



Global Campaign News – Issue #66 12 May 2006

Welcome to the *Global Campaign News*! The *Global Campaign News* is a forum for international exchange on microbicide activities and information with an aim to build a more informed and integrated movement for microbicide development and other prevention options against HIV and STIs. This and previous issues of *GC News* are available online at <http://www.global-campaign.org/gcnews.htm>

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Highlights from Microbicides 2006

Africa

The Fourth International Microbicides Conference (Microbicides 2006) took place from 23-26 April in Cape Town, South Africa with more than 1,300 participants. The biggest conference thus far, the event confirmed the increased interest in the microbicides field. Reflecting trends in the broader field, community interests and needs have finally joined center stage at the conference with a dedicated track in addition to a significant share of the plenary discussion. Additionally, rectal microbicides gained increased attention throughout the conference and in a dedicated symposium. The table below is just a snapshot of the sessions that were included in the plenary sessions and each track:

Plenary / Joint track sessions	TRACK A (basic science)	TRACK B (clinical trials)	TRACK C (social sciences)	TRACK D (community and advocacy)
??Microbicides: state of the art and its evolution ??Issues and implications for ARV-containing products ??Ethical challenges in research ??Potential role & evaluation of topical microbicide use by heterosexual men ??Vaginas and applicators: expanding the national discourse on microbicides, sex and sexuality ??Trial updates and preliminary data of phase IIb/III trials ??Assessing microbicide safety ??Implications for future microbicides once an effective product is identified ??Role of community and advocates in defining the microbicides research agenda	??Innate and adaptive immunity: susceptibility, inflammation and protection ??Host resistance factors in HIV transmission and/or susceptibility ??In vitro and animal models: current status, latest data ??Emerging microbicide candidates ??Other microbicide candidates and late breakers ??Functional delivery strategies	??Empirical findings of phase I and II trials of new microbicide products (including rectal microbicides) ??Adherence to trial procedures and product use (with track C) ??Setting standards of care in microbicide clinical trials ??Barrier methods and dual protection for HIV prevention (with track C) ??Testing methods/algorithms for measuring HIV endpoints ??Pregnancy issues in microbicides trials	??Acceptability research: empirical insights from product use ??Addressing ethical challenges in clinical trials ??Models and mechanisms for engaging community in research implementation (with track D) ??Methods used for male involvement and partner consent in women-initiated methods research	??HIV positive women and microbicides: moving research forward ??Beyond involvement: civil society's role in making ethical progress towards a microbicide ??Pathways to access a successful microbicide: advocacy, policy and mobilization ??Resource mobilization ??Donor panel on access and availability of microbicides

Although it is difficult to capture all of the information and networking that took place at the conference, here, we have pulled together a few of the highlights that you may find interesting, as well as links you can follow for more information.

High profile plenary speakers highlight the accomplishments of the field, but continuing urgency.

The conference plenaries featured presentations by such eminent figures as Archbishop Emeritus Desmond Tutu, Justice Edwin Cameron of South Africa's Supreme Court of Appeals, renowned women's and children's rights advocate Graça Machel, CNN's Charlayne Hunter-Gault, three African governmental Ministers and one European Ambassador – as well as several notable scientists. The conference opened with a video messages from Nelson Mandela and closed with one from Peter Piot of UNAIDS, as well as a fiery speech by Zackie Achmat, Chair of the Treatment Action Campaign and one of the world's foremost AIDS activists.

In her opening address to the conference, Graça Machel invited a truly global effort with political leadership, financial resources, and community mobilis ation from both developed and developing countries. “We know all too well in this part of the world what happens when profits take precedence over lives. We do NOT want to repeat the struggles in the efforts to get affordable access to anti-retroviral treatment to people living with AIDS.” She also emphasized the need for a strong women's movement to take part in the effort: “We must move from rhetoric to action. We must demand the enforcement of laws that protect women. We must say, individually and collectively, enough is enough. Our sisters and daughters are dying and we will not stand for this any longer! Women must be at the forefront of every decision that is taken about their lives - whether it is in the halls of parliament, or in their own homes. I must say I am impatient for change.”

Archbishop Desmond Tutu, the Special Guest of Honor at the opening ceremony, commended the conference organizers as well as the efforts of the activists who he said are the driving force in the research into microbicides. According to him, “we will not be here if you were not there.”

At the closing plenary session, Joy Phumaphi, the assistant director of Family & Community Health for the World Health Organization offered a challenge to “any policy maker to give me one convincing argument why microbicides should not be given a fair chance...” She urged global stakeholders to commit the required resources “to the research and development process, to health systems, to training and development, to community empowerment and participation, and to production, distribution and supply challenges.”

Throughout the conference, nothing was more evident than the sense of urgency with which all participants – scientists, policy-makers and civil society advocates alike – approach this work. At the closing of the conference, Zackie Achmat, the director of the AIDS Law Project and a leader in the Treatment Action Campaign in South Africa, gave voice to this shared passion in the closing ceremony. “HIV/AIDS represents the most critical challenge for humanity and our response to it must be based on a vision of social justice, freedom and equality,” he said. “Governments and the private sector have a legal and moral duty to meet the resource demands of the epidemic. This included the demand that the pharmaceutical industry must invest in microbicides research and development.”

AMAG / GCM Pre-conference Workshop prepares advocates for the full conference.

The African Microbicide Advocacy Group and Global Campaign for Microbicides' pre-conference workshop attracted almost 250 participants from a number of different backgrounds. After the opening presentations, the workshop broke out into four sessions – the basics of microbicides for new advocates, gender and rights advocacy for microbicides, microbicides messaging and the media, and strategies for national microbicides advocacy. One theme that repeated through the day was the need for post-trial care for participants who seroconvert during a clinical trial. AMAG and GCM received overwhelming positive anecdotal feedback from workshop participants and will be conducting a more formal evaluation in the coming weeks. Presentations from the pre-conference will be posted on the Global Campaign website: <http://www.global-campaign.org/microbicides2006.htm>

AMAG/GAF/NHVMAG leads dialogue on Nonoxynol-9 with advocates and researchers.

Advocates, community members, policy makers and researchers had an opportunity to talk about lessons learned and outstanding questions about the Nonoxynol-9 trials at a session organized by the African Microbicides Advocacy Group, Gender AIDS Forum, and Nigerian HIV Vaccine and Microbicides Advocacy Group. An outcome report from the meeting will be produced shortly to summarize the dialogue and include next steps.

Positive Women's Panel highlight research needs.

The Global Campaign and the International Community of Women Living with HIV/AIDS co-convened a roundtable session called "HIV Positive Women and Microbicides". Among the issues raised by the positive panelists was the importance of doing safety trials among HIV positive women, given that microbicides are likely to be used by women who don't know their status as well as by those using them for secondary prevention. If these safety trials aren't done, how will women know what to expect in terms of side effects, possible drug interactions and the impact that a microbicide could have on a positive woman's vaginal ecology? Panelists also asked how data would be gathered on potential drug resistance issues among positive women using an ARV-based microbicide.

Another area of expressed concern was the potential benefits and risks a microbicide could have for positive women wishing to become pregnant. When non-contraceptive microbicides become available, women living with HIV may want to use them to protect their partners while attempting to conceive. When and how will research be done to see what safety issues this might raise for both the woman and her future baby?

While research is underway to answer some of these questions (specifically pharmaco-kinetic studies to assess the probability of drug resistance developing), the scientists on the panel acknowledged that research to answer other questions has barely begin. The tools with which microbicide safety is assessed are still evolving and more refined measurements of impact are needed before some of these questions can be answered. All panelists agreed that this roundtable should be repeated at Microbicides 2008 to examine and document the progress made in this area in the next two years.

The role of civil society stakeholders in shaping the microbicides research agenda.

The term "community involvement" previously referred only to interaction between researchers and members of communities in which their trials were conducted. It is gradually being replaced, however, with a much broader view of civil society's role which includes the involvement of national and international NGOs and the governmental policy-makers overseeing trial authorization – as well as the leaders and institutions within local trial site communities. Presenters pointed out that it is not enough for research institutions to simply inform communities of what they are doing and/or seek their advice through CABs. Instead, the cultivation of authentic partnerships between civil society stakeholders (including community members) and research entities is essential to assuring a trial's success.

Such partnerships are, admittedly, labor-intensive and require reciprocal "literacy training" (research literacy training for civil society and community literacy training for researchers) – as well as on-going collaboration, communication and transparency. The clinical trial site developed by the BOTUSA Project (a joint effort of the Botswana government and the US CDC) was cited as possibly the best-realized example of this kind of partnership. Under the able leadership of Dawn Smith, MD, BOTUSA is about to initiate microbicide trials after a lengthy period of preparing and integrating the project into existing community and civil society networks.

Rectal microbicides report calls for significant increase in funding.

The first-ever report tracking rectal microbicide research and development expenditures, "Rectal Microbicides, Investments and Advocacy" was released by the International Rectal Microbicide Working Group (IRMWG) at a special symposium titled "Rectal Microbicides – A New Frontier in HIV Prevention". According to the report, funding for rectal microbicide research rose from US\$2 million in 2000 to \$34 million in 2006. The full report is available at www.lifelube.org

Scientific research focuses on safety and new ideas.

The scientific sessions in Tracks A and B reiterated that assessment of safety is a "moving target" even though all candidate products are subjected to rigorous safety studies. Frequent genital examinations, colposcopy, blood testing and participant reporting of symptoms are the main tools currently used to gather safety data. While extremely useful, these measures can also be difficult to interpret. So researchers are now examining the potential utility of other bio-markers such as inflammatory cytokine levels to determine which ones provide reproducible and clinically relevant safety data.

Researchers in these tracks also reported on the diversity of compounds now in the microbicides pipeline. The first generation of candidates (those now in Phase 3 trials) are expected to display relatively broad activity against a

range of STIs and partial efficacy against HIV. They are also coitally dependant products requiring insertion prior to sex.

The second generation candidates, most of which are based on anti-retroviral drugs, may allow for increased specificity and potency against HIV. They may also be formulated as coitally independent products that could be delivered by once-daily application or through sustained release devices like vaginal rings that remain in place for a month or more. This second generation, however, may lack effectiveness against other STIs. They also raise the possibility of drug resistance if used by women who are HIV positive – an issue currently under investigation.

Rapid movement was reported in strategies for creating these second and third generation products including progress in developing CCR5 blockers and combinations of fusion inhibitors (CCR5, gp120 and gp41 blockers) that have shown increased vaginal protection in animals. There is strong consensus in favor of combination products – both to increase efficacy against HIV and to generate products that are effective against HIV and other STI -- especially HSV, a known co-factor in HIV transmission.

One of the most exciting future directions under discussion is a proposal to develop a mucosal vaccine specifically targeted to activate immune cells in the vaginal epithelium. If such a vaccine could be formulated for delivery as a needle-free, topical product, it could potentially be combined with a microbicide and, thus, re-boosted every time the microbicide is applied. Such a method might confer immunity specifically in the vagina -- the most probable site of infection for women -- and eventually induce whole body immunity. Led by Robin Shattock of St George's Hospital, London, an international team of researchers has embarked on the creation of such a product. This consortium is funded for the next five years and hopes to have a candidate ready to enter clinical trials within that time.

Social scientists address male involvement, pregnancies in trials, and standards of care.

Currently, more than 15,000 HIV negative women are enrolled in vaginal microbicide trials. The challenges these trials face include high pregnancy rates among participants (which requires the immediate discontinuation of test product use), the unreliability of self-reported adherence to protocol, and lower than expected HIV incidence in trial areas (clearly a benefit to the population but also a complicating factor in terms of measure the test product's impact).

While male involvement has always been encouraged, the idea of mandating partner consent or involvement in trials recruiting women has been resisted because it impedes the woman's right to make an autonomous choice about trial participation. The value of involving men was addressed repeatedly, however, in the case studies presented. Providing men who are interested with information about the trial and test product can help assure adherence to the trial protocol as well as the safety and well-being of participants whose partners may react negatively if they are uninformed. The provision of male partner and couple counseling to those who want it is now perceived as vital for adherence and acceptability.

In the wake of the cancellation of the tenofovir PREP trials last year, the issue of post-trial care for participants who sero-convert during an HIV prevention trial was also a hot topic. Solomon Benetar, a noted South African ethicist, said that the field has made real "moral progress" in this area. Dr. Gita Ramjee (one of the conference chairs) described the arduous work being done at the HIV Prevention Research Unit of the South African Medical Research Council to create and sustain networks capable of assuring such care in a resource poor settings.

The need for additional investment continues to be apparent.

While funding has tripled in the last five years, current levels are still only about half of what is needed to keep the microbicide trials pipeline moving rapidly. Advocacy is also needed to assure that regulatory and licensure pathways are prepared for efficient product evaluation and approval and that plans for mass procurement are put in place now so that a successful product can be made available without delay. The UNFPA, World Bank, IPPF, DfID and USAID all reported that they are developing mechanisms to assure procurement and access.

Polly Harrison receives lifetime achievement award

At each microbicides conference, a lifetime achievement award is presented to one person whose commitment to, and achievements within, the microbicides field has been an invaluable contribution. We are happy to report that

this year, the recipient of this honor was awarded to Polly Harrison, Director of the Alliance for Microbicide Development and a long-time friend of the Global Campaign.

Links for more information.

- ?? The official conference website has daily summaries and the text from a few of the plenary speeches: www.microbicides2006.org
- ?? We will be posting presentations from the AMAG/GCM pre-conference workshop on the Global Campaign website: <http://www.global-campaign.org/microbicides2006.htm>
- ?? Webcasts and transcripts of many of the conference sessions are sponsored by Kaiser Family Foundation and are available at: http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=1689
- ?? The Alliance for Microbicide Development's weekly news digest #42 from 5 May has a summary of the media coverage related to the conference: <http://www.microbicide.org/publications/>
- ?? Later this summer, the Alliance will be producing a special issue of The Microbicide Quarterly dedicated to covering the conference. We will let GC News readers know when it is released.
- ?? Please send us conference-related links to info@global-campaign.org and we can include them on the Global Campaign website: www.global-campaign.org/microbicides2006.htm

Recent activities across Europe

Europe

On 6-7 March, the Global Campaign participated in, and showed the Giving Women Power Over AIDS exhibit, at the International Conference on Sexual Health organised by the World Population Foundation and Youth Incentives. A total of 225 participants from 31 countries on five continents participated. Participants demonstrated that, regardless of their own cultural, social and religious backgrounds, it can be easy – and even fun – to talk about sexuality. A 'Call for Action' highlighted the fact that sexual health and sexuality are rarely discussed at the policy, programme and grassroots levels. Evidence shows that countries adopting an open and comprehensive approach to sexuality, information and services achieve better health outcomes. Download the 'Call for Action' at: http://www.wpf.org/uploads/1195/Call_for_Action.pdf.

On 20 March, the UK African Microbicides Working Group, administrated by the African HIV Policy Network (AHPN), organised a Microbicides Information Day in London to discuss the issue of microbicides and the implications for African communities in the UK: "What do we do about...Microbicides?". Following presentations by the Global Campaign, IPM, Positively Women and Interact Worldwide, over 40 key workers within African community organisations brainstormed how to proceed within their constituencies. The Working Group is part of the UK Campaign on Microbicides, a coalition of 13 British NGOs. For more information about the meeting, go to: http://www.ahpn.org/activities/index.php?meeting_id=26.



An "MTV" (Microbicides, Treatment and Vaccine) symposium was organised on 30th March by Spanish partner GTT (Grupo de Trabajo sobre Tratamientos del VIH) in collaboration with IAVI, GCM, IPM and the Catalan International Development Agency (ACCD) to promote a human rights based approach to the pandemic. The meeting took place as a satellite event during the annual Spanish conference on AIDS, which focuses on new treatment research. Dr Frans van de Boom reminded the audience that an HIV vaccine is possible, while Tessa Mattholie of IPM emphasised the importance of having methods such as microbicides that women can initiate and which meet their reproductive and sexual health needs. From the treatment perspective, Pablo Anamaria talked of the overwhelming need to increase access to treatment in countries like Peru and Bolivia, which leaves little time to think about new prevention options. Debate centred on how to balance the immediate needs of treatment in comparison to the more long-term needs of research into new prevention options and concluded with a call to align advocacy strategies towards policy makers in Spain. Contact Marion Zibelli: mzibelli@gtt-vih.org for further information.

African Civil Society position paper on HIV and AIDS

Africa

From 10-12 April, over 80 representatives of civil society organisations in Africa, including women' groups, youth networks, associations of people living with HIV, the media, national NGO networks, trade unions, faith-based organisations etc, met in Abuja, Nigeria to deliberate on key HIV and AIDS advocacy challenges confronting the continent. It was a momentous occasion for civil society organisations on HIV and AIDS in Africa, with participants from 17 countries coming together to form the African Civil Society Coalition on HIV and AIDS, to provide an advocacy and communications platform for energising HIV and AIDS campaigns by African civil society groups.

The statement issued at the end of the consultation, titled “African Civil Society Position Paper on HIV and AIDS in Africa: Moving to Action”, outlines a clear call by the Coalition to African leaders and governments on urgent steps that need to be taken to accelerate action to reverse the HIV and AIDS epidemic on the continent. This call is especially timely as the leaders prepare to gather in Abuja, Nigeria in May 2-4 for the African Union Summit on AIDS, Tuberculosis and Malaria, and in New York, USA on May 31-June 1, for the United Nations Special Review Session on HIV/AIDS.

The statement clearly represents the Coalition’s vision of a comprehensive approach to the pandemic: “Unshakeable in our belief that comprehensive prevention, care and support and treatment are indivisible: action in one area without equivalent actions in the other areas is unacceptable.” In addition, the statement urges African states to “commit to financial and human resources for the research, development and planning for future access of vaccines, microbicides and other female-controlled methods of preventing new HIV infections - nationally and regionally”.

We commend the members of the Coalition for an excellent gathering and action plan, with special recognition to Omololu Falobi, of Journalists Against AIDS Nigeria, for his leadership in this process.

Microbicide Development Strategy moves forward Global

For the past two years, a group of donors in the microbicide field have gathered semi-regularly to discuss status of and challenges in the field. This group, known as the Microbicide Coordinating Board asked the Alliance for Microbicides Development to coordinate a series of meetings and working group discussions to identify the main bottlenecks that are delaying the development of microbicides and to recommend ways and means for overcoming them. The resulting analysis, entitled the Microbicide Development Strategy (MDS) is a result of a series of working group meetings and correspondence over the course of eight months in 2005. The working groups consisted of leading researchers and donors who focused on four parts of the field: basic science, clinical trials, manufacturing and formulation, and finally, commercialization and access. The Alliance for Microbicide Development’s annual meeting from 27-28 March in Washington DC provided an opportunity to bring together members of these working groups to examine gaps in the strategy.

There was virtually no advocates and community groups involved in the development of the document and the Global Campaign identified this as a major gap. At the Alliance meeting, we proposed that the field either take the time to add in perspectives of communities and advocates into the document before it is finalized or that a parallel document be created to focus on needs of communities and advocates.

Giving Women Power Over AIDS exhibit featured at the European Commission Europe

On 18 April, the Campaign’s photographic exhibit “Giving Women Power Over AIDS” debuted at the European Commission in Brussels, with an opening reception attracting over 40 representatives and staff of the EU institutions as well as ambassadors and officials of several African and European member states. The exhibit remained in the award-winning Mondrian Building until 2 May.



Dr. Lieve Franssen, Head of Human and Social Development within the Commission and long-time champion of microbicides, opened the event, congratulating the Global Campaign for creating a powerful tool for raising awareness. Dr. Janneke van der Wijgert, (pictured here) Global Campaign steering committee member, and Director of Prevention Research at the IATEC Foundation (an NGO focusing on medical research) spoke of her experience living in Zimbabwe and the importance of giving women greater prevention options. She urged policymakers not to view microbicides as a ‘magic bullet’ that will empower women overnight: “We must also work to give girls like Martha more confidence and economic assets so that she can negotiate as an equal with her husband”.

Hugh Richardson, Director of EuropeAid, the department which coordinates the Commission’s aid to developing countries, concluded by outlining efforts within the EU to accelerate microbicides development and how critical it is for policymakers to know about them. “People simply need to realise that you can’t have children without unprotected sex”, he said.

Microbicides were also featured in the European Voice, a weekly newspaper published in Brussels, the same week as part of a special report on women in the European Union.

Media coverage: Op-Ed by Melinda French Gates in Newsweek Global

The 15 May 2006 edition of the weekly magazine, *Newsweek*, includes a thoughtful and persuasive op-ed written by Melinda French Gates, co-chair of the Bill & Melinda Gates Foundation. The article, entitled “What women really need” focuses on marriage as a risk factor for HIV/AIDS around the world, the potential of new prevention technologies, and concrete steps to make microbicides available to the people who need them. The full article is available on-line at: <http://www.msnbc.msn.com/id/12665685/site/newsweek/>

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