



Global Campaign News – Issue #61 December 21, 2005 – revised version (20 Jan 2006)

Welcome to the biweekly *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 STDs. This and previous issues of GC News are available online at <http://www.global-campaign.org/gcnews.htm>

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What happened to the Savvy trial in Ghana?

Africa

Editor's note: Parts of this article were edited in response to a letter that the Global Campaign received from Rosalie Dominik from Family Health International. (See GC News #62 for complete details).

In November, researchers at Family Health International (FHI) announced that they were discontinuing the phase 3 trial of the candidate microbicide Savvy. There was no evidence of any safety concerns based on data collected from the 2,142 volunteers enrolled in the trial since its initiation in March 2004. Rather, the trial's Data Monitoring Committee (DMC), an independent body which reviews ongoing trial data periodically, determined that the trial would not be able to answer the actual research question among the group of women enrolled.

Several factors are involved in designing a phase three trial and determining appropriate sites in which to carry it out. One is the incidence of HIV among women in the area. *Incidence* is the number of new infections in a population over a period of time. If five people out of every hundred in a certain area become infected with HIV over the course of a year, the incidence in that area is 5%. This is different from *prevalence*, which describes the percentage of people living with HIV in a population at a certain time. In Microbicide trials, people are provided with either the candidate microbicide or a comparable, inactive gel (a placebo) and asked to use these in addition to condoms each time they have sex. Given that condom use tends to happen with the same frequency in both arms of the trial, the trial measures whether the fewer women in the microbicide arm of the trial become HIV positive over time than women in the control arm. The incidence of HIV infection among women eligible for participation in a microbicide trial is an important factor in determining how many women will need to enroll in order for a trial of a truly effective gel to show that the gel does indeed reduce HIV infection better than a placebo. The chance that a trial will show that a truly effective gel does reduce HIV infection better than placebo is known as the power of the study to show a statistically significant result.

When the DMC reviewed the interim data, they noted that the *incidence* among all women enrolled in the Ghana Savvy trial was lower than anticipated- sufficiently low, in fact, that conducting this trial among this population would not be able to show a result. Under these circumstances, it is unethical to ask women to continue to comply with the burdens of participation, and to spend scarce resources, on a phase three trial that will not show evidence of product effectiveness.

Although this represents a disappointment for all of us in the microbicides community, there is definitely good news in that there was no evidence of safety concerns. And fewer women in the study communities in Ghana contracted HIV than previously anticipated, which represents a bright spot in an epidemic short on messages of hope.

Nevertheless, the difference between expected and actual HIV incidence is a big deal, which we should try to understand. It is probably due to a combination of factors, which include:

- **Lack of core data that directly measures incidence.** Current incidence data are rare and expensive to collect, and can add significantly to the cost of a trial- both in financial and human resources. Where data do not exist, incidence is estimated based on prevalence data. But since we don't always understand or can't predict the changing dynamics of the epidemic in a certain location until after the fact, these data represent an imprecise measure at best.
- **Effectiveness of prevention services and counseling provided by the trial.** The experience of many prevention trials has shown that the rate of HIV incidence does decrease somewhat among all women enrolled in the trial when compared to their peers outside the trial. This decrease has been attributed to the prevention services (including free condoms, condom counseling and STI screening and treatment) provided to participants and their partners, should they choose to involve them. Researchers are taking these reductions into account when designing trials, but the extent of the impact is unclear.
- **Age of the participants-** Microbicide trials enroll women of "reproductive age"-- generally 15 to 49 years old (though most trials don't enroll women under 18, and some have no upper age limit). However, the highest risk of HIV exists among people in the lower range of that age group. If a disproportionate number of older women enroll in the trial, the incidence rates will be lower than those predicted across the entire age range. Some microbicide trials are seeing more older than younger women volunteering to participate.

For research institutions and funders, the implications of the Savvy Ghana experience will undoubtedly inform future and perhaps even current clinical trial designs. For the Ghanaian women who volunteered, although the trial has ended early and without reaching its intended conclusion, they have contributed valuable data about the safety of Savvy as a possible microbicide. Each participant will have a final visit for counseling, and FHI will keep one clinic in each research site open to provide follow-up care for the participants until June 2006--the original end date of the trial. The women who sero-converted during their participation in the trial will receive care and treatment, including ARVs when necessary, through referral to the Ghanaian health system and possibly other mechanisms (according to personal communication from FHI). Savvy trials in Nigeria are still in progress.

To see the original press release from FHI, go to:

<http://www.fhi.org/en/AboutFHI/Media/Releases/Nov082005GhanaSavvyTrial.htm>

For more information about the Ghana study closure, please contact Beth Robinson, media@fhi.org

New Resource: WHO Multi-Country Study on Violence Against Women Global

The World Health Organization, PATH, and the London School of Hygiene and Tropical Medicine released a landmark study to coincide with the 16 Days of Activism Against Gender Violence (November 25 to December 10). The *WHO Multi-country Study on Women's Health and Domestic Violence against Women* involved more than 24,000 women in ten countries: Bangladesh, Brazil, Ethiopia, Japan, Namibia, Peru, Samoa, Serbia and Montenegro, Tanzania, and Thailand. Specially trained interviewers surveyed random samples (by household) of women aged 15 to 49 years.

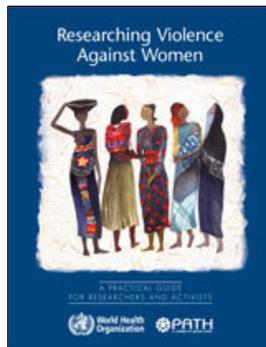
The study reveals that intimate partner violence is the most common form of violence in women's lives - much more so than assault or rape by strangers or acquaintances. The study reports on the enormous toll physical and sexual violence by husbands and partners has on the health and well-being of women around the world and the extent to which partner violence is still largely hidden.

Data are included on non-partner violence, sexual abuse during childhood and forced first sexual experience. Information is also provided on women's responses: Whom do women turn to and whom do they tell about the violence in their lives? Do they leave or fight back? Which services do they use and what response do they get? The report concludes with 15 recommendations to strengthen national commitment and action on violence against

women. Data from the report show that violence against women is widespread and demands a public health response.

Just a few of the findings include:

- In 13 of the 15 study sites, one-third to three-quarters of women had been physically or sexually assaulted by an intimate partner.
- At some sites, as many as 28 percent of women who had been pregnant had been assaulted during pregnancy.
- Much of this violence had been hidden and previously unreported—more than one-fifth of women reporting violence during the study had never told anyone about it before.
- In at least half the study sites, women reported believing that it is acceptable for a man to beat his wife under certain circumstances, including if she disobeys him, refuses sex, does not complete the housework on time, or is unfaithful.



In addition to informing policies and health interventions, the Multi-country Study presents a model for research that is methodologically rigorous and yields information that can be directly applied to violence-prevention activities. To help others undertake similar research, PATH and WHO have produced an additional resource, *Researching Violence Against Women: A Practical Guide for Researchers and Activists*. The guide draws on the experience of researchers from more than 40 countries and presents methods for performing surveys and qualitative research on gender-based violence in low-resource settings. It covers all aspects of the research process, from study design to training field workers. It also describes ways to use findings to influence decision-makers. Most important, it presents clear guidelines for protecting the safety of women participating in the research.

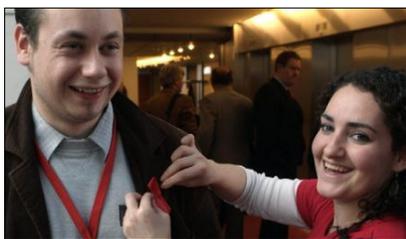
Finally, an article about the study's findings appeared in the November 25, 2005, issue of *Science* (volume 310, page 1282) and was authored by Claudia Garcia-Moreno and Henrica A. F. M. Jansen of the World Health Organization, Lori Heise and Mary Ellsberg of PATH, and Charlotte Watts of the London School of Hygiene and Tropical Medicine. The web address for *Science* is www.sciencemag.org.

Copies of the WHO Multi-country study are available online:

http://www.who.int/gender/violence/who_multicountry_study/en/index.html

HIV prevention: promises, progress and reality

Europe



On World AIDS day, NGOs in Brussels, the Global Campaign for Microbicides, ActionAid, Stop Aids Alliance, MSF and IAVI, jointly called upon the EU to take urgent action on HIV/AIDS.

Representatives from several international NGOs came together in the European Parliament in Brussels to mark World AIDS Day by raising awareness and distributing red ribbons to all Members of the European Parliament (MEPs).

At the end of the day, more than 2500 persons in the European Parliament were wearing a red ribbon. During the day, the group of international NGOs were invited by the chair of the Development Committee, MEP Ms. Luisa Morgantini, to be part of the Development Committee taking place on World AIDS Day.

The group took this opportunity to share with the members of the committee the experience of Geena Gonzalves, a person living positively with HIV/AIDS in a developing country, and the consequences of living with stigma.

A doctor from MSF, Dr. Delphine Sculier mentioned the challenges of responding to HIV/AIDS from a health perspective, talking about the scale of the problem of access to treatment, with 6.5 million urgently needing anti-retroviral treatment. The NGOs called on MEPs to ensure and promote the involvement of people living with HIV/AIDS in decision making at all levels.



The group of international NGOs concluded by giving recommendations to the European Parliament to scale up prevention policies, to ensure access to affordable medicines, to promote research and development on preventive and medicinal tools, and to ensure sufficient funding to respond effectively to HIV/AIDS in developing countries.

Picture on previous page: Global Campaign Europe's Arwa Meijer pins a ribbon onto a willing passerby; Bottom picture from left to right: Mamadou Diallo (IAVI), Barbara Prammer (Deputy Leader of the SPOE), Ivy Kakiiza (Action Aid International), Geena Gonsalves (Action Aid International) and Shibananda Phurailatpam (Action Aid International)

Microbicides featured in U.S. media on World AIDS Day Global

In observance of World AIDS Day, US advocates captured the media's attention to bring more awareness to the need for new women-controlled prevention options:

Los Angeles:

In partnership with the Global Campaign for Microbicides and Gilead Sciences, Inc., the AIDS Research Alliance (ARA) hosted the Los Angeles premiere of the *Giving Women Power Over AIDS* exhibit at the Los Angeles City Hall's Council Chambers and Rotunda on World AIDS Day. ARA hosted a press conference with scientists and advocates working in the field of microbicide research. The event was covered by Channel 35 (The LA City TV Channel), LA Indie Media (web based), KFWB Radio, and KABC Radio.



The World AIDS Day event was followed by a more intimate reception on 5 December at the Hoffman Medical Research Center at University of Southern California. Although the formal portion of the reception lasted less than 30 minutes, students were so interested by the topic that their questions lasted longer than the presentations.

As stated by Martell Randolph (*pictured left*), the lead event organizer in a thank you letter to volunteers, "both events were hugely successful in that they helped to raise awareness about the microbicide issue and shed light on why they are so desperately needed around the world. When we work together for a single cause, the universe reaches out to amplify our collective efforts."

Chicago:

Representative Jan Schakowsky, one of the lead-sponsors of the Microbicide Development Act (H.R. 3854) distributed a press release focused on women, HIV, and the potential of microbicides. The press release, entitled "Schakowsky Urges U.S. Action on World Aids Day", is available at: http://www.house.gov/schakowsky/PressRelease_12_1_05_WorldAIDS_Day.html

In addition, Dazon Dixon Diallo, the president of SisterLove and member of the Global Campaign steering committee, was featured in a live interview on Chicago's WVON – Voice of the Nation. For 40 years, WVON has been a forum for the African-American community in Chicago to discuss current, social, economic, and political issues.

Seattle:

Jessica Cohen, the co-coordinator of the Northwest Microbicide Coalition appeared on the Seattle affiliate of National Public Radio to discuss HIV/AIDS along with the Executive Director of Lifelong AIDS Alliance and the Director of the HIV/AIDS Program at Public Health for Seattle & King County.

Changes to the Global Campaign Steering Committee

Global

The Global Campaign for Microbicides Steering Committee provides vital feedback to the secretariat about the workings of the Global Campaign and the wider needs of the field. Steering Committee members commit to three year terms and represent the geographic regions in which the Campaign works and the issues that the Campaign grapples with.

Four members of the Steering Committee are leaving this year. The Global Campaign steering committee and secretariat are most grateful to these three advocates who have been an essential part of our strategic thinking in the past few years:

* Cory Richards, The Guttmacher Institute, US

* Laurie Sylla, Yale AIDS Program, US

* Joan Tallada, Grupo de Trabajo sobre Tratamientos del VIH, Spain

We look forward to continuing our work in other capacities with these individuals and their organizations for many years to come.

In their place, we are happy to announce and welcome the three newest additions to the Global Campaign Steering Committee for 2006: Susan Chong, Francoise Welter, and Caroline Sande.

Susan Chong, *Asian Pacific Coalition of AIDS Organizations*. Susan lives and works in Kuala Lumpur, Malaysia. She has been assisting us with our organizing efforts in Southeast Asia for the last few years and is now overseeing a sub-contract we have negotiated with APCASO for mapping of advocacy allies and opportunities in three countries in the region (Malaysia, Thailand and the Philippines). She had community organizing, fundraising and management experience that spans twelve years and thirteen countries. Her knowledge of the advocacy landscape and the NGO allies and potential allies in the region has been instrumental in helping the Global Campaign expand its efforts in Southeast Asia to date.

Francoise Welter, *Global Network of People Living with HIV/AIDS (GNP+)*. Francoise is Policy Coordinator for GNP+, a global network for and by people with HIV/AIDS aiming to improve the quality of life of people living with HIV/AIDS. Rwandan by birth, Ms Welter holds over twenty years of professional experience in the United Nations system. She has previously worked with UNDP, UNAIDS and the Global Fund to Fight AIDS, Tuberculosis and Malaria. She has also worked with the German NGO, AIDS Hilfe, and currently serves as a Vice Chair of one of its regional boards.

Caroline Sande, *ActionAid International*. Caroline is the Director of ActionAid International's Southern Africa Partnership Programme based in Johannesburg. In this capacity, she designed a programmatic framework and coordinates ActionAid's campaign in southern Africa on women, girls and HIV. Prior to this, she spent eight years with Oxfam International; designing, developing and managing programs in Africa, Eastern Europe and the Middle East. A Kenyan by birth, Caroline now lives and works in South Africa. She has been an outspoken voice for the needs of Africa at the last two G-8 summits, as well as in many other venues.

For a full roster of Steering Committee members for 2006, please see: <http://www.global-campaign.org/governance.htm>

European donors contribute almost US\$30M

Europe

As announced on World AIDS Day, the International Partnership for Microbicides has recently received nearly \$30 million of new funding from four European governments. The new commitments from the United Kingdom (GBP 7.5 million, over three years), the Republic of Ireland (EUR 9 million, over three years), Denmark (DKK 27.5 million, over three years) and Sweden (SEK 10 million) will significantly contribute towards the development and accessibility of microbicides. The Global Campaign would like to congratulate our colleagues in the UK, Ireland, Denmark and Sweden for their advocacy work in the past several years. The complete press release is available at: http://www.ipm-microbicides.org/news_room/english/press_releases/2005/2005_1201_30_million.htm

Microbicides 2006 abstracts invited - deadline extended to 15 January

Global

A Message from the Track D Committee of Microbicides 2006:

Microbicides 2006 will for the first time feature a track focusing on Community and Advocacy. Activities and presentations for this new Track D will explore community and advocacy experiences and initiatives related to research and development of vaginal and rectal microbicides.

Track D will highlight the contributions of advocacy and community to furthering microbicides research and development in ways that respond to the priorities of diverse communities and constituencies. The primary theme is PARTNERSHIP- looking at models and mechanisms for effective partnerships among stakeholders in order to maximize our collective progress. Specifically, we will look at models and mechanisms for partnership in these areas:

- HIV positive women and microbicides: Moving the research forward
- Pathways to access to a successful microbicide- advocacy, policy and mobilization
- Models and mechanisms for engaging community in research implementation
- Beyond Involvement: civil society's role in making ethical progress toward a microbicide
- Resource Mobilization

We hope to receive abstracts that address such questions as,

- Who sets the research agenda and how can communities participate?
- How can communities and advocates effectively work with clinical and social science researchers to facilitate research that is ethical and responsive to community?
- How can a rights-based discourse inform and strengthen microbicides research, development, access and use?
- How do we create effective collaborations and lay the groundwork for broad access to a microbicide once it is proven effective?

We invite abstracts from advocates and activists, community members, ethicists, researchers, policy makers and regulatory experts to contribute to what we are sure will be a conference full of challenging and stimulating discussions.

Abstract submission deadline extended to: **January 15, 2006.**

Go to www.microbicides2006.org for more information

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.