cbas Newsletter
published by the Cervical Barrier Advancement Society

Volume 15, Number 1 **May 2018**

FEMALE CONDOM NEWS

STATUS UPDATE: US FDA PROPOSED FEMALE CONDOM CHANGES

As we reported in our last issue, in December 2017 the US Food and Drug Administration (US FDA) announced a proposed rule changing the classification and name of the female condom. By the end of the open comment period in February 2018, advocates and individuals submitted over 75 comments and letters to the US FDA in response to the potential changes. Supporters of the proposed rule hope that the name change from "female condom" to "internal condom" will de-stigmatize use of the device for individuals of all gender identities. Similarly, changing the indication to include anal use and reducing the classification of the device from a level III to a level II are intended to better reflect its actual use and the safety demonstrated by the decades of research on the female condom since it originally came to the US market. The comments are now under review. You can read all of the publicly available comments here.

FEMALE CONDOM DOCUMENTARY

In late 2017, production company Smith & Nasht released the documentary film Joyride featuring the development of two new products: the Luvli and the Wondaleaf female condoms. Interviews from colleagues in the field provide history and context for the development of the female condom, and the filmmakers follow Luvli creator Frank Sadlo and Wondaleaf creator Dr. John Tang to explore the experience of developing new female condom products and the barriers faced in bringing them to market.

The Luvli condom has been designed as a "unibody" latex shape using a traditional female condom design, but is free of rings, sponges, or other additional pieces. In contrast, the Wondaleaf designer describes it as a "regional barrier" internal condom with an adhesive polyurethane shield that is applied over the genital region.

The documentary first aired on Australia's ABC2 in December 2017. More information about the film can be found on Smith & Nasht's project page.

RESEARCH DEVELOPMENTS

The full list of ongoing and completed research on cervical barriers and female condoms has been updated to reflect published literature through April 30, 2018.

RECENTLY PUBLISHED RESEARCH

Quaife M, Terris-Prestholt F, Eakle R, Cabrera Escobar MA, Kilbourne-Brook M, Mvundura M, Meyer-Rath G, Delany-Moretlwe S, Vickerman P. The cost-effectiveness of

multi-purpose HIV and pregnancy prevention technologies in South Africa. Journal of the International AIDS Society. 2018 Mar 1;21(3).

INTRODUCTION: A number of antiretroviral HIV prevention products are efficacious in preventing HIV infection. However, the sexual and reproductive health needs of many women extend beyond HIV prevention, and research is ongoing to develop multi-purpose prevention technologies (MPTs) that offer dual HIV and pregnancy protection. We do not yet know if these products will be an efficient use of constrained health resources. In this paper, we estimate the cost-effectiveness of combinations of candidate multi-purpose prevention technologies (MPTs), in South Africa among general population women and female sex workers (FSWs).

METHODS: We combined a cost model with a static model of product impact based on incidence data in South Africa to estimate the cost-effectiveness of five candidate co-formulated or co-provided MPTs: oral PrEP, intravaginal ring, injectable ARV, microbicide gel and SILCS diaphragm used in concert with gel. We accounted for the preferences of end-users by predicting uptake using a discrete choice experiment (DCE). Product availability and protection were systematically varied in five potential rollout scenarios. The impact model estimated the number of infections averted through decreased incidence due to product use over one year. The comparator for each scenario was current levels of male condom use, while a health system perspective was used to estimate discounted lifetime treatment costs averted per HIV infection. Product benefit was estimated in disability-adjusted life years (DALYs) averted. Benefits from contraception were incorporated through adjusting the uptake of these products based on the DCE and through estimating the costs averted from avoiding unwanted pregnancies. We explore the additional impact of STI protection through increased uptake in a sensitivity analysis.

RESULTS: At central incidence rates, all single- and multi-purpose scenarios modelled were cost-effective among FSWs and women aged 16-24, at a governmental willingness-to-pay threshold of $1175/DALY averted (range: $214-$810/DALY averted among non-dominant scenarios); however, none were cost-effective among women aged 25-49 (minimum $1706/DALY averted). The cost-effectiveness of products improved with additional protection from pregnancy. Estimates were sensitive to variation in incidence assumptions, but robust to other parameters.

CONCLUSIONS: To the best of our knowledge, this is the first study to estimate the cost-effectiveness of a range of potential MPTs; suggesting that MPTs will be cost-effective among higher incidence FSWs or young women, but not among lower incidence older women. More work is needed to make attractive MPTs available to potential users who could use them effectively.

ABOUT US

Mission of CBAS

Established in 2004, the Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods, including diaphragms, caps, female condoms, and other devices, and to share the latest news and resources related to these methods.

CBAS contact information

For more information, contact Laura Fix, CBAS Executive Director, at info@cervicalbarriers.org.

CBAS is coordinated by Ibis Reproductive Health.

Ibis Reproductive Health

www.ibisreproductivehealth.org

Note: We are always updating our research listings on the CBAS website. Please contact us at info@cervicalbarriers.org with study updates or information on new research related to cervical barriers or female condoms.

Join CBAS

- Subscribe/Unsubscribe to CBAS newsletter only
- Archives of the CBAS newsletter

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