

Engaging Advocates from Concept to Results:
Summary report of the Advocates' Consultation on HIV Prevention
Trials: Carraguard and VOICE Studies

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INTRODUCTION

Advocate consultations are increasingly becoming the rule, not the exception in the HIV prevention research field. As an increasing number of Phase III trials enter the field, research groups are seeking new ways to collaborate with advocates and maximize civil society input and engagement.

The *Advocates' Consultation for HIV Prevention Trials: Carraguard and VOICE studies* provided leaders from African NGOs on the frontlines of the epidemic a unique opportunity to learn about the clinical trial process from beginning to end, and to collectively identify ways to influence how scientific research is formulated.

Participants represented a wide range of advocacy groups from Southern African countries, including advocates working in women's health, treatment access, gender-based violence, legal and regulatory issues, human rights and PLWHA groups. The strong diversity allowed for lively and healthy debate and many opportunities for cross learning.

The consultation focused on two HIV prevention trials: the recently completed Carraguard microbicide trial by the Population Council and the upcoming Vaginal and Oral Interventions to Control the Epidemic (VOICE) study by the Microbicide Trials Network (MTN), which will evaluate a candidate microbicide gel and oral pre-exposure prophylaxis (PrEP). Both trials are focused on preventing sexual transmission of HIV in women.

The two-day consultation was divided into three sections. The first day focused on building HIV prevention research literacy amongst the advocates, enhancing their understanding of how clinical trials are developed and discussing ways to actively engage advocates in the ongoing process from trial protocol development to results dissemination.

The second day provided an opportunity for advocates to contextualize this learning on key issues surrounding the scientific design of the clinical trials, rooted in the specifics of the Carraguard and VOICE studies.

This report is divided into four sections:

1. Key issues in HIV prevention research advocacy
2. The Carraguard Study and its upcoming results
3. Developing the VOICE Study
4. Next Steps: Recommendations and action items

KEY TERMS:

Microbicide: Any substance, such as a gel or cream that can substantially reduce the risk of acquiring HIV through sex, when it is applied to the vagina or rectum.

PrEP: Pre-exposure prophylaxis is an experimental strategy where one or more of the ARV drugs normally used for AIDS treatment is taken by HIV negative individuals in the hope of preventing HIV.

Randomized clinical trial: These studies test if an experimental product works by dividing participants by chance into two or more groups, and comparing the group given the active product with a group made up of similar people who have been given a placebo, a product that looks like the experimental product but lacks the active component.

Trial protocol: The document that lays out the particulars of a trial including the question the study is trying to answer, the trial design, criteria for participation, and the care provided to participants.

KEY ISSUES IN HIV PREVENTION RESEARCH ADVOCACY

Key issues raised during the consultation reflected both long-standing concerns of advocates, including standard of care for participants and ethical considerations in trial design, as well as emerging scientific and social issues, such as potential for resistance with ARV-based microbicides. The following section highlights the main issues that came up for advocates and activists during the consultation.

Community involvement: The consultative time line and process

Strengthening community engagement is an ongoing process in the HIV prevention and microbicides field. While lack of communication and meaningful involvement are still problematic at times, participants acknowledged an improvement and pointed to consultations such as these as a welcome and much-needed part of the process. Advocates accepted their share of responsibility for educating themselves, staying engaged and accessing information that is readily available.

At which point in a protocol's development should advocates be engaged was also discussed. Some participants felt the consultative process should start very early, perhaps as early as the concept development phase, and carry through to results dissemination. However, others noted that overly extensive consultation could prove burdensome to advocates, and their time and skills should be utilized strategically.

Research literacy, training and information dissemination

HIV prevention research is complicated, both scientifically and ethically. Advocates and researchers alike have recognised an urgent need to conduct trainings for advocates to build and strengthen their scientific research literacy. Participants were eager to identify opportunities to incorporate information on microbicides and PrEP trials into existing training programs on HIV prevention, women's issues and gender-based violence, such as those run by South Africa's Treatment Action Campaign and Gender AIDS Forum.

But training is only one piece of the puzzle. Advocates emphasized the importance of regular information dissemination to their groups. This would help ensure advocates are well prepared for unexpected announcements and the official release of trial results, especially when they are called upon by the media to comment.

When the Cellulose Sulfate microbicide trial closure in South Africa led to sensationalised news coverage by local newspapers, advocates helped to set the record straight and played a critical role in "damage control."

Ensuring advocates receive proper training and remain well informed can assist scientists and research groups. As members of the research communities, advocates often know the best ways to reach their communities, deal with negative media situations and help research groups develop effective communication strategies.

Funding advocacy groups without compromising them

One advocate pointed to the disjuncture between the “paid” work of science and the often “voluntary” nature of advocacy. Lack of resources often makes it difficult for advocates to improve and expand upon their work in communities. While prevention research trials are seeing increased budget for community outreach and results dissemination, more funding may be required for independent advocacy groups to be able to disseminate information more effectively, especially at the grassroots level.

This begs the question, who pays?

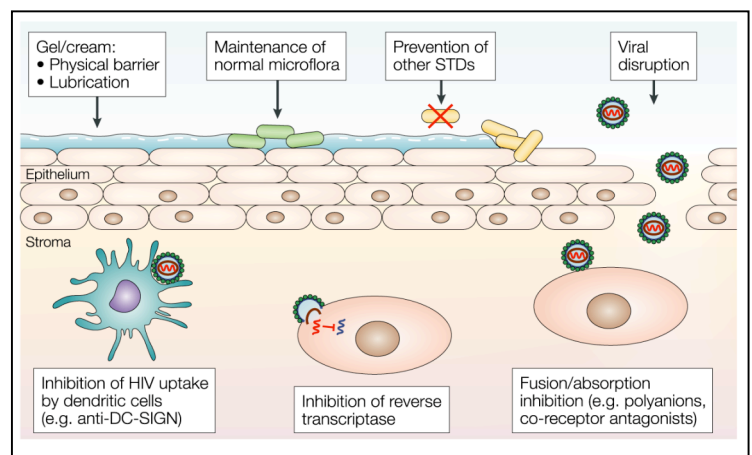
There is a fine line to balance when considering if research organizations should finance external advocacy work. While everyone agreed that consultative processes funded by research groups are necessary, few were comfortable with the idea of research organizations funding civil society groups directly. Receiving direct funding from researchers could hinder civil society’s independent watchdog mandate and potentially create conflicts of interest.

Instead, private and public donors must be encouraged to contribute more funds for advocacy purposes.¹ It was also suggested that advocates should include provisions for microbicide advocacy into existing funding proposals. This would allow advocacy groups to integrate microbicides-related activities into their broader strategic work plans and enable local leadership of organizations to determine their own priorities.

Finding a product that is effective and practical

As more research is conducted, microbicide candidates are becoming more sophisticated. Early microbicide candidates are non-specific to HIV and must be used close to the time when people had sex. For example, Carraguard, one of the first products to enter large-scale trials, is based on a natural product, carrageenin, from seaweed. Newer studies, including VOICE, are beginning to test products that contain anti-retroviral drugs, gels known as ARV-based microbicides.

How microbicides might work



Different products employ different ways to protect the body from HIV infection. How a product works is referred to as its “mechanism of action.” The table above summarizes

¹ One possibility that the Global Campaign for Microbicides is exploring is the establishment of a “funding window” within a professional grant-making entity that would facilitate access to easily accessible small grants for national, regional or local advocacy groups for this kind advocacy work. Such a mechanism could help bridge the gap between the needs of smaller organizations for capacity building and advocacy funding and their access to more substantial funding from other sources.

the main “mechanisms of action” of microbicide candidates currently being tested. The future may bring products that include combination microbicides. These products may use multiple mechanisms of actions simultaneously, which could potentially offer more protection than one product used alone. This research remains to be done.

Finding a product that is safe and effective at preventing HIV transmission is critical. It is also essential to find a product that is acceptable and feasible for women to incorporate into their daily lives.

A product could prove effective in the context of a clinical trial—meaning that *it is scientifically safe and has the ability to prevent HIV when used consistently and properly*. However, if for example, the product is required to be used within 30 minutes of sex or must be refrigerated, women in the “real world” may find its use impractical.

The goal is to find a product that is efficacious—meaning *it is reasonably effective at reducing HIV risk within real-world settings*. With this in mind, scientists are exploring products with different dosing strategies that may be more practical and effective. For example, the VOICE study will evaluate approaches in which women will use the product once daily independent of when they have sex.

We need products that meet the standards of scientists and the needs of the women.

Standard of prevention and care for participants

Everyone agreed that better meeting the needs of trial participants, from receiving a high-quality prevention package to ensuring care and treatment services for participants who sero-convert during the study, was a high priority. The group openly discussed raising the standard of prevention services, including requests that free female condoms, hormonal contraceptive and pap smears be included in the VOICE protocol and made available at all sites. These demands for services are not unique to the VOICE study. They are increasingly being asked of many HIV prevention research studies.

Post-trial access issues

It is never too early to discuss post-trial access to products once they have been shown to be effective. Many treatment activists who have led the charge in making anti-retroviral treatment available for people living with HIV/AIDS in Africa were concerned about regulatory issues, licensing an effective product in Africa, and making sure a proven product will be accessible and affordable to the people who need it most.

Although many questions were left unanswered, an important dialogue was launched. Most importantly, the research teams were ready to engage, and committed to working with the advocates to find the answers together.

THE CARRAGUARD™ STUDY AND ITS UPCOMING RESULTS

Population Council was represented by presentors, Sumen Govender, clinical study manager, Khatija Ahmed, principal investigator, Setshaba Research Centre, and Malebo Rathlagana, microbicides trial community outreach team member, Setshaba Research Centre.

Population Council began its Microbicide Programme in the late 1980's, and has been testing the microbicide candidate Carraguard or similar carrageenan formulations for more than ten years. The research group has held a handful of advocate and community consultations similar to this one, all of which have informed their clinical trials and interactions with local communities.²

During this consultation, members of the Carraguard trial team provided background about the product and the trial. They shared their plans for disseminating results in South Africa and globally. The following section covers the main issues discussed in regard to the possible outcome scenarios of this clinical trial and the implications they could have on the microbicides research field and potentially for HIV prevention and women around the world.

What is the microbicide product, Carraguard?

Carraguard is the Population Council's lead candidate, and one of the earliest microbicide products to be tested in a large-scale study. It is made from carrageenan, which is made from seaweed. Carrageenan is generally recognised as safe³ and is currently used as a thickener in many products found on the market. Qualities that make it an ideal candidate for a microbicide are:

- It is not likely to be absorbed into the bloodstream via vaginal use
- It is odourless, tasteless, and colourless in its microbicide form
- It is inexpensive, stable, and widely available

The Carraguard Phase III Study

The Carraguard Phase III, large-scale efficacy trial included over 6,000 trial participants at three sites in South Africa: Gugulethu (Cape Town), Soshanguve (Pretoria) and Isipingo (Durban).⁴ The trial was designed to evaluate the efficacy and long-term safety of the candidate microbicide Carraguard for preventing male-to-female sexual transmission of HIV. The study was completed 31 March 2007, and results are expected in February 2008. Carraguard was the first novel microbicide candidate to have completed a Phase III clinical research study.

² The Population Council hosted consultations bringing together advocates and scientists – one in 1997 and one in 1998 – in South Africa to gather input on the protocol before starting the Phase 2 trial. Population Council has included budgets for community consultations during their Phase III study to support the community advisory groups at the two sites that chose to have them. At their third site at the Medical Research Council, regular interactions with the community have taken place.

³ Generally Recognized As Safe (GRAS) is an official designation given by the US Federal Drug Administration.

⁴ The study was conducted in collaboration with the South African Medical Research Council, the University of Cape Town, and the University of Limpopo/Medunsa campus.

Recruiting trial volunteers

Population Council invested a lot of energy in developing new tools for the Carraguard study to strengthen the informed consent process. The team shared the study's informed consent forms and a 20-minute video developed and used at the trial sites to educate potential volunteers about the study.

While most of the advocates found the video interesting and useful in explaining the study and what a microbicide is, some raised issues with the use of the traditional healer in the video. The video has been pre-tested in the trial communities and reviewed by community advisors. Still, the differences in opinions voiced during the consultation underscore that what may work in one community with a group of constituents may not work for another group.

Additionally, advocates suggested that, in order to add weight to the informed consent process, educational videos, facilitated by recruitment officers, could be shown on televisions in the waiting rooms. In fact, these activities did take place during the trial.⁵

Ensuring quality of prevention services, prevention services, sexuality and STI counselling

The health services provided at clinical trial sites often surpass services available in the public sector in resource-limited settings. This disparity presents challenges for researchers, as some women get screened simply to find out their sero-status or receive free STI screening. As some regions report as high as 50% of women screening out, this presents an incredible burden on the sites and their recruitment efforts.

Despite these pressures, trial sites must be held to the high standards of services as outlined in their study protocols and committed to the research communities. For example, one participating advocate who was also a trial participant in a separate study shared her personal experience. She told the group that there was inadequate STI and sexuality counselling at the Gugulethu research centre she attended. She also revealed that condoms were not given to women at this site and that her health care worker did not demonstrate how to insert the microbicide applicator properly, as they are supposed to do.

Astonished by this testament, the investigators from the Population Council assured the group that under no circumstances was this kind of service acceptable, nor likely, and promised to follow up. This scenario highlights the need for advocates and researchers alike to maintain close ties at the site level and to ensure sites are providing the quality of services and provision of care they promise to uphold.

Issues around results dissemination

Population Council plans to release the results to the public in February 2008 in advance of the upcoming Microbicides 2008 Conference in India. The timing of the release of results was

⁵ All three Population Council sites showed educational videos in their waiting rooms throughout the trial, as well as bringing in speakers to talk to women about healthcare.

discussed extensively. It was agreed that a multi-pronged approach is needed and that researchers need to be aware of advocates' information needs. Some advocates who often serve as media spokespersons for their groups felt it was critical to be briefed confidentially in advance of the public announcement to help prepare them to talk with the media.

These negotiations are often tricky, as the trial has responsibilities to communicate the results to their trial participants, government officials, and funders first. Still, advocates have a stake in the results, and the group discussed ways to strike a balance between respecting the embargo and preventing leaks while preparing stakeholders to communicate the results to the public.

If the results are positive: Steps to getting the product on the shelf

If Carraguard releases significant results indicating the product is 40-60% effective at reducing women's risk to sexually-transmitted HIV infection, Population Council will work urgently and closely with regulatory bodies to get Carraguard registered and licensed in South Africa, where the trial took place, and the world.

Advocates have a key role to play in facilitating the regulatory process, especially in countries like South Africa, where the urgent need is often challenged by tedious processes.

Advocacy can also occur around the threshold for efficacy, and advocates should hold research groups accountable for its decisions around which products they push through the pipelines, and the regulatory process.

If proven effective, Population Council is committed to getting Carraguard to market at the lowest price possible. The research group would consider licensing the product to pharmaceutical companies to manufacture, but Population Council would retain intellectual property rights, helping to ensure their continued ability to work toward universal access to women.

If the Carraguard results reveal that the product is not an effective microbicide, the field nonetheless has learned, and will continue to learn much from this trial. Regardless of the results, this trial clearly shows that this much-needed research takes time, money, and a strong commitment to the research process.

How good is "good enough"?

The Carraguard study was designed to be able to see if there was at least a 33% difference in the number of HIV infections between the Carraguard group and the placebo group. The study enrolled more than 6,000 women because statistically, that is how many women would be needed to show a significant difference between the incidence of HIV in the placebo group and 1/3 fewer infections in the Carraguard arm.

The study was designed to show 40-60% effectiveness, which means the product could offer significant protection, but would not offer 100% protection.

If a product shows only a 10% effect, this means the results were not "statistically significant" and could be attributed to chance or other factors. Here, the study would have shown "no harm, no effect"—meaning that although the product is not harmful to use, it also does not offer protective benefit to women.

DEVELOPING THE VOICE STUDY:

Study presentations by: Sharon Hillier, MTN principal investigator; Ian McGowan, MTN co-investigator; Mike Chirenje, VOICE Study co-chair; and John Mellors, MTN Virology Core Director. Jeanne Marrazzo, VOICE Study co-chair, participated in discussion but did not present.

The newly formed research group, Microbicide Trials Network, is planning the Vaginal and Oral Interventions to Control the Epidemic (VOICE) study. The VOICE study has not begun to enrol volunteers yet, and in fact, is still in the early stages of developing their trial design and protocol—guidelines for running the study. However, the study team felt it was important to consult with advocates at this early stage to inform civil society groups about their plans and get input early in the trial design process to ensure the trial they develop meets the needs of the trial communities.

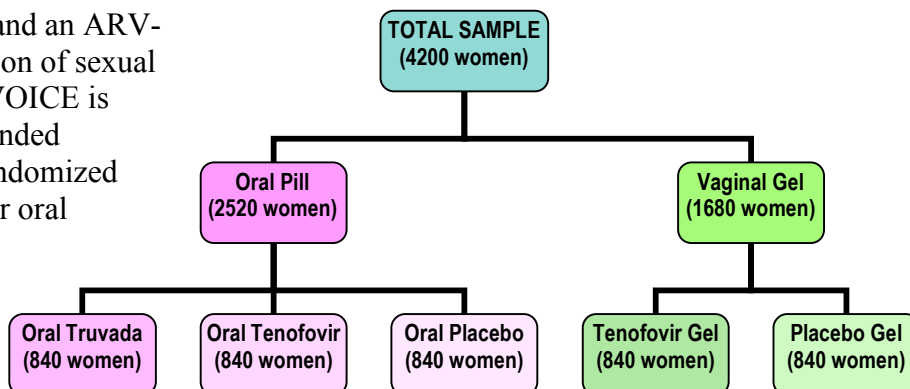
Advocates were given the most current version of the protocol, and requested by the trial team to review it and provide comments. This level of engagement at this early stage in trial development is setting a new precedent in the prevention research field, and advocates welcomed the change as a step in the right direction.

The following sections reflect some of the key issues raised around the VOICE study, and specific challenges surrounding researching ARV-based microbicides and PrEP.

The VOICE Study

The VOICE Study is the first study to evaluate the safety and efficacy of both oral pre-exposure prophylaxis (PrEP) and an ARV-based microbicide gel for prevention of sexual transmission of HIV in women. VOICE is designed as a five-arm, double-blinded study in which women are first randomized to receive either microbicide gel or oral PrEP, and then within each group, randomly assigned to either tenofovir topical gel or placebo gel; or to oral tenofovir, oral Truvada or oral placebo.

The VOICE Study: What it will look like



Currently, the study plans to enrol 4,200 women at 10 sites in South Africa, Malawi, Uganda, Zambia and Zimbabwe.⁶ Women will use study product—either gel or oral tablet—once a day. In addition to evaluating safety and effectiveness of the two approaches, researchers also will measure differences in adherence.

⁶ The consultation included advocates from all of the proposed VOICE trial site countries.

Why ARV-based prevention?

Anti-retroviral (ARV) drugs have changed the HIV/AIDS pandemic, allowing people with HIV/AIDS to live longer and more productive and healthy lives. They have also been used for prevention, such as by health workers who have been exposed to HIV, an approach known as post-exposure prophylaxis, and most widely for preventing mother-to-child transmission (PMTCT).

Pre-exposure prophylaxis, or PrEP, is an HIV prevention approach that typically involves the daily use of oral ARVs by people who are HIV-negative. The idea is that taking a medicine every day would prevent infection if HIV should enter the body, such as through sexual intercourse.

Two ARVs that are already widely used for treatment, tenofovir and Truvada, are being evaluated in different HIV prevention PrEP trials. The VOICE Study will be looking at both ARVs as well as an ARV-based microbicide called tenofovir gel. Tenofovir gel is also already being studied separately.

Both tenofovir and Truvada have strong safety profiles as an effective drug that is well tolerated by most people, meaning that the drug causes minimum side effects. However, ARV-based microbicides and PrEP also present new challenges for the field, and many advocates did not hesitate to raise the burning questions surrounding potential for drug resistance.

Potential for resistance to ARV-based prevention approaches

Anti-retrovirals are effective drugs for extending the lives of people living with HIV/AIDS. Some people with HIV/AIDS, especially those who do not take the drugs everyday as prescribed, can form drug resistance—making the drugs ineffective at fighting the virus. People are concerned and want to know what this could mean for healthy, HIV-negative individuals who may be using anti-retrovirals everyday as a prevention method.

The fact is, we do not yet know if ARV-based microbicides could increase the chances of resistance to ARVs in trial participants who become infected with HIV during or following the VOICE Study. While it is a possibility, researchers hope that a number of measures being worked into the study design will help mitigate any possible risk.

Learning the different names, doses and forms of the VOICE Study's ARV products

Tenofovir and Truvada, the brand name for a combination drug consisting of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC), are a type of ARV called nucleotide reverse transcriptase inhibitors (NRTIs).

Tenofovir, known by the brand name Viread, is taken as treatment as a 300 mg tablet once a day. Truvada, sometimes referred to as tenofovir+FTC, is a tablet containing 300 mg of tenofovir and 200 mg of FTC and is also taken once a day. As approved drugs for the treatment of HIV/AIDS, each is considered a first-line treatment for people starting anti-HIV drug therapy and each is used in combination with other products.

Tenofovir gel contains the same active ingredient in the oral form of the drug. It is an attractive candidate microbicide because it specifically targets HIV. In its current formulation, each dose of tenofovir gel contains approximately 40 mg of active drug.

Commonly Asked Questions about ARV-based HIV prevention approaches

Will ARV resistance be a problem?

- We don't know yet. No scientific or clinical information is available about the nature of resistance or the incidence of resistance among those using vaginal gel or oral ARVs for prevention.

Will those who get infected have HIV that is resistant to the PrEP ARVs or ARV-based microbicide?

- We don't know anything for sure, but researchers will monitor women monthly for HIV infection and will stop the study products immediately if infection is detected.
- In monkey studies, the virus that is initially transmitted is usually not drug-resistant, but resistance does become more likely with time if the PrEP ARV is continued.

Will this affect their subsequent care and choice of ARV treatment?

- Some research suggests that resistant virus may be overtaken by sensitive virus within weeks of stopping ARVs for PrEP.
- In mothers who took single dose nevirapine for pMTCT and developed nevirapine resistance, there was no decrease in response to ARV treatment if it was initiated after 6 months.
- But we don't know if this will be the same for PrEP.

For example, all participants will receive monthly HIV testing⁷ so that investigators can quickly identify women who have become infected with HIV while in the study and immediately stop their use of the study product (topical gel or oral pill). These and other procedures are intended to minimize as much as possible ARV exposure by a woman who has become infected. Limiting exposure will help decrease the selection of drug resistance and reduce potential problems with treatment in the future.

Drug resistant virus has an advantage only in the presence of the ARV, so that's why it is important to minimize exposure. However, nothing is certain until the trial is conducted and results are known. The dilemma here is that, although resistance is a concern, it is unknown the extent to which it will be a factor in HIV prevention trials. At this point, researchers believe the benefits of such a trial outweigh the risk of resistance.

Prevention package and standard of care

At the time of this consultation, the VOICE Study planned to provide all study participants with free laboratory tests and physical exams, counselling on preventing HIV infection and free male condoms. STI risk-reduction counselling, testing and treatment will be provided at no charge to both women and their partners. VOICE Study participants who acquire HIV will be linked with appropriate services and care in the study site communities.

⁷ There was an extensive discussion on the form of HIV testing to be used during recruitment for the VOICE trial. Some advocates wanted every woman to receive a PCR (Polymerase chain reaction) test at screening, which is highly accurate and would eliminate the window period and chance that an HIV-positive woman could enter the study. However, the current protocol calls for PCR only at the end of the trials, as the cost for multiple PCR tests is prohibitive. Researchers promised to look into the possibility of changing the protocol.

While the prevention package met essential standards, some advocates urged for additional services, including free female condoms and pap smears, to be offered at all of the trial sites. Following the advocates' consultation and a consultation MTN had with its Community Working Group, the VOICE team has decided to provide funds to its sites to purchase approved male and female condoms for study participants. In regard to pap smears, the researchers note it is extremely difficult to provide pap smears at all of the sites because most sites do not have the pathologists available to read them.

It's never too early to think about post-trial access

Although the study is still in a pre-trial planning phase, questions around post-trial access arose. In South Africa, advocates have been fighting for years to get oral tenofovir included in the national guidelines' first line treatment regimen for people living with HIV/AIDS. As this drug is still not readily available for life-saving treatment purposes, advocates questioned the feasibility that it could be accessible if proven effective for prevention purposes. Should the VOICE Study show encouraging results, issues surrounding access will become more pressing.

NEXT STEPS: RECOMMENDATIONS AND ACTION ITEMS

The relationship between researchers and advocates has often been marked by tension, distrust and suspicion. While at times this sentiment is born from real experience, often suspicion evolves more from the absence of any avenue for communication, than because of real transgressions. *As researchers and advocates strengthen their relationships and allow for open dialogues, they increasingly realize that the two groups have the same interests at heart—to find effective and empowering ways to help women and men prevent HIV infection.*

We conclude this report by identifying the main action items each group asked of each other. We hope that advocates and researchers will undertake these steps to help strengthen each other's ability to serve the field, build stronger bridges between advocates and scientists, and contribute to the growing HIV prevention research advocacy movement.

What advocates asked of researchers

Research literacy: There was an overwhelming consensus that more opportunities should be provided to gain and strengthen advocates' understanding about how clinical trials and HIV prevention research work. Specifically, groups recognised a need for training on substantive issues, such as how clinical trials are conducted and how microbicides work, and skills-building trainings focused on technical issues, such as how to read a trial protocol.

Civil society consultation at all stages of trial development: Advocates appreciated being consulted early on in the development process of the VOICE Study and hope it sets a precedent for future clinical trials. Likewise, they want to stay informed throughout trials, not just at the time when results are disseminated.

Support in securing funding for advocacy: International advocacy groups are exploring more ways to funnel funds to local and grassroots groups working in study communities. These funds could include small and easily accessible grants for immediate and ongoing microbicide advocacy, or identifying opportunities to include microbicides in existing and larger grant proposals. Research groups can support these efforts by letting funders know the important role that advocates play in supporting and improving HIV prevention research.

Ongoing consultation with other advocacy groups: Recommendations were made for cross-group training and site visits to build networks and capacity. There was a suggestion that a global Community Advisory Board (CAB) be formed that would advise and consult with HIV prevention research groups.

What researchers asked of advocates

Constructive input and substantive feedback: Researchers are open to consulting with advocates and sharing protocols. In return, they request that advocates provide constructive ideas and input on issues such as, which kind of HIV test to use during the screening process and how to disseminate trial results in communities. It is easy to criticize a trial, but what is really needed are advocates willing to roll up their sleeves and help in ways that enable trials to be conducted as efficiently and ethically as possible.

Ideas on improving adherent use of the trial product: One of the main challenges currently faced in HIV prevention research trials, and especially microbicides studies, is the issue of consistent use of the product. Many studies have found that participants either do not use the product or falsely report the extent to which they use the product. Poor adherence can impact and skew the outcomes of a study, which leads to inconclusive or incorrect trials results.

Scientists are actively looking for new ways to improve women's adherence through better and more rigorous adherence counselling, and finding new ways for women to privately report product use for more accurate data analysis. Researchers welcome input and ideas from advocates who have a close ear to the ground and may be able to provide insight into the difficulties women have with adherence and how to address these circumstances.

Advocacy for affordable prices and effective regulatory processes: As more and more products enter Phase III trials, researchers will increasingly need support and assistance from advocates, who can help put pressure on government regulatory bodies and groups holding patents, to ensure speedy licensure and access to scientifically-proven products.

SPONSORING RESEARCH GROUPS

MICROBICIDE TRIALS NETWORK

The Microbicide Trials Network (MTN) was established in 2006 by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH), as the newest of six NIAID-funded HIV/AIDS clinical trials networks. With co-funding from the National Institute of Mental Health and the National Institute of Child Health and Human Development, both NIH institutes, the MTN brings together international investigators and community and industry partners who are devoted to reducing the sexual transmission of HIV through the development and evaluation of microbicides, working within a unique infrastructure specifically designed to facilitate research required to support licensure of topical microbicide products for widespread use. MTN is guided by an agenda that aims to complement rather than duplicate the research programs of its global research partners. It also seeks participation by and collaborations with representatives of diverse scientific disciplines related to HIV prevention, as well as from the lay communities where MTN trials are being conducted. www.mtnstopshiv.org

POPULATION COUNCIL

The Population Council conducts research worldwide to improve policies, programs, and products in three areas: HIV and AIDS; poverty, gender, and youth; and reproductive health. The goal of the HIV and AIDS program is ambitious: to arrest the spread of the HIV epidemic in developing countries and to enable people to mitigate or eliminate the impact of HIV on their own health, and on their families, communities, and societies. To achieve these goals, the Council brings its wide array of capabilities, including basic research in immunology; the development and introduction of an effective microbicide; social science and health-related research to understand better the social, behavioural, and biomedical aspects of HIV and AIDS; the formulation of evidence-based policies; and the development, evaluation, and scale-up of effective service-delivery models. www.popcouncil.org

CO-CONVENING ADVOCACY GROUPS

AFRICAN MICROBICIDES ADVOCACY GROUP

Launched at the 2004 International Microbicides Conference, the African Microbicides Advocacy Group (AMAG) is a regional network that leads a co-ordinated African engagement in setting and moving forward the international microbicides advocacy and research agenda. AMAG works towards the availability of, access to, and use of, an expanded range of woman-initiated HIV prevention options. It seeks to advance the recognition of the legitimacy of African women's voices, responsiveness to, and respect for, African realities and priorities. <http://www.global-campaign.org/amag.htm>

AIDS VACCINE ADVOCACY COALITION

Founded in 1995, the non-profit AIDS Vaccine Advocacy Coalition (AVAC) seeks to create a favourable policy and social environment for accelerated ethical research and eventual global delivery of AIDS vaccines and other prevention methods as part of a comprehensive response to the pandemic. www.avac.org

This work is guided by the following principles:

- Translate complex scientific ideas to communities AND translate community needs and perceptions to the scientific community.
- Manage expectations.
- Hold agencies accountable for accelerating ethical research and development.
- Expand international partnerships to ensure local relevance and a global movement.
- Ensure that policy and advocacy are based on thorough research and evidence.
- Build coalitions, working groups and think tanks for specific issues.
- Develop and widely disseminate high-quality, user-friendly materials.

AIDS AND RIGHTS ALLIANCE FOR SOUTHERN AFRICA

Established in 2002, the AIDS and Rights Alliance for Southern Africa (ARASA) is a regional partnership of non-governmental organisations working together to promote a human rights approach to HIV/AIDS in Southern Africa through capacity building and advocacy. It is constituted in the form of a trust and all partner organisations are members of the trust. Three steering committees, comprising trust members, act as advisory boards for the three ARASA programme areas: training and awareness raising, advocacy and lobbying and regional treatment literacy and advocacy. ARASA seeks to achieve its primary objective through: Advocacy and lobbying; training and awareness raising; and capacity building for access to treatment and prevention. www.arasa.info

GLOBAL CAMPAIGN FOR MICROBICIDES

The Global Campaign for Microbicides is a broad-based, international effort to build support among policymakers, opinion leaders, and the general public for increased investment into microbicides and other user-controlled prevention methods. Through advocacy, policy analysis, and social science research, the Campaign's diverse network of over 285 NGOs works to accelerate product development, facilitate widespread access and use, and protect the needs and interests of users, especially women. The Campaign Secretariat is housed at PATH, an international, nonprofit organization that improves the health of people around the world. www.global-campaign.org

Specifically, the goals of the Campaign are to:

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

PARTICIPANT LIST

Khatija Ahmed

Population Council, University of Limpopo
Pretoria, South Africa
kahmed@setshaba.org.za

Deborah Baron

HIV/AIDS Advocacy and
Communications Consultant
Johannesburg, South Africa
deborah.baron@gmail.com

Jonathan Berger

AIDS Law Project
Johannesburg, South Africa
bergerj@alp.rg.za

Edward Chikhwana

Malawi Network of AIDS Service
Organisations
Lilongwe, Malawi
chikhwanae@yahoo.com

Michael Chirenje

Microbicide Trials Network
Harare, Zimbabwe
Chirenje@uz-ucsf.co.zw

Busi Dlamini

ABC Ulwazi
Johannesburg, South Africa
busi@abculwazi.org.za

Nomfundo Eland

Treatment Action Campaign
Cape Town, South Africa
nono@tac.org.za

Anna Forbes

Global Campaign for Microbicides
Washington DC, US
ASForbes@path.org

Gregg Gonsalves

AIDS and Rights Alliance for Southern
Africa
Cape Town, South Africa
gregg.gonsalves@gmail.com

Sumen Govender

Population Council
Durban, South Africa
sumen.crs@gmail.com

Sharon Hillier

Microbicide Trials Network
Pittsburgh, PA, US
shillier@mail.magee.edu

Prudence Mabele

Positive Women's Network
Johannesburg, South Africa
pmabele@mweb.co.za

Ntokozo Madlala

Gender AIDS Forum
Durban, South Africa
ntokozo@gaf.org.za

Jeanne Marrazzo

Microbicide Trials Network
Seattle, Washington
jmm2@u.washington.edu

Ian McGowan

Microbicide Trials Network
Pittsburgh, PA, US
mcgowanim@mail.magee.edu

John Mellors

Microbicide Trials Network
Pittsburgh, PA, US
mellors@dom.pitt.edu

Steve Mfuno

Salima AIDS Support Organization
Salima, Malawi
saso@malawi.net

Cecilia Mhiti

Southern Africa AIDS Information
Dissemination
Harare, Zimbabwe
Cecilia@safaids.org.zw

Etukoit Micheal

The AIDS Support Organization
Kampala, Uganda
etukoitm@tasouganda.org

Margaret Muganwa

SWAA International Uganda/Makerere
University of Public Health
Kampala, Uganda
mmuganwa@musph.ac.ug

Clementine Mumba

Treatment Action and Literacy Campaign
Lusaka, Zambia
cmkasasa@hotmail.com

John Mutsambi

Global Campaign for Microbicides
Johannesburg, South Africa
jmutsembi@path.org

Zuki Nthshunsha

Community Media Health Trust
Cape Town, South Africa
zuki@beatit.org.za

Laurentia Ogle

South African AIDS Vaccine Initiative
Durban, South Africa
laurentia.ogle@mrc.org.za

Anna-Colletor Penduka

Women's Aids Support Network
Harare, Zimbabwe
acpenduka@yahoo.com

Dorothy Phiri

Family Health Trust
Lusaka, Zambia
dortiephiri@yahoo.co.uk

Malebo Ratlhagana

Population Council
Setshaba, South Africa
malebo@setshaba.org.za

Lisa Rossi

Microbicide Trials Network
Pittsburgh, PA, US
rossil@upmc.edu

Caroline Sande-Mukulira

Southern African Regional Poverty Network
Pretoria, South Africa
amakobesande@yahoo.com

Fiona Scorgie

Gender AIDS Forum
Durban, South Africa
Fiona@gaf.org.za

Tandiwe Song Wevu

Positive Women's Network
Johannesburg, South Africa
info@pwn.org.za

Amelia Vukeya

AIDS Law Project
Johannesburg, South Africa
Amelia.vukeya@gmail.com

Sydney West

Global Campaign for Microbicides
Johannesburg, South Africa
swest@path.org