

## FEATURED RESEARCH

### **FemCap™ with removal strap: ease of removal, safety and acceptability.**

Mauck CK, Weiner DH, Creinin MD, Archer DF, Schwartz JL, Pymar HC, Ballagh SA, Henry DM, Callahan MM. *Contraception*. 2006;73:59-64.

Objectives: FemCap™ is a silicone-rubber barrier contraceptive approved for marketing in the United States. To address reported problems with removal and dislodgment, the device's developer added a strap to the device and increased the height of the brim. This trial assessed whether the new design reduced removal difficulties and had any effects on dislodgment, genital pain/discomfort, safety, and acceptability. Methods: Women used the strapped device for eight weeks with follow-up visits at 2 and 8 weeks. Data from these 120 women were compared with data from 419 women who used the unstrapped FemCap™ in a



FemCap™

previous effectiveness study. Results: The strapped device was not significantly easier for users to remove than the unstrapped device. Similar odds of dislodgment and cervical/vaginal irritation were seen with the two devices. Both female and male participants were significantly more likely to report pain/discomfort with use of the strapped device. Conclusions: The modifications to the FemCap™ did not significantly improve the ease of device removal and appears to have resulted in significantly more female and male partner pain/discomfort and decreased acceptability, compared with the unstrapped device.

### **SILCS Diaphragm: postcoital testing of a new single-size contraceptive diaphragm**

Schwartz JL, Mauck CK, Rountree RW, Ballagh SA, Creinin MD, Kilbourne-Brook M. *Obstetrics & Gynecology*. 2006;107:S12.

Objective: To compare the effectiveness of a new, single size silicone contraceptive diaphragm developed by PATH used with either spermicide or petroleum jelly to prevent sperm from penetrating midcycle cervical mucus. Methods: A crossover postcoital testing in 33 healthy, sexually active women not at risk for pregnancy due to previous bilateral tubal ligation or salpingectomy was conducted at Eastern Virginia Medical School and University of Pittsburgh Medical Center. Qualified participants underwent up to 2 test cycles using the SILCS diaphragm (metal spring) with either N-9 or petroleum jelly. Some



SILCS diaphragm

participants underwent a third test cycle using the SILCS diaphragm (polymer spring) with N-9. Results: The SILCS diaphragm (metal or polymer spring) with N-9 reduced the average number of progressively motile sperm per high power field from a baseline of 12.5 to 0. The SILCS diaphragm (metal spring) with petroleum jelly reduced the number of progressively motile sperm per high power field to 0.5. Conclusion: Results from this most recent postcoital testing indicate that the current SILCS diaphragm design with the polymer spring and used with N-9 performed well and is acceptable for contraceptive effectiveness testing.

## The 9<sup>th</sup> meeting of the Alliance For Microbicide Development

By Betsy M. Finley

The 9<sup>th</sup> meeting of the Alliance for Microbicide Development was held in March 2006 in Washington, DC. The purpose was to initiate a "mapping exercise" to mirror gaps, needs, and priority actions identified by the *Microbicide Development Strategy (MDS)* Working Groups.

At its second meeting in April 2005, the Microbicide Coordinating Board (MCB) concluded that articulation of a *Microbicide Development Strategy* would be timely, since almost five years had passed since the Rockefeller Initiative produced the first major analysis of the status of the microbicide field. Such an exercise would produce a framework for decision-making by funders, researchers, and developers alike and would be particularly valuable in a context of limited resources. The activity was launched in late 2005 and a document was generated by four Working Groups: Basic Science and Preclinical Development; Clinical Trials; Manufacturing and Formulation; and Commercialization and Access. After many meetings, discussions, and consultations with a range of experts, the MDS is now in a wide-ranging review by almost 50 individuals within and outside of the field.

At the third meeting of the MCB in late November 2005, the Working Groups presented the results of their efforts to funders and a small group of representative stakeholders. The notion of a "mapping exercise" emerged when the funders recommended a "map" of ongoing efforts be overlaid on the gap analysis, to not only illuminate needs in key areas but also to describe the extent to which the needs were, or were not, being met.

Presenters updated meeting participants on their organization's work and provided information on current or planned activities or projects according to the priority gaps identified by the MDS Working Groups. Representatives from the following organizations and programs presented: the National Institute of Allergy and Infectious Disease; Microbicide Quality Assurance Program and Microbicide Research and Development Portfolio; National Institute of Child Health and Human Development; PATH; Microbicide Trials Network; Centers for Disease Control and Prevention; CONRAD; International Partnership for Microbicides; Family Health International; Centre for the AIDS Programme of Research in South Africa; UK Medical Research Council; Medical Research Council of South Africa; Population Council; World Health Organization; and the Global Campaign for Microbicides. Additional presentations included an update on how rectal microbicide research might be integrated into the broader microbicide agenda; a proposal by the Global Campaign for Microbicides to create a "development strategy" for microbicide civil society and community involvement; an update on US policy; a multidisciplinary panel around new research on lime juice as a microbicide; and a meeting synthesis which extracted major themes from the presentations, focused general discussion, and suggested next steps.

Nearly 50 organizations participated in what proved to be a highly collaborative and productive meeting, and a solid first step toward mapping activity in the microbicide field against its priority needs as a base for the many decisions on investments of time, money, and capacity that will be required going forward.

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### What will microbicide trials really tell us about microbicide efficacy?

In a recent publication (Trussell J, Dominik, R. *Contraception*. 2005;72: 408-413.), researchers address the question of whether microbicide trials will provide unbiased estimates of microbicide efficacy. Using hypothetical trial designs and scenarios, the researchers evaluate the potential impact of microbicide nonadherence and different patterns of condom use on microbicide trial results. Their calculations demonstrate that nonadherence to microbicide use and some patterns of condom use may seriously impair researchers' ability to identify an effective microbicide. For example, in many possible scenarios, trial results may

significantly underestimate the efficacy of the study product meaning that researchers may be studying a highly efficacious microbicide and not know it. Furthermore, high levels of condom use will impact trials by lowering the overall HIV incidence rate among the study population necessitating larger sample sizes to detect the microbicide effects. Despite these obstacles, the researchers do offer some hope. Although, trial results may not accurately reveal how well a microbicide works, if a trial does show some evidence of effectiveness, it would be reasonable to conclude that the microbicide itself works to prevent infection.

## CBAS Website Evaluation Survey Results: Executive Summary

The Cervical Barrier Advancement Society (CBAS) website was established in June 2004. From September 2005 through January 2006, Ibis undertook an evaluation of the CBAS website to understand more about site users and their perceptions of the site as well as to update the site based on users' comments.

In total, forty-four people responded to the survey, nearly three quarters of whom were female. The majority of respondents (73%) were between 20 and 49 years of age. Almost 90% were from North America or Europe (the vast majority from the US), while 10% were from India or Africa. The majority of respondents (59%) were interested in cervical barriers as researchers or health care providers, which supports other research findings showing that providers are increasingly using the Internet as a source of health information. One-third of respondents learned about the CBAS site through links from other websites, which indicates that posting links is an effective awareness raising strategy. Respondents also learned about CBAS from professional colleagues.

Ninety-three percent of respondents rated the site content as "excellent" or "good", while 80% rated the site's layout as "excellent" or "good." Sixty-eight percent of respondents said that none of the pages were difficult to use.

The Cervical Barrier Methods page was considered the most useful by respondents, followed by the Clinical Trials & Research page.

The demographic profile of the survey respondents highlights the importance of presenting the site in a manner that appeals to researchers and providers, in particular. Further, given that professional networking attracted many CBAS website visitors, hosting outreach activities at professional conferences may have increased awareness of CBAS. Ibis will continue efforts to expand the CBAS network through establishing links on the websites of appropriate organizations, increasing the number of newsletter subscribers and identifying opportunities for raising the profile of CBAS at appropriate events and in relevant publications.

Using the information gathered from survey respondents, Ibis will update the CBAS website accordingly. First steps will include: adjusting the layout for easier reading; clarifying and updating information on various topics; clarifying cervical barriers' potential role in preventing STIs/HIV while ensuring that the information clearly describes that research is still ongoing; and increasing the amount of information that might attract users from outside North America.

Thanks to everyone who participated in the CBAS survey!

*"Important information, difficult to find in a comprehensive and non-commercial form elsewhere."*

*"There were certain female barrier methods that I was not aware of, and I now have a wide variety of methods to offer my patients."*

—Comments from CBAS survey respondents

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## CBAS Outreach Activities

In support of the first annual National Women and Girls HIV/AIDS Awareness Day on March 10, 2006, CBAS co-sponsored an exhibit with Massachusetts for Microbicides, the state chapter of the Global Campaign for Microbicides, at an event in Dorchester, MA hosted by the Women of Color Roundtable. The community gathering brought together local activists who moderated discussions on youth involvement, male perspectives and sexuality, among other topics.

The Civil Liberties and Public Policy Program held their Annual Reproductive Rights Conference at



*In Her Mother's Shoes*

Hampshire College April 7-9, 2006. CBAS and Massachusetts for Microbicides co-hosted an outreach table that included the traveling photo exhibit "Giving Women Power Over AIDS." The exhibition gives the pandemic a human face and offers a compelling account of why everyone should support efforts to provide women with female-controlled alternatives for HIV prevention. For more information about the exhibit, go to <http://www.global-campaign.org/exhibit.htm>.

## UPCOMING EVENTS

**Event:** Public Health 2006 Conference

**Date:** May 15-17, 2006

**Location:** Johannesburg, South Africa

**Website:** [www.wits.ac.za/phasa/](http://www.wits.ac.za/phasa/)

**Description:** The conference will be co-hosted by PHASA, the Gauteng Department of Health, the University of the Witwatersrand School of Public Health, the International Epidemiological Association and the Health Systems Trust. This conference brings together professionals working in all disciplines of public health to share research findings pertinent to population health in the Southern African Region.

**Event:** American College of Nurse Midwives Annual Meeting & Exhibit

**Date:** May 26 - June 1, 2006

**Location:** Salt Lake City, Utah

**Website:** <http://www.midwife.org/news.cfm?id=209>

**Description:** At the completion of this conference, participants will be able to describe the clinical relevance of at least five new sources of evidence affecting the provision of women's health care services, critique the current guidelines for midwifery practice based on new knowledge, identify four risk management activities designed to monitor patient satisfaction and deal effectively with patient complaints, and discuss the profession of midwifery from an international perspective.

**Event:** International Conference on Global Health

**Date:** May 30-June 2, 2006

**Location:** Washington, DC

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

**Description:** Over its 33-year history, the Global Health Council has convened thousands of public health professionals from close to 100 countries at our annual conference. During that time, the conference has featured a wide range of health themes on women, children and youth, the environment, and post-conflict settings, to name a few. It is this diversity that has given the annual conference its reputation as one of the premier gatherings in the field of global health.

**Event:** 2<sup>nd</sup> Africa Conference on Sexual health and Rights

**Date:** June 19 -21 2006

**Location:** Nairobi, Kenya

**Website:** [www.africalsexuality.org](http://www.africalsexuality.org)

**Description:** The goal of the conference is to bring the discourse of sexuality, sexual health and sexual rights to the forefront in Africa. Specifically, the conference aims to give participants an opportunity to meet and discuss issues of sexuality, sexual health and rights, to share experiences and innovative programs, to build alliances and networks, and to disseminate research findings on current and emerging sexuality issues in Africa.

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### 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.

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*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).*