



## **GC News #113: August 3, 2009**

*GC News is a forum for exchange on new HIV prevention options, especially for women.*

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## **Global**

### **Meet GCM's Africa Programme Team**



The Global Campaign for Microbicides (GCM), with staff in Canada, Kenya, South Africa, the UK and the US, would like to introduce the *GC News* readership to our Africa Programme team.

Based in GCM's Johannesburg office, Dr. Samukeliso Dube (Samu for short) oversees GCM's work on social mobilization, community involvement, and capacity building in East and Southern Africa. Dr. Dube is a public health physician with more than eight years experience in clinical management, policy, programming, and advocacy of public health programs in Southern Africa. She has worked in the HIV/AIDS field with a number of international

Dr. Samukeliso Dube

NGOs and is a committee member of Physicians for Human Rights in her home country of Zimbabwe.

Pauline Irungu, a long-time GCM staffer, works in Nairobi, Kenya as our East Africa Coordinator strengthening GCM's collaborations with community groups and HIV prevention research teams throughout eastern Africa. Pauline has substantial experience in advocacy, networking, documentation, and information management. She holds a BS in Information Sciences from Moi University and is currently pursuing a Masters degree in Sociology and Community Development from the University of Nairobi.

Recognized internationally for her expertise in mobilizing communities to fight stigma and discrimination against people living with and affected by HIV/AIDS, Nomampondo (Noma for short) Barnabas came to GCM from the Centre for the AIDS Programme of Research in South Africa (CAPRISA). As part of her work with the Campaign in Johannesburg, South Africa, Noma works to build relationships and strengthen capacity with partners across Southern Africa. In addition, she serves as a board member for the Aids Legal Network, trustee for the Anglican Aids Health Care Trust, strategic advisor to the Higher Education HIV & AIDS Programme in South Africa, and serves on the Data Safety Monitoring Board of an ongoing research study conducted by the World Health Organization.



Nomampondo Barnabas and Pauline Irungu



Sairumanie Vivienne Naidoo

Sairumanie Vivienne Naidoo (Viv for

short), is the Global Campaign's newest Africa team member. Based in Johannesburg, Viv organises meetings, conferences, and events for the Campaign throughout Africa and provides high-level administrative support to GCM's Africa Programme. Viv comes to the Campaign with over 10 years experience in events management, business development, and communications.

Also based in Johannesburg, South Africa, Deborah Baron coordinates the

Microbicides Media and Communications

Initiative (MMCI), a "community of practice" group comprised of microbicide developers, advocates, and clinical research organizations working to improve communications around microbicide research, especially large-scale studies in Africa and other resource-limited setting. MMCI was the brain-child of our former director Lori Heise and is staffed by GCM.



Deborah Baron

Deborah has extensive experience in communications, media training, and community and advocate engagement in HIV prevention research. Prior to her work in the prevention field, Deborah organized grassroots advocacy campaigns and international collaborations around access to HIV/AIDS treatment and protecting the rights of people living with HIV/AIDS. She holds masters' degrees from Columbia's School of Public Health and School of International and Public Affairs (SIPA), where she studied international health policy and human rights.

To learn more about the Global Campaign staff and Africa Programme, visit our website at [www.global-campaign.org](http://www.global-campaign.org). For more information on the Africa Programme team, please visit our [Africa](#) page. For more information about Global Campaign staff based in Africa and other regions, please visit the [Meet Our Staff](#) page.

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## ***Research Update***

### **GCM Releases First Extensive Survey of Microbicide Trial Sites' Standards of Care Global/Africa**

Over the years there has been considerable public debate regarding the types and amount of health care and prevention services provided to participants in HIV prevention trials. Although this topic (commonly known as the "standards of care" in clinical trials) has been the subject of ethics deliberations in international fora, these discussions have not, historically, been informed by an accurate picture of either the daily realities of trial participants or the real-life challenges inherent in implementing trials. In 2005, the Global Campaign for Microbicides (GCM) and allied groups posed the following question with the release of a document entitled *Consensus Points on Access to Treatment and Standards of Care in Microbicides Trials*:

*To what extent do conditions on the ground conform to the aspirations of advocates or to the various ethics guidance documents that inform the field?*

In an attempt to answer this question, GCM spent most of 2006 and 2007 systematically mapping the standards of care provided to participants enrolled in late-stage microbicide trials, as well as one trial evaluating the diaphragm for HIV prevention. The goals of this exercise were to:

- conduct an independent assessment of the health care and prevention services provided;
- better understand the factors that inform care-related decisions at trial sites;
- to explore the microbicide field's progress toward achieving key ethical aspirations; and
- make recommendations to strengthen the field's ability to respond to care-related challenges in the future.

The mapping exercise included a comprehensive desk review, interviews with international and local researchers, and visits to a representative cross-section of microbicide trial sites in Africa. The specific services that the trial sites provided -- and how they did so -- varied significantly according to a range of factors. Overall, however, the mapping found that the majority of trials had made significant progress toward meeting evolving ethical standards of care and prevention.

Among critical issues explored was the thoroughness with which HIV prevention counseling and services were delivered to trial participants. Special attention was given to this issue in response to suspicions raised in some communities that trial staff were not committed to helping women protect themselves from HIV because the ability of a trial to measure a candidate microbicide's effectiveness depends on the number of HIV seroconversions occurring among participants. Despite concerns that this resulted in a conflict of interests among trial staff, the authors saw no evidence that the intensity or effectiveness of prevention services that delivered to participants was in any way compromised.

The resulting report, *Mapping the Standards of Care at Microbicide Clinical Trial Sites*, not only captures the on-the-ground realities and challenges of conducting large-scale HIV prevention trials, but should also help to inform the design and implementation of future trials as the field moves forward. The report, which details the findings of the exercise and the twenty-eight consensus and

author recommendations derived from these findings, is now available for download from the Global Campaign for Microbicides.

- **Full Report:** <http://www.global-campaign.org/clientfiles/SOC.pdf>
- **Executive Summary:** <http://www.global-campaign.org/clientfiles/SOC-ES.pdf>

For more information about the standards of care mapping, or to receive a printed copy of the report, please contact Katie West Slevin at [kwest@path.org](mailto:kwest@path.org).

## Data and Safety Monitoring Board Recommends CAPRISA 004 Study Continue

A Data and Safety Monitoring Board (DSMB) held a scheduled review of the CAPRISA 004 Tenofovir Gel Phase IIb trial on 27 July 2009. This microbicide trial is assessing the safety and effectiveness of 1% tenofovir gel to prevent HIV infection in women in South Africa. The DSMB congratulated the study team on trial conduct and recommended that the study continue.

"We're heartened that the DSMB has given us the green light to continue," said Prof. Salim Abdool Karim, director of the Centre for the AIDS Programme of Research in South Africa (CAPRISA). "All of us who work in HIV prevention research have high hopes that our collective efforts will result in a way for individuals to protect themselves from HIV. While we won't have final study results for awhile, we're pleased that the interim data seems to suggest that CAPRISA's community engagement process and ongoing participant counseling are contributing to good retention rates, low incidence of pregnancy, participant understanding of the trial, and ongoing community support."

The CAPRISA 004 study is a collaborative effort between CAPRISA at the University of KwaZulu-Natal in Durban, South Africa, Family Health International, and CONRAD. It is funded by USAID and the South African Department of Science and Technology through LIFElab in South Africa.

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## GCM in Action

### GCM and IAVI Partner to Enable Environments for HIV Prevention Research South Africa

Over the course of two months, May 30—July 30, the Global Campaign for Microbicides (GCM), co-hosted a series of workshops with the International HIV/AIDS Vaccine Initiative's (IAVI) Southern Africa Regional office. Through 7 different sessions, GCM and IAVI trained more than 150 participants in Southern Africa, including vaccine and microbicide trial site staff (community liaison officers, counselors, community mobilisers), community advocates, adult & adolescent community advisory board members on a wide range of topics to achieve our goal of creating an enabling environment for clinical trials.

These workshops covered a variety of subjects, including an overview of the status of microbicides, the measures taken in order to ensure the safety of trial participants throughout the duration of a clinical trial, and ethical concerns regarding adolescents in clinical trials. In addition to creating a platform in which to espouse GCM's mission in an international setting and providing constituents information from the *Microbicides Essentials* course, GCM gained insight on the stigma experienced by trial participants in the trial community



GCM and IAVI Training Participants in South Africa



through discourse with workshop participants. This information is especially important as it provides GCM with direction on how to create a welcoming and supportive community environment for clinical trials in the future.

The partnership between GCM & IAVI benefitted both organizations as it empowered participants with education on vaccines and microbicides while training community advocates on their roles in clinical trials as well as how to deal with challenges encounter in their work to create enabling environments for HIV prevention research.

### **GCM at the 5th IAS conference on HIV Pathogenesis, Treatment and Prevention**

Last week, Cape Town hosted the largest open scientific conference on HIV Pathogenesis, Treatment and Prevention. Although there were no ground-breaking discoveries, the conference did mark the official start of a new phase for the Global Campaign for Microbicides (GCM). Starting with a pre-conference satellite and ending with a poster on the last day, GCM brought critical issues and emerging concerns of civil society, advocates and women end-users to the forefront of discussions throughout the conference.

GCM's new Director, Yasmin Halima, and Africa Programme Leader, Dr. Samu Dube, both participated on panels during the satellite, "The Promise and Perils of ARV-Based Prevention: A Dialogue of Optimism & Informed Scepticism." As the panels of researchers, donors and opinion-makers debated issues of access and demand for microbicides, Yasmin Halima assured the audience that "GCM does women" and was committed to ensuring their HIV prevention needs would be prioritized. Yasmin Halima also co-chaired a session,

Operations Research to Strengthen HIV Prevention, and presented on "Mass rape in conflict-affected countries could substantially increase the incidence of HIV: implications for prevention and intervention".



Stephen Becker (left) from the Bill & Melinda Gates Foundation and Dr. Carl Dieffenbach (right) of the National Institutes of Health enjoying a drink with Deborah Baron of GCM at the IAS Reception

On Tuesday, July 21, the GCM Africa Team hosted a cocktail reception for over 100 people, from treatment activists, rectal microbicide advocates, and prevention researchers to industry representatives, donors, and government officials, in support of GCM's new Director, Yasmin Halima. With five staff now based in Johannesburg and Nairobi, the event also offered a special opportunity to share our work and vision for the field from an African perspective.



From left to right: Nomampondo Barnabas, Dr. Samukeliso Dube, Yasmin Halima, Pauline Irungu, Deborah Baron and Sairumanie Vivienne Naidoo at the GCM reception at the IAS Conference

Finally, the Global Campaign's mapping study, "Standards of Care at Microbicide Clinical Trial Sites" was presented during a poster session. Throughout 2006-2007, GCM undertook an exercise to systematically map the health care and prevention services that were being provided to participants enrolled in late-stage microbicide trials, as well as one trial evaluating the diaphragm for HIV prevention. The resulting report, Mapping the Standards of Care at Microbicide Clinical Trial Sites, captures the on-the-ground realities and challenges of conducting large-scale HIV prevention trials. The findings and recommendations detailed in the report will also help inform current discussions around standards of care, will

help researchers and sponsors improve the design and conduct of future trials, and will help strengthen the relationship between community, advocacy, and research. To download the report, please visit <http://www.global-campaign.org/EngDownload.htm#ethics>. To view the poster presented at IAS 2009, please visit <http://www.global-campaign.org/IAS2009.htm>.

All in all, it was GCM breaking new ground at the IAS.

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## ***Materials Update***

### **GCM Releases First Extensive Standards of Care Survey**

The Global Campaign is excited to announce the release of a new report, *Mapping the Standards of Care at Microbicide Clinical Trial Sites*. The report outlines the findings and recommendations which are the result of a year-long effort to map the health care and prevention services provided to participants in HIV prevention trials.

For more information about the standards of care mapping report, please refer to the above article entitled "GCM Releases First Extensive Survey of Microbicide Trial Sites' Standards of Care". The report is available for download from the Global Campaign for Microbicides' website:

- **Full Report:** <http://www.global-campaign.org/clientfiles/SOC.pdf>
- **Executive Summary:** <http://www.global-campaign.org/clientfiles/SOC-ES.pdf>

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## ***What is GCM Doing this Month?***

### **GCM Co-convenes First Ever South African Women's Prevention Summit 20-21 August, Johannesburg, South Africa**

GCM in partnership with the South African National AIDS Council (SANAC) Women's Sector, the Treatment Action Campaign (TAC), International AIDS Vaccine Initiative (IAVI) and Reproductive Health and HIV Research Unit (RHRU) will convene a South African Women's Prevention Summit, 20-21 August. The summit will bring together over 65 participants, including policymakers, women's rights advocates and HIV prevention experts from across South Africa. In convening the summit, GCM and its partners hope to provide a platform for women and HIV organizations to review the implementation of the National Strategic Plan for HIV 2007-2011 on women and HIV prevention, to set an advocacy agenda for women's HIV prevention research needs in South Africa by identifying areas for further exploration and focused collaboration, and discuss issues around access to existing and new HIV prevention technologies in South Africa.

### **2009 National HIV Prevention Conference 23-26 August, Atlanta, Georgia**

GCM staff members will travel to Atlanta, Georgia to participate in the 2009 National HIV Prevention Conference, "Promoting Synergy Between Science and Program". Of particular interest, GCM, along with the Center for HIV Identification, Prevention and Treatment Services, is co-sponsoring a one-day Pre-conference satellite on PrEP entitled "Preparing for PrEP: A Stakeholder's Dialogue". This satellite meeting will gather diverse stakeholders in HIV prevention and treatment, including researchers, policy-makers, providers, consumers and community representatives, to hear the latest news on Pre-Exposure Prophylaxis (PrEP). More importantly, this conference provides the opportunity to discuss what the future of HIV prevention might look like if this revolutionary biomedical intervention is found to be effective and is added to the existing menu of HIV prevention options.

In addition, Anna Forbes, GCM Deputy Director, will present at the 2009 National HIV Prevention Conference on Tuesday, August 25<sup>th</sup>. Her abstract, *In the **real** world, what would PrEP mean for high risk women?*, will address the questions and concerns about PrEP raised by women in countries where large scale trials are occurring.