



## Global Campaign News – Issue #95 3 June 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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## Research update

### Are fingerprint scanning and photography the solution to co-enrollment in trials? Africa

On 5 May, the Microbicide Trials Network (MTN) issued a letter announcing that, to the best of their knowledge, approximately 96 participants at the Durban, South Africa, site of the HPTN 035 microbicide trial had been found to be also enrolled as participants in the Centre for AIDS Prevention and Research in South Africa (CAPRISA) 004 study. The two study sites are approximately 25 kilometres from each other.

HPTN 035 is a Phase 2/2B trial conducted by the Microbicide Trial Network to assess the safety and potential efficacy of BufferGel and 0.5% PRO2000/5 Gel. The CAPRISA 004 study is a Phase 2B trial of Tenofovir gel. The MTN letter noted that the "women who joined both studies did not disclose to either study team that they were also enrolled in another microbicide study" and that MTN is "actively considering measures to prevent future co-enrollment of participants in HIV prevention trials."

The field has long been aware of the risk of co-enrollment, especially in resource poor communities where women's need for the access to money and other trial-related benefits is acute. To help surface and explore these issues from the participants' viewpoint, the Global Campaign co-convened a lively interactive Advocates Corner session entitled, "**Overcoming co-enrollment in trials - are fingerprint scanning and photography the solution?**" during the recent international microbicides conference in New Delhi. The idea for this session—presented by GCM staffer Pauline Irungu and Rhonda White, the Community Involvement Manager for Family Health International and MTN—came from an MTN Community Working Group (CWG) call held in January where the issue was raised by CWG members.

At the session, Rhonda White described the process whereby trial staff mechanically scan and store a participant's fingerprints as a part of her trial record. These, combined with stored participant photographs, are used to verify her identity at each return visit.

The majority of those attending the 27 February conference discussion were African advocates from trial host countries. The group collectively acknowledged the important of preventing co-enrollment for safety reasons, since

no data are yet available about potential side effects that could result from use of more than one product at a time. They also agreed that co-enrollment violates study protocols and damages the trial's ability to collect the accurate data necessary to obtain a real answer about the whether the candidate product works or not.

They pointed out, however, that being fingerprinted and photographed has negative connotations in many countries. Since these practices are primarily used for legal and governmental record-keeping, it is not surprising that they raise the following concerns:

- Are the trial identification data shared with foreign missions or embassies in ways that could influence the person's future ability to acquire travel visas?
- Can the data on trial participants who may have had a brush with the law be used to link them to these past events? Also, given the ongoing global war against terrorism, can trial data be seized by a government to track people it deems to be connected to suspected groups?
- Finally, how can participants be assured that all the identifying information is kept confidential at the community level? Several advocates present pointed out that, for many participants, the risk that study staff might share information about them is their greatest privacy concern. The thought of identifying data being shared across study sites heightens this concern.

Fingerprint scanning is still unfamiliar to most people but the advocates viewed it as potentially "more private" than the use of photographs. They expressed doubt, however, about whether either fingerprint scans or photographs could be shared across studies and/or trial sites without risking breaches of confidentiality. They also questioned whether these identifying data would be shared among trial networks researching different technologies – such as between microbicides trials and vaccine trials that are happening in the same host communities.

They also asked whether the adoption of new identification procedures by trials already underway would make it necessary to develop new informed consent forms – and what impact the process of re-consenting all currently enrolled participants would have on a trial adopting these methods.

Advocates at the 27 February session agreed that intensive community education will be required to address the above concerns. It must include the opportunity for community members and other stakeholders to observe and understand the trial's mechanisms for collecting and storing their identification data. To avoid suspicion and allegations of privacy violation, each trial will also need to make sure that participants understand the scope of their legal privacy rights and how the trial's procedures are designed to protect those rights.

Finally, there was strong consensus on the need to seek input from a much wider range of stakeholders in order to develop and implement not only the most *effective* but also the most *acceptable* interventions to prevent co-enrollment in trials.

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## ***Advocacy in action***

### **Victory for advocates: NIH microbicide research branch chief appointed! North America**

After over a decade of work and unrelenting advocacy, we would like to share news of a hard-won victory for microbicides! The Division of AIDS at the NIH National Institute of Allergy and Infectious Diseases (NIAID/DAIDS) has appointed as the new Microbicides Research Branch Chief, Dr. Roberta Black. Congratulations and thank you to all of the advocates who made the Microbicide Research Branch a reality. It is your dedication that has helped us achieve this impressive goal!

Dr. Black received her PhD in Microbiology from the University of Chicago in 1981. Following a short staff fellowship in the Laboratory of Experimental Pathology at the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases, she did a fellowship in the Laboratory of Molecular Oncology at the National Cancer Institute from 1982 to 1985. Upon completion of her fellowship, she joined the Uniformed Services University of the Health

Sciences as a Research Associate and later served there as Research Assistant Professor. Dr. Black joined DAIDS as an Associate Scientist in the Developmental and Therapeutics Branch of the Basic Sciences Program in 1989 and later served as a Senior Scientist in that Branch. In 2000, she left BSP to join the Prevention Sciences Branch, where she became the Microbicide Team Leader in 2004 and has continued in that role. Dr. Black's years of experience at DAIDS, as well as her pioneering role in the field of microbicides, are the great assets she brings to the role of Microbicide Branch Chief.

## **PEPFAR: Where we are and what we're doing**

### **North America**

The US PEPFAR Reauthorization bill (The Hyde/Lantos US Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008 (S. 2731)) contains language that recognizes the need for microbicides and supports access to microbicides after they are developed, ensures access to HIV treatment for 3-4 million people, and addresses issues such as malaria and tuberculosis. As 30 May, seven Senators are delaying a vote on this important global health bill.

On 20 May, microbicide advocates from all over the US made sure that their voices were heard by calling their Senators and asking that the Senate Majority Leader, Harry Reid, make PEPFAR a priority. Thank you to everyone who took the time to speak up for the millions of people for whom this bill will provide life-saving care.

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## **Highlighted Resources**

### **AVAC Report: *The Search Must Continue***

On 18 May, the AIDS Vaccine Advocacy Coalition released its 2008 report entitled, "The Search Must Continue" in anticipation of HIV Vaccine Awareness Day on 18 May. The report provides:

1. A global "to-do" list for HIV prevention research
2. Top-line questions that have emerged post-STEP and offers opinionated answers
3. Lessons that can be learned from STEP and Phambili vaccine trials
4. A look at the International AIDS Vaccine Initiative that was founded 13 years ago
5. A synopsis of some of the scientific questions and research areas demanding priority attention in the post-STEP era.

Download the full report at [www.avac.org/reports.htm](http://www.avac.org/reports.htm).

### **French translation of briefing paper on safety of vaginal microbicides**

After the success of the briefing paper about "Evaluating the Safety of Vaginal Microbicides: The fundamentals," the French translation, *Évaluation de la Sécurité des Microbicides Vaginaux: le b.a. – ba*, is now available in at <http://www.global-campaign.org/clientfiles/Sécurité-fr.pdf>

We invite you to forward this resource as well as a link to our entire French Download Centre to your French speaking contacts and networks. <http://www.global-campaign.org/FRDownload.htm>

### **Alliance for Microbicide Development launches *Trial Site Catalogue* and website**

The Alliance for Microbicide Development recently launched the *Clinical Trial Site Capacity Catalogue*, which compiles information about recent, current, and potential microbicide and PrEP trial sites. This catalogue is intended to allow sponsors and developers to make more informed decisions about where to conduct a given trial based on an inventory of each site's potential participant population as well as clinical, laboratory, and staffing capacity. The catalogue also helps optimize efficient use of existing sites and minimize costly and possibly inappropriate development of new sites. If the reader is aware of a site that should be included, please contact the Alliance by email at [info@microbicide.org](mailto:info@microbicide.org). The Catalogue can be downloaded at the Alliance's newly designed website: [http://www.microbicide.org/cs/other\\_alliance\\_reports](http://www.microbicide.org/cs/other_alliance_reports)

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We welcome your input and contributions for future issues! Please send emails to: [info@global-campaign.org](mailto: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