

cbas Newsletter

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Female Condom Development and Advocacy Updates

Universal Access to Female Condoms: The Paper Doll Campaign

The Universal Access to Female Condom (UAFC) Joint Programme, a non-profit partnership working for accessibility and availability of female condoms, has launched the Paper Doll Campaign to illustrate the growing demand for female condoms by creating long chains of paper dolls containing individual messages about female condoms. The campaign collected hundreds of paper dolls from NGOs and organizations across the globe, including CBAS/Ibis Reproductive Health, and displayed them at the United Nations High Level Meeting on HIV/AIDS on June 8th, 2011, in New York City. The dolls created a stunning display that contained a powerful message: women worldwide want access to female condoms. Additionally, Kathleen Ferrier, member of the Parliament of the Netherlands and Maria da Luz Dai Guebuza, the first lady of Mozambique, spoke of the importance of access to female condoms at a rally at Dag Hamarskjold Plaza. CBAS supports the goal of this project to spread information and awareness about female condoms. To participate or to learn more about the project, please visit: <http://library.constantcontact.com/download/get/file/1101693812286-119/UAFC+Letter.pdf>. To learn more about the Universal Access to Female Condom Joint Programme, please visit: <http://www.condoms4all.org>.



Paper dolls with individual messages about female condoms on display at United Nations, June 8th, 2011

Another Step Forward for the Woman's Condom: Shanghai Food and Drug Administration Grants Approval

By Patricia Coffey, PATH (CBAS steering committee member)



PATH's Woman's Condom

On May 27, 2011, the Woman's Condom received Shanghai Food and Drug Administration (SHFDA) approval. PATH's licensee and the manufacturer of the product, the Shanghai Dahua Medical Apparatus Company (Dahua), submitted the application. SHFDA approval allows Dahua to register the Woman's Condom for sale in the Chinese market, a significant achievement given that one in five individuals in the world resides in China. Dahua is planning for a product launch later this year with an initial focus on private-sector markets in large cities such as Shanghai. In addition, the Protection Options for Women Product Development Partnership (POW) is working to create awareness and demand for the Woman's Condom in the public sector in China with the end goal of including the Woman's Condom in the national family planning program. This latest approval from the SHFDA, combined with CE Mark approval for sales in Europe (granted in December 2010), continues to build confidence about the quality of the Woman's Condom product among donors, distributors, and end users.

For more information regarding the Woman's Condom product, please contact:
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PATH
PO Box 900922
Seattle, WA 98109, U.S.A.
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For commercial inquiries, please contact:
Hua Chen, President
Shanghai Dahua Medical Apparatus Co., Ltd.
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Shanghai, China
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WHO/UNFPA Female Condom Technical Review Committee Meetings: Development of a Generic Specification for Female Condoms for Bulk Procurement and Technical Review of Manufacturers' Dossiers

By Maggie Usher-Patel, WHO, and Mags Beksinska, MatCH (CBAS steering committee member)

The World Health Organization, Department of Reproductive Health and Research (WHO/RHR), in collaboration with the United Nations Population Fund (UNFPA) and Family Health International (FHI), convened two Female Condom Technical Review Committee meetings at the WHO headquarters in Geneva, Switzerland, in April 2011. These meetings followed the WHO/UNFPA/FHI Female Condom Workshop held in Bangkok, Thailand, in December 2010 (see February 2011 CBAS newsletter for information about this workshop, which was undertaken to assist manufacturers interested in the design, clinical evaluation, testing, and manufacturing of new female condom products: http://www.cervicalbarriers.org/newsletter/index_cfm_MMtmp0cd96609/CBASVol8No1FINAL.pdf).

In preparation for the Female Condom Technical Review Committee meetings, female condom manufacturers were invited by WHO/RHR and UNFPA to submit product dossiers and site master files which included such information as product specifications of the design and finished product, manufacturing processes used, safety and performance test data, and clinical evaluation. Nine manufacturers submitted a total of ten dossiers for review (one product is manufactured in two different locations). Specific criteria were established for the review process and a team of manufacturing, quality assurance, testing, and clinical experts reviewed each dossier.

During the first committee meeting, from April 4-8, 2011, committee members reviewed the scientific and technical basis for establishing a generic specification for the female condom. Between April 11-15, 2011, per request from the UNFPA, the committee was reconvened to undertake a second technical review of product dossiers and site master files of female condom manufacturers to determine which products, if any, can be recommended for bulk procurement by UNFPA. WHO/RHR and UNFPA had agreed at the Bangkok workshop to manage this review process in tandem with the WHO/UNFPA pre-qualification process. This decision was made because each female condom is a unique product and must be assessed individually to determine its suitability for bulk procurement.

The reviews were collated and a confidential report was prepared for each manufacturer. Each manufacturer must respond to the issues raised in their confidential reports within a specified timeframe if the pre-qualification process is to proceed. The technical review process is ongoing and the committee will continue to advise and guide manufacturers through the required procedures that need to be undertaken to bring a new female condom to market and to complete the pre-qualification process for bulk procurement. The official report from this technical review process will be released soon; please contact Mags Beksinska for more details (mbeksinska@match.org.za).

Participate in a Cervix Sizing Study

Rhea Care, Inc., a new sister company to APEX Medical Technologies, aims to develop a range of new barrier methods and is recruiting women to participate in a cervix sizing study and a menstrual products use survey. We hope this research will help build a knowledge base to support development of novel female health products that respond to women's needs. If you are interested in participating in either of these studies, please visit <http://www.rheacare.com>, and click on the "Research" tab for more information.

Updated MIRA Trial Key Findings and Publications Brief

We are excited to share with you an updated version of our Key Findings and Publications Brief on the MIRA trial, a phase III trial of the diaphragm and lubricant gel for HIV prevention in women. Although findings did not support addition of the diaphragm to HIV prevention strategies, the results have provided critical data on diaphragm and condom acceptability, covert use of HIV prevention technologies, vaginal practices, contraception use and effectiveness, prevention trial recruitment and retention, and discrepancies in diagnosis of incident HIV infection between antibody-based and DNA-based tests, among others. Please visit our website (<http://www.cervicalbarriers.org/documents/MIRAbriefv3FINAL28June11.pdf>) to download a copy of this updated brief which includes over 20 trial publications since 2007.



Featured Research

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

HIV prevention by enhancing compliance of Tenofovir microbicide: Using a novel delivery system

Shihata A, Brody S.

HIV&AIDS Review 2010; 9(4): 105-108.

Background: CAPRISA 004 (Centre for the AIDS Programme of Research in South Africa) revealed that women who had high self-reported adherence with Tenofovir microbicide application achieved a 54% reduction in HIV seroconversion in comparison to placebo. Conversely, there was only a 28% reduction in the poor compliance group.

Materials and Methods: To enhance the adherence of Tenofovir application, we investigated an alternative to the vaginal applicator which was used before and after intercourse in CAPRISA study. The FemCap contraceptive device has a unique delivery system for microbicides on its cervical and vaginal sides to ensure better coverage, and retention of gel on the cervix and vagina. To evaluate this delivery system, 20 women compared the use of the vaginal applicator to deliver a vaginal lubricant before and after intercourse versus the FemCap to deliver the

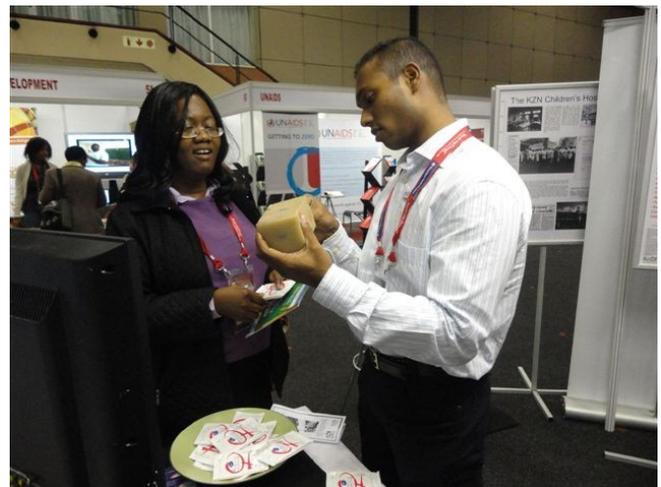
same lubricant once before intercourse.

Results: Forty percent of women missed the application of the lubricant with the vaginal applicator before intercourse and 10% missed it after intercourse. Of the FemCap users, 10% missed application of the vaginal lubricant before intercourse and both inserted it after intercourse. The gel was better retained over the cervix by single application with the FemCap versus two applications with the applicator.

Conclusions: Participants preferred the FemCap, due to elimination of leakage and the single application, versus two applications with the vaginal applicator. The increased adherence and retention of gel over the cervix by using the FemCap may potentially increase the efficacy of Tenofovir.

Featured Conference: 5th Annual South Africa AIDS Conference

The 5th Annual South Africa AIDS Conference was held in Durban, June 7-10, 2011. The conference included presentations highlighting current research and advocacy efforts related to HIV and AIDS across six different tracks: Basic Sciences; Clinical Sciences; Epidemiology and Prevention; Social and Economic Sciences; Community Exchange Encounters; and Health Systems, Programmes, Human Rights and Ethics. Two posters presented at the conference featured research conducted in KwaZulu-Natal on the acceptability of the FC2 female condom (Presented by Mags Beksinska, MatCH), and the impact of provider training on demand for the female condom at healthcare facilities (Presented by Jacqueline Pienaar, MatCH). In addition, the Maternal, Adolescent, and Child Health Department of Obstetrics and Gynaecology at the University of the Witwatersrand (MatCH) held female condom demonstrations for conference attendees at their booth. For more information about the conference and to view the entire conference program, visit this link: <http://www.dirasengwe.org/>.



Female Condom demonstrations during conference at MatCH booth

Featured Reports

CHANGE Female Condoms and United States Foreign Assistance Report

The Center for Health and Gender Equity (CHANGE) has released a report titled "Female Condoms and U.S. Foreign Assistance: An Unfinished Imperative for Women's Health." The report notes that, despite excellent evidence that the female condom is an acceptable and efficacious pregnancy and HIV/STI prevention method that offers unique benefits and increases the total number of protected sex acts, U.S. foreign assistance commitment to female condoms is negligible compared to other global prevention strategies. While U.S. government agencies such as the U.S. Agency for International Development (USAID) and the Office of the U.S. Global Aids Coordinator (OGAC) are applauded for their efforts to increase access to female condoms, the report also makes recommendations for how these agencies can ensure effective programming, oversight, program tracking, and outreach to civil society. These recommendations include: 1) Allocating funds for the purchase of female condoms through the Commodity Fund, 2) Creating an interagency task team of OGAC and USAID members to engage in solutions to support and evaluate female condom programs, 3) Funding trainings about use of the female condom for doctors, nurses, and counselors who are affiliated with PEPFAR and USAID programs, 4) Funding prevention programs which specifically include female condoms in their materials, 5) Disaggregating male and female condoms in data collection efforts, and 6) Expanding technical assistance to additional countries' HIV prevention initiatives. Please visit CHANGE's website to download the full report: <http://www.genderhealth.org/files/uploads/change/publications/unfinishedimperative.pdf>.

AIDS Legal Network/ATHENA Network Report on the Future of Microbicide Trials

In the wake of debates surrounding the microbicide Tenofovir's effectiveness, future trials, and availability, the AIDS Legal Network and the ATHENA Network have released a series of discussions presenting varying perspectives on these matters titled, "Transparency, Accountability, and Feminist Science—What Next for Microbicide Trials?" The report offers insight from epidemiologists and NGO staff on how the HIV and AIDS prevention community should move forward following the results of the CAPRISA 004 trial which found that application of 1% Tenofovir gel before and after sex significantly reduced risk of HIV infection in women. Questions raised include: are the data convincing enough to prove 1% Tenofovir is currently effective and safe enough to be made available? How can researchers ensure that future trials maintain appropriate standards of ethics given this new data? How can the effectiveness of 1% Tenofovir be estimated accurately? What remaining questions should new trials seek to investigate? Each of these lingering questions concerning the future of 1% Tenofovir gel are relevant for efforts to develop and test new barrier methods for women-initiated HIV prevention. Please visit the ATHENA Network's website to download the full report: http://www.athenanetwork.org/assets/files/microbicide_0215.pdf.

Upcoming Events

Event: The 19th Meeting of the International Society for Sexually Transmitted Diseases Research

Date: July 10–13, 2011

Location: Quebec City, Canada

Website: <http://isstdr.org/>

Description: The International Society for Sexually Transmitted Diseases Research exists to promote research on sexually transmitted diseases and facilitate the timely exchange of information among research investigators. To these ends, ISSTD sponsors a biennial, interdisciplinary scientific meeting, at venues that historically have alternated between Europe and North America. During the three decades since the Society was founded, the ISSTD meetings have been the premier scientific conferences that address the entire

breath of research on STD, including HIV infections and the acquired immunodeficiency syndrome, and encompassing microbiology, virology, immunobiology, pathogenesis, and other basic sciences; clinical sciences, social and behavioral sciences, epidemiology, and prevention; and research in health services, public health, and prevention policy.

Event: North American Forum on Family Planning

Date: October 22–24, 2011

Location: Washington D.C., U.S.A.

Website: <http://societyfp.org/events/conference.asp#abstracts>

Description: Beginning in 2011, the Society of Family Planning's (SFP) annual meeting will be part of the new North American Forum on Family

Planning, sponsored jointly by SFP and Planned Parenthood Federation of America (PPFA). This two-day meeting, along with the SFP pre-conference Career Development Seminar, is held each autumn in a different city. Session topics include new research and clinical practice issues related to contraception, abortion, STIs, sexuality, and how to translate the best evidence into clinical practice. Additionally, SFP will be the lead partner in managing the scientific abstracts.

Event: American Public Health Association Annual Meeting and Exposition

Date: October 29-November 2, 2011

Location: Washington D.C., U.S.A.

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

Description: The APHA Annual Meeting & Exposition is the oldest and largest gathering of public health professionals in the world, attracting more than 13,000 national and international physicians, administrators, nurses, educators, researchers, epidemiologists, and related health specialists. APHA's meeting program addresses current and emerging health science, policy,

and practice issues in an effort to prevent disease and promote health. APHA has a world of public health in store for you.

Event: Prevention, Pleasure and Protection- International Conference on Female Condoms

Date: November 17-18, 2011

Location: The Hague, the Netherlands

Website: <http://condoms4all.org>

Description: "Prevention, Pleasure and Protection" is a two-day conference that will bring together a multi-disciplinary group of internationally renowned people in the field of female condom programming, from politicians to leaders of community based organizations. The comprehensive conference programme will address several topics connected to female condoms. Successes and lessons learned in research and development, programming, advocacy, and supply chain management of the female condom as well as cross-cutting issues will be discussed and plans for the future can be made. Co-organized by the UAFC Joint Programme in co-operation with Population Services International Zimbabwe and CHANGE Washington.

CBAS Steering Committee

Mags Beksinka: Maternal, Adolescent, and Child Health, Department of Obstetrics and Gynaecology, 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

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 our broader definition includes Lea's shield, female and male condoms, and the sponge. For more information about the range of cervical barrier methods, go to <http://www.cervicalbarriers.org/information/methods.cfm>.

Mission of CBAS

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 (<http://www.ibisreproductivehealth.org>).