

## FEATURED RESEARCH

### Sex Preparation and Diaphragm Acceptability in Sex Work in Nairobi, Kenya

Sharma A, Bukusi E, Posner S, Feldman D, Ngugi E, Cohen CR.

*Sexual Health*. 2006; 3(4): 261–8.

**Background:** Women in sex work stand to benefit if the contraceptive diaphragm alone or with a microbicide proves to be an effective barrier method against HIV and sexually transmissible infection (STI). Currently, contraceptive diaphragm users are advised to leave the diaphragm in situ without concomitant use of other intravaginal substances for at least 6 hours after intercourse.

**Methods:** We conducted in-depth interviews on sexual behaviour including post-coital intravaginal practices with 36 women in sex work and 26 of their clients and held two focus-group discussions, each with 10 women.

**Results:** The women described adapting several potentially harmful substances, such as cloth and soapy water, for post-coital vaginal use to ensure personal hygiene, disease prevention and client pleasure. Some wanted to clean themselves and remove the diaphragm

early, fearing exposure to HIV infection for themselves and their subsequent clients. Clients indicated their desire for 'dry sex', vaginal cleanliness and reduced risk of infection through vaginal cleaning.



Diaphragms

**Conclusions:** The diaphragm as a female-controlled barrier method for HIV/STI prevention may have limited acceptability among women in sex work if its effectiveness depends on a 6-hour post-coital wait before removal, along with avoidance of concomitant use of intravaginal substances. In keeping with the beliefs of the female sex workers and their needs and practices, alternative intravaginal substances and modes of insertion that will not disrupt vaginal flora, injure vaginal epithelium, damage the diaphragm or counteract potentially beneficial effects of microbicides are needed. The possibility of removing the diaphragm sooner than the recommended 6 hours for contraception should be further studied.

### Effect of Replens® Gel Used with a Diaphragm for Human Papillomavirus and Other Lower Genital Tract Infections

Smith-McCune KK, Tuveson JL, Rubin MM, Da Costa MM, Darragh TM, Shiboski SC, et al.

*Journal of Lower Genital Tract Disease*. 2006; 10(4): 213-8.

**Objective:** Little is known about effects of vaginal lubricants with barrier contraceptives on detection of sexually transmissible infections. We hypothesized that Replens gel used with a diaphragm would neither inhibit human papillomavirus (HPV) detection in cervical samples and chlamydia (CT) and gonorrhea (GC) detection in urine samples, nor affect cervical cytology quality.

**Materials and Methods:** After a clinician-collected cervical sample and a self-collected vaginal sample for HPV detection ("pregel" specimens), women placed a diaphragm containing Replens gel into the vagina. Participants (n = 77) removed the diaphragm after 6 hours and performed vaginal HPV self-sampling at several time points thereafter. Clinicians performed cervical cytology sampling and HPV testing ("postgel" specimens) 24 hours after diaphragm removal. Pregel and postgel specimens were analyzed with and without added SiHa cells (source of defined numbers of HPV16

genomes). HPV was detected by polymerase chain reaction using MY09/11 primers. Urine samples were obtained for CT and GC testing. Proportions of samples testing positive were compared using relative risk (RR) regression models.

**Results:** Proportions with detectable HPV in the clinician-collected cervical pregel and postgel samples were not statistically different for samples with added SiHa cells (88.3% vs 93.2%, RR = 1.06, 95% confidence interval = 0.96 -1.14) or for native HPV infection (32.9% vs 28.2%, RR = 0.87, 95% confidence interval = 0.71-1.06). In self-collected vaginal postgel samples, there was no trend for decreased HPV detection after gel exposure. Gel affected neither urine tests for CT and GC nor cytological quality.

**Conclusions:** Recent Replens gel use with a diaphragm does not inhibit cervical HPV testing, urine testing for CT and GC, or cervical cytology quality.

# Exploring Options for Administering Vaginal Microbicides in Brazil

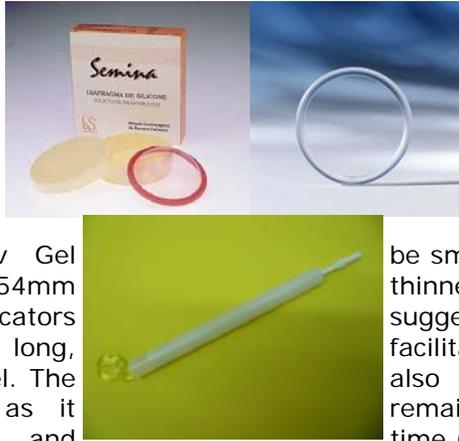
Hardy Ellen<sup>1,2</sup>; Hebling Eliana Maria<sup>2</sup>, Sousa Maria Helena<sup>2</sup>.

Important but less well studied aspects of microbicide research are users' preferences for the physical characteristics and the mode of administration of microbicides. Researchers in Brazil compared the difficulties and adherence to use of three devices that could be used by women to administer a microbicide. They also examined couples' preferences among the three devices and solicited suggestions on potential device modifications.

This was a cross-over study design with 405 couples recruited from two states in Brazil. Couples used three different devices in a randomly assigned order for one month each: a Semina diaphragm (silicone, 65mm, coil spring) with Preserv Gel lubricant; a vaginal ring (NuvaRing, 54mm diameter, 4mm thick); and applicators (dull white, rigid plastic, 12cm long, 0.09cm wide) containing Preserv Gel. The vaginal ring is a contraceptive as it releases etonogestrel (0.12mg) and ethinyl-estradiol (0.015mg) continuously for three weeks. Preserv Gel is a lubricant only and does not contain any spermicidal or other active substances.

Each couple was instructed on use and followed weekly by a trained interviewer. Instructions were to administer gel with the applicator before each sex act; the diaphragm with gel was to be inserted up to two hours before sex and removed 24 hours later; and the vaginal ring had to be inserted once, between the first and fifth day of menstruation, and removed three weeks later. After use of each device, couples were asked about their experiences and adherence to each product as well as their preferences among the devices and suggestions on possible modifications to make each one more attractive to users.

Results showed that few women had difficulties with the use of the applicator (3.0%) and the vaginal ring (14.5%). However, almost two-thirds experienced difficulties with the diaphragm. Approximately half of the women and men preferred the ring and the applicator, respectively. Slightly over 10% of the women and men preferred the diaphragm. About one-fourth of the women and 28% of the men suggested that the vaginal ring be more flexible, softer and smaller. One-third of the women and men stated that the applicator could be improved by being more flexible, softer, shorter, and having a rounded end. Seventy-nine percent of the women and 55% of men suggested improvements for the diaphragm including that it could be smaller, softer and more flexible, with a thinner rim. More women than men suggested the need for a mechanism to facilitate removal of the diaphragm. They also would prefer that the diaphragm remain in the vagina for a longer period of time (like the ring) and be disposable.



Above images (r-l): Semina diaphragm, NuvaRing, and

Researchers note that their study demonstrates the need for alternative forms of microbicide administration, including a device that releases the drug continuously. In addition, they point to the fact that the diaphragm requires a greater investment in training and support to make it as attractive to users as the other devices. For more information, contact Ellen Hardy at [hardy@unicamp.br](mailto:hardy@unicamp.br).

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## Breakthrough in Male Circumcision Research

Two studies looking at the potential protective effect of male circumcision against HIV acquisition were stopped early in December 2006 by the National Institute of Allergy and Infectious Diseases' Data Safety Monitoring Board. Both randomized controlled trials compared a group of HIV-negative men who were medically circumcised after enrolling in the study and another group of HIV-negative men who remained uncircumcised. Early data from the trials showed a 48% reduction in HIV acquisition in the Uganda study and a 53% reduction in the Kenyan study among the circumcised men. These results were too promising to ethically continue the trials without offering the intervention to the uncircumcised participants. These results bolster findings from an earlier trial in South Africa which was halted in 2005 after review of that trial's data showed a 60% reduction in HIV infection in circumcised men compared to their uncircumcised counterparts. Researchers stress that this data is likely to be generalizable to men who contract HIV through heterosexual intercourse but it is uncertain what impact circumcision has on HIV acquisition among men who have sex with men. The possible affects of circumcision on male to female HIV transmission also is currently unknown. For more information, visit the website of the AIDS Vaccine Advocacy Coalition at [www.avac.org](http://www.avac.org).

## Microbicides and Cervical Barrier Methods at the American Public Health Association 2006 Conference

The American Public Health Association's annual conference took place this year in Boston, Massachusetts and covered a wide variety of health topics. For CBAS readers, we have highlighted the few pertinent abstracts from the conference that highlighted potential female-initiated methods for HIV prevention.

*Expressing acceptability of microbicide use among family planning clinics in the southern US* authored by Lucy Annang and fellow researchers at the University of Alabama at Birmingham, School of Public Health focused on the willingness of women to try microbicides. Nearly two thirds of the 100 women in the study responded positively which the author suggests reflects that microbicides can practically be used as an HIV preventive method for many women.

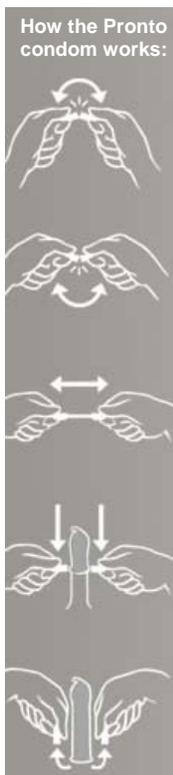
*Exploring perceptions of microbicide acceptability and utility in Ghana: Implications for HIV prevention* by Amanda Tanner of Indiana University looked at the acceptability of microbicide use in Ghana. This study focused on some of the issues particular to method use, negotiation and contraceptive selection for Ghanaian women. As in the Annang study, the majority of those interviewed (ten individuals working in the reproductive health field and two focus groups of community women aged 24-28) suggested that Ghanaian women were likely to be interested in and open to future microbicide use.

*Assessing the acceptability of female-controlled barrier methods among sex workers in the Dominican Republic* and *Assessing the comprehension of STI risk reduction hierarchical messages among sex workers in Dominican Republic* were both presented by Sandra G. Garcia, Daniel Grossman, and Diana Lara, along with fellow researchers. Approximately 240 sex workers in the Dominican Republic were followed for five months to explore their willingness to use female condoms, male condoms, and diaphragms and to investigate the effects on method use by the presence or absence of hierarchical risk reduction messages. High use of the female and male condom in sex relations in comparison with use of the diaphragm alone showed that sex workers were able to put in practice the hierarchical STI risk reduction messages. Findings have also demonstrated a decrease in the incidence of Chlamydia and gonorrhea over the course of the study.

Lastly, the rarely covered topic of sexual pleasure was the focus of *Acceptability of pleasure: The sex appeal of vaginal microbicides* by Rochelle K. Rosen and Kathleen Morrow from the Miriam Hospital in Rhode Island, US. Their research investigates what role, if any, sexual pleasure has in making decisions about microbicide clinical trials. The researchers focus on cultural preferences, relationship factors, and how products are designed with respect to sexual pleasure.

### The Pronto Condom

"Ruins the mood" is no longer an excuse now that there is a condom that promoters say can be put on in just one second. The Pronto condom was recently launched in South Africa. Condom designer, Willem van Rensburg, a Cape Town-based inventor, says he hopes the new condom, which does not need to be unwrapped from a package – will help to encourage condom use in the country. The product manufacturer says the Pronto condom is easier to use, compared to regular condoms. Users only need to crack the pack open and unroll the condom directly onto the penis. (See diagram at right.) The condom was promoted using some creative adverts poking fun at former Deputy President Jacob Zuma and Health Minister Manto Tshabalala-Msimang. Both had come under fire from AIDS activists for promoting inaccurate information about the prevention and treatment of HIV/AIDS. For more information, visit the Pronto website at <http://www.prontocondoms.co.za/index.htm>.



### Infant HIV Vaccine Trial: The First of Its Kind

The focus of preventing HIV between mother and child has been on reducing transmission at birth despite the fact that between fifteen and forty percent of HIV positive babies are infected through breastfeeding in Uganda. A current vaccine trial testing ALVAC-HIV may offer some hope for breastfeeding children at risk for HIV. This trial is run by Makerere University-John Hopkins Project in Uganda and is currently in its second and third phase and is the first of its kind to be conducted in Africa. Researchers hope ALVAC-HIV will help prevent mother-to-child HIV transmission via breastmilk. If the vaccine proves effective, it is expected to help prevent 8,000 out of Uganda's 22,000 infant infections annually. The study will ultimately consist of forty infants receiving the vaccine and ten receiving a placebo, all randomly assigned. For more information, please visit: <http://allafrica.com/stories/200612040309.html>.



## UPCOMING EVENTS

**Event:** XVIII World Congress of the WAS, 1<sup>st</sup> World Congress for Sexual Health

**Date:** April 15—19, 2007

**Location:** Sydney, Australia

**Website:** <http://www.sexo-sydney-2007.com/>

**Description:** The conference theme, *Achieving Health, Pleasure and Respect*, captures the essentials of sexual health. This meeting will introduce to participating clinicians, researchers, educators, activists and policy makers to the manifold, diverse and often controversial perspectives of contemporary sexual health.

**Event:** Global Health Council Conference

**Date:** May 29—June 1, 2007

**Location:** Washington, DC

**Website:** <http://www.globalhealth.org/conference/>

**Description:** This yearly conference is sponsored by the Global Health Council and this year's theme is Partnerships: Working Together for Global Health. This conference focuses on all aspects of global health and brings participants from a large array of disciplines.

**Event:** SisterSong's 2007 National Conference: "Let's Talk About Sex"

**Date:** May 31—June 3, 2007

**Location:** Chicago, IL

**Website:** [http://](http://www.sistersong.net/2007_NationalConference/2007_NC_index.html)

[www.sistersong.net/2007\\_NationalConference/2007\\_NC\\_index.html](http://www.sistersong.net/2007_NationalConference/2007_NC_index.html)

**Description:** This four-day conference will include workshops and plenaries on topics such as birth control, senior sexuality, STDs, microbicides, gynecological health and wellness, erotica, militarism, and more, all through a reproductive justice lens.

**Event:** South African AIDS Conference

**Date:** June 5—8, 2007

**Location:** South Africa

**Website:** <http://www.sa-aidsconference.com/>

**Description:** The 2007 AIDS conference aims to serve as a platform for deliberations on the key contentious issues relating to prevention, treatment and care. In particular, the conference will highlight state-of-the-art developments in prevention technologies; new approaches to prevention; the long-term impact of highly active antiretroviral therapy on incidence, prevalence, morbidity and mortality; the role of nutrition in HIV/AIDS; and the role of research into the use of complimentary and traditional medicines in HIV/AIDS.

## CBAS Steering Committee

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**Kelley Ryan:** [Duke Clinical Research Institute](#)

### What are cervical barriers?

Most people think of cervical barriers primarily as the diaphragm and cervical cap but a broader definition would encompass Lea's shield, female and male condoms, the sponge and microbicides. For more information about the range of cervical barrier methods, go to <http://www.cervicalbarriers.org/information/methods.cfm>.

### Mission of CBAS

Established in 2004, the Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods for pregnancy prevention and provide information about research on the potential of cervical barriers to prevent sexually transmitted infections, including HIV.

### Membership

CBAS membership is free and open to all who are interested in joining. CBAS's goal is to create an international, professional networking organization including clinical and social science research groups, academic institutions, advocacy groups, trade associations, and pharmaceutical, biotech, and medical device companies. As a member, you will have the opportunity to network and collaborate with other professionals in the field; keep abreast of new research; share information and ideas; and receive a semi-annual newsletter.

**CBAS Contact Information:** For more information, contact Julia Matthews, CBAS Executive Director at [jmatthews@cervicalbarriers.org](mailto:jmatthews@cervicalbarriers.org). CBAS is hosted by Ibis Reproductive Health and based in Cambridge, Massachusetts.

To comment on anything you read in the CBAS newsletter or to contribute a story, event, or news item, please email [info@cervicalbarriers.org](mailto:info@cervicalbarriers.org).