



Global Campaign News – Issue #86 13 September 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

BufferGel May Provide Spermicidal Alternative to N-9

Global

Data just published in *Obstetrics & Gynecology*, the Journal of the American College of Obstetricians and Gynecologists (see <http://www.greenjournal.org/cgi/content/abstract/110/3/577?ct=ct>), indicates that the product BufferGel may have comparable or greater contraceptive effectiveness than Nonoxynol-9 (N-9) when used with a diaphragm. The need for a non-detergent topical contraceptive has been evident since 2000 when trial data showed that frequent use of N-9 gel could increase HIV risk by causing vaginal and rectal epithelial disruptions.

N-9, the active ingredient in all the topical spermicides sold over the counter in the US, is still promoted as a viable contraceptive option for women at low risk of HIV who do not engage in multiple acts of intercourse in one day. Since diaphragms and cervical caps are designed to be used with spermicides, women who use these contraceptive methods must have uninterrupted access to these products, as well as full knowledge of their potential impact on HIV risk.

BufferGel is product designed to maintain the vagina at or near its natural state of mild acidity. Developed by the US-based biotech ReProtect Inc., BufferGel has been studied in candidate microbicide and contraceptive trials for almost a decade. Unlike N-9, BufferGel does not work as a detergent. Instead, it simply keeps the vaginal pH low (acidic) even in the presence of semen.

Sperm prefer a neutral pH so, after unprotected intercourse, the alkaline semen raises the vaginal pH to a neutral level and keeps it there for several hours. This helps both sperm and acid-sensitive STD pathogens (including HIV) to survive. The ReProtect scientists hypothesize that, by keeping the vaginal environment acidic, BufferGel might be able to both prevent unwanted pregnancy and reduce the risk of STIs, including HIV. To test the first part of this hypothesis, a total of 975 women were enrolled in a Phase 2/3 randomized, double-blinded, non-inferiority study at 11 trial sites in six US states.

In one arm of the trial, women used BufferGel plus diaphragm for contraception for 6 months and, in the other, used Gynol II (a commercially available N-9 gel) plus diaphragm. The 6-month pregnancy rate per hundred women was slightly lower among the BufferGel users than among the N-9 gel users (10% versus 12%). Consistent and correct use is always a factor with user-initiated prevention methods. In this study, the rate of consistent use and product acceptability was very similar in both trial arms. The trial researchers concluded that BufferGel “used with a diaphragm is a safe, acceptable contraceptive with efficacy comparable to that of a common commercial spermicide with diaphragm.”

Another Phase 2/3 trial of BufferGel used with a diaphragm also showed strong contraceptive effectiveness, thus providing confirmatory data. Results of a Phase 2/2B trial assessing BufferGel’s potential effectiveness as a microbicide are expected in 2009.

Whether it works as a microbicide or not, the possibility that BufferGel may provide an effective spermicidal alternative to N-9 for women using topical forms of contraception is very good news in terms of providing non-hormonal contraceptive options that do not potentially exacerbate their HIV risk.

Questions Remain About Circumcision’s Ability to Protect Female Partners Global

In previous issues of *GC News*, we’ve reported on recent research suggesting that routine male circumcision could significantly reduce a man’s risk of acquiring HIV infection. Three randomized controlled clinical trials undertaken in Kenya, Uganda and South Africa demonstrated that circumcision reduced a man’s risk of infection through heterosexual sex by about 60 percent. The World Health Organization (WHO) is now officially promoting male circumcision as part of a comprehensive HIV prevention package, and the US President’s Emergency Plan for AIDS Relief (PEPFAR) recently announced plans to provide money for circumcision programs as part of its effort to reduce the spread of HIV in some African countries.

One of the biggest unanswered questions, however, is whether male circumcision will also help protect the female sexual partners of circumcised, HIV-positive men. A prospective study of serodiscordant couples in Uganda suggested otherwise, but that trial was stopped early and the data available were limited. An epidemiological survey of almost 5,000 sexually-active women in Uganda and Zimbabwe, published in the August 20th edition of *AIDS*, found that male circumcision had little influence on the female partner’s risk of acquiring HIV.

4,417 sexually-active, low risk, HIV-negative women were enrolled at trial sites in Uganda and Zimbabwe. An additional 393 Ugandan women considered at high risk of infection—sex workers and patients from sexually transmitted infection clinics—were also enrolled, for a total of 4,810 study participants. At enrollment, women were asked the circumcision status of their current partners, as well as detailed questions about their reproductive, contraceptive and sexual behaviours. The women were then followed for an average of two years, with frequent clinic visits to test for HIV and other sexually transmitted infections; treat any active STIs; and collect additional information about sexual behaviour, including the circumcision status of any new partners.

A total of 210 women became infected during follow-up. No protective effect from circumcision was seen for women considered at low risk of HIV infection when these data were analyzed -- after taking into account a woman’s age, age at sexual debut, contraceptive use, husband’s employment status, level of education, and number of sexual partners in the previous three months. Low-risk Ugandan and Zimbabwean women had a similar risk of infection, regardless of their partner’s circumcision status. High-risk Ugandan women appeared to derive a small protective effect from having a circumcised partner, but this result was based on an analysis of relatively few HIV infections (19 infections total, with only two among women with circumcised partners) and did not achieve statistical significance.

For more information about male circumcision as an HIV prevention option, visit <http://www.global-campaign.org/malecircumcision.htm>.

Advocacy in action

Join the Global Campaign Staff!

The Global Campaign for Microbicides is currently recruiting for a number of staff positions:

- **Executive Assistant** (based in Washington, DC, USA)
- **Media & Communications Initiative Officer** (based in Johannesburg, South Africa)
- **Project Administrator** (based in Washington, DC, USA)

For full job descriptions and information on how to apply, please visit <http://www.global-campaign.org/employment.htm>, and continue to check back as we post new positions. The Global Campaign has staff based in Washington, DC, U.S.; Belgium, Brussels; Nairobi, Kenya; Johannesburg, South Africa; and New Delhi, India.

M2008 Call for Scholarship Applications!



The M2008 organizing committee is now accepting applications for scholarships to the Microbicides 2008 Conference, scheduled to occur on February 23-27, 2008 in New Delhi, India. A limited number of scholarships will be awarded to researchers, health care providers and community advocates, covering registration fees and/or housing and travel expenses.

The conference organizers have stated that preference for scholarships will be given to individuals who: have submitted abstracts; are from developing countries; have a background in HIV/AIDS research, prevention, care and/or treatment; are likely to communicate knowledge gained at the conference back to their colleagues and communities; represent diverse professional disciplines and/or geographical areas most affected by the HIV/AIDS pandemic; and/or demonstrate an unusual commitment and desire to attend the conference.

We strongly encourage advocates on the *GC News* list to submit scholarship applications to the Conference Scholarship Committee. To do so, please visit <http://www.microbicides2008.com/scholarship.asp>. Also, let us know if you've submitted an application by emailing Katie West at kwest@path.org.

The deadline to submit scholarship applications and to [submit conference abstracts](#) is September 30th, 2007.

More Action from the Unproven Product Claims Watch

Global

The Global Campaign's Unproven Product Claims Watch has been kept busy for the last several months with still more products claiming to be microbicides entering the market. GCM has maintained an Unproven Product Claims Watch for the last five years to raise public awareness of products that are promoted as effective microbicides without substantiating evidence and to advocate for the removal of such products from the market wherever possible.

At present, we are working collaboratively with the International Rectal Microbicide Working Group (IRMWG), Terrence Higgins Trust (in the UK), SENSOA (in Belgium) and other allies to investigate the claims of Kirklees Medical Limited, a UK-based lubricant manufacturer. Kirklees has been making explicit advertising claims on their website and on other internet lubricant marketers' sites regarding the ability of its K-Lube products to reduce HIV risk. We have



repeatedly asked Kirklees to either provide with peer-reviewed scientific data supporting its anti-HIV/anti-STI claims or to cease making them.

Kirklees has not complied with either of these two requests so GCM and IRMWG sent a letter on September 7 to the UK Medical and Healthcare Regulatory Authority regarding this matter. The text of the letter is available at: http://www.aidschicago.org/irmwg/docs/letter%20to%20UK%20regulators%20v%202%20_2_.pdf

Rebekah Webb, GCM's European Coordinator, has also written a forceful letter on this subject to the editor of *+ve (Plusv/e/)* magazine, a UK-based magazine "aimed at everyone infected or affected by bloodborne viruses, including HIV, viral hepatitis (A, B, C etc) and STIs". *+ve's* summer issue featured an article called 'Russian Lube-lette' that described several products, including K-Lube, as effective microbicides. Until we actually have a microbicide of proven safety and effectiveness, misleading claims of this kind are a significant threat to public health. The article appears on-line at <http://www.plusve.org/data/usercontentroot/magazine/2007/issue%2074/features/Feature%201.asp> and Rebekah's response will appear in the magazine's December issue.

Meanwhile, our work on Genvia is on-going. As reported in *GC News* last November, Genvia is a spray-on iodine-based product promoted as a broad-spectrum microbicide that "acts to kill major STD's, including the HIV/AIDS virus". We are receiving pro-bono assistance with this work not only from Freshfields Bruckhaus Deringer, a



leading international law firm, but also from three State Attorneys General offices in the US. There are several legal strategies underway and it would be pre-mature to report on them at present. **The main thing we need now is to know exactly where Genvia is actually being sold or advertised for sale.** If have seen Genvia for sale anywhere in your community or on the internet, please contact Anna Forbes (asforbes@path.org).

Please note that we *do not* need examples of internet postings discussing Genvia. We have several of those already. What we need to know is where one can actually buy it. Any information you can provide on this would assist our efforts to prevent false claims from being made and false hope being offered to people at risk of HIV infection.

In separate but related news, we are gratified to learn that a businessman in Australia who claimed to have invented an "invisible condom" is now facing a fine of up to \$400,000 for making "misleading" statements to the Australian Stock Exchange in 2005. Citrofresh International and Ravi Narain, its managing director, were charged with violating Australia's Corporations Act by making unproven claims that this product, a post-intercourse spray for use by men, could "offer a global solution to reduce and eventually stop the spread" of HIV. (See the Daily Telegraph at <http://www.news.com.au/dailytelegraph/story/0,22049,22371882-5001021,00.html> for full coverage)

Spotlight on Bernice Heloo & the Society for Women and AIDS in Africa Africa

Bernice Heloo is the President of the Society for Women and AIDS in Africa (SWAA International), a Pan African NGO working in 41 African countries. SWAA's aims are to mitigate the impact of HIV and AIDS on women and children in Africa and empower women to enjoy their economic, social and political rights.

Bernice holds an M.Phil. degree in Adult Education from the University of Ghana and M.Ed in Adult Education Literacy for Rural Development from the University of Manchester, UK. Bernice has been working in working in HIV/AIDS and women's health for close to two decades. She is the Executive Director of Pro-link, a non profit development organisation she founded in 1993 and a member of the Steering Committee of the African Microbicides Advocacy Group (AMAG).



Bernice is married and the mother of three. She believes that human beings, irrespective of their literacy levels and where they live, have the capacities and potentials to transform their lives and are the authors of their own development.

As an ardent promoter of female controlled devices, she sees microbicides as empowering tools for women and other minorities. Her first encounter with the female condom, another female controlled prevention option, was in 1996 when as the project manager of CARE International's Sexually Transmitted Diseases and AIDS Prevention Mining Areas (SAPIMA) project, she carried out an acceptability study of female condoms among wives of formal and non-formal miners and sex workers. This study strengthened her commitment for prevention tools for women as she says "I could see the strong desire coupled with fear among the women who see the female condoms as the savior. Their husbands and sexual partners were cheating and they knew it".

In recognition of her work, UNAIDS appointed her to serve on the National Female Condom Promotion Committee which was instrumental in the launching of the Ghana female condom promotion project in 2000. She got introduced to microbicides in 2001 in a sensitization meeting for SWAA and other partners organized by Global Campaign for Microbicides.

She was instrumental in the establishment of the Multi-disciplinary Microbicides Advocacy Group in Ghana. The group works all levels of leadership to ensure literacy and support for microbicides development. She says that putting the team together and gaining their support required establishing rapport with scientists, advocates, policy makers and other stakeholders. This was built on earlier efforts and collaborations. In establishing this group, the team held discussion with a variety of leaders including the Ghana AIDS Control Programme, AIDS Commission, trials sites, community leaders, women groups and the media and traditional authorities whose involvement is a critical part of HIV prevention research.

As the current president of SWAA International, Bernice is working with all 41 branches to sensitize and educate policy makers to support microbicides development and female condom campaigns in order to ensure that women have access to tools that they want and deserve. One of the priorities of SWAA is advocating for access to technologies that women can initiate to save their lives in male dominated societies. Bernice acknowledges the need to involve men in the process of developing tools that women can use, especially in Africa where they still remain the decision makers at home. She sites this as a lesson learnt from work in promoting the female condom where some of the men who were reached through the campaign sometimes purchased the female condoms for their spouses. Most men were interested in its dual protection capabilities.

Bernice's dream is that, in her current position, she will contribute to making every SWAA member microbicides literate so that they can confidently pass the information to their constituents – that is, grassroots women and men who are sometimes forgotten by macro-level programs. To achieve this, she is working with the different country chapters to ensure that the SWAA workshops, seminars and international conference have skills building sessions on microbicides and female condoms. SWAA will be holding its 11th International Conference slated for 3rd to 7th February 2008 in Burkina Faso where microbicides and female condoms will be features prominently on the agenda. (Please visit the website at www.swaaburkina.org).

Bernice argues that building synergy between different technologies and diverse stakeholders will help launch, promote and sustain work with new technologies. Undue competition among the various players would also be avoided. A major challenge is that, "... a lot of lip service is been paid to promotion of the female condom. Some people talk about it without believing in it for several reasons." There is need, therefore, as advocates of female controlled prevention technologies to genuinely push for access to the existing tools as the focus also remains on new prevention technologies.

Highlighted Resources

Evaluating Safety of Vaginal Microbicides: The Fundamentals

A Global Campaign Briefing Paper

This paper explores the questions that scientists hope to answer when they conduct safety evaluations of microbicides, including how safety is evaluated and the strengths and limitations of current methods used. Readers will appreciate the way that the paper explains terms like *mutagenicity*, *cytokines*, and *biomarkers* in easy to understand language. This paper is essential reading for advocates who want to engage more in scientific discussions about microbicides.

To download this briefing paper, please visit:

<http://www.global-campaign.org/clientfiles/GCMBrief-Safety-Evaluation-Fundamentals.pdf>

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