

FEATURED RESEARCH

Diaphragm and Lubricant Gel for Prevention of HIV Acquisition in Southern African Women: A Randomized Controlled Trial

Padian NS, van der Straten A, Ramjee G, Chipato T, de Bruyn G, Blanchard K, Shiboski S, Montgomery ET, Fancher H, Cheng H, Rosenblum M, van der Laan M, Jewell N, McIntyre J, the MIRA Team.  
*Lancet*. July 21, 2007;370(9583):251-61.

**Background:** Female-controlled methods of HIV prevention are urgently needed. We assessed the effect of provision of latex diaphragm, lubricant gel, and condoms (intervention), compared with condoms alone (control) on HIV seroincidence in women in South Africa and Zimbabwe.

**Methods:** We did an open-label, randomised controlled trial in HIV-negative, sexually active women recruited from clinics and community-based organisations, who were followed up quarterly for 12–24 months (median 21 months). All participants received an HIV prevention package consisting of pre-test and post-test counselling about HIV and sexually transmitted infections, testing, treatment of curable sexually transmitted infections, and intensive risk-reduction counselling. The primary outcome was incident HIV infection.

**Findings:** Overall HIV incidence was 4.0% per 100 woman-years: 4.1% in the intervention group

(n=2472) and 3.9% in the control group (n=2476), corresponding to a relative hazard of 1.05 (95% CI 0.84–1.32, intention-to-treat analysis). The proportion of women using condoms was significantly lower in the intervention than in the control group (54% vs 85% of visits,  $p < 0.0001$ ). The proportions of participants who reported adverse events (60% [1523] vs 61% [1529]) and serious adverse events (5% [130] vs 4% [101]) were similar between the two groups.

**Interpretation:** We observed no added protective benefit against HIV infection when the diaphragm and lubricant gel were provided in addition to condoms and a comprehensive HIV prevention package. Our observation that lower condom use in women provided with diaphragms did not result in increased infection merits further research. Although the intervention seemed safe, our findings do not support addition of the diaphragm to current HIV prevention strategies.

The Inevitability of Infidelity: Sexual Reputation, Social Geographies, and Marital HIV Risk in Rural Mexico

Hirsch JS, Meneses S, Thompson B, Negroni M, Pelcastre B, del Rio C.  
*American Journal of Public Health*. June 2007;97(6):986-96.

Marriage presents the single greatest risk for HIV infection among women in rural Mexico. We drew on 6 months of participant observation, 20 marital case studies, 37 key informant interviews, and archival research to explore the factors that shape HIV risk among married women in one of the country's rural communities. We found that culturally constructed notions of reputation in this community lead to sexual behavior designed to minimize men's social risk (ones that endanger one's social status), rather than viral risks and that men's desire for companionate intimacy may actually increase women's risk for HIV infection. We also describe the intertwining of reputation-based sexual identities

with structurally patterned sexual geographies. We propose that, because of the structural nature of men's extramarital sexual behavior, intervention development should concentrate on sexual geographies (i.e. the social spaces that shape sexual behavior) and risky spaces rather than risky behaviors or identities.



## What Do the MIRA Results Mean for Female-controlled Methods?

Although the MIRA diaphragm trial results (page 1) are disappointing, this was a critical question for the HIV prevention field. Female-controlled methods for HIV prevention are urgently needed and the full range of potential options to protect the health of women and girls must be pursued. As noted in the article's accompanying editorial, prevention trials also are important for informing policies and "disappointing results must not discourage the testing of other novel approaches." The MIRA trial furthered learning in the HIV prevention field, provided health services to trial participants and their partners, educated women and their communities about HIV prevention options, and worked to strengthen the health services where the trial took place, with a particular focus on linking HIV-positive women to available services. Additionally, qualitative findings from the trial will be available later this year that will provide insights into the acceptability of the diaphragm and gel to women and their male partners, discreet use and disclosure to partners, etc.



Products used in the trial

The original reasoning that launched the trial—the cervix is more vulnerable than other parts of the vaginal tract—still remains. The study authors identified future research areas such as how to validate self-reported behavior by participants and adherence to study products and improve strategies to measure modest levels of protection.

In the meantime, new kinds of cervical barriers are being developed such as the SILCS diaphragm by PATH, designed with input from users, and the BufferGel Duet™, a combination microbicide and diaphragm-like device. In the future, the diaphragm may also be an ideal applicator for microbicides as it is an available and reusable device.

In addition to continued research on female-controlled methods, it is critical that greater investment be made in the female condom—the only existing female-initiated HIV prevention method (although male cooperation is still needed). Improving access to the female condom should be a priority as we continue to research other methods, like microbicides and AIDS vaccines. No one method will be right for every woman or girl. Women and girls also need help to overcome the gender imbalance in their relationships. They need opportunities to advance themselves economically, educationally and socially. But until they do not need their partners' permission to protect their health, women and girls must have as many tools at their disposal to prevent HIV and help stop the spread of the pandemic.

## New Report on Female-initiated HIV Prevention Trials



A new report, *Female-initiated HIV prevention: What will we learn from upcoming trials?* was recently released by the AIDS Vaccine Advocacy Coalition (AVAC). The report was designed to help HIV prevention advocates understand the ramifications of findings from two studies of female-initiated HIV prevention methods: the MIRA diaphragm trial and the Carraguard microbicide trial. This report gives information on the two methods and the ways that they were studied, and also explores the broader implications of potential trial results for all female-initiated HIV prevention options. This publication is part of AVAC's *Anticipating Results* series that provides timely analysis of trials of AIDS vaccines and other new HIV prevention technologies. For other publications in this series, visit [www.avac.org](http://www.avac.org).

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## What Will It Take for Us to Welcome the Concept of Choices for Women?

This is the question that Erica Gollub poses in her recently published article\* discussing the importance of adopting a "sexual risk reduction" approach to HIV prevention for women and girls. This strategy proposes providing women with a range of choices to protect themselves from HIV infection. It includes counseling women to use male condoms whenever possible, but when not possible to use other lower efficacy methods. Detractors of this strategy state that women should be offered the best possible prevention methods and doing otherwise is detrimental to women. Other opponents argue that too many choices are confusing for women and that women might use lower-efficacy methods mistakenly in place of more effective prevention products. However, these arguments assume that women already can negotiate male condom use, which is often not the case due to unequal power relations with men. By offering other options, women could well increase the level of protection from what they currently have. Gollub suggests that if the HIV prevention community would wholeheartedly endorse female condoms, STI/HIV infections could be reduced while also cutting a path for future technologies. She also encourages a collaborative rather than competitive environment among the various potential technologies. Gollub concludes by stating, "A choice platform is the prevention approach likely to make the greatest difference in reducing HIV incidence in women in the immediate future."

\*Gollub EL. Choice is empowering: getting strategic about preventing HIV infection in women. *International Family Planning Perspectives*. 2006;32(4): 209-12.

## Advocating for Female-Initiated HIV Prevention Methods at IWS

The World YWCA Council hosted the *International Women's Summit: Women's Leadership on HIV and AIDS* from July 4 to 7 in Nairobi, Kenya. The event brought together more than 2,000 women and men who participated in a series of workshops, presentations and community meetings. The Center for Health and Gender Equity, CBAS and the Global Campaign for Microbicides held an interactive session with conference participants in the Women's Networking Zone, a forum for linking global and local actors. Presenters addressed advocacy challenges specific to female condoms, cervical barriers and microbicides as well as the need for a comprehensive approach to promoting a range of female-initiated and –controlled HIV prevention options. In order to engage local community members, a team of local and international organizations convened a town hall meeting where panelists introduced current and potential HIV-prevention methods, the latest clinical research, the importance of working with women living with HIV and ways to mobilize local communities to advocate for new technologies. CBAS also collaborated with a number of groups including the International Partnership for Microbicides and the International AIDS Vaccine Initiative to host the workshop, *ListenLearnLead on HIV Prevention Options for Women and Girls*. Pauline Muchina of UNAIDS opened the workshop by explaining why a range of prevention options for women and girls is essential and the importance of advocating to governments and international agencies to support methods currently available and others under development. UNFPA representatives then outlined the basic steps required to promote male and female condom programs at the community level and shared examples of successful community involvement activities in Nigeria and Zimbabwe. The case was also made for an integrated HIV/AIDS toolkit that includes technologies that would potentially work prior to exposure, at the point of transmission, and after infection. The AIDS Vaccine Advocacy Coalition outlined the timeline for new prevention technologies research—including cervical barriers, microbicides and an AIDS vaccine—and shared several lessons learned from prevention trials. The workshop concluded with a robust question and answer session with panelists and participants exchanging their experiences from around the world.



## WHO Sets Forth Definitions on Female Condom Failure Modes

Recently, the World Health Organization through the work of a Technical Review Committee has determined standardized definitions for failure modes of female condoms.<sup>^</sup> The definitions, like those already established for male condoms, seek to facilitate comparison and review of different female condoms and reduce variability in current study reporting. The guidelines call for individual and combined failure rates to be reported on a per-user basis and on a per-condom package basis. Authors note that researchers will need to develop data collection tools and methodologies in order to solicit accurate information from study participants reporting failure events with condom usage. The hope is that with these new guidelines in place, reporting can be standardized and female condom research can progress without the hindrance of inconsistent reporting.

<sup>^</sup>Beksinska M, Joanis C, Manning J, Smit J, Callahan M, Deperthes B, Usher-Patel M. *Contraception*. 2007;75(4):251-5.

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## Forensic Medicine Biomarkers Put to Use in STI/HIV Prevention and Contraception Research

As part of legal investigations, biomarkers of vaginal exposure typically have been used to establish whether sexual intercourse has taken place by determining whether vaginal exposure to semen has occurred. Now, researchers are turning to biomarkers for use in contraception and microbicide research trials. Semen biomarkers could be used in three ways: 1) evaluate the safety of a new physical or chemical barrier, 2) indicate early on whether diaphragms or condoms, for example, are effective physical barriers, and 3) provide evidence of whether female participants in research trials who have been advised to use condoms actually use them. The HIV pandemic has increased the urgency of identifying chemical and physical vaginal barriers and semen biomarkers have a role to play in advancing this important task as rapidly as possible. A working group of investigators recently published an article\* that describes an ideal semen biomarker, reviews data on current and potential biomarkers, and provides guidance for how to advance the search for an improved biomarker of semen exposure. Additionally, the new website [www.biomarkersconsortium.org](http://www.biomarkersconsortium.org) encourages researchers to submit biomarker project concepts.

\*Mauck CK, Doncel GF, et al. Biomarkers of semen in the vagina: applications in clinical trials of contraception and prevention of sexually transmitted pathogens including HIV. *Contraception*. 2007;75(6):407-19.

## UPCOMING EVENTS

**Event:** Women Deliver

**Date:** October 18—20, 2007

**Location:** London, United Kingdom

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

**Description:** This landmark global conference will focus on creating political will to save the lives and improve the health of women, mothers and newborn babies around the world.

**Event:** Global Safe Abortion Conference 2007: Whose Right? Whose Choice? Who Cares?

**Date:** October 23—24, 2007

**Location:** London, United Kingdom

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

**Description:** Hosted by Marie Stopes International in association with IPAS and Abortion Rights, this conference will confront both international and national issues associated with abortion. It will build consensus and momentum around international efforts to reduce the unacceptable toll on women's health and lives caused by unsafe abortion, through increasing access to safe services, recognizing women's right to self determination and encouraging legal reform.

**Event:** United States Conference on AIDS

**Date:** November 7—10, 2007

**Location:** Palm Springs, California, USA

**Website:** [www.nmac.org/conferences\\_trainings/usca/](http://www.nmac.org/conferences_trainings/usca/)

**Description:** Over 3,000 workers from all fronts of the HIV/AIDS epidemic—from case managers and physicians, to public health workers and advocates—come together at this meeting to build national support networks, exchange the latest information and learn cutting-edge tools to address the challenges of HIV/AIDS.

**Event:** 2007 National HIV Prevention Conference: Promoting Synergy between Science and Program

**Date:** December 2—5, 2007

**Location:** Atlanta, Georgia, USA

**Website:** [www.2007nhpc.org/backgroundinfo.asp](http://www.2007nhpc.org/backgroundinfo.asp)

**Description:** This conference offers the opportunity to share effective prevention approaches and research findings among governmental, community, and academic partners in HIV prevention. It aims to strengthen collaborations between program practitioners and researchers in a range of service areas.

## CBAS Steering Committee

**Marianne Callahan:** [CONRAD](#)

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**Gita Ramjee:** [Medical Research Council of South](#)  
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**Helen Rees:** [Reproductive Health Research Unit](#)

**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).