



Global Campaign News – Issue #96 23 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

First Ever Trial of Microbicide Safety in Pregnancy Planned North America

Because of safety concerns, trials to test the effectiveness of vaginal microbicides currently exclude pregnant and lactating women from enrollment. Study participants who become pregnant must also discontinue product use.

Such regulatory and ethical restrictions, however, present a challenge for the microbicide field. In many of the resource-poor countries where large-scale microbicide trials take place, women can spend one-third to one-half of their reproductive years pregnant or breastfeeding. These restrictions thus make it difficult to recruit trial participants. Moreover, if too many trial participants become pregnant and must discontinue product use, the loss of these volunteers may prevent the study from demonstrating if the microbicide is protective.



These restrictions also create a Catch-22 when it comes to safety and effectiveness. Even once an effective microbicide is found and approved for widespread use, researchers and regulators likely will have little data to show that these products are safe and effective when used by pregnant women. But a large number of pregnant women, particularly in the developing world, are likely to use these products.

Researchers from the Microbicide Trials Network (MTN) recently announced the formation of a registry to follow pregnancy outcomes in women who become pregnant while enrolled in MTN-funded studies of candidate microbicides or pre-exposure prophylaxis. This is an important first step in collecting the necessary data to convince regulators to allow trial participants who become pregnant to continue using the experimental product.

The same MTN researchers have also announced the start of MTN-002, the first ever study to look at safety and absorption of an ARV-based candidate microbicide when used by pregnant women. The study

will enroll 16 healthy HIV-negative women scheduled for elective caesarean delivery at the University of Pittsburgh Medical Center, each of whom will apply a single dose of topical 1% tenofovir gel vaginally prior to surgical delivery. Researchers will then monitor the amount of tenofovir absorbed by the woman's body and whether it is also transferred to the fetus.

Both the MTN-002 study and the MTN-funded pregnancy registry are important steps in developing microbicides that are safe and effective for all women to use. The Global Campaign for Microbicides will continue to monitor the results of these and similar studies and will update you regularly as new information arises. For more information about this and other trials of novel HIV prevention technologies, please see <http://www.global-campaign.org/>. You can also learn more about the MTN-002 and the pregnancy registry at <http://www.mtnstopshiv.org/news>.

Highlighted Resources

Microbicides Essentials Course Goes LIVE!

If you have always wanted to learn more about the science, the testing, and the field of microbicides...here is your chance!

The Global Campaign for Microbicides is pleased to announce the launch of the *Microbicides Essentials* on-line course at the Prevention Research E-Learning Centre. Take a look at: www.hivpreventionresearch.org

This course will help you be able to answer tough questions like:
How are microbicides designed to work?
Why do so many of the large trials take place in Africa?
What will it take before they will they be available?

You will be taken through a journey where topics are presented in a lively interface with graphics, interactive quizzes, scientific animations, and much more!

The course is already getting rave reviews:

"I would definitely use this course for not only our advocates, but also for staff members who would like a refreshed on basic HIV facts or would like to know more about microbicides." - AIDS Advocate

"I was most most most impressed." – Microbicides researcher

"My favorite part is the animation that shows how the microbicide is inserted into the vagina, boosts the body's natural defenses and then stops the virus from infecting healthy cells." – Women's health advocate

The best part:

The *Microbicides Essentials* course is available *Now & free of charge*. All learners will earn a certificate upon successful completion. Health care providers based in the U.S. can also register to earn continuing education credits.

CD-Rom versions will be available in August, and can be ordered at: <http://www.hivpreventionresearch.org/CDRom.aspx>

Email us with any questions: e-learning@global-campaign.org

New Factsheets on ARV-Based Microbicides & Resistance!

How much do you know about HIV Drug Resistance?

1. No idea! Is it related to the French Resistance?
2. I know a little bit about it, but please don't give me a quiz.
3. I am an expert, but I find it difficult to explain it to my peers.

If any of the above situations apply to you, it might be a good idea to consult GCM's new fact sheets.

Did you know?

Antiretroviral drugs (ARVs) have been used for over 10 years to treat individuals living with HIV/AIDS. ARVs have also been shown to prevent infection in some situations, such as when they are used to reduce the chance that a baby born to an HIV-positive woman will be infected at birth.

Scientists believe that ARVs could protect people from HIV if they are used to make microbicides and clinical trials are currently underway to see if an ARV-based microbicide can protect women and men who are exposed to HIV through vaginal and anal sex. But a number of questions remain unanswered. Will ARV-based microbicides work? Could they lead to drug resistance if used by women or men who are HIV-positive? Are there other safety issues associated with these products?

To help advocates and community members understand these issues, the Global Campaign for Microbicides has developed two new fact sheets to explain how ARV-based microbicides work, as well as to explain some of the basics about HIV drug resistance and how it occurs.

Read GCM's new factsheets!

To help you understand some of these complicated issues, download the easy-to-read fact sheets for free: [Antiretroviral \(ARV\)-Based Microbicides: The Promise and the Puzzle](#) and [Understanding HIV Drug Resistance](#).

These and other factsheets are available for download from the Global Campaign for Microbicides' Download Centre found at <http://www.global-campaign.org/EngDownload.htm>.

Advocacy in action

UK Commitment for Microbicides Research: A boost for UK advocacy efforts Europe

The UK Government recently reaffirmed its commitment to the development of an effective microbicide by announcing that it will increase funding for research and development of AIDS vaccines and microbicides between 2008 and 2013 by 50%.

This announcement was part of a broader commitment to make comprehensive HIV prevention a priority in their updated strategy for fighting AIDS in the developing world: '[Achieving Universal Access](#)'. This commitment was also supported in the related Department for International Development (DfID) Research Strategy 2008-2013, which outlined commitments to increase funding for product development partnerships, to undertake research into how new health technologies can be introduced, and to overcome barriers to their adoption.

The UK Campaign for Microbicides, a partner of the Global Campaign for Microbicides, has been active in advocating for an increase in UK support for the research and development of microbicides and other new prevention technologies. Over the past 12 months, the UK Campaign has collaborated with scientists, worked with the media and engaged parliamentarians to highlight the need for new prevention technologies and to explore the UK's unique role in promoting sexual and reproductive rights.

The announcement of additional funding has been welcomed by the Campaign as a significant illustration of the UK's leadership in the development of an effective microbicide. Campaign members will continue to influence DfID spending on new prevention technologies, in particular highlighting the need to support the development of both vaginal and rectal microbicides, as well as social research and local advocacy to begin to address potential microbicide access issues. The enthusiasm over the funding commitment needs to be sustained and UK campaigners will be watching closely to ensure that the UK government fulfills its promises.

Save the Date: Forum on HIV Prevention Research for Women & Girls Mexico City / AIDS 2008

Please join us for an exciting satellite session during the International AIDS Conference in Mexico City as we bring together government representatives, policy-makers and grassroots leaders working on the frontlines of HIV prevention research. We will discuss the work needed to develop and test a range of interventions addressing the complex gender inequality challenges that continue to exacerbate a feminized HIV/AIDS epidemic worldwide.

No Simple Solution: Investing in HIV Prevention Research for Women & Girls An Open Forum & Roundtable Discussion

**Monday, August 4, 2008
6:30-8:30 p.m.
IAC in Mexico City, Mexico**

Speakers include:

Stephen Lewis, Co-Founder, AIDS-Free World (moderator)
Hilda Esquivel, Mexicanas Positivas Frente a la Vida, Mexico
Julia Kim, University of Witwatersrand, South Africa
Elizabeth Mataka, United Nations Special Envoy for HIV/AIDS in Africa
Matilda Mogale, HIV Vaccine Trials Unit at Baragwanath Hospital, South Africa

Co-sponsored by: AIDS Vaccine Advocacy Coalition, Center for Health and Gender Equity, Global Campaign for Microbicides, Ibis Reproductive Health, International AIDS Vaccine Initiative, International Partnership for Microbicides, International Women's Health Coalition.

For more information please contact Kate Bourne, kbourne@iwhc.org or [download the flyer](#).

The flyer can be downloaded directly from <http://www.global-campaign.org/clientfiles/womenhivflyer.pdf>.

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