CBAS Newsletter: Volume 2, Number 2 June 2005

FEATURED RESEARCH

Predictors of diaphragm use as a potential sexually transmitted disease/ HIV prevention method in Zimbabwe.

van der Straten A, Kang MS, Posner SF, Kamba M, Chipato T, Padian NS. Sex Transm Dis. 2005 Jan; 32(1):64-71

PUBLISHED ABSTRACT

BACKGROUND: Women who are the most vulnerable to sexually transmitted diseases/HIV are often unable to consistently use condoms. One potential alternative method currently under investigation is the diaphragm. GOALS: The goals of this study were to assess diaphragm uptake and use over time in Zimbabwe and to identify factors associated with self-reported consistent diaphragm use. STUDY: Women attending family planning clinics who were inconsistent condom users received a diaphragm intervention and were followed for 6 months.

RESULTS: Of the 186 participants, 99% ever reported using the diaphragm, and, at study exit, 96% had used it in the previous 2 months. Consistent diaphragm use since the previous visit was reported by 13% to 16% of the women, and in multivariate regression analysis, it was significantly associated with never using condoms (adjusted odds ratio, 24.08; 95% confidence interval, 6.71-86.34). Other factors included discreet use, preferring diaphragms to condoms, timing of insertion, domestic violence, and contraception. CONCLUSION: Diaphragms were well accepted among women at risk for sexually transmitted diseases/HIV.

Critical Issues in Contraceptive and STI Acceptability Research

Severy LJ, Newcomer S. Journal of Social Issues. Vol 61(1), Mar 2005. pp. 45-65.

PUBLISHED ABSTRACT

We review conceptual issues and theoretical frameworks related to users' acceptability of new technologies designed to protect reproductive health and prevent unwanted pregnancy. Special attention is given to distinctions among different perspectives users' kinds of regarding acceptability, as well as differentiating acceptability from assessments of the efficacy of

innovative methods. Emphasis is also given to the larger context of couple decision-making and cultural variation. We argue that concern for sexual pleasure plays a central role in determining user perspectives regarding new methods. The female condom, contraceptive ring, contraceptive skin patch, microbicides, vaccines, emergency contraception, and PERSONA are discussed within the context of the identified critical issues.

Supply News article on MIRA, Cervical Barriers

Supply News, the bi-monthly newsletter of the Reproductive Health Supply Initiative (www.rhsupplies.org/news/news.shtml), features an article in its latest issue on the role of cervical barrier methods in the fight against HIV. The newsletter is available <a href="https://example.com/here/newsletter-newslet

SAfAIDS News Feature Article on Cervical Barriers

SAFAIDS (www.safaids.org.zw) is one of the leading HIV/AIDS information sources in Southern Africa. The most recent issue of SAFAIDS News includes a feature article on cervical barrier methods. This issue is available here (pdf) or in the CBAS download center.

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Prentif™ Cervical Cap No Longer Available in the United States

The Prentif™ Cavity-Rim Cervical Cap, the only cap approved for distribution in this country, will no longer be available in the United States as a barrier method of contraception. The distributor, Cervical Cap, Ltd., has served women and health care providers since 1988. A statement released Cervical Cap, Ltd. on their (www.cervcap.com), reports that Lamberts (Dalston), Ltd. U.K., the manufacturer of the Prentif[™] Cervical Cap, will no longer carry product liability insurance and has substantially increased prices due to declining sales. In addition, they report that the U.K. manufacturing plant for the Prentif[™] Cervical Cap will close in a few months. Beyond this statement, there is no additional information available from Cervical Cap, Ltd. about whether or not the Prentif™ Cervical Cap will continue to be available outside of the U.S.



Prentif™ Cervical Cap display

The cervical cap has been used in Europe since the mid 1800's and in the U.S. since the 1920's. The Prentif™ Cervical Cap was approved by the Food and Drug Administration in 1988.

The Cervical Barrier Advancement Society (CBAS) is disappointed by the recent news that the Prentif™ Cervical Cap will no longer be available in the U.S. Cervical Cap, Ltd., which closed its doors in March 2005, was the sole distributor of the Prentif™ Cervical Cap in the U.S. With the company's closure, American women lose access to a safe, effective contraceptive option. While cervical cap use has been declining in the U.S., this method remains an important option for many women, including those who need or want a non-hormonal contraceptive method.

We hope that women who currently use the Prentif™ Cervical Cap will be able to access information on other cervical barrier options (the <u>CBAS website</u>, www.cervicalbarriers.org, provides detailed information on cervical barriers), and hope to see new products come on the market in the future.

New Report on Female Condom

The UNAIDS Global Coalition on Women and AIDS (GCWA) and the Global Campaign for Microbicides (GCM) sponsored an experts' consultation in December 2004 to examine barriers opportunities for increasing access to the female The meeting sought input from a condom. number individuals with experience of researching, programming, advocating for and/or funding female condom programs.

The main recommendations of the report are to re-orient the public health paradigm of providing people with a range of options, tailoring messages to specific audiences, and helping people reduce their HIV/STI risk, by:

- Positioning female condom as an integral (not optional) part of HIV prevention, care and treatment strategies--both existing and future.
- Integrating female condom provision specifically into the expansion of voluntary counseling and testing (VCT) programs, accompanying the roll out of antiretroviral therapy (ART) programs, as part of risk reduction counseling for serodiscordant couples, and into mother to child transmission (MTCT) programs that identify HIV positive and negative women through perinatal testing.
- Evaluating the pros and cons of actively promoting re-use of the female condom as a risk-reduction strategy.

A short report from the meeting is available here (www.global-campaign.org/clientfiles/

Reproductive Health Technologies Project Updates Site

The Reproductive Health Technologies Project (RHTP), a member of CBAS, has launched an updated version of their website: www.rhtp.org. The new site contains information on cervical barriers and many other reproductive health products and issues.

RHTP is a Washington, DC-based non-profit organization working to advance the ability of every woman to achieve full reproductive freedom with access to the safest, most effective, and preferred methods for controlling her fertility and protecting her health.

U.S. Government Report on Nonoxynol-9

The United States General Accountability Office (GAO) recently released a report entitled "Efforts to research and inform the public about Nonoxynol-9 and HIV." The GAO is the audit, evaluation and investigative arm of Congress and issues reports periodically to help improve the performance and accountability of the federal government for the American people.

This report, prepared at the request of four members of the U.S. Congress (Souder, R-IN; Coburn, R-OK; Pitts, R-PA; and Weldon, R-FL), describes the federal agencies' and product

manufacturers' actions to assess the safety and effectiveness of N-9 as a microbicide and the level of information subsequently provided to the public about this topic. The report is posted on the Global Campaign for Microbicides website (www.global-campaign.org).

The information released in the GAO report regarding Nonoxynol-9 is fair and accurate, and while there has been some confusion in the past regarding the potential efficacy of N-9 for the prevention of HIV/STIs before it's

effects were well-known, the following guidelines are now widely accepted:

- N-9 is a safe, effective contraceptive option for women at low risk for HIV/STIs who do not use the product more than once a day;
- N-9 should not be used to prevent HIV/ STIs; and
- N-9 should not be used rectally.

The GAO report notes that the U.S. Food and Drug Administration is finalizing its rule to require warning labels on vaginal contraceptives containing N-9 and expects to publish this final rule by September 2005. In addition, the FDA is planning to propose that new warning labels be added to condoms, and will be posting a draft of this proposal for public comment in May 2005. An N-9 Fact Sheet is available in the CBAS download center (www.cervicalbarriers.org).

FDA Re-approves Today Sponge® for Sale in the U.S.

On April 22, 2005 the U.S. Food and Drug Administration (FDA) announced it has granted regulatory approval for the contraceptive Today Sponge®, which was one of the best-selling nonprescription female contraceptives in the United States before it was taken off the market 10 years ago. The device, which is constructed of soft polyurethane foam and is inserted into the vagina for up to 24 hours, provides barrier protection prevent and spermicide to pregnancy. The Today Sponge[®] is 80% to 91% effective in preventing pregnancy (when used correctly and consistently), but does not protect

against sexually transmitted diseases. Because it contains nonoxynol-9 spermicide, the Today Sponge® label carries the following warning: "Frequent use (more than once a day) of this product can cause vaginal irritation, which may increase the risk of getting the AIDS virus (HIV) or other STDs from infected partners."

(HIV) or other STDs from infected partners."

The sponge was first introduced in 1983, but sales of the product were discontinued in 1995 because its manufacturer.

Whitehall-Robbins (now known as Wyeth Consumer Health Care) did not invest in the equipment upgrades necessary for maintaining FDA approval. However, in 2000, Allendale Pharmaceuticals purchased the manufacturing rights to the sponge and worked to meet FDA requirements. New Jersey-based OSG Norwich Pharmaceuticals in March 2003 received a three-year, renewable contract from Allendale to be the sole manufacturer of the Today Sponge[®], which had sales of approximately 250 million between 1983 and 1995. Allendale is a member of CBAS.

Allendale plans to make the sponge available to U.S. women through their <u>website</u> (www.allendalepharm.com) in June and in U.S. stores by August. The sponges will be sold in packs of three and will be priced between \$2.50 and \$3.00 per sponge. Allendale, which is planning an advertising campaign for the sponge, says it expects to sell about 15 million sponges in the first year of sales.

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

Spanish Version of

Cervical Barriers

Presentation

America and Caribbean office, a

Spanish language version of the

CBAS general cervical barrier

methods presentation has been

produced and is now available

in the CBAS download center

(www.cervicalbarriers.org).

Population Council's

cooperation with the

Latin

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UPCOMING EVENTS

Event: 2nd South African AIDS Conference

Date: June 7-10, 2005

Location: Durban, South Africa

Website: www.sa-aidsconference.com

Description: The South African AIDS Conference aims to marshal the best of knowledge, practice and research on HIV into further united action and implementation and to spur a new spirit of unity

and accountability for all.

Event: 2005 National HIV Prevention Conference

Date: June 12-15, 2005 **Location:** Atlanta, Georgia

Website: www.2005hivprevconf.org

Description: The fourth National HIV Prevention Conference will give community organizations, individuals, public health professionals, clinicians and advocates the opportunity to exchange information about effective prevention approaches. Attendees include local, regional and national decision makers, researchers, policy makers, community leaders and practitioners working to prevent the spread of HIV/AIDS.

Event: 16th Biennial Meeting of ISSTDR

Date: July 10-13, 2005

Location: Amsterdam, the Netherlands

Website: www.isstdr.org

Description: The aim of the ISSTDR 2005 is to provide a forum for investigators and policy makers and to discuss recent advances in research

and control of all STDs including HIV.

Event: IUSSP International Population Conference

Date: July 18-23, 2005 Location: Tours, France Website: www.iussp.org

Description: The International Union for the Scientific Study of Population (IUSSP) promotes scientific studies of demography and population-

related issues.

Event: International AIDS Society Conference

Date: July 24-27, 2005

Location: Rio de Janeiro, Brazil **Website:** www.ias-2005.org

Description: The scientific program of the 3rd IAS Conference on HIV Pathogenesis and Treatment aims to provide new insights into HIV disease development, prevention and care that can lead to new research directions, help advance translational research and move theoretic advances into clinical practice and prevention programs.

Event: Research Methods Course in Sexual and

Reproductive Health and HIV **Date:** July 25-August 19, 2005

Location: Johannesburg, South Africa

Website: www.rhru.co.za/site/methods.htm
Description: The course seeks to introduce researchers, health service managers and clinicianns to the fundamentals of research methodology and key SRH/HIV issues relevant to the African region.

Event: Forum 9 Annual Meeting: "Poverty, equity

and health research"

Date: September 12-16, 2005

Website: www.globalforumhealth.org

Location: Mumbai, India

The program will examine research needs and gaps and policy options based on evidence. The meeting will highlight research to reduce inequities in health through effective action on the social

determinants of health.

Event: 10th International Women and Health

Meeting

Date: September 21-25, 2005 Location: New Delhi, India Website: www.10iwhmindia.org

Description: This conference seeks to highlight politics, policies and issues that have adverse effects on women's health and simultaneously bring out the linkages and interconnections of these

seemingly disparate phenomena.

Event: Realizing Sexual Rights **Date:** September 28 - 30, 2005

Location: Brighton, UK

Email: J.A.edwards@ids.ac.uk

Description: Rather than focusing on pain, harm and wrongs, a more positive, pleasure-oriented, view of sexuality offers an entirely different set of entry points for work to make sexual rights real. This workshop aims to provide a space for thinking about the possibilities of such an approach, and its implications for development.

Event: 3rd SAHARA African Conference: Bridging the gap between policy, research and intervention

Date: October 10-14, 2005 Location: Dakar, Senegal Website: www.sahara.org.za

Description: The conference will bring together stakeholders interested in the social aspects of HIV/AIDS research in Africa. The conference is expected to be welcoming to all institutions, net-

works and alliances.