



Global Campaign News – Issue #93 18 April 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

IOM report focuses on methodological challenges in prevention trials Global

Late last month, the Institute of Medicine (IOM) of the United States' National Academies of Science released a new report entitled "Methodological Challenges in Biomedical HIV Prevention Trials."

Commissioned by the Bill and Melinda Gates Foundation, the IOM report examines the scientific and ethical challenges of designing and running large-scale clinical trials of microbicides, pre-exposure prophylaxis (PrEP), and other novel HIV prevention technologies. The final report also provides recommendations on how future trials could be designed in ways that increase the likelihood of success. Although the report makes mention of the recent HIV vaccine trial closures, the committee's focus did not include HIV vaccines.

The premature closure of the cellulose sulfate and Savvy trials and the disappointing results of the MIRA and Carraguard™ trials demonstrate that there is need for careful reflection on this topic, particularly with regard to accurately estimating HIV incidence in trial communities and to improving participant enrollment, retention and adherence.

Trials at several sites have been cancelled or stopped prematurely, for example, because HIV incidence among trial participants was much lower than originally estimated. Any reduction in HIV incidence in at-risk populations is a cause for celebration, but cancelling trials or closing sites because of lower-than-expected incidence wastes resources, disrupts the local community, and may foster disappointment and distrust among trial participants. In light of this, the IOM committee recommended that accurate incidence estimates first be collected through prospective cohort studies of HIV-uninfected individuals in the communities where the trials will occur.

The high rate of pregnancy among trial participants—almost 50% at some PrEP trial sites in Ghana, Nigeria, and Cameroon and close to 30% at some microbicide trial sites in Southern Africa—also poses a challenge. Women who become pregnant during a trial are usually taken off product because of potential risks to the fetus. Exclusion of these women, however, can result in a significant loss of trial participants. Preventing pregnant women from using these products also raises concerns about real-world use of approved products by pregnant women in the future. The IOM committee concludes that researchers should try to determine the safety of the intervention in pregnant women and allow pregnant women to continue in microbicide and PrEP trials under certain circumstances.

Copies of the IOM report are available for purchase or download (free with registration) at the National Academy website (http://www.nap.edu/catalog.php?record_id=12056).

HSV-2 treatment does not reduce the risk of HIV infection, part 2

Global

Infection with Herpes simplex virus 2 (HSV-2), the virus that causes genital herpes, increases an individual's risk of acquiring HIV. This observation has led some researchers to test whether suppressing HSV-2 with a drug like acyclovir could reduce the risk of HIV infection among those with genital herpes. To date, however, no large-scale trial of HSV-2 suppressive therapy has proven effective, including a recent trial of over 3,000 participants in Peru, South Africa, the United States, Zambia and Zimbabwe. (More information at: <http://www.global-campaign.org/clientfiles/GC-News91.pdf>)

A new study of 821 women in Tanzania, all of whom had genital herpes and were at high-risk of acquiring HIV sexually, also failed to show that effective HSV-2 treatment reduces rates of HIV infection. Participants were randomised to receive either 400 mg acyclovir twice daily (400 participants) or placebo pills (421 participants). Over an average of 18 months of follow up, 27 new HIV infections occurred among the trial participants receiving acyclovir and 28 new infections among trial participants in the placebo group.

GCM will continue to monitor the results of this and similar STI treatment trials and will update you regularly as new information arises.

Highlighted Resources

Article focuses on Community Advisory Boards at three research sites

Global

The most recent issue of *Clinical Trials* features an excellent article that follows the evolution of community advisory boards (CABs) at three HPTN research sites in Peru, Zimbabwe, and Thailand. Through a variety of data collection methods, the study found that over the course of five years, all three CABs expanded their original function and became advocates for broader community interests beyond HIV prevention. In each case, there were certain "critical incidents" that seemed to be important turning points in how the CABs matured. At each site, a conflict or challenge arose that heightened the level of interaction among community, the CAB, and researchers; the CAB weighed in; and the CAB became especially valuable to the research team and to the future success of the research. The researchers conclude that "CABs can be dynamic entities, capable of evolving to meet critical and often surprising roles."

The abstract of the article is available at: <http://ctj.sagepub.com/cgi/content/abstract/5/2/147>

Full citation: Stephen F Morin, Simon Morfit, Andre Maiorana, Apinun Aramrattana, Pedro Goicochea, John Michael Mutsambi, Jonathan Leserman Robbins, and T Anne Richards. Building community partnerships: case studies of Community Advisory Boards at research sites in Peru, Zimbabwe, and Thailand. *Clinical Trials*, April 2008; 5: 147-156.

Advocacy in action

Advocates follow the progress of PEPFAR reauthorization

North America

As part of a comprehensive strategy in the U.S., advocates are tracking on the reauthorization of the President's Emergency Plan for AIDS Relief (PEPFAR). On 2 April, the U.S. House of Representatives passed H.R. 5501, a

bill that will authorize \$50 billion over the next five years through PEPFAR. While the House version of the bill contains minimal microbicides language, advocates are hopeful that the Senate version—which contains language authorizing the distribution of microbicides after development and recognizes the importance of microbicides in the fight against AIDS—will be included in the final bill.

Some positive aspects of the current House version include the removal of the one-third abstinence-only earmark for PEPFAR funds, and the dramatic increase in HIV/AIDS programming related to women and girls. However, concerns have been raised surrounding restrictions on family planning and the inclusion of the Anti-Prostitution Pledge in the new legislation.

Introducing the Advocates: Ntokozo Madlala, South Africa Africa

As a part of GC News, "Introducing the advocates" profiles the activities of individual or a group advocating for new prevention technologies. To be considered for a profile or to nominate a colleague for future issues, send a short note to info@global-campaign.org.

For Ntokozo Madlala, the motivation behind her work as a microbicide advocate is easy. "HIV prevention for women is in my heart, and we are not doing enough," she insists. "But if we do focus on HIV prevention, we can make a change."

Known as Ntoks to fellow activists and friends, Ntokozo Madlala has worked with South Africa's Gender AIDS Forum since 2001. Gender AIDS Forum (GAF) is a Durban-based South African NGO committed to enabling a deeper consciousness in women and men about the links between gender and HIV and AIDS.

GAF works diligently in South Africa to support microbicides development as a potential tool to help empower women to protect themselves from HIV. In 2006, GAF successfully lobbied for the inclusion of language in support of microbicides development in South Africa's *National Strategy Plan for HIV/AIDS and STDs 2007-2011*.

As GAF's Program Coordinator, Ntoks organizes and facilitates trainings on HIV prevention for women, including microbicides. GAF targets communities in Durban, Pietermaritzburg and other communities in the Kwa-Zulu/Natal region where microbicide studies are taking place.

Ntoks notes, "GAF works to facilitate relationships between researchers and communities. We help bring issues from the communities to the attention of researchers, and provide opportunities to bring information back to the communities in return." For example, GAF works to translate microbicides materials into Zulu and hosts regular update meetings for advocates, where leading researchers from CAPRISA and the South African Medical Research Council have come to present the latest results or data on studies.

Recently, Ntoks returned from a two-month training program sponsored by MAC AIDS Fund at Columbia University in New York City. Ntoks is now back at GAF in Durban, where she will implement a project she designed at Columbia that focuses on advocating for access to female condoms and women-controlled methods at three sites in Durban.

When asked why microbicides advocacy is important, Ntoks did not hesitate to acknowledge the long-term commitment this work requires. She said, "Advocating for microbicides needs people who have a vision and who understand the realities of what women are going through. Even if we ourselves don't find a microbicide, we must leave a mark. We must contribute our piece to this important work so that women in the future will have ways to protect themselves."

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