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Spotlight on Female Condoms in South Africa

Female Condoms Distributed at the 2010 FIFA World Cup

By CBAS Steering Committee member Mags Beksinska

In June and July 2010, South Africa hosted the FIFA Soccer World Cup. Ten stadia held 64 matches over 43 days in nine cities across the country, and thousands of tourists visited South Africa during this period. Fan parks were set up to screen matches for those without tickets. The years of planning and build-up to this international event included a focus on ensuring that prevention of STI and HIV infection and unplanned pregnancy was a key World Cup activity. The South African National and Provincial Departments of Health, MatCH (Maternal, Adolescent, and Child Health) of the University of the Witwatersrand, and the Society for Family Health (SFH), worked together on an exciting and challenging project supported by UNFPA and aimed at ensuring country-wide distribution of free male and female condoms before, during, and after the World Cup. Condoms were provided for South Africans, soccer teams, fans, and tourists—approximately 50 million male condoms and over 520,000 female condoms were distributed at fan parks and around stadia all over the country. Demonstrations on use of the female condom were particularly popular among men, many of whom had never seen a female condom before. The female condom program in South Africa—one of the most comprehensive programs globally—aims to use the momentum gained for condom promotion during the World Cup as a springboard to ongoing HIV prevention activities in the country.



Zonke Mabude from MatCH demonstrates use of a female condom to soccer fans at the World Cup in July 2010

Lack of Access to Female Condoms Makes News in South Africa

A recent article published in the *South Africa Mail & Guardian* highlights efforts to increase distribution and acceptability of the female condom in South Africa. Although South Africa has one of the largest distributions of female condoms in the world, only about 3.5 million were distributed last year compared to 350 million male condoms distributed annually. To read the *Mail & Guardian* article, visit this link [<http://www.mg.co.za/article/2010-08-05-hunt-is-on-for-elusive-female-condom>].

Female Condom Tracking on the CBAS Website

CBAS has long provided information on recently completed, ongoing, and planned cervical barrier research on our website, www.cervicalbarriers.org. We have recently begun tracking female condom research on our website, and are excited to share this expansion with the CBAS community. Please visit our website to view these updates on planned [<http://www.cervicalbarriers.org/information/plannedResearch.cfm>], ongoing [<http://www.cervicalbarriers.org/information/ongoingResearch.cfm>], and completed [<http://www.cervicalbarriers.org/information/recentResearch.cfm>] female condom research, including several exciting Phase III clinical studies evaluating the PATH Woman's Condom and other female condoms not yet approved by the United States Food and Drug Administration. We welcome updates on additional female condom and cervical barrier research; please contact info@cervicalbarriers.org with information.



Woman's Condom, courtesy of PATH

Featured Research

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

The female condom: The international denial of a strong potential.

Aenny P, Jansen W, van Driel F.

Reproductive Health Matters. 2010; 18(35): 119-128.

The female condom has received surprisingly little serious attention since its introduction in 1984. Given the numbers of women with HIV globally, international support for women's reproductive and sexual health and rights and the empowerment of women, and, not least, due to the demand expressed by users, one would have expected the female condom to be widely accessible 16 years after it first appeared. This expectation has not materialised; instead, the female condom has been marginalised in the international response to HIV and AIDS. This paper asks why and analyses the views and actions of users, providers, national governments and international public policymakers, using an

analytical framework specifically designed to evaluate access to new health technologies in poor countries. We argue that universal access to female condoms is not primarily hampered by obstacles on the users' side, as is often alleged, nor by unwilling governments in developing countries, but that acceptability of the female condom is problematic mainly at the international policy level. This view is based on an extensive review of the literature, interviews with representatives of UNAIDS, UNFPA and other organisations, and a series of observations made during the International AIDS Conference in Mexico in August 2008.

Female condom technology: New products and regulatory issues.

Beksinska M, Smit J, Joanis C, Usher-Patel M, Potter W.

Contraception. 2010 (published online ahead of print)

Like male condoms, female condoms (FCs) provide protection against unplanned pregnancy and most sexually transmitted infections including HIV. The first FC made by the Female Health Company was approved by the US Food and Drug Administration (USFDA) in 1993. Since 2000, several different types of FCs have become available or are in development to lower the cost and/or improve acceptability. Although similar in function, new FCs often differ in design and materials. Classified as Class III medical devices

by the USFDA, FCs have a regulatory process that is more complex than that for male condoms. This, coupled with the lack of an international standard to verify the quality of new devices, has hindered new products gaining regulatory approvals and entering the market. We review the existing regulatory pathway for FCs, the progress made in developing standards specifically for FCs and the FCs available now or in development, including their current status regarding approval.

Adherence to diaphragm use for infection prevention: A prospective study of female sex workers in Kenya.

Bukusi EA, Gallo MF, Sharma A, Njoroge B, Jamieson DJ, Nguti R, Bell AJ, Eschenbach DA.

Infectious Diseases in Obstetrics and Gynecology. 2009; 2009:1-11.

Objective: To assess adherence to and acceptability of the diaphragm among 140 female sex workers in Kenya in a six-month prospective study. Methods: At baseline and bimonthly visits, participants were interviewed on diaphragm knowledge, attitude, and practices. We used principal component analysis and logistic regression to identify predictors of consistent use. Results: At 50% of 386 bimonthly visits, women reported consistently using a diaphragm with all partners during the preceding two weeks. Consistent use was significantly higher at the six-month than the two-month visit. Women reported less covert use with "helping" (regular sex partners to whom she could go for help or support) than with "other" partners. Perceptions

that diaphragms are easier to use than condoms and that their lack of coital interruption is important were associated with consistent diaphragm use with both partner types. Partner support of diaphragm use is correlated with consistent use with "helping" partners only while higher parity, consistent condom use, and perceived lack of need of condoms as a benefit of diaphragms were associated with consistent use with "other" partners. Conclusions: Diaphragm acceptance among female sex workers in Nairobi was high. Future studies should distinguish between partner types when evaluating diaphragm adherence.

Acceptability and use of the diaphragm and Replens® lubricant gel for HIV prevention in Southern Africa.

Montgomery ET, Cheng H, van der Straten A, Chidanyika AC, Lince N, Blanchard K, Ramjee G, Nkala B, Padian NS, and The MIRA team.
AIDS and Behavior. 2010; 14(3): 629-638.

The acceptability and use of the diaphragm and lubricant gel were assessed as part of a large randomized controlled trial to determine the effectiveness of the methods in women's HIV acquisition. 2,452 intervention-arm women were enrolled at five Southern African clinics and followed quarterly for 12-24 months. Acceptability and use data were collected by face-to-face interviews at Month 3 and Exit. Participants were "very comfortable" with the physical mechanics of diaphragm use throughout the trial, and approval

of the gel consistency, quantity, and the applicator was high. At Exit, consistent disclosure of use (AOR 1.97, 95% CI: 1.10-3.55); an overall high diaphragm rating (AOR 1.84, 95% CI: 1.45-2.34); and perception of partner approval (AOR 1.75, 95% CI: 1.35-2.26) were the most significant acceptability factors independently associated with consistent use. Despite being female-initiated, disclosure of use to male partners and his perceived approval of the products were factors significantly associated with their consistent use.

Diaphragm for STI and HIV prevention: Is it a safe method for women at high risk?

Njoroge B, Gallo MF, Sharma A, Bukusi EA, Nguti R, Bell AJ, Jamieson DJ, Williams D, Eschenbach DA.
Sexually Transmitted Diseases. 2010; 37(6):382-385.

Female sex workers (n = 140) were enrolled in a six-month acceptability trial of the diaphragm. We randomized a subset (n = 40) to receive colposcopies after one month of diaphragm use or after one month of observation before

commencing diaphragm use. Adverse events were mild in nature. Frequency of colposcopic findings did not differ between women randomized to immediate versus delayed diaphragm use (P = 0.25).

Challenges, strategies, and lessons learned from a participatory community intervention study to promote female condoms among rural sex workers in Southern China.

Weeks MR, Liao S, Li F, Li J, Dunn J, He B, He Q, Feng W, Wang Y.
AIDS Education and Prevention. 2010; 22(3): 252-271.

China faces a rapidly emerging HIV epidemic and nationwide resurgence of sexually transmitted infections associated with a growing sex industry. Community empowerment and capacity building through community-based participatory research partnerships show promise for developing, testing, and refining multilevel interventions suited to the local context that are effective and appropriate to address these concerns. However, such efforts are fraught with challenges, both for community collaborators and for researchers. We have built an international team of scientists from Beijing

and the United States and collaborating health policy makers, health educators, and care providers from Hainan and Guangxi Province Centers for Disease Prevention and Control and the local counties and towns where we are conducting our study. This team is in the process of testing a community-wide, multilevel intervention to promote female condoms and other HIV prevention within sex-work establishments. This article presents lessons learned from our experiences in the first two study sites of this intervention trial.

Can Medicaid reimbursement help give female condoms a second chance in the United States?

Witte SS, Stefano K, Hawkins C.

American Journal of Public Health. 2010; 100(10): 1835-1840.

The female condom is the only other barrier contraception method besides the male condom, and it is the only "woman-initiated" device for prevention of sexually transmitted infections. Although studies demonstrate high acceptability and effectiveness for this device, overall use in the United States remains low. The female condom has been available through Medicaid in many states since 1994. We provide the first published summary of data on Medicaid reimbursement for

the female condom. Our findings demonstrate low rates of claims for female condoms but high rates of reimbursement. In light of the 2009 approval of a new, cheaper female condom and the recent passage of comprehensive health care reform, we call for research examining how health care providers can best promote consumer use of Medicaid reimbursement to obtain this important infection-prevention device.

Three new female condoms: Which do South-African women prefer?

Joanis C, Beksinska M, Hart C, Tweedy K, Linda J, Smit J.

Contraception. 2010 (published online ahead of print)

Background: The widespread distribution of female condoms (FCs) in developing countries has been hindered by high unit cost, making new, less expensive devices a priority for donor agencies. Study design: Randomized, crossover study assessing product preference, safety, acceptability, and function of three new FCs (PATH Woman's Condom, FC2, and V-Amour) among 170 women in Durban, South Africa. A subsequent "simulated market" study provided participants with free choice of FCs and assessed condom uptake over three months. Results: Of the 160 women who used at least one FC of each type, 47.5% preferred the PATH Woman's Condom

(WC), 35.6% preferred FC2, and 16.3% preferred V-Amour ($p < .001$). Women rated the WC better than FC2 and V-Amour for appearance, ease of use, and overall fit and better than V-Amour for feel. WC was rated worse than FC2 and V-Amour for lubrication volume. The simulated market demonstrated similar preferences. Total clinical failure rates (i.e., the types of failures that could result in pregnancy or STI) were low ($< 4\%$), regardless of condom type. Conclusions: Three new FC types functioned similarly and were generally acceptable. Most participants preferred WC and FC2 over V-Amour, and WC was preferred over FC2 in several acceptability measures.

The importance of male partner involvement for women's acceptability and adherence to female-initiated HIV prevention methods in Zimbabwe.

Montgomery ET, van der Straten A, Chidanyika A, Chipato T, Jaffar S, Padian N.

AIDS Behavior. 2010 (published online ahead of print)

Enlisting male partner involvement is perceived as an important component of women's successful uptake of female-initiated HIV prevention methods. We conducted a longitudinal study among a cohort of 955 Zimbabwean women participating in a clinical trial of the effectiveness of a female-initiated HIV prevention method (the diaphragm and lubricant gel) to: (a) describe the extent to which women involved their male partners in the decision to use the study products, and (b) measure the effect perceived male partner support had on their acceptability and consistent use of these methods. Reported levels of male partner involvement in discussions and decisions regarding: joining the study, study activities, the

outcome of HIV/STI test results, and product use were very high. In multivariate analyses, regular disclosure of study product use and partner approval for the diaphragm and gel were significantly associated with women's acceptability and consistent use of the products, an essential component for determining efficacy of investigational prevention methods. These results support the need for more sophisticated measurement of how couples interact to make decisions that impact study participation and investigational product use as well as more rigorous adaptations and evaluations of existing strategies to involve male partners in female-initiated HIV prevention trials.

Featured Recent Conferences

Global Teleconference on Female Condoms



The Center for Health and Gender Equity (CHANGE) held a strategy call on female condom products, research and development, programming, and advocacy to expand access on September 30, 2010. It was co-sponsored by the AIDS Foundation of Chicago, AVAC, and PATH with presentations on each organization's work in the field.

Visit CHANGE's Prevention Now! website for more information [<http://www.preventionnow.net/>

[news_and_events/events/teleconference_townhall_female_condoms_of_today_and_tomorrow/](http://www.preventionnow.net/news_and_events/events/teleconference_townhall_female_condoms_of_today_and_tomorrow/)].

XVIII International AIDS Conference



The 2010 International AIDS Conference was held in Vienna, Austria, July 18-23, 2010. The theme of the conference was "Rights Here, Right Now," highlighting the crucial connection between human rights and HIV. Here we feature two sets of conference activities of interest to CBAS members.

Universal Access to the Female Condom Joint Programme at AIDS 2010

The Universal Access to the Female Condom (UAFC) Joint Programme held female condom demonstrations, workshops, and a poster presentation at the 18th International AIDS Conference in Vienna, Austria. UAFC also held a press

conference which drew attention from worldwide media sources reporting on the need for expanded access to the female condom. More information is available at the UAFC website [http://www.condoms4all.org/newsarticle/287/UAFC_at_IAC_2010%3A_Success_%26_Call_for_Action] and the AIDS 2010 conference website [www.aids2010.org].

Cervical Barrier Research at AIDS 2010

Please see below a list of posters and presentations that highlighted cervical barrier methods, including the diaphragm and Duet®, at the conference. You may also visit the conference website Programme-at-a-Glance feature [<http://pag.aids2010.org/>] to browse the approximately 40 female condom-related presentations and posters.

- Change in barrier method use after an HIV prevention trial in Zimbabwe (van der Straten et al.) [<http://pag.aids2010.org/Abstracts.aspx?AID=8016>]
- Intimate partner violence and non-adherence to male condoms and the diaphragm among women in an HIV prevention trial in Sub-Saharan Africa (Kacane et al.) [<http://pag.aids2010.org/Abstracts.aspx?AID=11220>]
- Potential of female controlled contraceptives in preventing maternal incident HIV infection amongst postpartum women in Kenya (Osoti et al.) [<http://pag.aids2010.org/Abstracts.aspx?AID=13178>]
- Women's empowerment? Contradictory reports of female autonomy towards female-initiated HIV prevention methods in Zimbabwe (Montgomery et al.) [<http://pag.aids2010.org/Abstracts.aspx?AID=16341>]

Upcoming Events

Event: American Public Health Association 2010 Annual Meeting and Expo
Date: November 6 – 10, 2010
Location: Denver, CO, USA
Website: <http://www.apha.org/meetings/>
Description: The 138th Annual Meeting and Exposition unites the public health community and offers them the opportunity to enhance their knowledge and share information on best practices and new trends in public health. The theme this year is "Social Justice," which lies at the heart of public health. Sessions will explore why certain populations bear a disproportionate burden of disease and mortality and what the public health community can do to better address the causes of these inequities. There will be more than 1,000 cutting-edge scientific sessions and 700 booths of information and state-of-the-art public health products and services.

Event: International Students' Conference on Reproductive Health
Date: November 18 – 20, 2010
Location: Kampala, Uganda
Website: <http://www.iscorh.org/index.html>
Description: Makerere University College of Health Sciences in Uganda has been organizing International Students' Conferences for 10 years. This year, the theme is "Reproductive Health: Prioritizing Maternal, Newborn, and Adolescent Health," which is inspired by the Gates Institute family planning conference in November 2010. Organizers are expecting 300 local and 100 international participants who will include: medical, nursing, paramedical, public health, and pharmacy undergraduate and postgraduate students, doctors, nurses, public health specialists, clinical officers, health policy makers, government and non-government organizations involved in reproductive health, other researchers, religious leaders, and the private sector.

Event: 2010 HIV Prevention Leadership Summit
Date: December 12 – 15, 2010
Location: Washington, DC, USA
Website: <http://www.2010HPLS.org>
Description: The 2010 HIV Prevention Leadership Summit (HPLS) will address the theme: "Above and Beyond: Taking HIV Prevention to the Next Level." The Summit will offer AIDS directors, program managers, executive directors, HIV prevention program staff, CPG members, and other HIV prevention partners a forum to disseminate and exchange information to enhance their program planning and management with innovative strategies to for implementing HIV prevention programs. Attendees will also receive important information, skills building, and opportunities to share lessons learned.

Event: International Workshop on HIV & Women, from Adolescence through Menopause
Date: January 10 – 11, 2011
Location: Washington, DC, USA
Website: http://www.virology-education.com/index.cfm/t/1st_International_Workshop_on_HIV__Women__from_Adolescence_through_Menopause/vid/F44E4528-ED5E-2045-E7E7BDD3062358A3
Description: The 1st International Workshop on HIV & Women, from Adolescence through Menopause will present a unique and much needed platform for international scientific exchange on the increasingly recognized problems of HIV and women. It will gather a cross-disciplinary team of experts and trainees involved in research on HIV and women, in order to present and discuss the latest developments and strategies for the future, in an interactive and science-focused setting. The meeting will have a two-day program consisting of invited lectures, abstract-driven scientific presentations, and poster sessions. The latest developments will be reviewed and evaluated in order to identify important topics for future research, develop better approaches to treatment, and create a strategic agenda for future management problems associated with HIV and Women.

Event: International Society for the Study of Women's Sexual Health

Date: February 10 – 13, 2011

Location: Scottsdale, AZ

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

Description: The ISSWSH provides opportunities for communication among scholars, researchers, and practitioners about women's sexual function and sexual experience; supports the highest standards of ethics and professionalism in research, education, and clinical practice of women's sexuality; and provides the public with accurate information about women's sexuality and sexual health.

Event: Commission on the Status of Women

Date: February 22 – March 4, 2011

Location: New York, NY, USA

Website: <http://www.un.org/womenwatch/daw/csw/55sess.htm>

Description: In accordance with its multi-year programme of work (ECOSOC resolution 2009/15), the 2011 priority theme of the Commission on the Status of Women is "Access and participation of women and girls to education, training, science and technology, including for the promotion of women's equal access to full employment and decent work." The Commission will also evaluate progress in the implementation of the agreed conclusions from its fifty-first session on "The elimination of all forms of discrimination and violence against the girl child."

CBAS Steering Committee

Mags Beksinka: Maternal, Adolescent and Child Health, Department of Obstetrics and Gynecology, University of the Witwatersrand (MatCH)

Marianne Callahan: CONRAD

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

Patricia Coffey: PATH

Bidia Deperthes: United Nations Population Fund

Maggie Kilbourne-Brook: PATH

Helen Rees: Reproductive Health & HIV Research Unit of the University of the Witwatersrand

Kelley Ryan: Duke Clinical Research Institute

Jill Schwartz: CONRAD

Ariane van der Straten: Women's Global Health Imperative, RTI

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 three newsletters per year.

CBAS Contact Information: For more information, contact Kelsey Holt, CBAS Executive Director, at info@cervicalbarriers.org. CBAS is coordinated by Ibis Reproductive Health (www.ibisreproductivehealth.org).