

Woman's Condom

Health need

The World Health Organization (WHO) estimates 499 million new infections of curable sexually transmitted infections occur each year. In 2011, an estimated 2.5 million people became newly infected with HIV, with heterosexual contact as one of the primary modes of transmission. Women represent slightly more than half of the 34 million people living with HIV worldwide, and 60 percent of this population is in sub-Saharan Africa. In addition, some 86 million unintended pregnancies occur annually. Complications associated with pregnancy and childbirth claim the lives of an estimated 287,000 women each year, and unsafe abortion accounts for a high percentage of maternal deaths. Many women lack power over sexual decisions; they are not in a position to ask their partners to abstain from sex with others or to use male condoms. An estimated 222 million women wish to delay or space their pregnancies but do not have access to modern contraceptives.

Technology solution

A female condom can protect against sexually transmitted infections, including HIV, as well as pregnancy. Experience with currently marketed female condoms has shown that women and men are interested in and will use these barrier devices if they are acceptable and easy to use. With user input from several countries, PATH designed the Woman's Condom to be more acceptable to use for both partners. Couples evaluated prototypes and offered design suggestions to improve acceptability, thus making it more likely that the barrier will be used consistently and properly. The Woman's Condom is comfortable and easy to use. Its unique design features enable easy insertion, secure fit during use, good sensation, and easy removal.

Current status and results

In 2008, PATH transferred production of the Woman's Condom to the Dahua Medical Apparatus Company (Dahua) in Shanghai, China. Dahua has received the South Africa Bureau of Standards certification mark (2013), Shanghai Food and Drug Administration approval (2011), and CE Mark approval (2010)—allowing for distribution and marketing in South Africa, China, and Europe. The Woman's Condom is currently under review by the WHO/United Nations Population Fund Technical Review Committee; the committee's approval could lead to bulk public-sector purchase by United Nations agencies. Two clinical studies of performance and safety have been implemented recently, these results will be available for additional regulatory applications: a contraceptive effectiveness study (2011-2013) by the Eunice Shriver National Institute of Child Health and Development (NICHD) and a comparative study of performance and failure mode of Woman's Condom compared to the FC2 female condom (2011-2012) by CONRAD.

In 2011, PATH received funding from the Netherlands Ministry of Foreign Affairs to support the Protection Options for Women (POW) product development partnership. With this funding, we and our POW partners—CONRAD, Dahua, and NICHD—are increasing protection options, verifying safety and efficacy, and developing markets for the Woman's Condom. Initial introduction activities for the Woman's Condom are being conducted in China and South Africa.



PATH/Glenn Austin

A next-generation female condom.

“The participants rated the Woman's Condom better than two [other products] in terms of appearance, ease of use, and overall fit, and better than [another product] in terms of feel.”

Joanis C, Beksinska M, Hart C, et al. Three new female condoms: which do South-African women prefer? *Contraception*. 2011;83:248–254.

Availability

For more information regarding this project, contact Patricia Coffey at pcoffey@path.org.

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