

# cbas Newsletter

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## Family Health International's DVD2: A New Vaginal Device



Photo courtesy of FHI

Family Health International (FHI) has developed a new product that makes it easier for women to insert medications and lubricants into the vagina. If shown to be safe and effective, it could be used to apply vaginal microbicides. Known as DVD2, the device is an oval piece of white, non-woven fabric with a string attached to one end to facilitate removal. The soft, pliable material can easily deliver gels, liquids, and creams. In an upcoming acceptability trial in South Africa, women will be asked to assess both the general comfort and the ease of insertion and removal of the device. In the trial, DVD2 will be treated with Pre', a vaginal lubricant said to be sperm-friendly. If researchers

conclude that the device is acceptable to women, future clinical trials will go on to evaluate whether DVD2 is safe and effective when used with a microbicide to protect against HIV. It could also be used with an anti-fungal cream, a spermicide, or other medication.

## Updated MIRA Trial Key Findings and Publications Fact Sheet

We are excited to share with you an updated version of our Key Findings and Publications Fact Sheet on the MIRA trial, a phase III trial of the diaphragm and lubricant gel for HIV prevention in women. Please visit our website at [http://www.cervicalbarriers.org/documents/MIRAResultsandPublications\\_July09FINAL.pdf](http://www.cervicalbarriers.org/documents/MIRAResultsandPublications_July09FINAL.pdf) to download a copy of this updated fact sheet which lists the latest publications on the MIRA trial and a new summary of the STI outcomes from the trial.

**MIRA** METHODS FOR IMPROVING REPRODUCTIVE HEALTH IN AFRICA: A phase III trial of the diaphragm and lubricant gel for HIV prevention in women

The Methods for Improving Reproductive Health in Africa (MIRA) trial was a multi-site, open-label, randomized controlled trial to determine the effectiveness of the diaphragm and Regen<sup>®</sup> lubricant gel in preventing heterosexual acquisition of HIV and other STI infections in Zimbabwe and South Africa women. Both products evaluated in this study are commercially available; the diaphragm has been used by women for decades.

**Summary**  
Enrollment of participants began in August 2003 and the study was completed in December 2006. 2,045 HIV-negative, sexually active women were recruited from clinics and community-based organizations of three sites in South Africa and Zimbabwe. Women attended study clinics for quarterly follow-up visits for up to 24 months (median was 21 months) of follow-up. All participants received a comprehensive HIV prevention package consisting of pre-test and post-test counseling about HIV and sexually transmitted infections, testing, treatment of sexually transmitted infections, intensive risk reduction counseling, and provision of condoms. During the trial, free hormonal contraceptives were made available to participants. Half of the participants were randomly assigned to receive, in addition, an Ortho A2F<sup>®</sup> latex diaphragm and a non-contraceptive lubricant (Regen<sup>®</sup> gel). The primary outcome of the MIRA trial was incident HIV infection.

**HIV Infection**  
Overall HIV annual incidence in the trial was 4.0%. There was no statistical difference in the rate of new HIV infections in the two study groups: in the diaphragm group (those who received a diaphragm plus lubricant along with risk reduction) 1.0% out of 2472 women became HIV infected (a 1% HIV incidence) and 1.0% women seroconverted in the control group (those who received risk reduction only) 1.1% out of 2476 women became HIV infected (a 1% HIV incidence) per 100 women-years. Therefore, the study findings do not suggest an addition of the diaphragm to current HIV prevention strategies.

## Participate in an Interview about a New Cervical Barrier Device

Quintiles Consulting is working with a non-profit group in their development of a new cervical barrier device. They would be interested in hearing your opinions about contraception, and cervical barriers in particular. If you would be willing to participate in a telephone interview about these topics, please contact either David Mustalish, M.D. ([David.Mustalish@Quintiles.com](mailto:David.Mustalish@Quintiles.com)) or Cameron Dunnan ([Cameron.Dunnan@Quintiles.com](mailto:Cameron.Dunnan@Quintiles.com)) for more information. All information will be kept confidential and your participation will be greatly appreciated.

## Featured Research

*The following are published abstracts of research studies on topics related to cervical barrier methods.*

### **Duet® for menstrual protection: a feasibility study in Zimbabwe.**

Averbach S, Sahin-Hodoglugil N, Musara P, Chipato T, van de Straten A.

*Contraception*. 2009;79(6):463-468.

**Background:** Managing menses is a challenge for women in developing countries. Duet® is a cervical barrier being developed for contraception and STI prevention. We explored the hypothetical acceptability of using Duet as a menstrual cup, among Zimbabwean women.

**Study Design:** A survey and focus group discussions (FGD) were conducted with 43 women aged 18–45 years to gain information about their menstrual practices and attitudes regarding the use of Duet for menstrual protection.

**Results:** All 43 women reported that if Duet were available, they would “definitely” try it, and that it

was “very important” that Duet is low cost and easy to clean; 86% reported that using it would make a difference in their lives. FGD findings highlighted unhygienic practices due to the lack of affordable options for menstrual management and a genuine interest in Duet, including its potential use for multiple purposes (contraception, disease prevention and menstrual protection).

**Conclusions:** Accessing affordable and hygienic menstrual protection was a problem for these Zimbabwean women. Duet appeared acceptable and it would be feasible to conduct a user-acceptability study of Duet as a menstrual cup in Zimbabwe.

### **Adding the female condom to the public health agenda on prevention of HIV and other sexually transmitted infections among men and women during anal intercourse.**

Kelvin EA, Smith RA, Mantell JE, Stein ZA.

*American Journal of Public Health*. 2009;99(6):985-987.

Legal barriers to conducting public health research on methods of protection for anal intercourse were lifted in the United States in 2003 when the US Supreme Court invalidated all state antisodomy laws. Although research funding has been available for the development of rectal microbicides, the female condom, which has already been approved for vaginal use, has not

been evaluated for anal use. Although there is no evidence that the female condom is safe for anal intercourse, it has already been taken up for off-label use by some men who have sex with men. This demonstrates the urgent need for more protection options for anal intercourse and, more immediately, the need to evaluate the safety and efficacy of the female condom for anal intercourse.

### **Secrecy, disclosure and accidental discovery: Perspectives of diaphragm users in Mombasa, Kenya.**

Okal J, Stadler J, Ombidi W, Jao I, Luchters S, Temmerman M, Chersich MF.

*Culture, Health & Sexuality: An International Journal for Research, Intervention and Care*. 2008;10(1):13-26.

The diaphragm is receiving renewed attention as a promising female-controlled method of preventing HIV and other sexually-transmitted infections. It is anticipated that female-controlled technologies will reduce women's biological susceptibility and assist in counteracting their sociocultural vulnerability to HIV. Understanding the subjective experiences of diaphragm users in different settings has the potential to inform the development and promotion of such methods. This paper explores the perspectives of female sex workers and women attending sexual and reproductive health services in Mombasa, Kenya. Data are reported from focus group discussions and in-depth interviews with women and men, following a prospective study investigating diaphragm

continuation rates over six months. Discussions highlighted covert use of the diaphragm, during sex work or with casual partners, and coital independence as favourable attributes. These features were especially pronounced compared with male condoms. Few difficulties with diaphragm use were reported, although its insertion and removal occasionally presented problems. Many women—especially those in long term partnerships—wished to disclose its use but found the disclosure process highly problematic. Accidental discovery often resulted in partner conflict. Although future uptake of the diaphragm may be high in this setting, its use may be limited to certain types of relationships and relationship context.

## Male partner involvement and assistance in female condom use.

Beksinska M, Smit J, Mabude Z, Vijayakumar G, Jabu L.

*The European Journal of Contraception & Reproductive Health Care.* 2008; 13(4): 400-403.

**Objective:** To investigate how males assist their partners in using the female condom.

**Methods:** A multi-site, randomized, cross-over trial was conducted to test the performance and acceptability of the Reality1 female condom compared to a prototype similar in design and appearance but made of synthetic latex (FC2). In this study women were asked about male partner assistance in FC use.

**Results:** Partner assistance in FC use was similar across FC type. Of the women who returned for

the first follow-up visit (n=233), just over a third (35.2%) reported that the male partner assisted in the insertion compared to 26.4% of the 201 women who returned for the second visit. In most cases where the partner assisted, the device was inserted using the inner ring, as recommended in the instructions for use. A small number (6%) mentioned that partners assisted in removal.

**Conclusion:** Men have a role to play in the use of the female condom and are willing to assist their partners in using it.

## Featured Events

### Advancing Prevention Technologies for Sexual and Reproductive Health



A strategy symposium was held March 24-25, 2009 in Berkeley, California, to discuss the development of multi-purpose technologies to prevent pregnancy, sexually transmitted infections, and other common reproductive tract infections. Advocates, researchers, and clinicians came together to identify critical biomedical, social science, regulatory, programmatic, and advocacy priorities and challenges, and explore best practices for developing and implementing these new technologies.

Nancy Padian from RTI presented on lessons learned from the MIRA trial in a session entitled "Deconstructing the MIRA trial: what has been learned and how might remaining questions be answered" and Marianne Callahan of CONRAD presented on "Alternative Approaches to Advancing Cervical Barriers for Pregnancy and Disease Prevention;" other experts presented on the female condom, vaccines, microbicides, vaginal rings, and other possible multi-purpose technologies for sexual and reproductive health. The full conference agenda and links to the presentations can be found online at <http://www.cami-health.com/apsrh-symposium.html>.

### International AIDS Society 2009

The fifth conference in the HIV Pathogenesis, Treatment and Prevention series, IAS 2009 was held July 19-22, 2009 in Cape Town, South Africa, and featured reports on the latest developments in the areas of basic, clinical, and prevention science. Please see below a list of posters that highlighted cervical barrier methods; for a complete list of abstracts, visit the conference website at <http://www.ias2009.org/pag/PosterExhibition.aspx>.

Montgomery E, Musara P, Chandipiswa A, Chipato T, van der Straten A, Moench T, Woodsong C. Safety of the Duet used continuously or pre-coitally in Zimbabwean women. (<http://www.ias2009.org/pag/PDF/3835.pdf>)

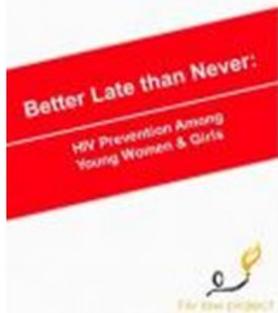
Montgomery ET, van der Straten A, Chidanyika A, Chipato T, Jaffar S, Padian N, The MIRA Team. The effect of male partner involvement on women's consistent use of investigational female-initiated HIV prevention methods in Zimbabwe. (<http://www.ias2009.org/pag/PDF/1964.pdf>)

Clouse K, Montgomery ET, Milford C, Watadzaushe C, Nkala B, Lince N, van der Straten A. The sustainability of care beyond HIV prevention trials: an evaluation of the MIRA standard of care programme. (<http://www.ias2009.org/pag/PDF/590.pdf>)

Lince N, Blanchard K, van der Straten A, Watadzaushe C, Nkala B, Gappoo S, Ramjee G, Bostrom A. Measuring informed consent: results from a randomized controlled trial of the diaphragm for HIV prevention. (<http://www.cervicalbarriers.org/documents/ICQuizNLince18Jul09FINAL.pdf>)

## Featured Reports

### Better Late than Never: HIV Prevention Among Young Women and Girls



The HIV Law Project's Center for Women and HIV Advocacy has released a report entitled "Better Late than Never: HIV Prevention Among Young Women & Girls." This report discusses the many biological, cultural, and socioeconomic factors that influence the rising rates of HIV infection among women and girls in the United States, particularly young women of color. The report also recommends several steps that should be taken to address these rising rates, including interventions with proven efficacy that recognize the need to integrate HIV prevention with sexual and reproductive health care. You can download the full report online at <http://hivlawproject.org/resources/cwha/Better-Late-Than-Never-05072009.pdf>.

### Smarter Programming of the Female Condom: Increasing Its Impact on HIV Prevention in the Developing World

The report "Smarter Programming of the Female Condom: Increasing Its Impact on HIV Prevention in the Developing World" was prepared by FSG Social Impact Advisors and Elliot Marseille and James G. Kahn on behalf of the Bill & Melinda Gates Foundation and published in October 2008. It presents the findings of a study designed to examine the value of the female condom for HIV prevention using four different research modules: landscape, programmatic, stakeholder, and cost-effectiveness analyses. The goal of the study was to recommend ways to effectively and efficiently include the female condom in HIV prevention strategies. The study's three key findings are that: 1) the female condom could benefit from a more consistent definition of success in order to better demonstrate its benefits for HIV prevention strategies; 2) the female condom is much less cost-effective than the male condom and other HIV prevention options and a focus on lowering marginal costs, substitution rates, and targeting to discordant couples, in addition to a focus on commodity costs, are important factors to consider when attempting to address the cost issue; and 3) the female condom is widely known for its potential role in empowering women, though these benefits are difficult to quantify. The authors recommend a move towards "smarter programming" for female condoms and propose a new definition of female condom success in the developing world: "the female condom should result in averted cases of HIV/AIDS and unwanted pregnancies that could not be more readily achieved through alternative approaches, notably additional promotion of male condoms, and be distributed in a manner that is as cost-effective as possible. Additional benefits, such as improved relationships with marginal groups or expanded women's rights, should be no more costly than when achieved by other interventions that bring about similar results." The full report can be found online at <http://www.fsg-impact.org/ideas/pdf/FemaleCondomImpact.pdf>.

### Today Sponge Back on the Market in the United States

The *New York Times* (May 22, 2009) reports that the contraceptive sponge has been reintroduced into the United States market by a new distributor, Mayer Laboratories in Berkeley, California. The Today Sponge is a small, pliable, polyurethane foam sponge containing Nonoxynol-9. A concave depression on one side fits against the cervix, and a soft loop on the other side can be grasped for removal. The product was introduced in the United States in 1983, taken off the market in 1994 because of manufacturing problems, placed back on the market in 2005 under new ownership, and finally taken off the market again in 2008 after the owner declared bankruptcy in late 2007. The product is now available online and in certain pharmacies in the United States and Canada. You can read the *New York Times* article online at [http://www.nytimes.com/2009/05/23/business/23sponge.html?\\_r=3&ref=health](http://www.nytimes.com/2009/05/23/business/23sponge.html?_r=3&ref=health) and visit the Today Sponge website at [www.todaysponge.com](http://www.todaysponge.com).

# Karabo Initiative: Menstrual Cups for Women in South Africa



The recently launched Karabo Initiative brings the Mpower menstrual cup, an economical and eco-friendly alternative to tampons and pads, to women in communities affected by poverty in South Africa. The cups are manufactured in Cape Town from 100% silicone and are non-porous, non-absorbant, and bio-compatible. The developer of the Mpower cup and the Karabo Initiative, Glenda Tutt, is passionate about making her product available to women in South Africa who cannot afford sanitary wear and you can read more about the initiative and find out how to pledge donations for cups online at <http://www.mpowercup.co.za>.

## Upcoming Events

**Event:** Reproductive Health 2009  
**Date:** September 30-October 3, 2009  
**Location:** Los Angeles, CA

**Website:** <http://www.arhp.org/Professional-Education/Annual-Meetings/RH2009>

**Description:** Reproductive Health 2009 is a partnership among the Association of Reproductive Health Professionals, the Planned Parenthood Federation of America National Medical Committee, and the Society of Family Planning. This is the 5th joint annual meeting of these three organizations.

**Event:** American Public Health Association Annual Meeting

**Date:** November 7-11, 2009

**Location:** Philadelphia, PA

**Website:** <http://www.apha.org/meetings/>

**Description:** The APHA Annual Meeting & Exposition is the oldest and largest gathering of public health professionals in the world, attracting more than 13,000 national and international physicians, administrators, nurses, educators, researchers, epidemiologists, and related health specialists. APHA's meeting program addresses current and emerging health science, policy, and practice issues in an effort to prevent disease and promote health. APHA has a world of public health in store for you.

## CBAS Steering Committee

**Marianne Callahan:** CONRAD

**Tsungai Chipato:** University of Zimbabwe-University of California San Francisco Collaborative Research Programme in Women's Health

**Patricia Coffey:** PATH

**Natalya Dinat:** Perinatal HIV Research Unit

**Nancy Padian:** Women's Global Health Imperative, RTI

**Gita Ramjee:** Medical Research Council of South Africa

**Helen Rees:** Reproductive Health Research Unit

**Kelley Ryan:** Duke Clinical Research Institute

## Contribute to the CBAS Newsletter

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).

## About CBAS

### 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 Kelsey Otis, CBAS Executive Director, at [kotis@cervicalbarriers.org](mailto:kotis@cervicalbarriers.org). CBAS is housed at Ibis Reproductive Health.