

cbas Newsletter

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Welcome to CBAS!

The Cervical Barrier Advancement Society (CBAS) is a new international professional networking organization that aims to raise the profile of cervical barrier methods both for preventing pregnancy and potentially HIV and other sexually transmitted infections. CBAS membership is free and open to all who are interested in joining.

The CBAS website (www.cervicalbarriers.org) is a tool for sharing information with members and with the general public. The website contains information about cervical barriers, downloadable materials, images of cervical barriers, and research updates.

This is the first issue of the CBAS newsletter. This newsletter is designed to keep subscribers abreast of new research, activities in the field, and relevant events. Recipients are encouraged to share the newsletter with others and to submit information for inclusion. All CBAS members receive the newsletter, but you don't need to be a member to subscribe. See the CBAS website for more information. CBAS will distribute this newsletter electronically several times a year.

Diaphragm acceptability in Zimbabwe

In Zimbabwe, the Women's Global Health Imperative (WGHI) at the University of California San Francisco (UCSF) and the UZ-UCSF Collaborative Program in Women's Health conducted a study of diaphragm acceptability among sexually active, urban women who were inconsistent condom users. Their study concluded that, if proven effective against STI/HIV, the diaphragm used alone or in combination with a microbicide could provide an acceptable alternative to male condoms in at risk Zimbabwean women.

About 60% of the women had heard of the diaphragm; none had ever used it before the study. Of the 181 women who completed the study, almost all used the diaphragm during the study and close to half said that the ability to use a diaphragm clandestinely was very or extremely important to them. Among women whose partner had other sexual partners or was reluctant to use condoms, this figure rose to over 80%. While most male partners generally knew about the woman using a diaphragm, only 20% of women informed their partners every time they used it, and 96%



reported "it is a method under my control" as a reason they liked using the diaphragm.

Almost all participants felt comfortable using the method: 95% reported feeling very comfortable inserting, wearing, and removing the lubricated diaphragm. The women ranged in age from 16 to 45, were almost all married, and were identified as using male condoms less than 100% of the time prior to entering the study

Diaphragm use could potentially be of great importance to women at risk for HIV and other STIs. "This study adds to the promise of the diaphragm as a potential tool to prevent HIV transmission because it shows that it can be used without one's partner knowing it is being used. Women urgently need an HIV prevention tool that they control," said WGHI's director and study co-author Nancy Padian, PhD, UCSF professor of obstetrics, gynecology and reproductive services and director of international programs at UCSF's AIDS Research Institute. Funding for this research was provided by the Centers for Disease Control and Prevention and the Contraceptive Research and Development Program. Findings will be published shortly.

Diaphragm fittings: a necessity or unchallenged practice?

Introduction

Currently, only 2% of women who practice contraception in the United States use diaphragms (Piccinino and Mosher, 1998). Usage is similarly low in other countries around the world. The need for fitting may be a factor that contributes to these low usage rates (Harvey and Bird, 2004). Most family planning guidelines recommend that women have a pelvic examination and be fitted by a clinician to determine their diaphragm size. Fitting can be time consuming for both women and clinicians and might be embarrassing and uncomfortable for some women. There is a need for more and better research to determine the simplest, most cost-effective protocol for diaphragm provision.

History of diaphragm fitting

The first modern diaphragms were developed in Europe in the mid 1800s, and by the early 20th century, the diaphragm and other cervical barriers had become popular among European women. Early efforts in the U.S., led by Margaret Sanger and others, promoted a grassroots birth control movement where women could use contraceptives (including pessaries, caps, diaphragms, and condoms) without reliance on doctors.



Diaphragms – 3 sizes

However, taking this position proved to be extremely challenging because of the Comstock Laws, which prohibited or restricted the sale and advertisement of contraceptive devices.

Sanger was later convinced by Dutch physician Aletta Jacobs to endorse physician control over the distribution of contraceptive information and technology, and subsequent promotion and advertisement of cervical barrier methods focused on claims that physician fitting greatly improved the contraceptive efficacy of barrier methods (Tone, 2001). Thus physician fitting became the norm and was codified into U.S. FDA labeling in 1976.

Nonetheless, there remains a lack of sufficient anatomical, historical and clinical evidence to fully support the necessity of fittings. Fitting is not an exact science, and practices have changed over time. Diaphragms were once fitted high in the vaginal vault but are now placed low in the vagina. Today, the clinician uses her fingers to measure the distance between the far end of the vagina and the pubic bone, and based on this measurement, she chooses a size that fits snugly in the vagina during an unaroused state. This process and its outcomes may differ based on different clinicians' assessments of a correct fit. Furthermore, research conducted in the 1960s shows that the upper vagina lengthens and expands significantly during arousal (Masters and Johnson, 1962), allowing the diaphragm to move around the cervix. This research led to questions about the connection between fitting and contraceptive efficacy. Subsequent clinical trials established to test the necessity of diaphragm fitting have been methodologically weak or inconclusive, and have not provided definitive evidence for or against the necessity of fitting (Mauck *et al.*, 2004).

Why address the issue now?

Simpler and less time consuming diaphragm provision protocols could increase access to the method, and could potentially attract new users (including women currently using no contraception). A one-size-fits-all diaphragm or a modified protocol could minimize the fitting burden placed on women and on clinicians and expand distribution of the diaphragm.

Clinical trials are now being conducted to test the diaphragm's effectiveness against a range of sexually transmitted infections (STIs), including HIV. There are also trials underway testing the effectiveness of microbicides, or chemical compounds which could potentially block HIV and STI transmission. If the diaphragm and microbicides prove to be even partially successful prevention techniques, using them in combination could potentially increase the overall degree of protection. Ensuring access to these technologies, should they prove effective as HIV/STI prevention methods, will be critical. A simplification of the provision protocol could significantly improve access to the diaphragm, especially in low-resource settings.

Further research

A recent analysis shows that providing all women with the same size diaphragm would result in correctly fitting 33% of women (Mauck *et al.*, 2004). However, expanding the definition of "correct" fit to include plus or minus one size would result in 78% of women receiving the "correct" size. Although the clinical significance of using this broader definition is unknown, it is speculated that being "off" one size is not likely to result in a greatly increased risk of pregnancy or STIs, given the fact that the difference between two sizes is only 5 mm (less than one quarter of an inch). This analysis suggests that it would be acceptable to conduct a one-size-fits-all trial, comparing fitted diaphragms to a one-size device. We need more data directly evaluating the usefulness of diaphragm fitting and determining the most user-friendly, cost-effective, medically appropriate protocol for diaphragm provision.

References

- Harvey, S.M. and Bird, S.T. A new look at an old method: Exploring diaphragm use among women in two U.S. samples. Poster presentation. *Microbicides 2004*. March 28-31, 2004. London, United Kingdom.
- Johnson, V.E. and Masters W.H. Intravaginal contraceptive study. I. Anatomy. *Western Journal of Surgery, Obstetrics and Gynecology* 1962; 70:202-207.
- Mauck, C. et al. Diaphragms in clinical trials: is clinician fitting necessary? *Contraception* 2004; 69:263-266.
- Piccinino, L.J. and Mosher, WD. "Trends in contraceptive use in the United States: 1982-1995." *Family Planning Perspectives* 1998; 30(1):4-10 & 46.
- Tone, A. *Devices and desires: a history of contraceptives in America*. Chapter 6, A medical fit. Hill and Wang: New York, 2001.

Instead, Inc. to test menstrual device as disposable diaphragm in Russia

Instead, Inc. is launching two new projects with its Softcup feminine hygiene product. The company plans to market the Softcup as a disposable contraceptive diaphragm in Russia, and in conjunction with the Russian Academy of Medical Sciences, will begin clinical trials of the effectiveness of the Softcup used with Instead's patented microbicide and spermicidal gel Amphora (previously called Acidform) to protect against pregnancy and HIV/STI.

The Instead Softcup is sold as a feminine hygiene product in the U.S., Canada and seven European countries. It fits over the cervix and collects, rather than absorbs menstrual blood. Instead, Inc. obtained the right to develop and sell the potential spermicidal and microbicide gel Amphora in early 2003, but the product has not yet been proven

effective or approved by the U.S. FDA for this purpose.

Amphora has undergone in vitro and animal studies and two Phase I clinical trials, which indicated its effectiveness as a spermicide as well as its safety when used consecutively for six days. Additional trials are scheduled to begin in Latin America, Asia, and Africa in the next year and results from the Russian trials are expected in the next few months. Instead, Inc. plans to market Amphora as a vaginal lubricant later this year.

SILCS research and development update

SILCS is an innovative 'one-size fits many' cervical barrier device developed in response to users' demand for a barrier method that is easier, more comfortable, and more convenient to use. CONRAD is conducting a Phase I post-coital trial of the most recent design; results are expected mid-2004. Couples' use acceptability studies in South Africa and Thailand began in March 2004. In the Dominican Republic, a couples' use acceptability study of the SILCS compared to the Ortho All-Flex diaphragm is scheduled to begin in mid-2004. PATH and its private sector partner SILCS continue to seek a private sector manufacturing partner or licensee for introduction and distribution of this new cervical barrier device.

Cervical barriers at Microbicides 2004

The Microbicides 2004 conference (London, March 27-31, 2004) brought together 764 researchers, public-health workers and advocates from around the world to share novel or innovative work in the microbicides field, provide updates on recent microbicides research, and discuss new developments in microbicide research including ethical, clinical, behavioral and methodological issues. For more information on the conference, see www.microbicides2004.org.

Conference events included plenary sessions, lectures, workshops, presentations, discussions, and poster sessions. Several of the posters presented at the conference focused specifically on research involving cervical barriers.

- Bird S, Harvey M. Microbicides, diaphragms, male condoms and HIV vaccines: intentions among a sample of US students.
- Coffey P, Levin C, Kelly K. Using Q methodology to assess stakeholder opinions about the use of cervical barriers in low-resource settings.
- Harvey M, Bird S. A new look at an old method: exploring diaphragm use among women in two US samples.
- Posner S, *et al.* The effect of introducing the diaphragm on male condom use.
- Van der Straten A, *et al.* Preferences for gel use with diaphragms in Zimbabwe.

UPCOMING EVENTS

Event: *XV International AIDS Conference Bangkok*

Date: 11-16 July 2004

Location: Bangkok, Thailand

Website: www.aids2004.org

Contact information: Email contact form on website

Description: The XV International AIDS Conference links community and science to galvanize the world's response to HIV/AIDS through increased commitment, leadership and accountability.

Event: *Association of Reproductive Health Professionals (ARHP) Annual Conference*

Date: 8-11 September 2004

Location: Washington, DC

Website: www.arhp.org/rh2004/index.cfm

Contact information: conferences@arhp.org

Description: This conference will focus on the diagnosis, treatment, and management of today's most pressing issues in reproductive health.

Event: *Asia/Pacific Women, Girls & HIV/AIDS Conference*

Date: 4-6 October 2004

Location: Islamabad, Pakistan

Website: www.amal-hdn.org

Contact information: mails@amal-hdn.org

Description: This conference is the first in a series of conferences that will address HIV/AIDS and women in the Asia-Pacific region.

Event: *Reproductive Health Priorities Conference*

Date: 5 - 8 October 2004

Location: Sun City, South Africa

Website: www.rhru.co.za

Contact information: Phone: +27 (0) 11 989 9212; Email: rhconference@rhrujhb.co.za

Description: This conference brings together and promotes interaction and collaboration between researchers, service providers, policy makers and governments from across the Africa region and beyond. Topics covered include STIs, HIV, microbicides, barrier methods, contraception, adolescent reproductive health, maternal health, male involvement in reproductive health care, gender, and gender-based violence.

Event: *United States Conference on AIDS*

Date: 21-24 October 2004

Location: Philadelphia, Pennsylvania

Website: www.nmac.org/conferences/USCA2004

Contact information: pwoods@nmac.org

Description: This conference gathers service providers, people living with HIV/AIDS, policymakers, public officials, funders and other leaders attending USCA, in the largest AIDS-related gathering in the United States.

Event: *AAUW International Symposium, International Perspectives: Women Leading Change in Public Health and Technology*

Date: 12-14 November 2004

Location: Washington, DC

Website: www.aauw.org/ef/symposium.cfm

Contact information: intsymp@aaauw.org

Description: Presenters at this conference will examine how women are using their education to create change in different regions of the world where access to and knowledge of technology and health concerns may vary.

Event: *Global Forum for Health Research: Forum 8*

Date: 16-20 November 2004

Location: Mexico City, Mexico

Website: www.globalforumhealth.org

Contact information: altuwajiris@who.int

Description: With the theme 'Health research to achieve the Millennium Development Goals', the meeting will address such topics as poverty, equity, gender, disability, research capacity strengthening, youth and ageing.



About CBAS

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