

cbas Newsletter

published by the Cervical Barrier Advancement Society

CBAS Newsletter: Volume 2, Number 3

Fall 2005

FEATURED RESEARCH

Effectiveness of female controlled barrier methods in preventing sexually transmitted infections and HIV: current evidence and future research directions

Minnis AM, Padian NS. *Sexually Transmitted Infections*. 2005;81(3):193-200.

Objectives: To evaluate evidence for the effectiveness of female controlled physical and chemical barrier methods in preventing STI/HIV transmission, to examine recent reviews on microbicide development, and to highlight promising research directions. To discuss challenges in conducting effectiveness research and in translating results to public health intervention. **Methods:** Systematic review of articles that examined the disease prevention effectiveness of at



Female condom

least one female controlled barrier method. Review of conference abstracts that presented clinical and preclinical microbicide data. **Results:** Randomized controlled trials provide evidence that female condoms confer as much protection from STIs as male condoms. Observational studies suggest that the diaphragm protects against STI pathogens. Several microbicide effectiveness studies are under way and new directions, such as adaptation

products, are being examined. Substantial attention is now given to product formulation and novel delivery strategies. Combining microbicide products with different mechanisms of action as well as combining chemical and physical barriers will be necessary to maximize prevention effectiveness. **Conclusions:** Increased investment in the development and identification of female controlled barrier methods offers promise that additional products will be available in the years ahead.



Diaphragm

Generalizing trial results to a community setting, promoting products that may be less effective than male condoms, and bringing an effective product to scale introduce public health challenges that warrant attention. The need for female controlled barrier methods that provide women with the opportunity to take an active role in reducing their STI/HIV risk are urgently needed and constitute an essential tool to prevent continued spread of these infections.

Lea's Shield®: colposcopic and microbiological testing during 8 weeks of use

Mauck C, Creinin M, Rountree W, Callahan M, Hillier S. *Contraception*. 2005;72:53-59.

Objectives: The aims of this study were to assess the effects of Lea's Shield® plus nonoxynol-9 spermicide on signs and symptoms of female genital irritation and cervical and vaginal microflora during 8 weeks of use with intercourse and to analyze problems associated with the use of the device. **Methods:** In this open-label, single-arm study, participants were evaluated by pelvic examination, colposcopy and vaginal and cervical cultures. **Results:** About 13% of women (4/30) reported symptoms of irritation, and minor product-related



Lea's Shield®

colposcopic findings were seen in about one third (11/30). Although average colony counts for enterococcus, Escherichia coli and anaerobic gram-negative rods increased during product use, no clinical diagnoses of infection were made. Most users reported at least one problem using Lea's Shield®. **Conclusion:** Lea's Shield®, when used for 8 weeks during intercourse, is associated with evidence of genital irritation in a minority of users and with changes in vaginal microflora that do not appear to correlate with clinical infections.

Bacterial Vaginosis and HIV Susceptibility

Bacterial vaginosis (BV) is the most common vaginal infection in women of childbearing age. It is a condition resulting from an overgrowth of normal bacteria in the vagina.

A recent study by Myer *et al.* points out that it is unclear from previous research whether BV predisposes women to HIV infection or whether HIV-infected women are more likely to develop BV. Therefore, the authors investigated the association between BV and HIV seroconversion in a cohort of women participating in a cervical cancer screening trial near Cape Town, South Africa. The study results showed that the diagnosis of BV was significantly associated with an increased risk of HIV seroconversion, after adjustment for demographic characteristics, other sexually transmitted infections, and sexual behaviors. The authors conclude:

"This study adds to the existing evidence that suggests that BV diagnosed on the basis of the Nugent criteria may increase women's susceptibility to HIV infection. Because of the relatively high prevalence of BV in this and many other settings where the risk of acquiring HIV is high, further research is required to evaluate interventions to reduce BV as a possible means of preventing HIV infections in women."

However, in an accompanying editorial, Jane R. Schwebke argues that widespread control of BV is not a practical solution for decreasing HIV infections given that BV cure rates are approximately 70 to 80 percent and recurrence rates are high. Schwebke concludes: "As a greater understanding of BV unfolds – including additional insights into pathogenesis, diagnosis, and therapy – there will be more opportunities to consider control efforts as a means to decrease acquisition and transmission of HIV infection. Until efficacious therapy, as well as an understanding of prevention methods, for BV is available, it will not be feasible to go forward with studies aimed at preventing the complications of this common vaginal infection."

Given the importance of HIV prevention methods, particularly for women, and the high prevalence of BV, more research is warranted to provide further evidence to inform this discussion.

¹Centers for Disease Control and Prevention Bacterial Vaginosis Fact Sheet.

²Myer L, Denny L, Telerant R, de Souza M, Wright TC Jr, Kuhn, L. Bacterial vaginosis and susceptibility to HIV Infection in South African women: A nested case-control study. *The Journal of Infectious Diseases*. October 2005 (192):1372-80.

³Schwebke, JR. Abnormal vaginal flora as a biological risk factor for acquisition of HIV infection and sexually transmitted diseases. *The Journal of Infectious Diseases*. October 2005 (192):1315-17.

CBAS Steering Committee

The composition of the CBAS steering committee is designed to be representative of clinical and social science work being done on cervical barriers and related products globally. The current steering committee members and their affiliations are listed below. We thank them for their contributions and commitment to CBAS:

- Katy Backes Kozhimannil, Harvard Ph.D. Program in Health Policy
- Marianne Callahan, CONRAD
- Tsungai Chipato, University of Zimbabwe-UCSF Collaborative Research Programme in Women's Health
- Natalya Dinat, Perinatal HIV Research Unit
- Nancy Padian, Women's Global Health Imperative—UCSF
- Gita Ramjee, Medical Research Council of South Africa
- Helen Rees, Reproductive Health and HIV Research Unit
- Kelley Ryan, Duke Clinical Research Institute
- Janet Vail, Program for Appropriate Technology in Health

Science Magazine Cites Diaphragm Study

In its August 12th issue, *Science Magazine* examined a number of "unflashy biomedical alternatives" that are currently being tested to determine their effectiveness in preventing HIV, including the diaphragm, in an article entitled, *HIV/AIDS: Prevention Cocktails: Combining Tools to Stop HIV's Spread*.

University of California at San Francisco's Nancy Padian described how the diaphragm may prevent HIV from reaching the cervix and endocervix, where most



Diaphragms

female infections occur. Helen Gayle of the Bill and Melinda Gates Foundation stated, "We really need to look at how we put together a combination of options that fit people's lifestyles."

<http://www.sciencemag.org/content/vol309/issue5737/#newsweek>

Harvard Health Policy Review Highlights Cervical Barriers

The *Harvard Health Policy Review (HHPR)* is a semi-annual journal published by the Exploring Policy in Health Care student organization at Harvard University to encourage discussion of health policy issues on the Harvard campus. In its Spring 2005 issue, *HHPR* featured an article, *One Choice is No Choice*, about the need for female-controlled HIV prevention tools for women and girls worldwide. Download the full article in [PDF](#), or visit the CBAS website [homepage](#).



CBAS EVALUATION: [Take our survey!](#)

Please go to the [CBAS website](#) to tell us what you think about www.cervicalbarriers.org. This information will help us improve this website and better meet the needs of CBAS members and website users. The survey will take about 5 to 10 minutes to complete. We will not ask you for any identifying information and the survey is completely anonymous.

Two HPV vaccines in development

By Jennifer Bergeson-Lockwood, Reproductive Health Technologies Project

There are roughly 30 sexually transmitted strains of the human papillomavirus (HPV). Many of these are harmless "low risk" strains that pose few health risks, including genital warts. Approximately ten "high risk" strains may lead to the development of cervical cancer. HPV is extremely prevalent. Roughly 80 percent of American women will be infected with HPV by age 50. Though HPV infection is undetectable within two years in 90 percent of women, persistent HPV infections have been linked to 99.7 percent of all cervical cancers.

If all goes according to plan, two groundbreaking cancer prevention vaccines will be available within two years. Merck Pharmaceuticals and GlaxoSmithKline (GSK) are each in the final testing stages for HPV prevention vaccines. In clinical trials, both vaccines have been 94 - 100 percent effective at preventing specific strains of HPV infection. Merck's vaccine, Gardasil™, has been shown to protect against "high risk" HPV strains 16 and 18, which cause 70 percent of cervical cancers. It also prevents "low risk" strains 6 and 11, which cause genital warts.

By the end of 2005, Merck plans to file with the U.S. Food and Drug Administration for approval for women and men, focusing on adolescents ages 10 to 15. If approved, the vaccine could reach consumers by the end of 2006.

GSK's vaccine, Cervarix, has also been effective in trials against HPV 16 and 18. Recent research has shown that Cervarix also protects against three additional "high risk" strains of HPV. These five strains cause 82 percent of cervical cancers. GSK plans to submit Cervarix for European regulatory approval early in 2006 and is expected to request authorization for women only.

For more information:

- Centers for Disease Control, HPV Infection Information: <http://www.cdc.gov/std/HPV/default.htm>
- American Social Health Organization: www.ashastd.org
- National Family Planning and Reproductive Health Association, HPV fact sheet: <http://www.nfprha.org/uploads/HPVfactsheetmay2005.pdf>

HPV Vaccine Candidates	High risk strains HPV 16 and 18	Low risk strains HPV 6 and 11	High risk strains HPV 31, 45 and 52
	Linked to 70% of cervical cancers	Cause genital warts	Linked to 12% of cervical cancers
Merck—Gardasil would prevent *	X	X	
GSK—Cervarix would prevent *	X		X

*94-100% effective

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

UPCOMING EVENTS

Event: Reproductive Health Priorities and HIV Conference

Date: October 18-21, 2005

Location: Spier, Stellenbosch, South Africa

Website: <http://www.rhru.co.za/site/PrioritiesConference/Priorities.htm>

Description: The conference is one of the major platforms for the sharing of regional research between researchers, clinicians, program managers and policy makers. Topics include HIV/AIDS, sexually transmitted infections, vaccines (HPV, HIV), microbicides, barrier methods, contraception, adolescent reproductive health, maternal health, medical abortion, male involvement and gender-based violence.

Event: International Federation of Professional Abortion and Contraception Associates (FIAPAC)

Date: October 27-28, 2005

Location: Moscow, Russia

Website: <http://www.fiapac.org/e/MoscowEprog1.html>

Description: The aim of this International Seminar is to exchange scientific data, modern achievements in safe abortion and contraception.

Event: 10th AWID International Forum on Women's Rights and Development

Date: October 27-30, 2005

Location: Bangkok, Thailand

Website: http://www.awid.org/forum/about_the_forum.htm

Description: This is both a conference and a call to action. The largest recurring event of its kind, the AWID Forum brings together women's rights leaders and activists from around the world every three years to strategize, network, celebrate, and learn.

Event: International Conference of HIV/AIDS and Sexually Transmitted Infections in Africa (ICASA)

Date: December 5-9, 2005

Location: Abuja, Nigeria

Website: <http://www.icasa2005.org.ng/english/index.htm>

Description: The conference provides a forum for scientists, policy makers, political leaders, people living with AIDS, and communities to share on the current advances and strategies in the management of HIV/AIDS and STIs.

Event: American Public Health Association (APHA)

Date: December 10-14 2005

Location: Philadelphia, PA

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

Description: The meeting theme is *Evidence-Based Policy and Practice* which will explore the processes of systematically finding, appraising and using scientific research as the basis for developing sound practices. The knowledge gleaned from this research is used to develop policies and practices that improve health outcomes and performance as well as allowing for more efficient use of resources.

Research Opportunity: Provider perspectives and beliefs on the diaphragm

The University of Alabama at Birmingham (UAB) is seeking providers with substantial experience with the diaphragm to participate in a web-based conference call to discuss their attitudes, experiences, and concerns with the diaphragm. Participants can take part in the discussion from their home/office and will receive an honorarium for their time (about 75 minutes). For more information, contact Dr. Andrzej Kulczycki, Department of Maternal and Child Health, UAB at andrzej@uab.edu or (205) 934-9875.

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 both for preventing pregnancy and potentially HIV and other sexually transmitted infections (STIs).

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. CBAS is hosted by Ibis Reproductive Health and based in Cambridge, Massachusetts.

www.cervicalbarriers.org