

cbas Newsletter

published by the Cervical Barrier Advancement Society

Volume 8, Number 1

February 2011

Report from a Workshop on the Use and Application of the WHO/UNFPA Pre-qualification Scheme for Female Condoms

By Mags Beksinska, MatCH, Trish Coffey, PATH, and Bidia Deperthes, UNFPA (CBAS steering committee members)

In spite of the difficulties faced in bringing new female condoms to market, there has been a resurgence of interest in female condom technology as evidenced by the emergence of several new innovative designs. These manufacturers urgently need more support and guidance to enable them to undertake all the required research and development, quality assurance testing, and clinical trials required to produce quality products and compile the required documentation needed for country regulatory and bulk procurement approvals by international donor agencies such as the United Nations Population Fund (UNFPA).

To assist manufacturers interested in designing and manufacturing new female condoms, UNFPA and the World Health Organization (WHO) Department of Reproductive Health and Research convened a three-day workshop that covered all manufacturer requirements for research, design, development, safety, efficacy, regulation, promotion, and procurement. The workshop was held December 7-10, 2010, in Bangkok, Thailand. Participants included technical experts in the condom field, condom manufacturers, donors, and international NGOs. The primary discussion topics were the technical review process and linkages with the WHO/UNFPA pre-qualification scheme.



Attendees of the December 7-10, 2010, Female Condom Workshop

An overview of the International Organization for Standards (ISO) standard for female condoms as well as the WHO/UNFPA specification for female condoms was presented and discussed. Clinical and non-clinical aspects of testing were reviewed, in particular for manufacturers interested in moving ahead with new female condom designs. The technical component was complemented by presentations and discussions around female condom programming and marketing, including updates on the Female Condom Initiatives, led by UNFPA, as well as programs and activities implemented by the Universal Access to Female Condom Joint Programme (UAFC), the Program for Appropriate Technology in Health (PATH), and Population Services International (PSI).

The meeting ended with concrete plans to move ahead with the WHO/UNFPA female condom technical review process beginning in April 2011. The WHO/UNFPA review process would be transferred to a prequalification scheme once the ISO standard for female condom specification is approved later this year (the vote is currently pending). Clear guidance on how to undertake, analyze, and report on the clinical evaluation of female condoms was disseminated to meeting participants. The publication and dissemination of research data was flagged as an urgent priority—particularly data related to comparative performance of male and female condoms to protect against unintended pregnancy and/or STIs. A key component of this ongoing process would be to increase capacity of national laboratories and regulatory authorities to enable them to move their products through the regulatory process.

Technical experts, donors, and international NGOs met for a fourth day to consolidate an action plan. Priority will be given to creating a strategic plan for female condom market development, gathering information on the global female and male condom market demand, investigating the potential of a patent pool, and facilitating formation of a manufacturers consortium. The creation of a civil society advocacy working group for the female condom was also identified as a key action. Many of the participants had the opportunity to visit *Cabbages and Condoms*, a restaurant that promotes "the health and safety aspects of condom use in a fun and amusing manner." See this link for a peek at some of their condom art creations: www.pda.or.th/restaurant/restaurant.asp. Please contact Mags (mbeksinska@match.org.za), Trish (pcoffey@path.org), or Bidia (deperthes@unfpa.org) for more information about this workshop.

Spotlight on Difficulties Finding Diaphragms in Canada

Natalie Karneef investigates why diaphragms are no longer being made and distributed in Canada in a recent article published in *The Montreal Gazette*. Karneef urges companies to continue offering alternatives to hormonal birth control despite the lack of demand, and points to the need to raise awareness about diaphragms and caps among health care providers and women. To read *The Montreal Gazette* article, please follow this link: www.montrealgazette.com/health/What+want+take+pill/4124300/story.html.

CBAS has received numerous inquiries from women like Natalie searching for alternatives to hormonal methods of contraception since Janssen-Ortho discontinued their diaphragms in Canada in 2008. We are disappointed that there are now fewer options for women in Canada seeking diaphragms and caps for pregnancy prevention. Fortunately, however, the Miletex Wide Seal® diaphragm (www.coopersurgical.com) and the FemCap (www.femcap.com) are still currently available from distributors in Canada. Please see the products pages of our website for more information: www.cervicalbarriers.org/products/.

CAMI's New Multipurpose Prevention Technologies Microbicides and Devices Matrix

The Coalition Advancing Multipurpose Innovations (CAMI) and their Initiative for Multipurpose Prevention Technologies (IMPT) partners have been mapping the Multipurpose Prevention Technology (MPT) for sexual and reproductive health pipeline and developing the MPT Microbicides and Devices Matrix, which illustrates both available and emerging multipurpose prevention technologies for sexual and reproductive health. This online resource outlines indications and other product information and provides links for further information on each multipurpose prevention technology.

The matrix includes two product overview tables, Prevention Targets and Developer/Sponsor, in addition to individual product pages. The products are displayed according to availability and closeness to realization. The tables can be sorted to display the products by product name, stage of development, prevention target, and delivery system. Inclusion in the MPT Microbicide and Devices Matrix requires that products demonstrate, through pre-clinical or clinical studies, successful indication against two or more of the prevention targets listed in the matrix.

Please visit the CAMI website (www.cami-health.org/MPTs/Microbicides-and-Devices.html) for more information and to view this matrix.

Featured Research

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

Reddy female condom: Functional performance of a 90-mm shaft length in two clinical studies

Mauck C, Joshi S, Schwartz J, Callahan M, Walsh T.
Contraception. 2010 (published online ahead of print).

Background: We report on the functional performance, safety and acceptability of the 90-mm Reddy female condom in two clinical trials, one in Los Angeles, CA, and one in Pune, Maharashtra, India. **Study Design:** Both studies used a Phase I, crossover design involving 25 couples. Each couple used three condoms of each of two shaft lengths: in Los Angeles, shaft lengths of 150 and 90 mm were used; in Pune, shaft lengths of 120 and 90 mm were used. This paper focuses on the 90-mm condom since it is commercially available. The primary endpoint of each study was invagination, defined as the outer frame of the condom being pushed into the vagina during intercourse.

Secondary functionality endpoints included non-clinical breakage, clinical breakage, penile misdirection and complete slippage. Results: Invagination occurred in 26.9% of uses in Los Angeles vs. 6.8% of uses in Pune. Penile misdirection and complete slippage were reported only in Pune during 4.0% and 9.5% of uses, respectively. There were two clinical breaks in Pune and none in Los Angeles. Total clinical failure was 26.9% in Los Angeles and 23.0% in Pune. Conclusions: Two clinical studies of the 90-mm Reddy female condom suggest that its functional performance is inferior to other female condoms.

Introducing female condoms to female sex workers in Central America

Mack N, Grey TG, Amsterdam A, Williamson N, Matta CI.

International Perspectives on Sexual and Reproductive Health. 2010; 36(3): 149-156.

Context: Female condoms have a potential role in reducing HIV infection among female sex workers in Central America. Research on how to introduce female condoms to this population is warranted. Methods: Two rounds of focus groups with sex workers (115 in round one and 81 in round two) were conducted in El Salvador and Nicaragua in 2007–2008. In addition, we conducted structured interviews with 95 sex workers and direct observations of six health educators. Results: Women reported that the design of the female condom made insertion and removal difficult to learn. About one-third of participants reported inserting it for the first time alone. Most women reported practicing 2–10 times before feeling skilled enough to use it with partners. Positive perceptions included lubrication, size, comfort, and strength. Negative perceptions included the large package, initial physical discomfort, and the possibility that the device would scare clients away. The participants preferred to learn to use female condoms from an instruc-

tional brochure plus instructor-led training in their workplace. They cited lack of exposure to female condoms among men and women as a barrier to female condom use and recommended education for both men and women; they also recommended distribution of female condoms at places where male condoms are available. Conclusions: If provisions are made for instructing women on female condom use in places where women will not feel stigmatized, and if supplies are easily and consistently available, uptake of the female condom among female sex workers in Central America seems likely. Health educators' use of promotional tools such as checklists and standardized messages is strongly recommended.

Change in condom and other barrier method use during and after an HIV prevention trial in Zimbabwe

van der Straten A, Cheng H, Minnis AM.

Journal of the International AIDS Society. 2010; 13(39): 1-11.

Background: We examined the use of male condoms and the diaphragm following completion of a clinical trial of the diaphragm's HIV prevention effectiveness. In the trial, called Methods for Improving Reproductive Health in Africa (MIRA), women were randomized to a diaphragm group (diaphragm, gel, and condoms) or a condom-only control group. At trial exit, all women were offered the diaphragm and condoms. Methods: Our sample consisted of 801 Zimbabwean MIRA participants who completed one post-trial visit (median lapse: nine months; range two to 20 months). We assessed condom, diaphragm, and any barrier method use at last sex act at enrolment, final MIRA, and post-trial visits. We used multivariable random effects logistic regression to examine changes in method use between these three time points. Results and Discussion: In the condom group, condom use decreased from 86% at the final trial visit to 67% post trial (AOR = 0.20; 95% CI: 0.12 to 0.33). In the diaphragm group, condom use was 61% at the final trial visit, and did not decrease significantly post trial (AOR = 0.77; 95% CI: 0.55 to 1.09), while diaphragm use decreased from 79% to 50% post trial (AOR = 0.18; 95%

CI: 0.12 to 0.28). Condom use significantly decreased between the enrolment and post-trial visits in both groups. Use of any barrier method was similar in both groups: it significantly decreased between the final trial and the post-trial visits, but did not change between enrolment and the post-trial visits. Conclusions: High condom use levels achieved during the trial were not sustained post trial in the condom group. Post-trial diaphragm use remained relatively high in the diaphragm group (given its unknown effectiveness), but was very low in the condom group. Introducing "new" methods for HIV prevention may require time and user skills before they get adopted. Our findings underscore the potential benefit of providing a mix of methods to women as it may encourage more protected acts.

Upcoming Events



Event: The 55th Session of the Commission on the Status of Women

Date: February 22-March 4, 2011

Location: New York, NY, USA

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

Description: The Commission on the Status of Women is a functional commission of the United Nations Economic and Social Council (ECOSOC), dedicated exclusively to gender equality and advancement of women. It is the principal global policy-making body. Every year, representatives of Member States gather at United Nations Headquarters in New York to evaluate progress on gender equality, identify challenges, set global standards and formulate concrete policies to promote gender equality and advancement of women worldwide. The Commission was established by ECOSOC resolution 11(II) of 21 June 1946 with the aim to prepare recommendations and reports to the Council on promoting women's rights in political, economic, civil, social, and educational fields. The Commission also makes recommendations to the Council on urgent problems requiring immediate attention in the field of women's rights.



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Event: 23rd Annual Contraceptive Technology Conference

Date: March 9-12, 2011

Location: San Francisco, CA, USA

Website: www.contemporaryforums.com/en/Live-CE-Conferences/Contraceptive-Technology-San-Francisco/?gclid=CNeAv_re5KYCFRN-5QodInu8zw

Description: Health care reform promises to change health care in America for both consumers and providers. How will it change your practice and the family planning field? Stay until the end of the 23rd annual Contraceptive Technology Conference and you'll find out as you hear Dr. Michael Policar, the go-to expert when it comes to how policy affects hands-on practice. Leading up to his must-hear presentation is an exciting agenda of need-to-know management updates on contraceptives and a variety of GYN conditions and problems.

Event: 23rd Annual Contraceptive Technology Conference

Date: April 13-16, 2011

Location: Boston, MA, USA

Website: www.contemporaryforums.com/en/Live-CE-Conferences/Contraceptive-Technology-Boston/?gclid=CI_9xtKZ5aYCFUdN4AodthH32A

Description: Health care reform promises to change health care in America for both consumers and providers. How will it change your practice and the family planning field? Stay until the end of the 23rd annual Contraceptive Technology Conference and you'll find out as you hear Dr. Michael Policar, the go-to expert when it comes to how policy affects hands-on practice. Leading up to his must-hear presentation is an exciting agenda of need-to-know management updates on contraceptives and a variety of GYN conditions and problems.



Event: 5th South African AIDS Conference

Date: June 7-10, 2011

Location: Durban, South Africa

Website: www.saaid.com

Description: The theme of this AIDS conference is "Leadership, Delivery and Accountability." We have excellent treatment for HIV, but health systems failing in provision of care. We have good data on risk factors for HIV acquisition, but limited agreement on prevention strategies. We have excellent legislation, but evidence of widespread discrimination and stigma. The excitement and relative chaos that has occurred in the last few years, pushed on by the huge, increased funding and passion for changing the system, has meant that we need to pause and reflect.

Upcoming Events



Securing a Healthier Future
in a Changing World

June 13-17, 2011
Omni Shoreham Hotel
Washington, D.C.

Event: Global Health Council's 38th Annual Conference

Date: June 13-17, 2011

Location: Washington, DC, USA

Website: www.globalhealth.org/conference_2011/

Description: Demographic changes have shifted the disease burden. What challenges and innovative solutions are needed to address these transitions? If current demographic changes continue, the average age will be older in most parts of the world than it is today, more people will live in cities, and population growth will have slowed throughout the world except in Africa. These trends naturally result in changes in the burden of disease, most notably a transition from infectious to non-communicable diseases, from acute to chronic disease. This year's conference theme is "Securing a Healthier Future in a Changing World."



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

Date: July 10-13, 2011

Location: Québec, Montreal, Canada

Website: www.isstdrquebec2011.com/en/welcome.aspx

Description: Opinion leaders, researchers, and clinicians from around the world provide leadership in STI/HIV prevention, diagnosis, and treatment. The International Society for Sexually Transmitted Diseases Research (ISSTDR) Québec 2011 will bring them together to share their latest research results, innovation, good practice, and expertise. As the theme of the conference is "From research to intervention: successes and challenges," many sessions at the conference will focus on the use of research results to inform the implementation of better and more efficient clinical and public health practices. The meeting will also focus on rigorous scientific evaluation of clinical and preventive interventions and will emphasize what work best in these fields.

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

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

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).