



**Global Campaign News**  
**November 3, 2003**

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.

We welcome your input and contributions. Correspondence can be addressed 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.

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### **Male Circumcision may offer another tactic in combating HIV**

Uncircumcised men are at 8 times the risk of being infected with HIV-1 compared with those who are circumcised, according to a large study of Indian men, which is being presented at the 41st Annual Meeting of the Infectious Diseases Society of America.

\* Circumcised men have an 8-fold reduction in risk of being infected with HIV-1, compared to uncircumcised men, according to a large study of Indian men.

\* The findings from the study support a biological explanation for the protective effect of circumcision rather than an effect due to differences in sexual risk behaviors.

\* Worldwide circumcision rates vary widely, depending on religion and culture; about two-thirds of American male infants are circumcised.

Circumcision involves removal of the foreskin, which covers the tip of the penis, and typically is performed shortly after birth. In the United States, approximately two-thirds of male infants are circumcised annually, according to the Centers for Disease Control and Prevention (CDC). Worldwide, the rates vary widely, depending on culture and religion: in many countries, including India, circumcision is uncommon.

Results of the study being presented at IDSA suggest that removal of the foreskin is biologically protective against HIV infection, but not as protective against other sexually transmitted diseases (STDs). The inner surface of the foreskin doesn't have the same protective layer as the outside, and is potentially more vulnerable to HIV, researchers say.

"It's important that we offer measures to help curb the spread of AIDS, particularly in developing countries, where it continues to grow at an alarming rate," said Steven J. Reynolds, M.D., M.P.H., post-doctoral fellow in the division of infectious diseases at The Johns Hopkins University School of Medicine, Baltimore, and a study investigator. "Condoms are protective, but they still are not being used consistently in some settings.

This study suggests that circumcision, where safe and culturally acceptable, may offer the developing world another tactic in combating the spread of HIV."

Researchers also studied the risk of other STDs - including syphilis, gonorrhea and genital herpes - among circumcised and uncircumcised men. Although the incidence of the STDs was slightly higher among uncircumcised men compared to circumcised men, the difference was not statistically significant in this study, said Dr. Reynolds. This was in contrast to the reduced risk of HIV among circumcised men, which was highly statistically significant.

The research was part of a larger study investigating risk factors for HIV-1 infection based on men attending one of three STD clinics in Pune, India. Between 1993 and 2000, 2,298 men who tested negative for HIV-1 were enrolled in the study. During subsequent visits (an average of three visits in 11 months), 2 of 191 men who were circumcised and 165 of 2,107 who were uncircumcised tested positive for HIV. There are two types of HIV: HIV-1 is far more prevalent worldwide than HIV-2.

Demographics, sexual risk behaviors (including having sex with a prostitute), and condom use were remarkably similar between both groups, said Dr. Reynolds. Despite the similarity in risk profiles, researchers determined the incidence rate of HIV-1 among circumcised men it was 0.7 percent, whereas among uncircumcised men it was 5.5 percent, an 8-fold increase.

The findings suggest the benefit of circumcision may be biological rather than due to other factors, such as infection with another STD, or differences in behavior between circumcised and uncircumcised men, said Dr. Reynolds. The inner surface of the foreskin is not as thickly "keratinized" as the outside or other surfaces of the penis, meaning it has less of a protective layer and may be more easily penetrated by HIV, he said. It also has higher numbers of the cells that HIV infects, possibly contributing to the reduced risk of HIV infection observed when the foreskin is removed.

There are other potential methods uncircumcised men may be able to use to protect themselves against HIV, said Dr. Reynolds. In the future, a topical microbicide product might be applied to the foreskin before sex to protect against HIV. Such products are currently in development, said Dr. Reynolds.

Circumcision isn't totally protective and may not be culturally acceptable or safe in some settings, so regular condom use is still the best way of protecting against HIV and other sexually transmitted diseases, said Dr. Reynolds. Condom promotion remains a key strategy in the current fight against the spread of AIDS, he said.

"Circumcision as a potential prevention strategy requires confirmation by randomized clinical

trials, which are the gold standard in evaluating medical interventions," he said. There currently are clinical trials underway in Uganda, Kenya and South Africa.

*Co-authors of a paper on the topic being presented by Dr. Reynolds are Mary E. Shepherd, Arun R. Risbud, Raman R. Gangakhedkar, Ronald S. Brookmeyer, Anand D. Divekar, Sanjay M. Mehendale and Robert C. Bollinger.*

## **New Microbicides Trials in West Africa**

The Global Campaign learned through recent communication with investigators that a new nexus of microbicide trials is being established in West Africa. Family Health International (FHI) is preparing to conduct a randomized controlled trial to assess the effectiveness of SAVVY vaginal gel in preventing HIV among 2,264 Ghanaian women at risk for acquiring the virus. The trial, to be mounted in the cities of Accra and Kumasi, is expected to yield results by 2007.

FHI is also heading up a trial of cellulose sulfate in the Nigerian cities of Lagos and Port Hartcourt; as well as another study of Savvy to be undertaken at clinical trial sites in Lagos and Ibadan

A trial of pre-exposure prophylaxis using Tenofovir (PMPA) is also slated to start in three West African cities -- Duola, Cameroon; Ibandan, Nigeria and Tema, Ghana -- during the first quarter of 2004.

This mobilization of clinical trials in western African is very welcome news and underscores the need to expand the Global Campaign's microbicide preparedness and community involvement work in this region. Click [here](#) for a map of microbicide trial locations, courtesy of the Alliance for Microbicide Development.

## **Microbicides development at new stage with FDA**

Microbicides advocates face a new challenge in the acceleration of microbicides development. In the US, new drugs must go through a rigorous approval process with the Food and Drug Administration (FDA) before it can be marketed. Now with some microbicides entering the last Phase III clinical trials, the FDA must come to a decision on what criteria should be required to approve microbicides.

In August the FDA invited a group of people, including Lori Heise, director of the Global Campaign, to discuss issues approval before the Antiviral Drugs Advisory Committee. See [www.global-campaign.org/.....](http://www.global-campaign.org/) for the Global Campaign's testimony and other related articles to the FDA discussions. Issues of clinical trials were discussed, however many questions went were unresolved. Click on <http://www.amfar.org/cgi-bin/iowa/td/feature/record.html?record=106> for more for details.

## **Activists Rap Ugandan Government over Non-promotion of Female Condom** (Date: October 15, 2003, Source: The New Vision)

Women activists have attacked the government for the suspension of the promotion of the femidom (female condom). They said the move would put women at a higher risk of contracting HIV/AIDS.

"It is disheartening that the Ministry of Health has abandoned the only option that women would use to protect themselves," the president (and long time advocate of the Global Campaign) of the Society for Women against AIDS in Africa (SWAA), Dr Margaret Muganwa said. The Ministry of Health suspended the social marketing of the femidom, citing high costs, ill-preparation and poor acceptability of the condom. But Muganwa said women were more vulnerable to infections because of "their anatomical nature". "We needed to maintain an option for them to safeguard themselves," she said during a seminar on microbicides. SWAA is spearheading advocacy for microbicides in Africa.

The femidom was introduced in 1997. About 1.2 million condoms had been used at the time of the suspension. Citing examples from Ghana and Senegal where the femidom has been successfully used, Muganwa challenged the government to overhaul its promotion strategy. During its trial period, the Ministry of Health ascertained 85 per cent acceptability of the femidom, but most of the condoms imported expired without being utilized.

SWAA blamed the government for not involving men in trial and promotional process "Men have not been trained to appreciate and negotiate the use of the condom. If the government had done this we wouldn't have had such shortcomings," Muganwa said, adding that women needed an option to determine condom use.

## **Advocates in Print**

### **Sister to Sister**

Microbicides as an Alternative Solution, one of our partners in California, has produced a booklet called "Maya and Olivia's Straight Out Sister to Sister Sex Talk." Targetted to African American urban youth in California, this colorfully illustrated booklet uses an engaging story line to convey solid information on STDs, pregnancy risk and the need for microbicides. Thanks to support from a local funding source, MAS is able to make a limited number of free copies of the booklet available on request. Bulk supplies can also be purchased from MAS. Click on the title here to see "[Sister to Sister](#)" on line. For more information, contact MAS at [www.microbicidesnow.org](http://www.microbicidesnow.org).

### **Priority On Treatment, Conservatives' Approach to Prevention**

Heather Boonstra from the Alan Guttmacher Institute and public policy advisor on microbicides legislation, recently wrote an article on the state of US AIDS policy under the Bush Administration. Boonstra gives a great historic overview of actors and circumstances that resulted in the creation of the Global AIDS Bill. In particular, she addressed the limited

funds for prevention – an estimated \$600 million per year will be put to HIV prevention activities. She adds, “...of particular concern to sexual and reproductive health advocates – the relatively modest funds available for prevention will be constrained by a series of last-minute amendments to the legislation that largely reflect the ideology and interests of religious and social conservatives.” Boonstra also specifically discusses the two conservative strategies of the House Pro-Life Caucus in advocating for abstinence promotion in US-funded HIV prevention programs and an amendment that provides protection for faith-based groups to opt out of condom distribution if it violates their religious beliefs.

See <http://www.gutmacher.org/pubs/journals/gr060301.pdf> for the entire article.

### **Microbicides in Ms. Magazine**

Barbara Feder Ostrov, a seasoned microbicide journalist in the US, wrote “Microbicides: Worth the Wait?” which appeared in the fall issue of Ms. Magazine, an international feminist magazine. This is a huge victory since microbicides advocates have been trying to catch the ears and interest of the major feminist organizations in the US. Ostrov talks about the specific dilemma of the immediate need for microbicides and the long government and scientific reviews (in addition to lack of funding) that are stalling microbicides from getting onto the shelves of consumers. You can get a copy of Ms. Magazine at your local magazine store.