

Couples' use of Woman's Condom in China: results from a performance, safety, and acceptability study

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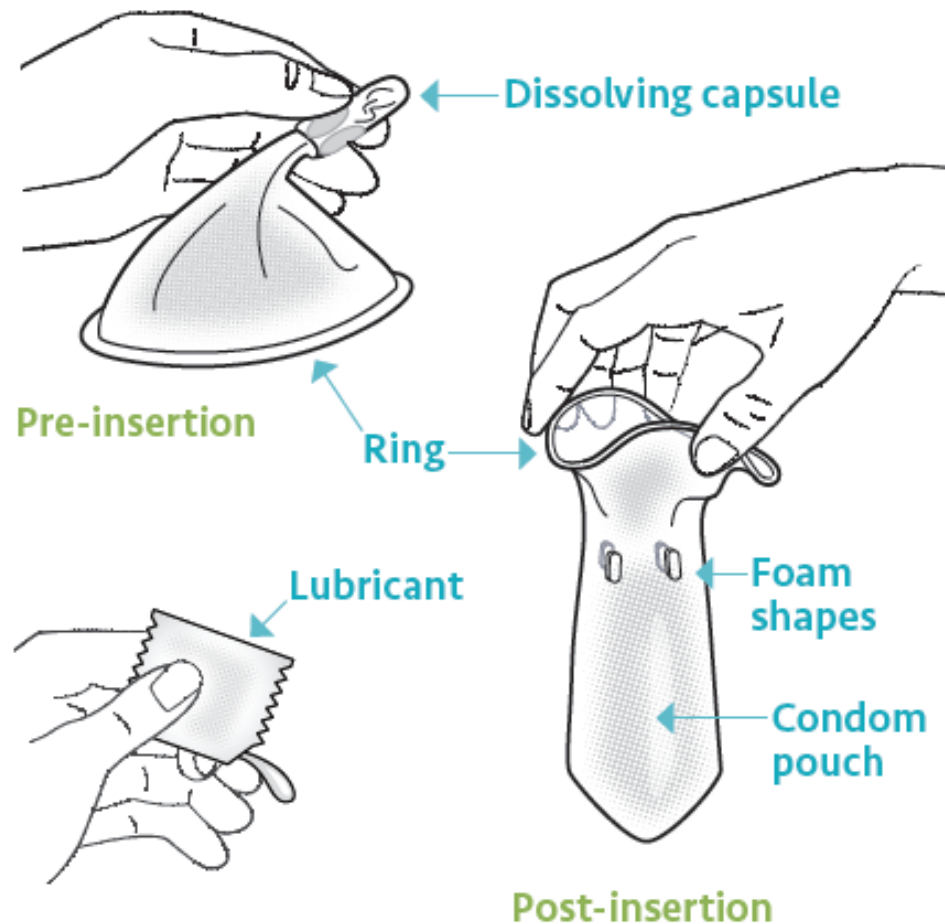
Woman's Condom – designed and validated through user-centered development process

Performance objectives:

- Easy to handle and insert
- Easy to use (especially for new users)
- Stable during use
- Comfortable for both partners
- Easy to remove



Woman's Condom – unique features allow ease of use and good sensation



Woman's Condom acceptability and performance confirmed in multiple studies

Three-country design verification study¹

- Majority of users found the device comfortable, easy to insert, and stable during use.

US Phase I comparative performance, failure mode, and safety study²

- Woman's Condom had fewer failures and less slippage, and it was preferred by men and women when compared with FC1.

South Africa comparative performance and acceptability study³

- Woman's Condom performed well and was preferred over two other female condom designs.

1. Coffey P, Kilbourne-Brook M, Austin G, et al. Short-term acceptability of the PATH Woman's Condom among couples at three sites. *Contraception*. 2006;73:588–593.
2. Schwartz J, Barnhart K, Creinin M, et al. Comparative crossover study of the PATH Woman's Condom and the FC Female Condom. *Contraception*. 2008;76:465–473.
3. Joanis C, Beksinska M, Hart C, et al. Three new female condoms: Which do South African women prefer? *Contraception*. 2011;83:248–254.

Formative research: 18 FGDs with potential user groups in preparation for Phase I study

- University students (F/M)
- College-educated professionals (F/M)
- Married couples (F/M)
- Migrant workers (F/M)
- Women in the entertainment industry



- Conducted in collaboration with Shanghai Institute of Planned Parenthood Research

Photo credit: iMorpheus flickr

FGD Participant Characteristics (n=130)

- 100% Han ethnicity; most were highly educated.
- About 50% used contraception (rates varied by group).
 - Highest rates: migrant women, married women, women in the entertainment industry.
 - Female students had much lower rates of contraceptive use.
- Low awareness of female condoms.
- Male condom used for contraception, not for STI prevention.
- Very low perception of risk of STIs.



Photo credit: PATH/Willow Gerber

FGD Key Findings

- Men expressed more willingness to use a female condom than women.
- Men expressed positive images about the Woman's Condom: *“fresh, mystical, brilliant, exquisite.”*
- Women's lack of interest possibly related to satisfaction with existing contraceptive method and perceived lack of risk for STIs.
- Women's concerns: unsure about insertion, partner's satisfaction, use of lubricant.
- Migrant women and women in the entertainment industry were most motivated to use Woman's Condom.

“Women can use it by ourselves; that's reassuring.”

Performance and failure mode study summary

- **Study design:** single-arm, multisite, non-blinded study implemented among 60 couples in Shanghai.
- **Research sites:** Shanghai Institute of Planned Parenthood Research and Fudan University OB/GYN Hospital.
- **Primary endpoints:** clinical and nonclinical failures, safety, and acceptability.
- **Data collection methods:** surveys completed after each product use; SMS text message after each product use; debrief interview after four product uses.

Performance and failure mode study: participant characteristics

- **Age:** (F) 25-55 years; (M) 27-57 years
- **Duration of current partnership:** average of 13 years
- **Education:** Over 70% completed junior high school; almost 50% of women attended university; about 30% of men attended university
- **Employment:** 70-80% of M/F were company or factory workers
- **Current contraceptive method use:** IUD, Oral Contraceptives
- **Previous female condom use:** None

Key Failure Modes for Female Condoms

- ***Clinical Breakage*** is defined as a female condom that breaks during intercourse or removal of the condom from the vagina
- ***Misdirection*** is defined as vaginal penetration whereby the penis is inserted between the female condom and the vaginal wall
- ***Invagination*** is defined as part or all of the external components of the female condom being pushed into the vagina during intercourse.
- ***Slippage*** is defined as a female condom that slips completely out of the vagina during intercourse.

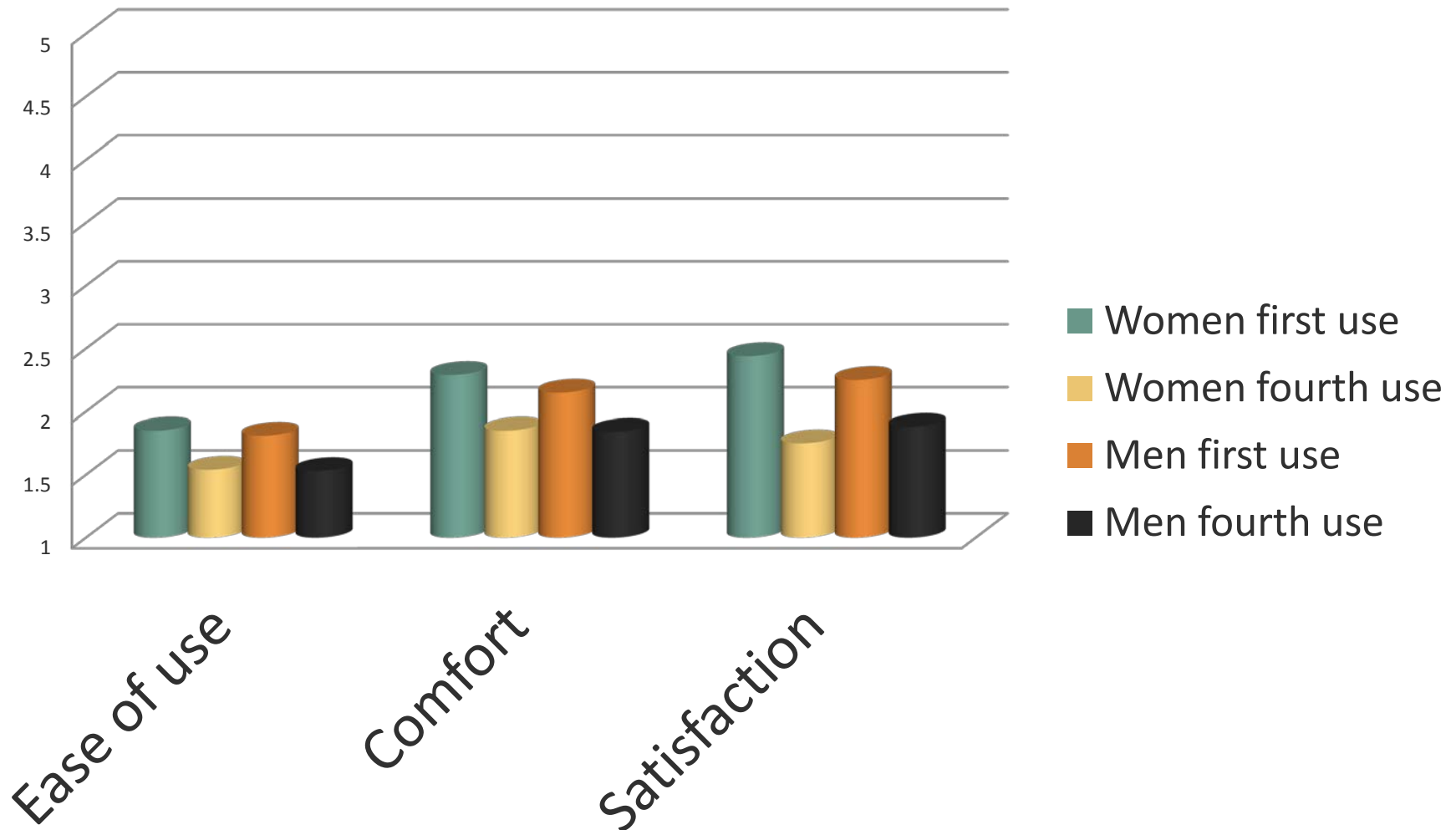
Clinical performance of Woman's Condom

Failure modes				
	Condoms	Events n (%)	Couples	Events n (%)
Total breakage	236	2 (1)	59	2 (3)
Nonclinical breakage	236	2 (1)	59	2 (3)
Clinical breakage	234*	0 (0)	59	0 (0)
Misdirection	234	5** (2)	59	2 (3)
Invagination	234	2† (1)	59	0 (0)
Slippage	234	3 (1)	59	3 (5)

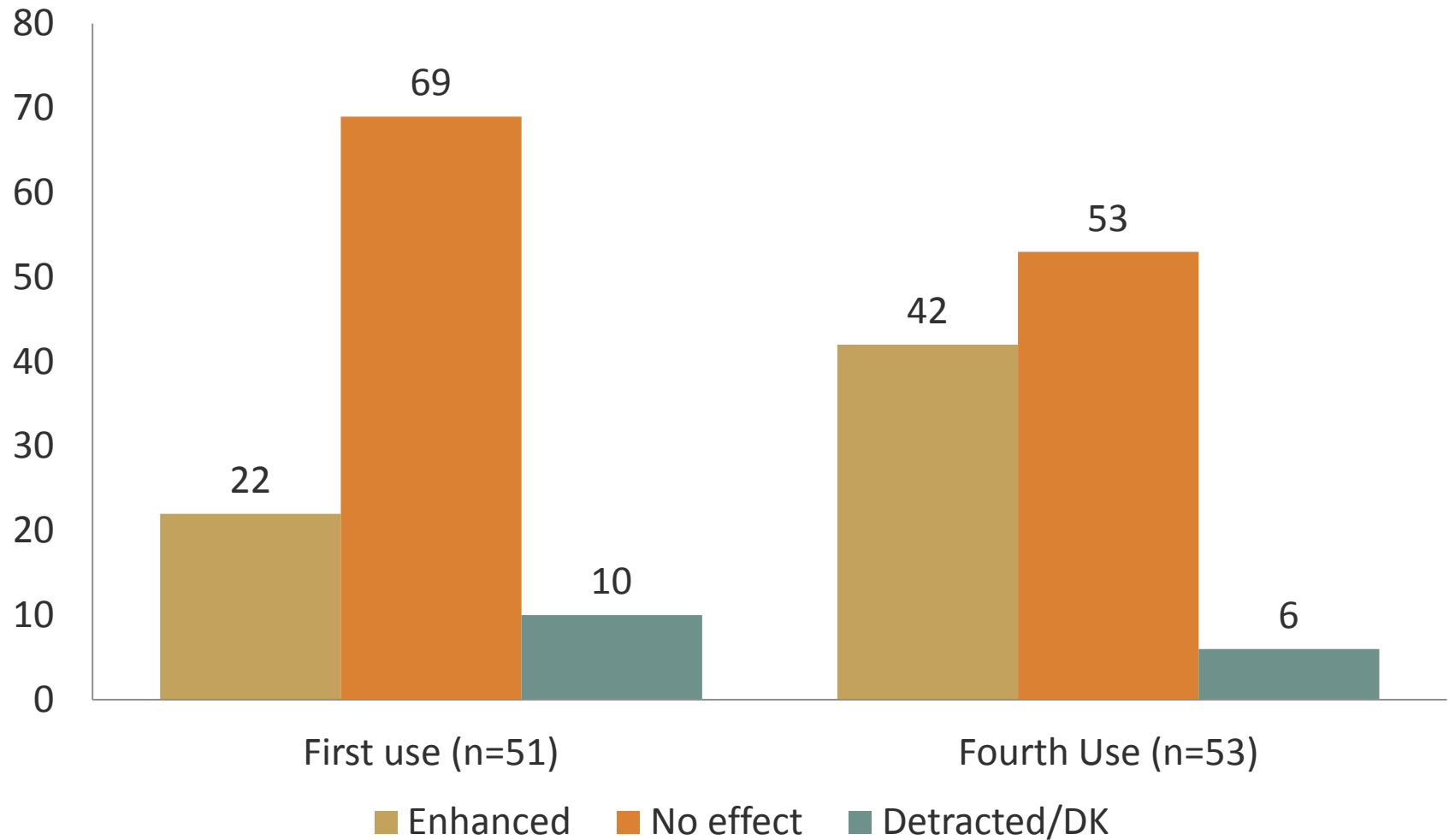
Adverse events by condom, female and male users

	Condoms used (n=234)	Women (n=59)	Men (n=59)
	With event, n (%)	With event, n (%)	With event, n (%)
Type of event			
Genital pain/discomfort	3 (1)	2 (3)	0 (0)
Burning, stinging, or pressure while urinating	4 (2)	2 (3)	0 (0)
Genital itching	7 (3)	2 (3)	2 (3)
Genital irritation/rash	1 (0.4)	0 (0)	1 (2)

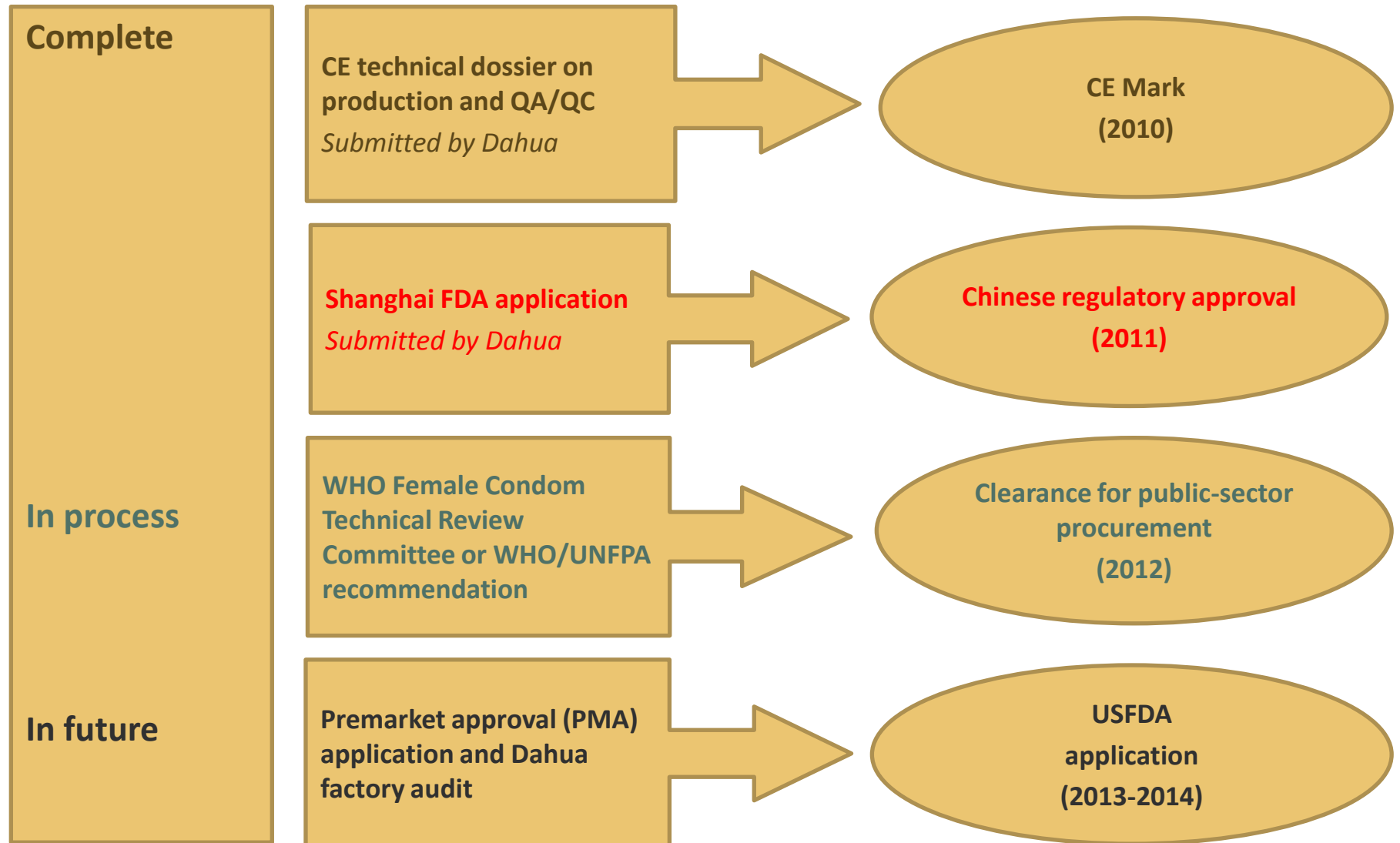
Trends in acceptability for female and male users



Effect of lubricant on sexual experience by percent of female users



Regulatory strategy



Key lessons learned

- Formative research helped prepare the researchers for the couples' use study.
 - Explored product perceptions; pretested the user instructions, developed language to describe the product.
- Important to liaise with regulatory authority regarding size/type of study necessary for market approval.
- Woman's Condom performed comparable to other female condom designs.

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Photo credit: PATH/Glenn Austin