



Global Campaign News – Issue #69 31 August 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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2006 International AIDS Conference – Toronto, Canada

The majority of this edition of *GC News* focuses on coverage of microbicides at the International AIDS Conference which took place from 13-19 August. The Conference was a five day event of scientific debate, activism, and learning, with the theme of “Time to Deliver”. At the end of this coverage, we have provided a link to an article by Edwin J. Bernard of Aidsmap which provides an excellent review of major news about other prevention technologies as well.

Plenary speeches

Talk of microbicides was the pulse of the conference. Microbicides moved from the sidelines to center stage at several plenaries, starting at the opening ceremonies where Melinda Gates stated, “We believe the most promising breakthrough that could be available soon is an effective microbicide or oral prevention drug.”

At the first morning plenary session, Louise Binder, a renowned HIV-positive activist from Canada spoke about the Global Campaign for Microbicides in an impassioned speech. Former US President William J. Clinton and Bill Gates, co-chair of the Bill and Melinda Gates Foundation further highlighted microbicides at the Monday symposium “Priorities in Ending the Epidemic”. On Tuesday, Gita Ramjee, the director of the South African Medical Research Council (MRC) presented an overview of microbicides and other prevention technologies and later in the week, Anthony Fauci, director of the U.S. National Institute of Allergy and Infectious Diseases (NIAID) highlighted NIAID’s commitment to prevention research.

Ethical issues in clinical trials: tenofovir and beyond

This report is extracted from the conference rapporteur reports written by Dr. Quarraisha Abdool Karim, Stephanie Nixon, and Aditi Sharma, available at www.aids2006.org.

In a vibrant session on Tuesday, five speakers examined ethical issues in clinical research for HIV prevention.

Anna Forbes presented the Global Campaign for Microbicides' experience in developing a broad consensus statement in 2005 that recommends that care and prevention packages be negotiated with the host community before the trial starts. The statement calls for the HIV prevention research field to design and negotiate durable mechanisms and contracts for the provision of future care when it is needed and to mobilize political pressure to make full access to care a sustainable reality in trial host communities.

Charles Weijer, University of Western Ontario, provided an ethical analysis of obligations to provide treatment in the context of HIV prevention trials in developing countries. He rejected the notion that there is a moral obligation to provide treatment to sero-converters, but instead proposed "moral negotiation" as a basis for determining care requirements based on the ethical principle of respect for communities. Within this framework, communities would contribute to trial design, influence study results, and share in the study benefits. He argued that because health priorities and values vary among communities, the idea of a predetermined obligation to provide one specific benefit does not respect communities' unique perspectives. Counter views were raised by audience members regarding the fact that negotiations between researchers and communities do not always take place on a level playing field, and that there may still be benefit to having a bare minimum set of obligations from which communities can begin the negotiations.

A study presented by Yasmin Halima, International AIDS Society, on stakeholder responses to the controversies over the Tenofovir trials highlighted the need to come up with adequate guidance on ethics in prevention trials given the current gaps in international guidelines.

Hugues Fischer from Act Up Paris spoke about France's national Community Advisory Board's (CAB) successful efforts to influence legislative processes in France. The role of parliamentary lobbying was an important factor alongside the legal re-working of the law. Amongst other achievements was the requirement that the medical care available post-trial is described in the consent form. He ended by saying that "PLWHA associations can change laws" and urged CABs in other countries to use relevant legislative opportunities more often.

Xolani Xaba from the South African AIDS Vaccine Initiative (SAAVI) presented findings from a study on informed consent that documented different levels of comprehension depending on the measure of participant understanding used. Close-ended response formats (checklists, self-report) yielded higher comprehension scores than open-ended methods (vignettes, narratives), suggesting that open-ended formats may be more revealing. In discussion, it was suggested that whatever the method used, trial participants consistently show fairly low levels of understanding of study processes and impacts. Therefore informed consent should not be relied upon as the only mechanism for protecting participants; rather an emphasis should be placed on other ethical requirements as well, such as balancing potential harms and benefits.

Panel on microbicide science

On Wednesday, Robin Shattock of St George's Hospital Medical School and Zeda Rosenberg of the International Partnership for Microbicides (IPM) co-chaired a session on microbicide development. Robin Shattock began the session with a basic scientific overview of microbicide development, discussing the possible initial forms in which microbicides may be available, how the vaginal ecology influences the chosen formulations, issues of cost effectiveness, user-friendliness, and the need for safety in spite of repetitive and sustained product use.

Joe Romano of IPM reported results from a safety trial of TMC120 delivered via an intravaginal ring. Romano detailed the various benefits of the ring: sustained drug delivery for 30 days, ease of use (vaginal rings do not require applicators for insertion) and low cost. However, to date, little acceptability research has been conducted on ring use in developing countries and the environmental impact of widespread use is still unknown (it is possible that the rings may not be biodegradable). Phase I safety trial results showed no clinically significant systemic absorption and that the same level of drug was delivered consistently throughout the study. TMC120 is showing good potential as a future microbicide.

Shezhad Iqbal reported on a study being conducted with a cohort of commercial sex workers in Nairobi, Kenya. His team's hypothesis is that high levels of the protein trappin-2 found in cervical secretions offer potential innate immune factors and possibly HIV resistance. A cohort of women who were HIV-uninfected in spite of repeated exposure to the virus had twice the amount of trappin-2 in their cervical secretions than an HIV-uninfected group

and a three fold increase when compared to an HIV-infected group. This biomarker of elevated trappin-2 protein seems to have biological relevance to HIV and may suggest a microbicide candidate for further investigation.

Microbicides networking reception – and reflections on moving forward

On Wednesday evening, the Canadian AIDS Society, the Microbicides Advocacy Group Network (MAG-Net), and the MaRS Discovery District hosted a reception to allow advocates and researchers a chance to meet each other and reflect on the week's events in an informal setting. Both speakers at the event, Robin Shattock of St George's Hospital Medical School, and Manju Chatani of the African Microbicide Advocacy Group voiced the sentiments of many present: It was remarkable to hear thousands of conference attendees endorse the need for prevention research, and especially microbicides. As Manju observed, for those who have been advocating for microbicides research for years, it is certainly a moment to celebrate. At the same time, we cannot "rest on our laurels" for too long.

Likewise we must ensure that realistic messages are being conveyed about microbicides so that expectations are not too high for introduction (See the Global Campaign's [Fact sheet #19 on Managing Expectations](#)). We need to continue to support those doing the research and running the trials, as they still face many challenges. We need to continue to support research into a broad range of new prevention technologies – as described in the Aidsmap article below. But in the meantime, we need to ensure access to the range of currently available prevention options -- such as male and female condoms, STD prevention and management, prevention of mother to child transmission, education for girls, and poverty reduction to name just a few.

And still more talk of microbicides and other prevention technologies...

In addition to the plenary speeches and sessions described above, three additional panels discussed the basics of microbicides to a suddenly much wider audience. Lori Heise, director of the Global Campaign for Microbicides, presented on microbicides as part of Tuesday's symposium session "Evolution and Change in Program Development". She highlighted the importance of tackling the gender inequality and gender/sexual violence that may prevent women from using new technologies once they are available.



Later that day, at the New Prevention Technologies panel hosted by the AIDS Committee of Toronto and MAG-Net, Rebekah Webb, of GC Europe, Kim Mulji of the Naz Foundation International, Edd Lee of the AIDS Vaccine Advocacy Coalition and Julia Matthews of Ibis reproductive health discussed microbicides, vaccines, PREP and cervical barriers on the main stage of the Global Village. Finally, on Thursday, Julie Becker of the International AIDS Vaccine Alliance, Jodi Jacobson of the Center for Health and Gender Equity, Julia Matthews of Ibis Reproductive Health, and Bindiya Patel of the Global Campaign presented a panel on "More choices for women" to 50 women seated at the comfortable couches at the Women's Networking Zone (pictured here).



Microbicides were also highlighted at the women's and girls' rally and march that led up to the opening plenary on Monday morning. Hundreds of women and men gathered early in the morning to hear renowned speakers including Mary Robinson, Stephen Lewis, and Louise Binder. (participants pictured here)

Release of the Microbicide Development Strategy

In an August 17 press conference at the AIDS 2006 conference, the *Microbicide Development Strategy (MDS)* was formally presented as a tool that, according to Renee Ridzon of the Bill and Melinda Gates Foundation, "will help donors target the biggest gaps in the field". In 2005 the Microbicide Donors' Committee (which represents 14 funding agencies and governments currently supporting microbicide research) spearheaded a consultative process to develop this strategy by convening four working groups to "map the scientific and practical gaps along the field's research and development pathways and identify and prioritize steps toward filling those gaps". The Working Groups addressed four primary areas:

- Basic and Pre-Clinical Science
- Clinical Research
- Manufacturing and Formulation
- Commercialization and Access

The *MDS* focuses on needs and priorities in these areas and the specific strategic efforts they require, and further addresses priority needs that crosscut the microbicide field as a whole. At its core, then, "is a list of high-priority actions aimed at accelerating the development and distribution of safe, effective, acceptable, and affordable microbicides".

The *MDS* takes as its starting point the status of the field in early 2006, yet many of its recommended actions are neither new nor surprising. In fact, a number of the issues it targets were described in monographs developed in 2002 under the auspices of the Rockefeller Foundation, including the urgency of understanding of how the sexual transmission of HIV occurs, the persistent lack of sufficient capacity in clinical trial sites, and the need for further research on the crucial matter of consumer preferences. What *is* new in 2006 is that the global microbicide endeavour has reached a point where many key issues can now be resolved, given the right strategies, new ways of working in key areas, and appropriate levels of support.

The *MDS* should be seen as a dynamic document to be revisited as the field advances. In fact, this has already occurred. At the first review of the draft *MDS* late last year, the Global Campaign, among others, expressed concern that civil society involvement and advocacy had not been explicitly addressed. In response, the donors agreed to support a process to generate a parallel document to explore how civil society groups can and should be involved in ongoing and future microbicide research and development.

A copy of the *MDS* is available at the Alliance for Microbicide Development website at <http://www.microbicide.org/microbicideinfo/reference/MDS.FINAL.10Aug06.pdf>. Hard copies and CDs of the document can also be obtained from the Lois Holston at the Alliance at lholston@microbicide.org.

Global village and exhibition area



The Global Campaign worked with partners to create *New Prevention Technologies (NPT) Networking Zone* in the Global Village (pictured here), and the *Partners in Prevention Research Advocacy* booth in the exhibition area. The NPT zone displayed the *Giving Women Power Over AIDS* exhibit in both French and English and the GCM film, *In Women's Hands*.

With new prevention technologies receiving so much attention both from the media, from conference delegates and from community members, both the NPT zone and the booth were buzzing with a vibe of curiosity and enthusiasm. These venues provided a good opportunity to distribute materials and have conversations to clarify the status of research, and the type of advocacy and partnerships that are needed to get access to these technologies once they are made available.

Aidsmap article:

Alphabet of prevention technologies expanding, but no 'magical solution'

We highly recommend that *GC News* readers take a look at a recent article written by Edwin J. Bernard of Aidsmap entitled, "Alphabet of prevention technologies expanding, but no 'magical solution.'" The article provides an excellent synopsis of research findings that were presented at the Toronto Conference on a range of prevention technologies including male circumcision, cervical barriers, microbicides, Pre-exposure prophylaxis, and HSV-2 suppressive therapy." You can view this article at: <http://www.aidsmap.com/en/news/66DF7489-44B4-42D9-BC76-54FCAA7C29BF.asp>

More information about the Toronto Conference

You can find more information about and the PowerPoint slides from the Global Campaign's presence at Toronto at <http://www.global-campaign.org/toronto2006.htm>. A short summary of microbicides coverage is available at: <http://www.global-campaign.org/TorontoMedia.htm>. Finally, webcasts, reports, and interviews with key figures are available from the Kaiser Network: <http://www.kaisernetwork.org/aids2006/>

Trials Watch

FHI and Cellegy Pharmaceuticals announce closure of Savvy trial

On August 28, Family Health International (FHI) and Cellegy Pharmaceuticals announced plans to discontinue a Phase 3 study being conducted in Nigeria to assess the effectiveness of Savvy, a candidate microbicide. The low rate of new HIV infections among study participants prompted a review of its interim data by the study's external, independent Data Monitoring Committee (DMC). A similar study of Savvy undertaken in Ghana was suspended earlier this year.

Based on the available evidence, the DMC concluded that the Nigerian trial was unlikely to detect a reduction in the HIV risk and, thus, recommended against continuation. No significant product-related medical problems were reported among study participants. In a press release, Dr. Paul Feldblum, FHI epidemiologist and principal study investigator explained that, "there was little reason to expect that the product would prove effective if the trial went to completion. We believe resources are better used to fund studies of more promising products to reduce HIV risk."

Enrollment of Nigerian trial participants began in September 2004. Based on local epidemiological data, the rate of new HIV infections expected among the trial's 2,152 volunteers was 3.7% annually. The actual rate at the time of the DSM review, however was less than 2% annually – suggesting that the trial's provision of prevention counseling and free condoms may have helped reduce HIV transmission rates. If there had been evidence of a positive effect of the candidate microbicide, investigators could have extended the trial and enrolled more women in order to compensate for the lower than expected incidence rate. But the interim analysis suggested no risk reduction related to Savvy.

With two early terminations (Ghana and Nigeria), it is very unlikely that additional public sector funding will be forthcoming for further research into Savvy for HIV prevention. Funding from the US National Institutes of Health will continue to support clinical trials in the US to test Savvy's potential utility as a contraceptive.

Carrageenan may be effective against human papillomavirus

Global

In vitro research conducted by the U.S. National Cancer Institute shows that Carrageenan has a high potential for inhibiting the human papillomavirus (HPV). Further clinical trials are needed to determine whether carrageenan-based products will be effective topical microbicides against genital HPVs. "Carrageenan Is a Potent Inhibitor of Papillomavirus Infection," was published in the Public Library of Science Pathogens (2006;2 (7):e69) and is available at <http://pathogens.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.ppat.0020069>

Advocacy around the world

Success! California resolution SJR22 passes unanimously

North America

Article contributed by Bethany Young Holt of CaMI and Grace Coopman of the CA Junior League SPAC delegation and Junior League Los Angeles.

On Monday, 14 August 2006 the California State Assembly unanimously passed Senate Joint Resolution (SJR) 22, which is to “memorialize the United States Congress and the President to enact the Microbicide Development Act (MDA).” This resolution caps a year’s worth of collaboration between the State Public Affairs Committee (SPAC) of the Junior Leagues of California, the California Microbicides Initiative (CaMI), the California Family Health Council, and the Global Campaign for Microbicides.



California State Senator Jackie Speier (D-San Francisco / San Mateo), who authored the resolution, hosted a press conference at the State Capitol, which included statements from Mariaelena Welch, SPAC Chair, Traci Bivens-Davis of Common Ground of Santa Monica (pictured here), and research scientist Dr. Bethany Young Holt of CaMI. Ms. Bivens-Davis' talk at the press conference was especially influential as Common Ground was the organization that brought the topic of microbicides to the Junior League of Los Angeles who then presented it to the SPAC delegation and sparked this partnership. Based on her daily interaction with HIV-infected women, Ms. Bivens-Davis spoke of the growing pandemic and how it affects heterosexual, monogamous women and their families. Her speech was heartfelt and it

only reinforced how vital microbicides can be to the health of women in California, the US, and worldwide.

We hope that the strong bipartisan support for SJR22 from California legislators will help encourage more federal level support for the MDA and bring further attention to the urgent need for microbicides here in California and worldwide.

Microbicides seminar in the Ukraine

Europe

On June 1, Anna Forbes of the Global Campaign presented a seminar in Kiev on microbicides and clinical trial ethics. The event was organised by Olena Davis, Project Coordinator of the Ukrainian Coalition of HIV-Service NGOs, a coalition of 58 member organisations, all working on HIV prevention in various ways.

Almost 30 clinicians and representatives from HIV/AIDS, reproductive health and women's health NGOs attended, as well Professor Zoreslava Skyryak-Nyzhnyk, the Ukrainian representative to the Council of Europe Steering Committee on Bioethics.

The seminar was part of the Coalition's project to promote "Community-based advocacy and networking to scale-up HIV prevention in an era of expanded treatment".

The morning session of the day-long seminar was devoted to updating participants on the status of microbicides research. In the afternoon session, the ethical challenges and human right issues that arise in HIV prevention trials were addressed. While large-scale microbicide trials are not likely to take place in Ukraine (because of the background prevalence of injection drug use), participants were familiar with HIV vaccine trials and had a lively concern about how the rights of trial participants could best be protected.

Professor Skyryak-Nyzhnyk suggested that Ukraine should have both an Ethics Review Board and a Community Advisory Board to monitor and review the protocols and implementation of locally-occurring HIV-related clinical trials. The Global Campaign applauds this suggestion and has since offered to help with efforts to get these mechanisms established by providing the educational materials and training tools we have developed for CABs and community groups elsewhere.

At the seminar, we also provided a sampling of the 23 documents (fact sheets and other materials) now translated into Russian and available on our website at <http://www.global-campaign.org/ru-download.htm>.

We welcome your input and contributions for future issues! Please send emails to: info@global-campaign.org. If you would like to unsubscribe to the *Global Campaign News*, please reply to this e-mail with the subject line: UNSUBSCRIBE.