



## Global Campaign News – Issue #87 4 October 2007

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

### Understanding results of the Savvy trial

#### Global

On 19 September 2007 Family Health International (FHI) provided an update on the data obtained through their now closed Phase 3 trials of the candidate microbicide Savvy (C31G) in Ghana and Nigeria. The Ghana trial was closed in November 2005 and the Nigerian trial in August 2006. These trials were not stopped not because of any detected problems with the product but because it became apparent that they weren't providing enough data to tell whether the product was working or not. A summary of the data FHI just released from these trials is posted on the GCM website at [www.global-campaign.org/trial-updates.htm](http://www.global-campaign.org/trial-updates.htm), along with a fact sheet that addresses questions being raised in connection with these findings.

The Ghana study showed no real difference between the number of women who sero-converted in the Savvy arm of the trial (0.7%) versus the placebo arm (0.8%). In the Nigeria trial, however, the difference was 2.0% in the Savvy arm versus 1.1% among those using placebo. While this is concerning, we must also recognize that the total number of infections in both studies was so small that it is not possible to tell whether the difference was product-related, caused by some other factor, or simply due to chance. The FHI researchers are further analyzing the data to look for factors associated with the appearance of increased risk. For example, they will look at whether the risk of HIV infection is higher among women who reported using the product more frequently or having sex more often – which would make sense if the product did increase risk.

Before the Savvy trial began, GCM advocated to ensure that there would be an 'early look' by the trial's Data Safety and Monitoring Board to assure maximum protection for participants in the event of early evidence suggesting the possibility of increased risk.

Savvy has now been ruled out of the picture completely as a potential microbicide. The scientific challenge now is to use these data to better understand what happened so that future trials are even better equipped to assess product safety before efficacy trials start. These results highlight the need for more research to identify 'biomarkers' that

may signal when an active ingredient may be problematic in the vagina. The Global Campaign is advocating for increased funding for this vital area.

For more information about how these data are gathered and interpreted, readers may want to review the article on HIV incidence that appeared in GC News in November 2006 (see <http://www.global-campaign.org/clientfiles/GCNews72.pdf>) and the GCM issue brief on Evaluating Microbicide Safety (Available at <http://www.global-campaign.org/briefing.htm>.)

## **Consultation on enrolling adolescents in research**

### **Global**

Globally, young women are particularly vulnerable to contracting sexually transmitted diseases and HIV/AIDS for a variety of biological and socio-cultural reasons. According to UNAIDS, for example, half of all new HIV infections occur among young people ages 15 to 24. In some parts of sub-Saharan Africa, young women are now up to six times more likely than young men to be living with HIV.

Given this unique vulnerability, adolescents would clearly benefit from the development of safe and effective HIV prevention technologies like microbicides and vaccines. From a regulatory perspective, however, agencies like the US Food and Drug Administration and the South African Medicines Control Council are unlikely to allow microbicides and vaccines to be marketed to young women and men unless there are data demonstrating that these products are safe and effective for use in an adolescent population. But enrolling adolescents in clinical HIV prevention trials poses a number of unique challenges. Although a small number of adolescents have participated in microbicide trials in Africa, to date no adolescents have been enrolled in HIV vaccine studies.

On 5-6 September, the HIV AIDS Vaccines Ethics Group (HAVEG) of the University of KwaZulu-Natal hosted a meeting in Durban, South Africa to examine the scientific, ethical, and legal issues associated with enrolling adolescents in HIV vaccine and microbicide research. The Global Campaign for Microbicides co-sponsored and provided funding for the event, which was the first time that vaccine and microbicide researchers, policymakers and regulators, advocates, and community members (including two teenagers who serve on community advisory boards) gathered together to explore these issues.

Through a combination of presentations, discussions and group exercises, the group worked toward the meeting goals:

- 1) To review the current status of adolescent involvement in vaccine and microbicide trials;
- 2) To explore the scientific, ethical and legal challenges associated with adolescent enrollment in clinical research; and
- 3) To develop a series of recommendations for both the vaccine and microbicide fields as they move forward.

Microbicide researchers and advocates identified the following needs:

- Need to gain greater scientific clarity about whether safety and effectiveness will differ among adults and adolescents for individual microbicide products,
- Need to review in-depth ethical and legal requirements for enrolling adolescents in clinical trials across different countries, and
- Need to develop clear justification within the scientific, regulatory and local community about the need to involve adolescents in HIV prevention trials.

Vaccine researchers and advocates identified similar needs, as well as the need to explore some unique areas of concern, such as the problem of false-positive HIV test results among vaccine trial participants. HAVEG and the Global Campaign expect to work with researchers and HIV prevention advocates to explore these issues further.

For more information about the adolescent consult meeting, please visit <http://www.global-campaign.org/consult-Ethical&LegalSept07.htm>

## **Survey on lubricants for anal sex concludes data collection**

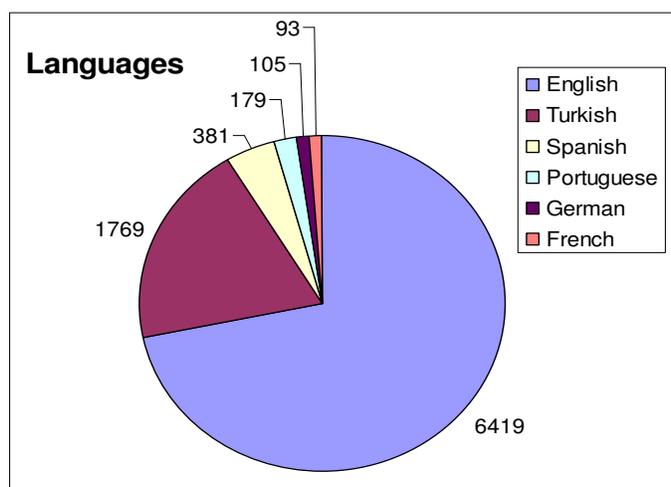
## Global

On 31 August, the survey developed by the International Rectal Microbicides Working Group (IRMWG) on lubricants used for anal sex closed after being available online for 6 months in 6 languages. Researchers at the University of California, Los Angeles are currently analyzing the data. IRMWG will disseminate their analysis as soon as it is available later in fall 2007.

From preliminary looks at the data, it appears that the respondents have provided a wealth of information from around the world relating to:

- Which lubes are more commonly used for anal sex
- How people use lube for anal sex
- Preferred lube characteristics
- Frequency of condom use during anal sex

This information will be useful in helping the field decide which lubes to test for rectal safety as a priority; understand which characteristics to aim for in rectal microbicide development and packaging; understand how to improve lube and condom access; gain some insight into differences across regions, genders and age; and think about anal sex practices as they relate to the sexual health of women and men from various regions.



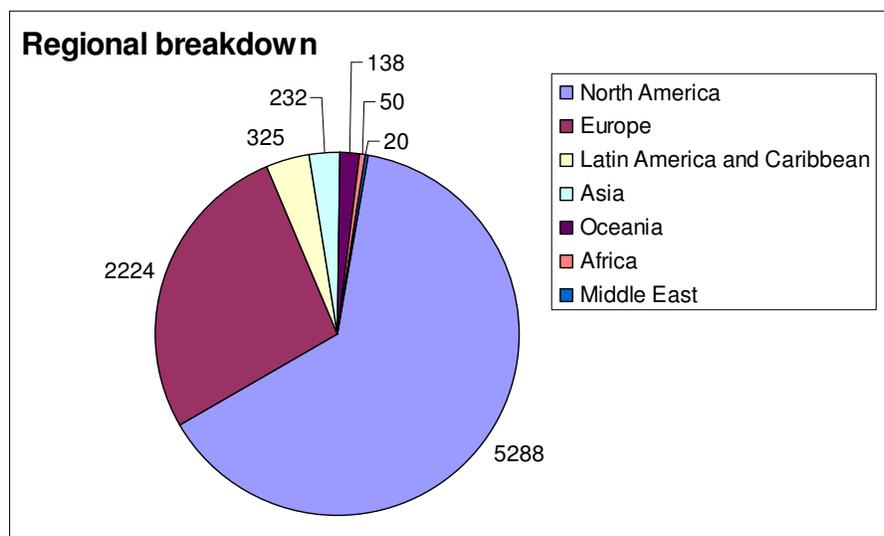
IRMWG received 8946 responses from 107 countries, with 6959 completed surveys (77.8%). Among those who indicated a gender, 88.1% are men, 10.3% are women, and 1.5% are transgendered people.

With the help of volunteer translators, IRMWG managed to increase the international reach of the survey. Non-English responses account for 28.2% of the responses.

IRMWG wishes to thank everyone who took the time to answer the survey and distribute it through networks around the world.

The following countries provided the most responses:

USA	Turkey	Canada	UK	Australia	Mexico	India	Portugal	Germany	Spain
4820	1283	468	467	121	113	95	94	73	63



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## **Advocacy in action**

### **Prevention advocacy and research meeting in South Africa Africa**

In August 2007, over 30 South African HIV prevention advocates and researchers met in Durban to review microbicides research, development and advocacy to date in South Africa.

Hosted by the Gender AIDS Forum and the African Microbicides Advocacy Group, the main objectives of the meeting were to:

- Give an update on microbicides research and development in South Africa;
- Understand recent HIV prevention trial results and closures; and
- Consider advocacy priorities for South African advocates.

The first day, researchers presented results from the MIRA diaphragm study and the rationale for the closure of the cellulose sulfate trial. Though the studies' results were disappointing, participants stressed that advocacy and research efforts must continue.

Community advocates were then briefed on communication plans for the results of the Population Council's candidate microbicide, Carraguard; current trials testing Buffer Gel and Pro2000; and upcoming microbicide research from both the Microbicide Trial Network and the International Partnership for Microbicides.

The terminology used by the researchers tended to be scientific, confusing many of the advocates. Thus, a bit of back-tracking and explanations were necessary. Advocates had many questions for the researchers: What research is being done involving women who have sex with women and men who have sex with men? What happens to women who sero-convert in these trials? What about the new ARV-containing microbicides and resistance?

Mitzy Gafos, a principal investigator from the Africa Centre, demonstrated how her study staff conveyed complicated terms like "blinded" and "double-blinded" to trial participants. It was a great example of how scientific concepts and rationales can be made easily understandable to potential participants. After interacting with the researchers, advocates spent some time discussing what questions remained and what their priorities were for microbicides research.

The meeting ended with the participants splitting into two groups and visiting trial sites to learn more about trial participants' really experiences. While it could be deemed an overall success, the meeting certainly highlighted the need for research literacy training for advocates, and community literacy training for researchers.

### **BBC TV highlights collaboration between advocates and scientists Europe**

While most advocates are content to raise the importance of microbicides with their representatives of Parliament and post an article in a newsletter, the UK African Microbicides Working Group has decided to broadcast directly to the nation and beyond. The Group, a dynamic coalition of African women and men living in the UK, are working closely with a leading research team at St. George's University of London to advise them about what they want from a microbicide and exactly how it should feel, smell and be used when it hits the market. Both advocates and researchers jumped at the chance to highlight their collaboration when approached by TV producers. The program was broadcast on Wednesday 19<sup>th</sup> September at 7.30pm and can be viewed over the internet at [http://www.bbc.co.uk/insideout/content/articles/2007/09/14/london\\_aids\\_12\\_1\\_feature.shtml](http://www.bbc.co.uk/insideout/content/articles/2007/09/14/london_aids_12_1_feature.shtml).

BBC reporter Anya Sitaram joined community workers as they toured the science labs to get a better understanding of what microbicide research involves. Trisha Fletcher, who has spent over 10 years researching microbicides, explained the slow and tedious process of the research where many failures were encountered along the way. "What helps keep me going is that ultimately what I'm doing one day could make a big difference."



Members of the UK African Microbicides Working Group with Prof. Robin Shattock -Photo Courtesy of St George's Hospital (London).

After the tour, Winnie Ssanyu Sseruma, a long-time supporter of microbicides, said: "I think these meetings are really important for microbicide advocates - for us to really get the knowledge we need in terms of what the process is like, what the end product is going to look like, so that we can give this information to the communities."

The next day it was the scientists turn to ask the questions when they went to the offices of Positively Women, a support centre for women living with HIV and their families. When asked whether they would actually want to use the microbicide gel, the women said that a product that could prevent the spread of HIV was much in demand and they appreciated the tireless efforts of the scientific research. But they all agreed that some serious market research was needed to come up with a more appealing name than microbicides!

Through such exchanges, the new project, known as "HIV Science In Action" enables scientists to understand the cultural context of microbicides — which products would best appeal to people in high-risk groups, the issues surrounding partner consent and the myths still surrounding HIV — and puts a face to the disease they are studying, bringing home how urgent the need is for new methods of protection.

Professor Robin Shattock emphasised the importance of bridging the gap between science and the community: "It benefits the advocates because it keeps them informed about the type of work the scientists are doing, and it benefits the scientists because it keeps them in touch with the needs of the people so they can develop a product that these people will want to use. It doesn't matter how good it is at blocking the virus, if those it is meant for aren't going to use it."

Yvonne Feare from the UK African Microbicides Working Group summed up the feelings of the Working Group: "To actually come here and see first hand your work and to imagine that in the laboratory there could actually be a miracle, a product that really empowers women, is amazing, so we are very grateful for the work you are doing and it keeps us going and gives us motivation to go for it, so let's go for it!"

The UK African Microbicides Working Group is administered by the African HIV Policy Network on behalf of the UK Campaign for Microbicides, a coalition of 13 NGOs hosted by Interact Worldwide. Their work was profiled in GC News #79 in which they invited (and subsequently received) contact from African advocates around the world. To get in touch, email [anamiba@positivelywomen.org.uk](mailto:anamiba@positivelywomen.org.uk) or [georgina.caswell@ahpn.org](mailto:georgina.caswell@ahpn.org)

*Sources: BBC Inside Out London and St George's University of London.*

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## Highlighted Resources

### Get to know the European microbicide advocates and their activities...

Check out the latest events in Europe, along with pictures of some of our favorite advocates: <http://www.global-campaign.org/euro-events.htm>

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## **Conference Announcements**

### **Microbicides 2008 scholarship and abstract deadlines extended.**

By popular demand, the deadline for abstract and scholarship submissions has been extended to 15 October 2007. Find more information at the Microbicides 2008 website at: [www.microbicides2008.com](http://www.microbicides2008.com)

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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