we are at the very early stages of our work.”

Lessons Learned

- **Involving communities** in trial design should be mandatory in all planned studies.
- **Understanding of research literacy** is vital for community advocates.
- **Involving local communities** is integral to the trial process. These include:
 - key civil society organizations such as experts on gender, sexual and reproductive health;
 - community advisory groups who both participate in the trials and represent community needs;
 - vulnerable communities from whom trial participants should be actively recruited and whose needs must be taken into account in the research process.



“In Kenya and other African countries we are in the process of cultivating links with vulnerable communities”

Creating an Advocacy Movement: The Nigerian HIV Vaccine and Microbicides Advocacy Group

Introduction

By the end of 2007, women represented over 70% of adults (15+) living with HIV in Nigeria, the most populous country in Africa, with the primary mode of transmission being heterosexual sex.¹² Factors that contribute to the spread of HIV include low levels of knowledge around sexual and reproductive health, early marriage, and a weak and fragmented healthcare system. Large areas of the country lack a basic healthcare infrastructure, hindering the provision of HIV testing and basic prevention services. For example, many Nigerian health centres do not provide male condoms, and the price of female condoms is out of reach for the average Nigerian.¹³

Despite these obstacles, Nigeria has effective civil society organizations oriented towards new prevention technology (NPT): The Nigeria HIV Vaccine and Microbicides Advocacy Group (NHVMAG) is the national coalition for advocates and activists working to raise awareness of the importance of NPT in Nigeria. NHVMAG has played a valuable role in convincing the government to approve of microbicide research in the country.

The Formation of the NHVMAG

Communities Promoting HIV Research

The roots of NHVMAG began in the late 1990s when Nigerian AIDS advocates recognized the need for a community group to promote HIV research. The NHVMAG was officially formed in May 2003 as an outgrowth of the National HIV Vaccine Plan and became the premier organization advancing research and development of NPT in Nigeria. Its strategy consists of:

1. **fostering NPT research;**
2. **facilitating research literacy;**
3. **ensuring access to new NPT products within a reasonable period of time.**

From its inception, members have explored opportunities to educate communities and the general public in a variety of ways:

- newsletters
- list serves
- training
- advocacy
- recruiting media personalities to facilitate round table discussions and offer public presentations
- creating opportunities to encourage advocate-researcher communication and facilitate public support for the research process

For example, researchers, advocates, and others had the opportunity to meet at a 2004 National Advocates meeting, funded in part by the Global Campaign for Microbicides. Special efforts were made to reach out to policy makers: training was organized for Institutional Review Board (IRB) members to review research protocols, and IRBs, along with the National Food and Drugs Regulatory Agency, received guidance on the ethics of NPT research.

Internationally, NHVAG has engaged in extensive networking with regional and international partners. Relationships have been formed and strengthened with international advocacy groups such as the African Microbicide Advocacy Group (AMAG), the Global Campaign for Microbicide, AVAC, and the International Partnership for Microbicide (IPM).

Elements of Success

Evolving and Improving

The NHVMAG attempts to strike a balance between maintaining the kind of organizational discipline necessary to influence national policy while retaining a structure flexible enough to collaborate with diverse NGOs and advocacy networks throughout the country. Its success is due to its efforts to continually evolve and improve its organizational structure. For example, two key NGOs, the Network of People Living with HIV/AIDS in Nigeria (NEPWHAN) and the Civil Society on HIV/AIDS in Nigeria (CiSHAN), were recently invited to become part of its Steering Committee. This strategic move made NPT advocacy and community awareness important elements on the national agendas of these key networks and that of their partner organizations. Other restructuring efforts included the creation of semi-autonomous zonal offices in the six geopolitical areas of Nigeria. In this way, NHVMAG is better placed to increase research and science literacy throughout the country.

The NHVMAG has been successful in influencing and informing community-based organizations and in incorporating its agenda into national policy. For example, providing and defining a standard of care for trial participants culminated in the development of a national consensus document. A NPT research desk was created within the office of the National Action Committee of AIDS (NACA), and NPT issues were included in the 2005 – 2009 national HIV and AIDS strategic document.

Lessons Learned

- Building a **core group of advocates** who understand the process and ethics of clinical trial research and can serve as “community watchdogs” for local trials is vital.
- Building **public support** for microbicide research by using a wide variety of tactics is effective.
- **Involving HIV and AIDS networks** is key to strengthening microbicide advocacy. Advocates must work to ensure local HIV and AIDS NGOs promote NPTs.
- Involving and **training policy makers** such as IRBs and drug regulatory agencies is critical for the inclusion of microbicides in national HIV and AIDS agendas.
- Involving **regional and international partners** strengthens the argument for microbicides on a national level.



“Build public support, involve AIDS networks, and train policy makers.”

Challenging Taboos and Catalyzing Rectal Microbicides Advocacy

Introduction

Worldwide, a significant percentage of all anal intercourse is unprotected, and anal sex is particularly risky because the rectal lining is more fragile than that of the vagina and its cells are more vulnerable to HIV. Anal sex partners, both receptive women and men, have a 10 to 100 times greater risk of HIV infection than insertive partners during unprotected sex.¹⁴

Although condoms provide effective protection against HIV and other sexually transmitted infections, power imbalances mean that many receptive sexual partners cannot insist on consistent condom use. Rectal microbicides have the potential to address this issue because they can be used without the permission of the insertive partner.

Current Status

Underfunded, but slowly building momentum

Rectal microbicide research and advocacy lags well behind that of vaginal microbicides. In 2005 the world's first rectal microbicide safety trial was conducted, and more Phase I trials are in the planning stages, but research remains under-funded and there is a lack of awareness of the need for rectal microbicides.

In many countries, the mere discussion of such preventative measures is taboo because of widespread homophobia (approximately 85 member states of the United Nations currently criminalize consensual same sex acts among adults)¹⁵ and because of the exclusive association of anal intercourse with gay men. In Jamaica, for example, advocates for rectal microbicides can only speak in front of gay groups and their supporters about this topic and cannot advocate publicly in the way that advocates for vaginal microbicides can.

While a large percentage of gay men and other MSM engage in anal sex, it is also practiced by heterosexual couples around the world. According to the International Rectal Microbicide Advocates (IRMA), “in absolute numbers, seven times more heterosexual women than gay men in the United States practice receptive anal intercourse”¹⁶. Women are no less susceptible to HIV through this transmission route than men, yet one of the biggest gaps in global HIV prevention has been research into anal sex between men and women.

IRMA is the main global advocacy group working to advance rectal microbicide research and development. IRMA serves as a central forum for advocacy and networking to promote a safe and effective rectal microbicide product. Its work is helping to legitimize the importance of rectal microbicide research worldwide, as well as to encourage rectal safety studies on viable vaginal microbicides.

Voices from the Field

An Ethical Obligation to Advance Research

Despite the enormous need for rectal microbicides worldwide, only one clinical rectal microbicide trial is currently underway. Participants in the trial revealed altruistic motives for their participation, such as the opportunity to be involved in groundbreaking research. Research staff acknowledged the enormity of their task and the urgency of its success. According to Dr. Peter Anton, Principal Investigator of the study,

“This work is so incredibly important. Every day we don’t move forward, thousands more get infected. There is an ethical obligation here to advance the research and development of rectal microbicides, with good science and community awareness.”

Participants who were interviewed confirmed that they had received volumes of information on the trial, including a patient’s bill of rights, and they expressed enthusiastic support for the transparency of the research process. While it is too early to determine results conclusively, early signs are encouraging. At the 2008 International AIDS conference in Mexico City, Dr. Anton noted possible signs of efficacy: not only is the candidate product potentially safe, but it may provide effective protection against HIV infection.

Obstacles to Progress

Homophobia

Despite optimism about trial success, rectal microbicides advocates in the majority of the world still face major obstacles. In Jamaica, for example, a small group of rectal microbicides advocates are seeking to raise awareness of new prevention technologies (NPTs) in a country where homophobia is rampant. According to one advocate,

“The situation is so tense that prominent gay rights activists operate in secrecy or out of the country.”

Sub-Saharan Africa is another region where the need for advocacy far exceeds any efforts taking place. In Nigeria, where culture and religion prohibit same sex practices, many MSM are in hiding. Alliance Right is an organization that operates as a voice for MSM and, despite strong taboos around anal sex, has held public forums on the issue and produced an advocacy tool for rectal microbicides to be used by partner organizations. In Kenya, homophobia similarly hinders the small but burgeoning microbicides movement. Recently, Kenyan microbicides advocates have been making efforts to link with vulnerable groups such as MSM, to ensure rectal microbicide issues are addressed.

In India, MSM organizations have been working to raise awareness of rectal microbicides for the last five years. While no rectal microbicide is currently being tested in India, pressure on policy makers is slowly growing. In 2006, a meeting organized by the National Working Group on Microbicides with support from PATH India and the Global Campaign for Microbicides re-energized the nascent advocacy movement. Calls for more funding, research on anal sex behaviour patterns, and the creation of a more strategic and long-term advocacy agenda are helping to break taboos. Public acknowledgement by the Indian Minister of Health at a 2008 conference on the importance of rectal microbicide research confirmed that the issue is reaching high level policy makers.

Lessons Learned

- Too little data exists on anal intercourse. **More research** must be done on the prevalence of anal sex in both homosexual and heterosexual communities in order for advocates to reach beyond the gay and/or MSM communities to gain widespread consensus for their cause.
- **Advocacy** for rectal microbicides must be integrated into larger microbicide awareness campaigns. Because vaginal microbicides currently in development will eventually be used rectally, stronger links between vaginal and rectal microbicides' advocates must be forged.
- Rectal microbicides' advocates must educate communities on broader issues of **gender and sexuality** in order to break taboos, partnering with organizations promoting human rights, and sexual and reproductive health and rights.
- Policy makers must make **specific funding available** for anal microbicide research. The more NPTs that are available on the market, the easier it will be for men and women to protect themselves from HIV.

End Notes

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