

cbas Newsletter

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Female Condom Update

FC2

Following approval by the US Food and Drug Administration (FDA) in March 2009, the FC2 female condom is now available for purchase in the US and is being distributed by US-funded programs around the globe. The FC2 female condom (<http://www.fc2femalecondom.com/>) is the second generation female condom manufactured by the Female Health Company, developed to provide the same safety and efficacy, as well as additional options for protection against sexually transmitted infections (STIs) and pregnancy, while improving affordability by employing new materials. FC2 introduction in the US has targeted the ten cities with the highest rates of STIs, including New York; Atlanta; Washington, DC; Chicago; San Francisco; and Los Angeles. USAID, which has increased delivery of female condoms around the world over the past few years, has transitioned from the FC1 to FC2, and will ship 5.5 million FC2s by the end of 2010. The agency will turn its focus from supply of the product to programs focused on technical assistance, best practices, and cultural sensitivity. Please see these notes from a recent conference call hosted by the Center for Health and Gender Equity, the National Women's Health Network, the AIDS Foundation of Chicago, and the Female Health Company for more information about the FC2: <http://salsa.democracyinaction.org/dia/track.jsp?v=2&c=cNdkxPWpt4wWR%2F6YBvb3%2FSIXrpjxoKkj>.



Woman's Condom

Cincinnati Magazine (February 2010) reports that recruitment is underway for a new trial to test the efficacy of a female condom developed by PATH. Called the Woman's Condom, the device includes an "insertion capsule" of polyvinyl alcohol which dissolves upon insertion into the vagina and small foam pads that adhere to the vaginal walls. It was designed as an alternative to the Female Health Company's first-generation female condom to be less expensive and have better heat-conduction, better sensation, and less noise. The study team, based at the University of Cincinnati, received an NIH grant to study the efficacy of the product; after completing this research stage, PATH may be able to apply for FDA approval. Please see the recent article published in *Cincinnati Magazine* for more information: <http://www.cincinnati.com/article.aspx?id=86276>.



Updated CBAS Diaphragm Bibliography

We are excited to share this updated resource with the CBAS community. Our bibliography of the literature on the diaphragm and cervical cap now includes the latest peer-reviewed, published articles. Please take advantage of the resource by downloading it from our website in chronologically (<http://www.cervicalbarriers.org/documents/Updateddiaphragmbibliography8Feb10Chronorder.pdf>) or alphabetically (<http://www.cervicalbarriers.org/documents/Updateddiaphragmbibliography8Feb10Alphaorder.pdf>) arranged formats. Also keep your eyes out for a forthcoming bibliography on the female condom, which we plan to make available in the coming months.

www.cervicalbarriers.org



The articles listed below represent a bibliography of research on the diaphragm. This is an update of the original vaginal diaphragm bibliography created in 2004 by the Cervical Barrier Advancement Society (CBAS). To update the 2004 bibliography, we searched and published for the terms "diaphragm," "cervical cap," and "cervical barrier" in titles and abstracts from articles published between January 2004 and December 2009. This version of the bibliography contains citations and abstracts as ordered by year of publication; please see the other versions of the bibliography for a list of studies in alphabetical order by first author's name.

2010
van der Vliet A, Selim-Honglaji N, Choso K, Mwaera S, Chiroga MZ. Feasibility and potential acceptability of three cervical barriers among vulnerable young women in Zimbabwe. *J Fam Plan Reprod Health Care* 2010; 36(1): 13-19.
Background: We explored the potential acceptability of three cervical barriers (CB) (Ortho All-Flex® diaphragm, S.C. Hill diaphragm, FrisCap™ cervical cap) among sexually experienced Zimbabwean young women.
Methods: Forty-five young women (aged 18-23 years) received an individual CB educational session. Participants were then randomly assigned to one of the three CBs as a 1:1:1 ratio, and practiced insertion and

Featured Research

The following are published abstracts of research studies on topics related to cervical barrier methods.

Feasibility and potential acceptability of three cervical barriers among vulnerable young women in Zimbabwe.

van der Straten A, Sahin-Hodoglugil N, Clouse K, Mtetwa S, Chirenje MZ.
J Fam Plann Reprod Health Care. 2010;36(1):13-19.

Background: We explored the potential acceptability of three cervical barriers (CB) (Ortho All-Flex® diaphragm, SILCS® diaphragm, FemCap™ cervical cap) among sexually experienced Zimbabwean young women.

Methods: Forty-five young women (aged 16-21 years) received an individual CB educational session. Participants were then randomly assigned to one of the three CBs in a 1:1:1 ratio, and practised insertion and removal of their device at the clinic. Next, participants were interviewed on their practice experiences, and their post-practice attitudes towards CB.

Results: All 45 young women were willing and able to insert their assigned device. The majority reported "easy" insertion and removal and 93% "liked" the device they tried. All showed interest in

participating in future CB studies: when asked which device they would like to try in the future, over half (58%) chose SILCS, regardless of the device they had tried. The majority felt comfortable touching their genitals to insert/remove the CB and most participants favoured methods' attributes associated with female-control and non-interference with sex. Over half the participants said they would prefer to use a CB continuously compared to episodic use. Two-thirds of them expressed interest in CB for dual protection.

Conclusion: The concept of CB, and initial insertion experience, were well accepted in this selected, small group of Zimbabwean young women. Evaluating CB in larger studies seems feasible in this population.

Acceptability and use of the female condom and diaphragm among sex workers in Dominican Republic: Results from a prospective study.

Lara DK, Grossman DA, Muñoz JE, Rosario SR, Gómez BJ, García SG.
AIDS Education and Prevention 2009;21(6):538-551.

To assess the acceptability and use of the female condom and diaphragm among female sex workers in the Dominican Republic, 243 participants were followed for five months. Participants received female and male condoms and a diaphragm along with proper counseling at monthly visits. Seventy-six percent reported use of the female condom at least once during the final month of the study, compared with 50% that used the diaphragm with male condoms and 9%

that used the diaphragm alone. The proportion of women reporting every sex act protected with some barrier method increased from 66% at first month to 77% at final month ($p < 0.05$). Participants reported higher acceptability and use of the female condom than the diaphragm. The introduction of female-controlled barrier methods resulted in the use of a wide range of prevention methods and a significant reduction in unprotected sex.

Predictors of adherent use of diaphragms and microbicide gel in a four-arm, randomized pilot study among female sex workers in Madagascar.

Penman-Aguilar A, Raharinivo MS.
Sexually transmitted diseases 2009;36(4):249-257.

Background: Participants' protocol adherence may influence assessments of the effectiveness of new female-controlled methods for sexually transmitted infection prevention.

Methods: In 2005 we conducted a randomized pilot study among female sex workers (FSWs) in Madagascar in preparation for a sexually transmitted infection prevention trial of diaphragms and a vaginal microbicide. Participants ($n = 192$) were randomized into four arms: diaphragm plus microbicide (Acidform), diaphragm

plus placebo gel hydroxyethyl cellulose (HEC), Acidform alone, or HEC alone. FSWs were seen weekly for four weeks. Using multivariable regression with generalized estimating equations, we assessed predictors of adherent product use during all sex acts in the last week. We collapsed the gel-diaphragm arms together and the gel-only arms together for this analysis.

Results: Between 43% and 67% of gel-diaphragm users (varying by visit) reported using study products during all sex acts in the last week,

compared with 20% to 45% of gel-only users. Adherence increased with follow-up [visit 4 vs. visit 1 risk ratio (RR) for gel-diaphragm users: 1.55, $P < 0.01$; for gel-only users, RR: 1.58, $P = 0.01$]. Gel-diaphragm users whose casual partners were never aware of products (RR: 2.02, $P = 0.03$) and who had experienced partner violence after requesting condom use (RR: 1.45, $P < 0.01$) were more adherent. Gel-only users reporting

lower sexual frequency (1-9 weekly acts vs. ≥ 19 acts, RR: 1.98, $P < 0.01$) and no sex with primary partners in the past week (RR: 1.54, $P = 0.02$) were more adherent.

Conclusions: Gel-diaphragm users had better adherence than gel-only users, and predictors of adherence differed between groups. Addressing modifiable factors during counseling sessions may improve adherence.

Degrees of disclosure: A study of women's covert use of the diaphragm in an HIV prevention trial in sub-Saharan Africa.

Sahin-Hodoglugil NN, van der Straten A, Cheng H, Montgomery ET, Kacaneck D, Mtetwa S, Morar N, Munyoro J, Padian N, MIRA team.

Social Science and Medicine. 2009;69(10):1547-1555.

In sub-Saharan Africa more women are infected with HIV/AIDS than men and new prevention methods are urgently needed. One major attribute of female-initiated HIV prevention methods is that they can be used covertly, without a male partner's knowledge. Using mixed methods, we explored the predictors and dimensions of covert use of the diaphragm in a randomized controlled trial that tested its effectiveness for HIV prevention. The Methods for Improving Reproductive Health in Africa (MIRA) trial was conducted in Zimbabwe and South Africa, and data collection took place between September 2003 and January 2007. This study is a secondary analysis of quantitative and qualitative data from participants randomized to the intervention group, and their male partners. It includes survey data from 2316 women (mean age = 28.3), 14 focus group discussions (FGD) conducted with 104 women, and 7 FGD and 10 in-depth interviews

with 37 male partners. The median follow-up for trial participation was 21 months (range: 12-24). At their final visit, approximately 9% of women had never disclosed to their primary partners that they were using the diaphragm (covert use). In multivariate analysis, predictors of covert use included being older, not co-habiting with the partner, having a partner who did not use condoms, and being from South Africa. Qualitative analysis revealed that covert use was not dichotomous, but ranged along a continuum, which we categorized into five levels (i.e. full disclosure; mostly open use; occasional covert use; mostly covert use; and completely covert use). We discuss the critical role of the option of covert use for many women in the context of an HIV prevention trial, as well as gender power dynamics which may influence women's decisions about disclosure.

Safety analysis of the diaphragm in combination with lubricant or acidifying microbicide gels: Effects on markers of inflammation and innate immunity in cervicovaginal fluid.

Anderson DJ, Williams DL, Ballagh SA, Barnhart K, Creinin MD, Newman DR, Bowman FP, Politch JA, Duerr AC, Jamieson DJ.

American Journal of Reproductive Immunology. 2009;61(2):121-129.

Objective: Diaphragms are being considered for use with vaginal microbicide gels to provide enhanced protection against sexually transmitted pathogens. The purpose of this study was to determine whether use of a diaphragm with microbicide or placebo gel causes cervicovaginal inflammation or perturbations in cervicovaginal immune defense.

Method of study: Eighty-one non-pregnant women were randomized into three groups and instructed to use Millex[®] (CooperSurgical, Inc., Trumbull, CT, USA) diaphragms overnight for 14 days in combination with one of the two acid-buffering microbicide gels [ACIDFORM[™] (Instead Inc., La Jolla, CA, USA) or BufferGel[™] (BG; ReProtect Inc., Baltimore, MD)] or placebo gel (K-Y Jelly[®]; Personal Products Inc., Raritan, NJ, USA).

Cervicovaginal lavages (CVLs) were performed prior to study entry and on days 8 and 16. Nine soluble mediators of vaginal inflammation or immune defense were measured in CVLs by Bio-Plex or ELISA.

Results: Use of diaphragms with placebo or microbicide gel was not associated with increased levels of inflammation markers. Concentrations of secretory leukocyte protease inhibitor (SLPI) were markedly reduced in the BG group.

Conclusion: Daily use of a diaphragm with placebo or acidifying microbicide gel did not cause cervicovaginal inflammation. However, diaphragm/BG use was associated with markedly reduced levels of SLPI, an important mediator of innate immune defense. Further studies are warranted to establish the safety of diaphragm/microbicide gel combinations.

Anal use of the female condom: Does uncertainty justify provider inaction?

Mantell JE, Kelvin EA, Exner TM, Hoffman S, Needham S, Stein ZA.

AIDS Care. 2009;21(9):1185-1194.

Despite limited safety data and the absence of efficacy data, several studies have reported that the female condom is being used for anal sex by men who have sex with men. We describe providers' awareness of female condom use during anal sex among their clients and their experiences in counseling clients. We conducted semi-structured interviews with 78 health-care providers recruited from various health-care delivery systems in New York City: a family planning agency, a sexually transmitted infections agency, a hospital-based obstetrics and gynecology clinic, and two community-based AIDS service organizations. While two-thirds of providers reported that they were uncertain as to whether the female condom could or should be used for anal intercourse, nearly one-third believed that anything is better than nothing to prevent HIV/sexually transmitted infections during anal sex. Few providers had actually talked with

clients about anal use of the female condom, and clients themselves had seldom mentioned nor asked for information about such use. Our findings highlight providers' uncertainty about anal use of the female condom. Lacking guidelines regarding the safety and efficacy of female condom use during anal sex, health-care providers are left to make their own well-intentioned recommendations (or not) to potential users. The dearth of information on female condom use during anal sex could encourage individuals to use the female condom for anal sex, which may increase HIV transmission risk or represent a missed opportunity for protecting non-condom users. There is a need for a series of harm-reduction safety, acceptability, and efficacy studies and, in the interim, for the development of a carefully qualified set of guidelines regarding anal use of the female condom for health-care providers.

Featured Recent Conferences

International Conference on Family Planning

The International Conference on Family Planning in Kampala, Uganda, in November 2009 provided an international forum for scientific and programmatic exchange on research and best practices in family planning. The three-day meeting focused both on research and on building on this knowledge to take action to improve family planning. Of the many valuable presentations, two were of particular relevance to cervical barrier advancement. Jill Schwartz from CONRAD presented on over-the-counter provision of the SILCS diaphragm (www.fpconference2009.org/media//DIR_169701/15f1ae857ca97193ffff8340ffffd524.pdf) and a team from Family Health International presented on acceptability and preferences for three female condoms among women in South Africa (www.fpconference2009.org/media//DIR_169701/15f1ae857ca97193ffff8342ffffd524.pdf). More information about the meeting and other presentation materials are available at: www.fpconference2009.org/2201.html.

Universal Access to Female Condoms Conference

Forty participants gathered in Amsterdam in October 2009 for the Universal Access to Female Condoms conference. The meeting was coordinated in order to strengthen support for the female condom, share knowledge, and garner the explicit commitment of stakeholders to female condom programming and advocacy. Speakers, including Nigerian Bishop Jolly Ehigiator Oyekpen and Dutch Ministry of Foreign Affairs representative Stella Ronner-Grubacic, spoke about the importance of female condoms to the achievement of millennium development goals and the urgent need for access. More details about the conference, including speeches, presentations, and a joint advocacy statement, are available at the UAFC website: www.condoms4all.org/subsection/31/International_Platform/Meeting_2009.

Featured Report

Female Condom Access in Southern Africa

As FC2 production is scaled up following approval in the US and worldwide distribution increases, it will become easier to access the product. For a resource illustrating the distribution of the female condom in countries in southern Africa, see the report from IRIN/PlusNews, available at: www.plusnews.org/Report.aspx?ReportId=86081.

Upcoming Events

Event: Africa Conference on Sexual Health and Rights

Date: February 8-12, 2010

Location: Addis Ababa, Ethiopia

Website: www.africalsexuality.org

Description: The purpose of the 4th Africa Conference on Sexual Health and Rights is to examine the interrelationship between sexuality and HIV and AIDS. The focus will be on identifying new and emerging vulnerabilities and vulnerable people using the concept of sexual rights and sexuality in the fight against HIV and AIDS; exploring how the application of the human rights framework to sexuality might provide new insights in developing interventions to reduce the spread of HIV and AIDS; and mapping out new and innovative strategies, programming, and funding.

Event: Contraceptive Technology

Date: March 24-27, 2010

Location: San Francisco, CA

Website: www.contemporaryforums.com/en/Live-CE-Conferences/Contraceptive-Technology-03-25-2010

Description: "Hot off the Press" is our theme for the 22nd Annual Contraceptive Technology Conferences, since we have a number of exciting updates to share with you in 2010! (See below for description of the conference that will take place in Boston.) Get the scoop on the new *STD Treatment Guidelines*, issued by the Centers for Disease Control and Prevention, from an expert involved in updating these guidelines, Dr. Ward Cates. Be among the first to review the new Medical Eligibility Criteria (MEC) for contraception—designed specifically for US women! Dr. Kate Curtis, who helped develop the US MEC, will cover what's new in the current guidelines and help you apply the criteria to patients with challenging conditions. Vaginitis, anyone? Dr. Jeanne Marrazzo knows it all and delivers the info with pizzazz. Ready to separate fact from fiction? Dr. Michael Policar tells you what's fact and what's fiction about drug interactions with contraceptives. So many of our conference attendees come to meet the world-renowned Dr. Robert Hatcher. You'll hear him talk about his great passion—condoms—and have the opportunity to meet and interact with him throughout the conference.

Abstracts: Due Wednesday, February 24, 2010

Event: Women's Health

Date: March 26-28 2010

Location: Washington, DC

Website: www.bioconferences.com/wh

Description: The 18th Annual Congress of the American Medical Women's Society (AMWA). The AMWA is an organization of women physicians, medical students, and other persons dedicated to serving as the unique voice for women's health and the advancement of women in medicine. AMWA functions at the local, national, and international levels to advance women in medicine and improve women's health, by providing and developing leadership, advocacy, education, expertise, mentoring, and through building strategic alliances. AMWA empowers women to lead in improving health for all within a model that reflects the unique perspective of women.

Event: Family Planning Peer-to-Peer, NFPRHA National Conference

Date: April 11-14, 2010

Location: Arlington, VA

Website: [www.nfprha.org/main/events.cfm?](http://www.nfprha.org/main/events.cfm?Category=National_Conference&Section=Main)

[Category=National_Conference&Section=Main](http://www.nfprha.org/main/events.cfm?Category=National_Conference&Section=Main)

Description: The National Family Planning & Reproductive Health Association's annual conference is the *only* forum which assembles the broad spectrum of providers addressing the family planning and reproductive health care needs of low-income and uninsured Americans. At *Family Planning Peer-to-Peer* presentations from experts will supplement opportunities for program administrators and practitioners to grapple with the service delivery and administrative realities they experience, sharing solutions to tough challenges and taking action to expand access.

Event: Contraceptive Technology

Date: April 14-17, 2010

Location: Boston, MA

Website: www.contemporaryforums.com/en/Live-CE-Conferences/Contraceptive-Technology-04-15-2010

Description: "Hot off the Press" is our theme for the 22nd Annual Contraceptive Technology Conferences, since we have a number of exciting updates to share with you in 2010! (See above for description of the conference that will take place in San Francisco.) Get the scoop on the new *STD Treatment Guidelines*, issued by the Centers for Disease Control and Prevention, from an expert involved in updating these guidelines, Dr. Ward Cates. Be among the first to review the new Medical Eligibility Criteria (MEC) for contraception—designed specifically for US women! Dr. Kate Curtis, who helped develop the US MEC, will cover what's new in the current guidelines and help you apply the criteria to patients with challenging conditions. Vaginitis, anyone? Dr. Jeanne Marrazzo knows it all and delivers the info with pizzazz. Ready to separate fact from fiction? Dr. Michael Policar tells you what's fact and what's fiction about drug interactions with contraceptives. So many of our conference attendees come to meet the world-renowned Dr. Robert Hatcher. You'll hear him talk about his great passion—condoms—and have the opportunity to meet and interact with him throughout the conference.

Event: Microbicides

Date: May 22-25, 2010

Location: Pittsburgh, PA

Website: www.microbicides2010.org

Description: The 2010 International Microbicides Conference (M2010) will feature state-of-the-art plenary lectures on HIV prevention research, cross-disciplinary symposia on microbicides and other HIV prevention research, oral abstracts, and poster sessions. The theme of our meeting, "Microbicides: Building Bridges in HIV Prevention," was developed with the intention of increasing collaboration between basic, clinical, and behavioral scientists, and bridging emerging research with community partners and advocacy groups involved in HIV prevention. There will be scholarships available for those who need assistance with meeting and travel support.

Upcoming Events

Event: Women Deliver

Date: June 7-9, 2010

Location: Washington, DC

Website: www.womendeliver.org/conferences

Description: The theme of the conference is "Delivering solutions for girls and women," and we plan to focus on political, economic, social/cultural, and technological solutions. This global meeting will expand on Women Deliver's hallmark of inclusivity, reaching out to new partners and new communities. With all these partners in one room, we will further prove that maternal and reproductive health is a global priority. Women Deliver 2010 will move the dialogue to the global arena with two strong messages: The Millennium Development Goals (MDGs) will not be achieved without investing in women, and there is just enough time, if the world commits funding now, to achieve MDG5—additional US\$10 billion annually by 2010 and US\$20 billion by 2015.

Event: Global Health Council's 37th Annual Conference

Date: June 14-18, 2010

Location: Washington, DC

Website: www.globalhealth.org/conference_2010

Description: On June 14, 2010, more than 2,500 practitioners, global health and world leaders, activists, multi-lateral organizations, the public and private sectors, members of academia, and researchers will descend upon Washington, DC, to discuss global health's goals and metrics at the Global Health Council's 37th Annual International Conference.

Event: AIDS

Date: July 18-23, 2010

Location: Vienna, Austria

Website: www.aids2010.org

Description: The International AIDS Conference is the premier gathering for those working in the field of HIV, as well as policymakers, persons living with HIV, and other individuals committed to ending the pandemic. It is a chance to assess where we are, evaluate recent scientific developments and lessons learnt, and collectively chart a course forward. Given the 2010 deadline for universal access set by world leaders, AIDS 2010 will coincide with a major push for expanded access to HIV prevention, treatment, care, and support.

CBAS Steering Committee

Marianne Callahan: CONRAD

Tsungai Chipato: University of Zimbabwe-University of California San Francisco Collaborative Research Programme in Women's Health

Patricia Coffey: PATH

Nancy Padian: Women's Global Health Imperative, RTI

Gita Ramjee: Medical Research Council of South Africa

Helen Rees: Reproductive Health Research Unit

Kelley Ryan: Duke Clinical Research Institute

Contribute to the CBAS Newsletter

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

About CBAS

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 (Updated!)

The Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods, including diaphragms, caps, female condoms, and other devices, for pregnancy prevention and to provide information about research on female condoms and 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 Kelsey Otis, CBAS Executive Director, at kotis@cervicalbarriers.org. CBAS is housed at Ibis Reproductive Health (www.ibisreproductivehealth.org).