

FDA Approval of a New Female Condom



Reuters (March 11, 2009) reports that a new, less expensive version of the Female Health Company's female condom was approved for marketing in the United States and that the decreased price and softer design (allowing for quieter use) may attract more women in the United States. Most other countries have already adopted the new synthetic rubber version, called the FC2, but FDA approval of the new, less expensive product will allow the US Agency for International Development (USAID) to buy it and potentially increase availability abroad, *Reuters* reports (December 11, 2008). *Reuters* (December 11, 2008) reports that the FDA panelists recognized the potential of the female condom to provide women more control over their ability to protect themselves against pregnancy and HIV infection. The Female Health Company is currently searching for marketing partners in the US (*Reuters*, December 11, 2008). You can read the March 11 *Reuters* article online here: <http://www.reuters.com/article/latestCrisis/idUSN10547381>.

Featured Research

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

Short term acceptability of a single-size diaphragm among couples in South Africa and Thailand.

Coffey PS, Kilbourne-Brook M, Beksinska M, Thongkrajai E.

Journal of Family Planning and Reproductive Health Care. 2008;34(4):233-236.

Background: The SILCS diaphragm is a new, reusable, single-size cervical barrier device that is designed to offer the same barrier protection as a standard diaphragm with improved user acceptability.

Methods: This non-randomised, non-blinded, non-significant risk, multi-site pilot study assessed the short-term acceptability of the SILCS diaphragm among women with no previous diaphragm experience. Sites in South Africa and Thailand recruited couples not at risk of pregnancy and at low risk of sexually transmitted infections. Couples used the SILCS diaphragm four times and provided feedback on the ease of handling, comfort, and sensation during sex. Data were collected via detailed product-use questionnaires, simple coital logs, and gender-specific debriefing interviews.

Results: A total of 41 couples completed the study, providing data from 164 product uses. The SILCS device fits women representing a range of diaphragm sizes, parity, and body mass index. Women from both sites reported that the SILCS diaphragm was easy to use and provided good comfort and sensation in over 80% of all product uses. Men from both sites reported good comfort and sensation in over 60% of all product uses.

Conclusion: The SILCS diaphragm appears to be acceptable to women and men in low-resource settings. These data suggest that the SILCS design should be tested in broader populations to assess effectiveness and acceptability.

Comparative acceptability of the SILCS and Ortho ALL-FLEX® diaphragms among couples in the Dominican Republic.

Coffey PS, Kilbourne-Brook M, Brache V, Cochón L.
Contraception. 2008;78(5):418-423.

Background: The SILCS diaphragm is a new, single-size contraceptive diaphragm. The objective of this crossover pilot study was to assess the fit and acceptability of the SILCS diaphragm compared to the Ortho ALL-FLEX® diaphragm to validate the product design among parous women in a low-resource setting.

Study Design: Sexually active couples not at risk of pregnancy and at low risk of sexually transmitted infection were recruited and randomly assigned to one of two groups to determine order of device use. Couples used each device four times and provided feedback on key performance indicators via product-use questionnaires, a simple coital log, and a gender-specific debriefing interview.

Results: Twenty couples provided data on a total of 160 product uses (80 for each device). Couples indicated that both diaphragms were acceptable with respect to ease of use, comfort, and satisfaction with sex. At the end of the study, 19 of 20 women and 15 of 20 men reported preferring the SILCS diaphragm over the Ortho diaphragm ($p \leq .01$ for both).

Conclusion: Short-term acceptability of the SILCS and Ortho diaphragms during use was comparable, although overall both women and men preferred the SILCS diaphragm over the Ortho diaphragm. Acceptance of diaphragms in general, and the SILCS diaphragm in particular, is likely among couples willing to use a barrier method.

SILCS diaphragm: postcoital testing of a new single-size contraceptive device.

Schwartz JL, Ballagh SA, Creinin MD, Rountree RW, Kilbourne-Brook M, Mauck CK, Callahan MM.
Contraception. 2008;78(3):237-244.

Background: This study was conducted to compare the effectiveness of a new, single-size silicone contraceptive diaphragm used with either spermicide [2% nonoxynol-9 (N-9)] or lubricant in preventing sperm from penetrating midcycle cervical mucus.

Study design: A crossover postcoital test (PCT) in healthy, sexually active women not at risk for pregnancy due to tubal occlusion was conducted. Couples had a baseline PCT without a device to verify normal fertility parameters. Qualified couples underwent up to two test cycles using the SILCS diaphragm with a metal spring. A subgroup of couples underwent a third test cycle with the SILCS polymer spring diaphragm used with N-9 gel.

Results: Fifteen couples completed a baseline cycle and were randomized to order of study gel. Of these, 14

couples completed a baseline cycle and at least one test cycle, 12 couples completed a baseline cycle and two test cycles and 8 couples completed a third test cycle with the polymer spring prototype. Sperm was detected in the vaginal pool in all completed test cycles. The SILCS metal spring diaphragms used with N-9 gel reduced the average number of progressively motile sperm per high power field in the cervical mucus from a baseline of 12.5 to 0, while use of this device with lubricant reduced the number to 0.5. The SILCS polymer spring diaphragm used with N-9 performed the same as the metal spring used with N-9.

Conclusion: The SILCS diaphragm used with N-9 gel performed well. It is likely that the SILCS diaphragm will give acceptable results in a contraceptive effectiveness study but that adjunctive use of a chemical barrier such as N-9 gel will be necessary for it to be most effective.

Using internet-based nominal group technique meetings to identify provider strategies for increasing diaphragm use.

Kulczycki A, Shewchuk RM.

Journal of Family Planning and Reproductive Health Care. 2008;34(4):227-231.

Background and methodology: The diaphragm, once the most commonly used female contraceptive method, is being re-evaluated for prevention against some sexually transmitted infections (STIs), including HIV. However, provider views about this prescription-based method are poorly understood. Using expert panels, this study aimed to identify facilitative strategies to increase diaphragm use. The nominal group technique (NGT) was employed using a novel web-based interface to systematically elicit and prioritise responses to a specific question about what can be done to encourage providers to recommend diaphragm use. Two NGT sessions were convened with 15 geographically dispersed panelists who had extensive knowledge and experience with the diaphragm. Participants were identified using purposeful and snowball sampling.

Results: Panel 1 identified 22 strategies for encouraging providers to recommend diaphragm use, with seven

perceived as relatively more important (67% of the total available votes). Panel 2 identified 31 strategies, nine of which accounted for 77% of the votes. Both sessions highlighted that to make the diaphragm a more plausible option, educational materials and tools are needed to better inform providers and patients about the method and its specific advantages.

Conclusions: The enhanced, Internet-based NGT offers the family planning and reproductive health care field a powerful and inexpensive tool for systematically collecting and analysing expert opinion. Results are being used to develop a questionnaire to further examine strategies that may help promote diaphragm use and to refine ideas for intervention design. This will facilitate method reintroduction, if the diaphragm is proven effective against STIs/HIV, especially when used with a microbicide.

The efficacy of female condom skills training in HIV risk reduction among women: a randomized controlled trial.

Choi KH, Hoff C, Gregorich SE, Grinstead O, Gomez C, Hussey W.
American Journal of Public Health. 2008;98(10):1841-1848.

Objectives: We evaluated the efficacy of skills training designed to increase female condom use among women.

Methods: We conducted a randomized controlled trial of 409 women, recruited from family planning clinics in northern California, who were randomly assigned to the experimental 4-session female condom skills training intervention or the comparison 4-session women's general health promotion intervention. Participants received condom use instructions at baseline and male and female condoms during the study. They completed audio computer-assisted self-interviews at baseline and at 3 and 6 months.

Results: At 3 and 6 months, women in the experimental group were more likely than those in the comparison group to have used the female condom at least once in the prior 3 months. The increase in the percentage of sexual acts protected by female condoms from baseline to the 6-month follow-up was greater for the experimental group. The percentage of sexual acts during which any condom was employed was higher in the experimental group at 6 months. There were no group differences in male condom use.

Conclusions: Outcomes suggest that skills training can increase female condom use and protected sexual acts without reducing male condom use among women.

Universal Access to Female Condoms Joint Programme



Recognizing the woman-initiated female condom's high levels of acceptability and its potential role in HIV and pregnancy prevention for women, several organizations have joined together to promote its availability, acceptability, and affordability. The Universal Access to Female Condoms (UAFC) Joint Programme was initiated by four organizations: Oxfam Novib, the World Population Foundation, IDA Solutions, and the Netherlands Ministry of Foreign Affairs. In order to achieve their goals of reducing the number of unwanted pregnancies and new cases of STIs and HIV

infection, the UAFC Joint Programme works concurrently on female condom research and development, large-scale programming at the national level, and international advocacy. The Programme was launched during the 2008 International AIDS conference in Mexico City. More information about the UAFC Joint Programme can be found online at <http://www.condoms4all.org> or <http://www.cervicalbarriers.org/documents/UAFCfactsheet.pdf>.

International Female Condom Accessibility

The year 2008 marked the 15th anniversary of the availability of the female condom as a tool in the fight against growing rates of HIV infection, yet female condoms remain only a small fraction of the global condom supply. In our last newsletter we featured a report by CHANGE's Prevention Now! Campaign entitled, "Saving Lives Now: Female Condoms and the Role of US Foreign Aid," that highlights the need for greater United States investment in female condom procurement, distribution, and programming (available online at <http://www.preventionnow.net/images/savinglivesnowfinal.pdf>). Another report highlighting the role of international institutions and governments in female condom promotion was published in 2008 by Oxfam International and the World Population Foundation (WPF). This report, entitled "Failing Women, Withholding Protection: 15 Lost Years in Making the Female Condom Accessible," emphasizes the urgent need to improve access to female condoms, particularly given that more than half of infected people worldwide are women. The Oxfam-WPF report can be found online at <http://www.oxfam.org/sites/www.oxfam.org/files/bp115-female-condom-0808.pdf>.

Update on Microbicide Research

On February 9th, 2009, the results of the HPTN 035 clinical trial of two candidate microbicides, BufferGel® and PRO 2000, were released. The study authors reported that women in the PRO 2000 gel with condom arm had 30% fewer HIV infections than those in the condom-only arm or in the condom plus placebo gel arm, but this difference was not statistically significant. You can read more about the HPTN 035 trial on the websites of the Global Campaign for Microbicides (<http://www.global-campaign.org/HPTN-035.htm>), Alliance for Microbicide Development (http://www.microbicide.org/cs/news_alert_detail?pressrelease.id=251), and HIV Prevention Trials Network (http://www.hptn.org/research_studies/hptn035.asp).

Reconsidering the Diaphragm and Other Cervical Barriers in India

A consultative meeting to discuss the potential for re-introducing the diaphragm and other cervical barriers (CBs) in India was held in Delhi in June of 2008. Various professionals representing sexual and reproductive health organizations in India were brought together to consider strategies for making the diaphragm and CBs more accessible to Indian women in an effort to expand contraceptive options in India. The meeting also aimed to consider the role of these products in HIV/STI prevention as well as improved menstrual hygiene. Presentations highlighted reasons for reconsidering the role of the diaphragm in India, current research on acceptability and efficacy of CBs for HIV/STI prevention, user perspectives on the diaphragm in India, as well as current cervical barrier methods. Discussion was focused on populations that could potentially benefit from increased access to CBs and concerns about their re-introduction. The detailed final report of this meeting and its recommendations was compiled by Kathy Shapiro and can be found at <http://www.cervicalbarriers.org/documents/UAFcfactsheet.pdf>.

HIV Prevention for Women at the XVII International AIDS Conference



The theme of the XVII International AIDS Conference held in Mexico City, Mexico in August of 2008 was "Universal Action Now!" and almost 25,000 leaders, policymakers, academics, scientists, and activists from around the world participated in the conference. Recognizing the increasing feminization of the HIV epidemic, particularly in Sub-Saharan Africa, and the need for more HIV prevention methods that women can initiate and control, CBAS and Ibis

Reproductive Health collaborated with a group of organizations to sponsor a satellite session entitled "No Simple Solution: Investing in HIV Prevention Research for Women and Girls." The sponsoring organizations also included the AIDS Vaccine Advocacy Coalition (AVAC), the Center for Health and Gender Equity (CHANGE), the Global Campaign for Microbicides (GCM), the International AIDS Vaccine Initiative (IAVI), the International Partnership for Microbicides (IPM), and the International Women's Health Coalition (IWHC).

This session's panel was designed to bring together government representatives, policy makers, researchers, and people working on the ground to discuss future directions for the prevention of HIV in women and girls. Stephen Lewis, Co-Founder of AIDS-Free World, moderated the session and Julia Kim from the University of Witswatersrand, South Africa gave a brief overview of issues related to HIV prevention for women before discussion began. In addition to Julia Kim, the panel included Agnes Binagwaho, Executive Secretary of the National AIDS Control Commission in Rwanda; Hilda Esquivel of Mexicanas Positivas Frente a la Vida in Mexico; and Matilda Mogale of the HIV Vaccine Trials Unit at Baragwanath Hospital in South Africa. Discussion centered on the need for new prevention strategies for women, structural interventions designed to decrease women's risk for HIV acquisition, and barriers to access and use of existing prevention strategies for women (i.e., the female condom).

CBAS Steering Committee

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Upcoming events

Event: Contraceptive Technology 2009**Date:** March 18-21, 2009**Location:** San Francisco, CA**Website:** <http://www.contemporaryforums.com/m411109/bene.asp>

Description: Covering the most important advances in women's health and contraception, Contraceptive Technology is designed for MDs, RNs, NPs, CNMs, PAs, and health educators. Chaired by Dr. Robert Hatcher, the conference faculty includes the authors of Contraceptive Technology and other nationally known reproductive health experts. Conference topics include: new and future methods of contraception, sexuality issues, recurrent vaginitis, case studies, adolescent health, STD treatment, flexible OC management and much more. Each attendee will receive a complimentary copy of the new edition of Contraceptive Technology.

Event: Women's Health 2009: The 17th Annual Congress**Date:** March 27-29, 2009**Location:** Williamsburg, VA**Website:** <http://www.bioconferences.com/Conferences/WomensHealth/index.aspx>

Description: The annual American Medical Women's Association congress will be held in Williamsburg and is presented by the Journal of Women's Health and the VCU Institute for Women's Health. The American Medical Women's Association is an organization which functions at the local, national, and international level to advance women in medicine and improve women's health.

Event: Raising Women's Voices 2009**Date:** April 1-2, 2009**Location:** New York, NY**Website:** <http://www.raisingwomensvoices.net/>

Description: The Women's Speak-Out for Health Care for All on April 1st will feature stories of women who have struggled to get the health care that they and their families need, and make the connection between these personal experiences and policy solutions. The Strategy Conference on April 2nd will move from women's stories about the health system to strategy about how to achieve real reforms that address the problems women have identified. National health policy experts will give an update on the progress of health reform in Washington. We will end the day with an agenda for action.

Event: Contraceptive Technology 2009**Date:** April 1-4, 2009**Location:** Washington, DC**Website:** <http://www.contemporaryforums.com/m411109/bene.asp>

Description: Covering the most important advances in women's health and contraception, Contraceptive Technology is designed for MDs, RNs, NPs, CNMs, PAs, and health educators. Chaired by Dr. Robert Hatcher, the conference faculty includes the authors of Contraceptive Technology and other nationally known reproductive health experts. Conference topics include: new and future methods of contraception, sexuality issues, recurrent vaginitis, case studies, adolescent health, STD treatment, flexible OC management and much more. Each attendee will receive a complimentary copy of the new edition of Contraceptive Technology.

Event: National Family Planning and Reproductive Health Association (NFPRHA) 2009**Date:** April 26-29, 2009**Location:** Bethesda, MD**Website:** http://nfprha.org/main/events.cfm?Category=National_Conference&Section=Main

Description: Eighty-nine percent of American voters support public funding for family planning services and products. Empowering the Majority: Expanding Access to Family Planning is the conference where family planning administrators, clinicians, researchers, and advocates will formulate strategies for leveraging this public support and empowering the pro-family planning majority to increase access to comprehensive family planning services.

Event: Global Health Council 2009**Date:** May 26-30, 2009**Location:** Washington, DC**Website:** http://www.globalhealth.org/conference_2009/

Description: The Global Health Council's 36th Annual Conference, *New Technologies + Proven Strategies = Healthy Communities*, will highlight the ways in which technologies in combination with best practices and evidence-based policies improve health around the world.

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. CBAS is housed at Ibis Reproductive Health.

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