



Global Campaign News – Issue #92 24 March 2008

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 other sexually transmitted infections. This and previous issues of *GC News* are available online at <http://www.global-campaign.org/gcarchives.htm>

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Did you attend the Pre-Conference Workshop? If so, please take a moment to complete our online evaluation available at http://www.surveymonkey.com/s.aspx?sm=AFheqz7aE2J_2bFtqv5pLMCw_3d_3d

Research update

Merck and IPM to Develop Novel Antiretroviral Drug as a Candidate Microbicide **Global**

Pharmaceutical giant Merck and Co., Inc. has agreed to license a novel antiretroviral compound called L'644 to the International Partnership for Microbicides (IPM) for development as a vaginal microbicide. L'644 belongs to a class of drugs called fusion inhibitors. Fusion inhibitors like L'644 and the FDA-approved drug Fuzeon™ (T-20) work by blocking a protein on the surface of HIV, called gp41, which the virus uses to enter and infect target cells. L'644 is not yet approved for use in humans, but preclinical laboratory studies suggest that the compound is a potent inhibitor of HIV infection. Merck and IPM will collaborate to develop and test L'644 as a candidate microbicide. This new licensing agreement, coming on the heels of a similar arrangement with Pfizer to develop Selzentry™ (maraviroc), means that IPM now has royalty-free licenses to develop five different antiretroviral compounds as candidate microbicides.

New Data Suggest Cellulose Sulfate Disrupts Vaginal Tissue Integrity **Global**

In early 2007, CONRAD and Family Health International (FHI) discontinued Phase III effectiveness trials of the microbicide candidate cellulose sulfate (CS) when early data from the CONRAD study suggested that CS might actually increase risk of HIV infection among trial participants using it. These data surprised scientists, as eleven earlier studies suggested that CS was safe to use.

The results of a new study, presented at the Microbicides 2008 conference last month in New Delhi, may provide some explanation for the increased risk of HIV infection seen in the CS trials. Using vaginal tissue explants, scientists at the Albert Einstein College of Medicine at Yeshiva University in New York found that cellulose sulfate can cause a loss of epithelial integrity by destroying the proteins that bind cells together (Mesquite PMMO. 2008. *Disruption of the epithelial barrier by cellulose sulfate: Development of a model to assess microbicide safety*. Abstract AO10-415. Microbicides 2008 Conference, New Delhi, India.).

“It is like the mortar eroding from around the bricks in a wall,” notes Sean Philpott, Science and Ethics Officer of the Global Campaign. “It undermines the strength and protection afforded by the vaginal epithelium.”

The same loss of epithelial integrity was seen when the researchers tested nonoxynol-9 (N-9) and, to a lesser extent, PRO 2000, a candidate microbicide currently undergoing clinical effectiveness testing. A fourth candidate microbicide, tenofovir gel, did not have an adverse effect on tissue integrity.

This microscopic loss of epithelial integrity, the New York researchers hypothesize, may allow HIV to leak into the tissues that lie underneath the epithelium which are rich in the target cells that HIV likes to infect. This type of damage, however, cannot be seen by using colposcopy or by measuring the inflammatory immune response, two standard ways of assessing microbicide safety.

Highlighted Resources

Presentations, Slideshows, Blog Posts and More from M2008!

The Global Campaign for Microbicides had a strong presence at this year’s microbicide conference. Visit our M2008 webpage, available at <http://www.global-campaign.org/M2008.htm>, to download the posters and presentations GCM staff presented at the conference and at our day-long Pre-Conference Workshop. Be sure to also check out the UK Campaign for Microbicides conference blog posts and our photo slideshow!

Also, be sure to visit the official M2008 Conference website at <http://www.microbicides2008.com>, for links to media coverage and daily scientific program updates.

New GCM Factsheets!

In anticipation of the Microbicides 2008 Conference, GCM staff developed two new factsheets to answer important questions about ARV-based microbicides and concerns of HIV drug resistance. Both factsheets are now available at the GCM Download Centre, <http://www.global-campaign.org/download.htm>, and can also be accessed directly at:

Understanding HIV Drug Resistance

<http://www.global-campaign.org/clientfiles/FS23-HIV-Drug-Resistance-FAQ.pdf>

Antiretroviral (ARV)-Based Microbicides: The Promise and the Puzzle

<http://www.global-campaign.org/clientfiles/FS24-ARV-Microbicides-FAQ.pdf>

Advocacy in action

IRMA Does Delhi

India

By Jim Pickett

Chair, International Rectal Microbicide Advocates (IRMA)

As chair of IRMA, you may say I have a certain booty bias in my perceptions – and I won't argue. But let me say, I think our burgeoning advocacy network really took the M2008 conference by storm.

It all started with the utterance of the melodious words – “rectal microbicides” in the opening remarks given by Dr. Anbamani Ramadoss, India's Minister of Health, and Family Welfare. Sure, just a mention, but so significant... and such a huge statement on how far the rectal microbicide field has come, from laughable and obscure to, as Dr. Ian McGowan likes to say, “almost embarrassing respectability.” I was absolutely thrilled.

The conference featured a Rectal Microbicide Update sponsored by amfAR, the UCLA AIDS Institute, and The University of Pittsburgh School of Medicine and was, in my opinion, the best attended Rectal Update compared to similar ones held in London (2004) and Cape Town (2006). Of all the great presentations, Dr. Peter Anton, the principal investigator of the MDP U19 study (the “rectal microbicide flagship”) delivered some of the most tantalizing science. While the group's Phase I trial, looking at rectal safety of the topical vaginal formulation of the NNRTI UC-781 is still wrapping up and data is still blinded, Anton and his group detected potential signals of efficacy. Efficacy! Needless to say, extremely exciting. We should know more soon once the final data is in. The slides from the Update presenters and all of Dr. Anton's slides from the Update and the general conference are available on IRMA's lovely new website – www.rectalmicrobicides.org – under the Community Presentation section in Resources.

One of the best aspects of the conference was the Advocacy Corner headed up by the Global Campaign for Microbicides in collaboration with other international groups such as IRMA. The space was always buzzing with activity and allowed for an enormous amount of information sharing and networking. We were thrilled to pass out hard copies of our new report, ‘Less Silence, More Science – Advocacy to Make Rectal Microbicides a Reality’ in the cozy space and to sign on well over 100 new advocates to our group – most of whom were from India and Africa.



You can find a copy of our report on our site, under IRMA Materials, by the way.

I have never seen so many people so revved up around rectal microbicides in one place... I am still high from the experience! Please visit our brand new blog at www.irma-rectalmicrobicides.blogspot.com to read the personal accounts of some of our “Delhi Dynamos,” particularly a number of very motivated advocates from Nigeria who have already birthed IRMA-Lagos and others who are planning community mobilization and education activities in their regions.

We have a long ways to go. We need more resources from a more diverse stream of funders. We need more research on the incidence and prevalence of anal intercourse globally, including better and more accurate information on the populations and contexts in which it occurs. And, quite simply, we need the rest of the field to adopt language that does not negate or obscure the rectal “compartment,” or hide the fact that men, as well as women, will also be end-users of safe, effective and acceptable microbicides. Receptive partners of both genders need prevention options they can control – pretending otherwise is no longer an option.

With less silence and more science, we can save millions of HUMAN lives. Will you be part of the solution?

Microbicides 2008: The Pre-Conference Workshop India

On Sunday, February 24th, over 185 international advocates, researchers and representatives from local Delhi NGOs gathered to prepare for the week ahead with overview presentations of the state of microbicide research and advocacy and a number of targeted skills-building and knowledge sessions. Hosted jointly by GCM, the African Microbicides Advocacy Group (AMAG), the Indian Network of NGOs (INN), the National Coalition of Health Initiatives (NCHI) and the Positive Women's Network (PWN+), the Pre-Conference was opened by Dazon Dixon Diallo of SisterLove who offered libation and a ceremonial lighting of the lamp to commemorate our ancestors and the women who have led us in the fight for new HIV prevention options. The session continued with an update on microbicide science, an overview of advocacy initiatives and an introduction to advocacy in India.

In the afternoon a number of break-out sessions were held: *Microbicides Basics*; an *Introduction to ARV-based Microbicides & Resistance*; *Starting to do Advocacy*, an Advocacy Training; and a session on *When Trials End – the Role of Advocacy*. Presentations from the opening session and break-out sessions are available on the GCM website at <http://www.global-campaign.org/M2008.htm>.

To conclude the day, participants reconvened in plenary to engage in a group discussion and to share any questions or issues raised in the various break-out sessions. Many concerns were raised around the role of media and a lively dialogue ensued in which participants were encouraged to respond to each other's questions.

To help Pre-Conference participants successfully navigate their way through the M2008 Conference, *Conference Roadmaps* were made available on the following topics: Access, Acceptability and Introduction; Adherence and Retention; ARV-Based Microbicides and Resistance; Community Involvement and Advocacy; Gender (including the role of men); HIV-Positive Women; Media; Rectal Microbicides and When Trials End (Closures and Results). One Roadmap was designed for those new to microbicides. Participants were also given an *Advocacy Networking Guide* to help them learn more about each other's work and build linkages.



Pre-Conference speakers open the event with a ceremonial lighting of the lamp.

Microbicides 2008: The Advocate's Corner



Previous microbicides conferences made it clear that, in addition to the Pre-conference Workshop, more space was needed where delegates representing community, advocacy and civil society could come together to network and build solidarity. In a scientific conference attended by many civil society groups, more attention needed to be focused on the microbicides movement behind the science. With this goal in mind and the support of the conference organisers, the Advocates' Corner was created by GCM and co-hosted by the African Microbicides Advocacy Group (AMAG), GUJARAT AIDS Project, International Rectal Microbicides Advocates (IRMA), the Indian Network of NGOs (INN), the National Coalition of Health Initiatives (NCHI) and the Nigerian HIV Vaccine and Microbicide Advocacy Group (NHVMAG).

The Advocates' Corner provided a schedule of events designed to address advocates' need for expanded knowledge and skills. One of the most successful sessions was 'Meet the Scientists', an opportunity not only for advocates to meet with leading names in the field of microbicides research, but also for scientists to hear advocates' questions and concerns. Discussion topics ranged from the intricate details of how trials are conducted to what protocol chairs and principal investigators actually do on a daily basis. The feedback from both advocates and scientists was that these exchanges need to happen more often.

A very interactive discussion came about at 'Microbicide Clinical Trials 101'. Questions from advocates on how microbicide clinical trials work and the similarities and differences between microbicide trials and other clinical studies were accompanied with explanations of the terminology and concepts in easily accessible language.

At the session, 'Carraguard: The Inside Story', advocates were invited to meet with local researchers involved in the Population Council's Carraguard trial. One advocate asserted the notion that, beyond the care requirements for women who seroconvert during their study participation, researchers should be more thoughtful about the long-term needs of trial participants who remain HIV negative. She argued that researchers should develop strategies to sustain risk reduction behaviours and assess whether or not those behaviours continue after the trial ends. After the session, Dr. Khatija Ahmed incorporated this point in her talk for the "Establishing the Standard of Care in HIV Prevention Trials" panel discussion.

The “Microbicide Trials in India: Experiences of Community Involvement” session brought two key Indian researchers together with advocates to discuss the importance of community involvement and how community preparedness is an essential component of research. The Cellulose Sulfate closure was discussed as a specific example that highlighted the importance of involving the community right from the beginning to facilitate transparency and trust between researchers and community.

The skills-building session “Challenges of Building National Campaigns: Sharing of Experiences” provided an opportunity for advocates involved in building national level NGO coalitions to share experiences and challenges. A key strategy highlighted in the session was focusing on those organisations and individuals who have a most vested interest in the mission and then slowly expanding on these efforts. The need for flexibility and sensitivity to the diverse expectations of coalition members was also flagged as a key skill that coalition leaders need to develop. As advocacy resources for microbicides are limited, advocates said that it is important to integrate advocacy into ongoing programs, thus allowing coalition members the flexibility to do whatever piece of work they could within their means.

“Overcoming co-enrollment in trials: Are fingerprint scanning and photographing the solution?” provided an opportunity for advocates to discuss some of the measures that trial sites are taking in addressing a serious problem with trial recruitment. Advocates’ concerns about these strategies included the potential for confidentiality to be compromised, particularly by the photographing of participants. Dr. Rhonda White clarified that the photographs would only be accessible to the trial staff. Concerns were also raised regarding fingerprint scanning as this has been associated with government and legal procedures. Recently, it has been associated with the tracking of terrorists. Advocates, however, agreed that with intense education and open communications between the trial sites and the communities, these challenges can be overcome.



One of the many skills-building sessions hosted at the Advocate’s Corner.

Besides the sessions, the Advocates Corner provided a space to network and share ideas, navigate through different NGOs websites and attend various receptions. It also provided an “Ask the Experts” question box in which participants could pose follow-up questions and a “Community Materials Table” that enabled organisations to share print information, T-shirts, videos, and other materials reflecting their work that delegates could take to share and inform their advocacy work back home. We’re very excited to have an even stronger Advocate’s Corner at M2010 in Pittsburg and we hope you’ll join us!

Please also be sure to visit our website to view our photo slideshow and to read conference blog posts by the UK Campaign for Microbicides. Both available at <http://www.global-campaign.org/M2008.htm>.

Lori Heise, GCM’s Director, Honored at M2008 India

In October 2006, we lost one of Africa’s brightest stars and a passionate advocate for justice, truth and research in new HIV prevention technologies – Omololu Falobi. He was a long-time HIV advocate and journalist; he founded the Journalists Against AIDS (JAAIDS) in Nigeria; was an instrumental pioneer member of the Nigerian Treatment Access Movement; and co-founded the Nigerian HIV Vaccine & Microbicide Advocacy Group (NHVMAG). He was tragically killed in 2006 in Lagos, Nigeria.

At the Microbicides 2008 (M2008) Conference, the first ever *Omololu Falobi Award for Excellence in HIV Prevention Research Community Advocacy* was awarded to Lori Heise of the Global Campaign for Microbicides and Mr. Aylur Kailasam Srikrishnan of the YRG Care



UNAIDS’ Peter Piot presents the Omololu Falobi award to Lori Heise at M2008.

Centre. Manju Chatani of the African Microbicides Advocacy Group and the award planning committee, noted in her speech that the award was being given to Lori for her leadership and commitment to the involvement of communities in microbicide research as partners, and her visionary leadership. She went on to say that, “in the words of one of her referees ‘the field of microbicide advocacy is the lengthened shadow of one woman, Lori Heise”.

Lori shared the stage with Mr. Aylur Kailasam Srikrishnan, the second winner of this inaugural award. Krishnan was honored for his pivotal role in working with and supporting marginalized communities in research settings.

Lori Heise and Aylur Kailasam Srikrishnan were both presented with a commemorative plaque and a monetary award to help cultivate their leadership skills and commitment to community advocacy within the HIV prevention research field.

This award, given in honour of Omololu’s memory and the important contribution of community advocacy in moving HIV prevention research forward, was done so in partnership and with the blessings of the Omololu Falobi Foundation, NHVMAG, JAAIDS, AMAG and in collaboration with GCM and the AIDS Vaccine Advocacy Coalition (AVAC).