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Expanded Retrospective:
Internal Condom

This retrospective was developed to inform Discerning Demand: A Guide to Scale-Driven Product Development and Introduction, a publication developed by the Center for Innovation and Impact, USAID that explores how global health practitioners (including funders, investors, innovators, implementing partners, etc) can better account for actual demand of new products. This retrospective is an in-depth historical analysis of how demand for this product was understood by different stakeholders supporting its development and introduction. The insights generated from this retrospective informed the recommendations in the full report.

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1. Introduction

1.1. Product Summary

Internal condoms are single-use contraceptive devices that are inserted into a woman's vagina before sexual intercourse. They are a woman-initiated tool developed for preventing unintended pregnancies, the spread of HIV, and other STI transmission. One manufacturer, Female Health Company (FHC), controls more than 90% of the market. The PATH Woman's Condom (WC) was designed by global health stakeholders to offer a new internal condom that addressed concerns with acceptability identified through the use of FHC products.

1.2. Fast Facts

Fast Facts (Note: sources noted in retrospectives)	Internal condom (IC)
Health Area	Family planning and HIV prevention
Market Archetype	New product with few suppliers
CII Global Health Innovation Index	Transformative
Expected Buyers/Procurers	Global Fund, PEPFAR, UNFPA
Funders	USAID, KfW Dvt Bank, UK Foreign, Commonwealth & Development Office
Countries	FC2 is available in more than 54 countries globally
Manufacturers	Female Health Company, Cupid Limited, HLL Lifecare
Intended Delivery Setting	Public clinics and hospitals, mostly for HIV prevention
Cost	$0.31-$0.50 per condom
Uptake	Less than 2% of women of reproductive age using contraceptive methods

Fast Facts (Note: sources noted in retrospectives)	Path Woman's Condom (WC)
Manufacturer	Shanghai Dahua (manufacturing discontinued)
Cost	$0.80-$1.41/condom
Funder	USAID, BMGF, Netherlands Ministry of Foreign Affairs

Fast facts sources: Innovation Index[2],Countries[3],Internal Condoms Cost[4],Uptake[5],PATH WC Cost.[6]

1 In 2018, the FDA started using the term 'internal condom' rather than 'female condom' to recognize that men who have sex with men as well as people of diverse gender identifies like to use this product: FDA, HHS. Obstetrical and Gynecological Devices; Reclassification of Single-Use Female Condom, To Be Renamed Single-Use Internal Condom. Final order. Fed Regist. 2018;83(188):48711-3.

2 USAID Center for Innovation & Impact. Global Health Innovation Index – A tool for identifying the most promising Global Health Innovations. Washington DC, USAID 2020.

3 Female Health Company Website. Link. Accessed Dec 15, 2022.

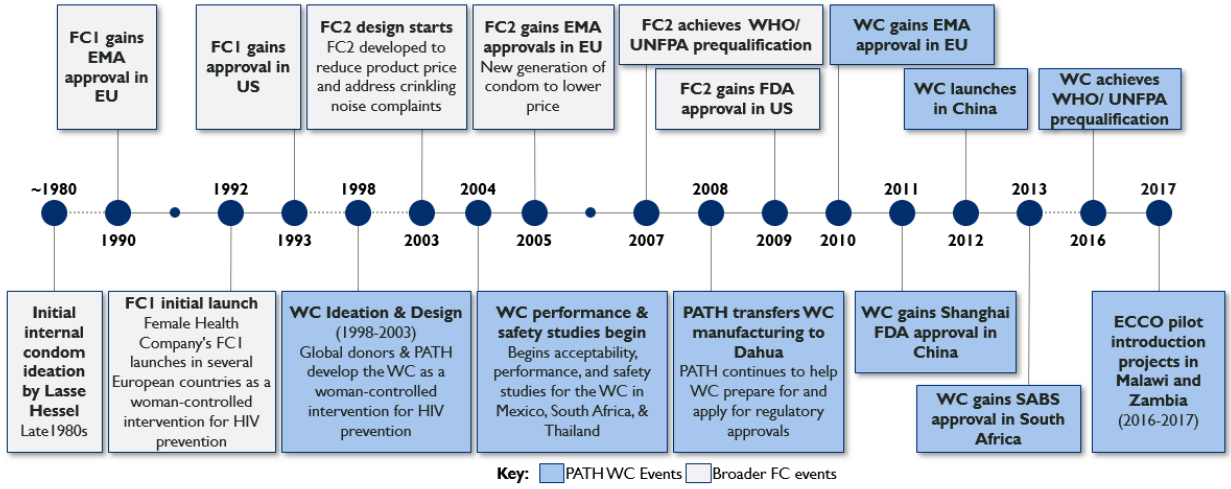
4 UNFPA. UNFPA Contraceptive Price Indicators. New York: UNFPA 2021.

5 UN. Contraceptive Use by Method 2019 Data Booklet. New York: UN 2019.

6 Mvundura M, Nundy N, Kilbourne-Brook M, Coffey PS. Estimating the hypothetical dual health impact and cost-effectiveness of the Woman's Condom in selected sub-Saharan African countries. Int J Womens Health. 2015 7:271-7.

2. Demand Story

2.1. Product Development Timeline



Abbreviations: EECO, Expanding Effective Contraceptive Options; EMA, European Medicines Agency; FC1, 1st generation Female Health Co. condom; FC2, 2nd gen Female Health Co. condom; SABS, South Africa Bureau of Standards; WC, PATH Woman's condom

Internal Condom

The internal condom was developed in the mid-1980s as a single-use contraceptive device to be inserted into a woman's vagina before sexual intercourse for dual purpose use: prevent unintended pregnancies and reduce STI transmission. Though the product was originally designed as a contraceptive method, the internal condom was positioned as an HIV-prevention tool due to an increase in the number of women that were being infected with HIV. FHC, a US-based manufacturer, obtained the worldwide rights to the patented product and quickly emerged as the dominant market leader for internal condoms.[1] FHC's first-generation internal condom (FC1) was launched in Europe and the United States in 1992 and 1994, respectively. FC1 was subsequently distributed around the world under different names in different markets, with a price point of around $0.55. Many brands (FC2, Velvet, Cupid) are now available in high-, middle-, and low-income markets at varying prices and through different funding channels. In LMICs, the internal condom, if available, is primarily purchased through out-of-pocket means.

Demand Challenges

As the only woman-initiated method for HIV prevention, uptake in LMICs affected by HIV was expected to be high. However, the internal condom faced numerous challenges.

- **No clear funding champion:** The internal condom lacked the programmatic champions, advocacy, and funding efforts that normalized the male condom during the AIDS crisis of the 1980s. Global internal condom distribution increased from 13.5 million to 50 million between 2005 and 2009 as part of successful scale-up campaigns led by various donors with a focus on HIV prevention.[2] The Family Planning (FP) community began to focus on increasing access in LMICs to long-acting reversible contraceptives (LARCs) such as injectables and implants (recommended by the American College of OBGYNs as first-line contraceptive methods in 2009)[3] that were widely available and used in HICs. The HIV prevention community lost interest as coital-independent methods came to market, such as VMMC (recommended by WHO in 2007),[4] test-and-treat (introduced in 2009),[5] and eventually oral

1 WHO, UNFPA, FHI360. Female Condom: Generic Specification, Prequalification. Geneva: WHO 2012.
2 UNFPA. HIV Prevention Gains Momentum: Success in Female Condom Programming. New York: UNFPA 2011.
3 Shoupe D. LARC methods: entering a new age of contraception and reproductive health. Contracept. Reprod. Med 2016.
4 UNAIDS. Voluntary male medical circumcision. Geneva: UNAIDS 2021.
5 Granich RM, et al. Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model. The Lancet 2009; 373: 48–57.

PrEP (introduced in 2012)[6], which weakened the relevance of the internal condom because these did not require women to negotiate with their partners and had a much larger user base. Though the internal condom remained recommended as part Family Planning (FP) and HIV programs, there was limited programmatic funding to support the demand generation and education among HCWs in both Family Planning (FP) and HIV service points. As a result, the internal condom was not seen as a priority intervention and ultimately struggled to get large-scale adoption, particularly as newer (and distinct FP and HIV) tools came to market.[7]

- **Misunderstanding of end-user preferences and needs:**
    - Because the focus of the product was HIV prevention, introduction in LMICs focused disproportionately on key populations such as female sex workers for feasibility and acceptability studies (there were more than 100 studies of this population) due to higher risk of acquired infection. Efforts to subsequently expand the product to the general population of women fell short of expectations, in part because there was limited effort to assess acceptability among broader populations and too narrow focus in the initial introduction.
    - End-users and partners expressed discomfort with various aspects of FC1, including insertion, removal, fit, and packaging, which were not assessed prior to launch. The sheer size was a concern for many end-users.
    - User promotion language that was suitable in North America and Europe was perceived as threatening in LMICs due to differing norms and ideas about women empowerment.
- **Insufficient funding for demand activation activities:** Internal condom introduction was not accompanied by the same level of demand activation activities as the male condom or other FP products. New FP products typically require investment for training and demonstrations to ensure beneficiaries and health providers are fully informed about the range of contraceptive choices.[8] Despite a number of successful small-scale efforts,[16] neither HIV nor FP advocates were able to identify sustainable funding for marketing campaigns, HCW education and training, or behavior change. This left providers without the time or skills to demonstrate use of the internal condom or promote to end-users, in contrast with other alternatives.[9]
- **Inaccurate comparisons to the male condom:** Demand expectations of the internal condom were inaccurately informed by uptake of the male condom, despite differences in end-user attributes, notably gender. This comparison likely led to inappropriate demand-sizing and overestimation of uptake.

PATH Woman's Condom

From 1998 to 2003, USAID and PATH developed the Woman's Condom (WC) as an internal condom brand that not only offered a woman-controlled intervention for HIV prevention, but also addressed key user-related issues with FC1 posed by women in LMICs: ease of use (especially for new users), stability during use, comfort for both partners, ease of removal, and cost concerns. PATH targeted $0.25 per device[10] and used a HCD approach to support ideation and design, developing and testing over 50 design iterations with over 200 women representing the broader population, not just female sex workers or key populations.[11] Ultimately, they partnered with Dahua Medical, a new manufacturer in China, to develop the product.

PATH WC Challenges

- During R&D for the PATH WC, FHC began designing a second-generation condom (FC2) to improve the affordability of their product. FHC was able to make FC2 available to the public sector at a price about 30% lower

6 AVAC. PrEP. New York: AVAC 2012. Accessed Dec 2, 2022.

7 This trend is also highlighted in the decrease of procurement of internal condoms by global procurers (Reproductive Health Supplies Coalition. Reproductive Health Supplies Visualizer. Belgium: RHS Supplies 2022. Accessed Dec 2, 2022.

8 Evans WD, Ulasevich A, Hatheway M, Deperthes B. Systematic Review of Peer-Reviewed Literature on Global Condom Promotion Programs. International Journal of Environmental Research and Public Health. 2020; 17(7):2262.

9 Frost LJ, Reich, MR. Access: How do good health technologies get to poor people in poor countries? Cambridge: Harvard University Press; 2008.

10 Coffey PS, et al. Short-term acceptability of the PATH Woman's Condom among couples at three sites. Contraception 2006; 73: 588–593.

11 Coffey PS, Kilbourne-Brook M. Using human-centred design to develop an innovative female condom. BMJ Innovations 2021; 7: 399–406;PATH. "Using human-centered design to develop a female condom that meets users' needs". Seattle: PATH 2015. Accessed Nov 14, 2022 .

than FC1 by switching the product material from polyurethane, which is labor-intensive to manufacture, to a proprietary nitrile polymer that was manufactured using a highly automated process. They also solved the issue of a "crinkling noise" that users complained about but did not address many of the other end-user concerns.[12]

- Despite addressing many end-user concerns, the WC—which was ultimately priced at $0.80—was undesirable to price-conscious public sector donors relative to FC2 and the Cupid condom. Ultimately, no purchases were placed through GH donor or government funding as originally anticipated.

- PATH attempted to pivot its go-to-market strategy from the public to the private sector by positioning the WC as a luxury product in South Africa and China[13], targeting customer segments with disposable income willing to pay for a better consumer experience. Due to lack of marketing investments required to reach and entice the target population, this strategy resulted in limited orders. Dahua decided to stop manufacturing the WC in 2017.

3. Learnings

Four key learnings from the demand story:

1. Need for funding allocated to demand-activation activities

[Relevant to both the internal condom and PATH WC]

Recall the challenge: Limited funding was allocated early on for demand activation, including training end-users to use the product, educating HCWs, distribution outside of the public sector, and marketing or social media campaigns, relative to the male condom and other distinct HIV prevention and FP interventions.

Forward-looking learning: For new products, especially those for which there might be a strong stigma, significant funding needs to be allocated up front to train end-users and HCWs. Funding should be sustained beyond initial scale-up to increase awareness and normalize use.

2. Need for a strong value proposition relative to other options

Recall the challenge: The lack of clear perceived value proposition in comparison to the new HIV prevention methods led to decreased interest among advocates (and buyers) for the product. FP advocates considered LARCs to be equally relevant as discrete, woman-controlled interventions and more efficacious than the internal condom. HIV prevention advocates were more interested in biomedical prevention interventions as they emerged such as VMMC, test-and-treat, and oral PrEP.[14] More broadly, the lack of champions for multi-purpose products weakened advocacy for the internal condom.

Forward-looking learning: Identifying KOLs and funding champions early on is essential for activating demand in later stages of product development, especially when new products and treatments are in the pipeline and end-users will be faced with many options to choose from.[15] If these funding champions are not readily available, perhaps donors should consider whether pursuing the later stages of product development is a worthwhile investment.

3. Inappropriate demand sizing and customer segmentation

Recall the challenge: Initial demand estimates for the internal condom were based on comparisons with the male condom despite significant differences between women and men. This led to overestimations of potential demand. Efforts to expand internal condom use were stymied by misguided promotional efforts that inadvertently stigmatized the product and unintentionally created the perception that women who use the internal condom are promiscuous.

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12 Gallo MF, Kilbourne-Brook M, Coffey PS. A review of the effectiveness and acceptability of the female condom for dual protection. Sexual Health. 2012; 9: 18–26.

13 The Protection Options for Women Product Development Partnership (POW PDP) | 2011-2015 (2015) Developing sustainable markets for the Woman's Condom. Seattle: POW PDP 2015; Introducing V Condom to South Africa: Expanding the female condom market. Seattle: POW PDP 2015; Introducing O'Lavie Woman's Condom to China: Expanding dual protection options. Seattle: POW PDP 2015.

14 As of December 2022, there are several long-acting multi-purpose technologies in the R&D pipeline. These may further affect the internal condom's value proposition.

15 UNFPA. Developing effective condom programmes. New York: UNFPA, 2020.

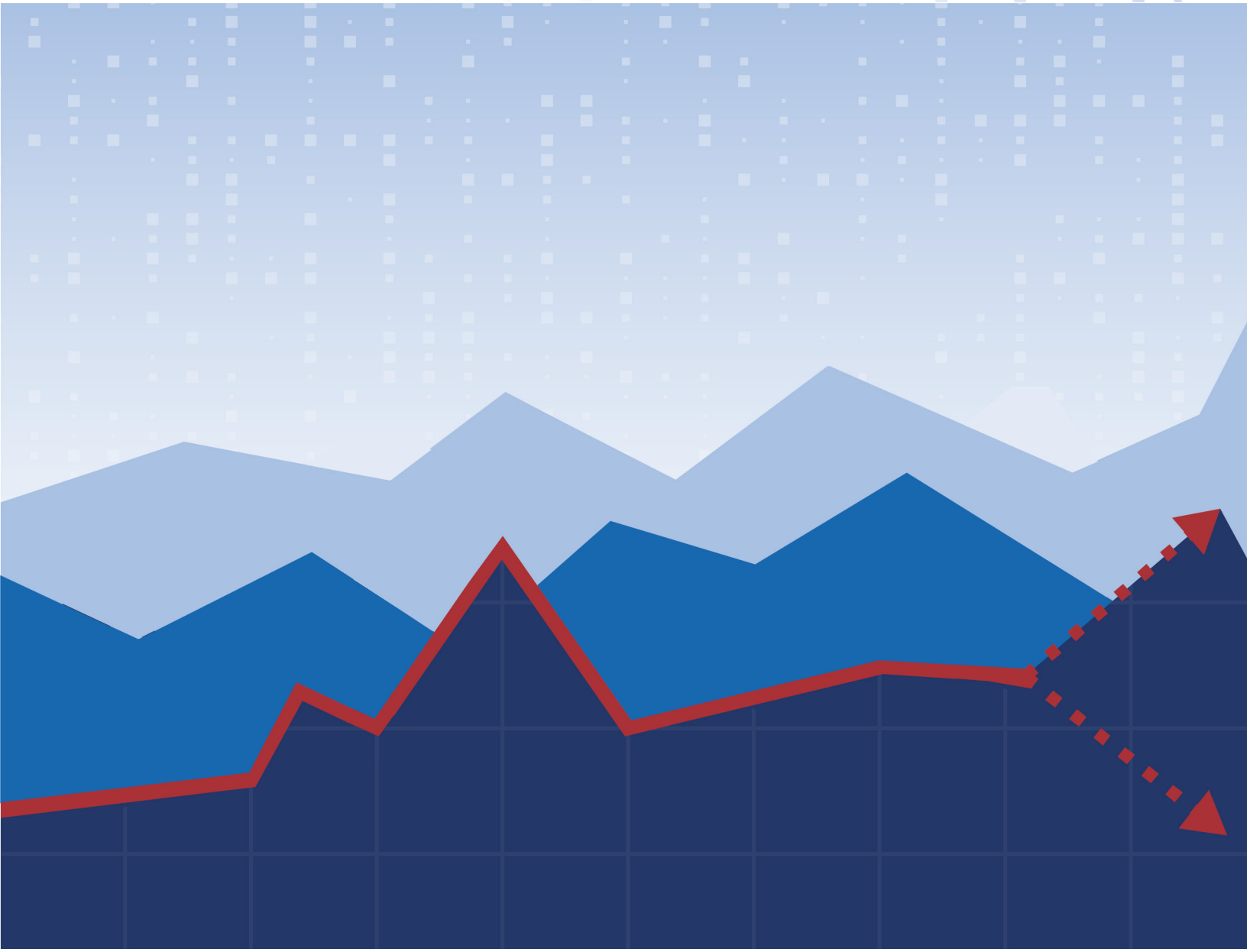
Forward-looking learning: Double- or triple-check assumptions on the user when designing forecasts. Product introduction strategies may evolve over time. When they do, any changes in target customers (both users and payers, if they are distinct) need to be accompanied by investments that inform decisions on whether further investments in product promotion are worthwhile.

4. Misalignment between user and payer needs

[Relevant to PATH WC]

Recall the challenge: While it met usability concerns, PATH WC could not meet price expectations of global payers, especially in comparison to other, more affordable products at the time.

Forward-looking learning: If a product does not meet target payer expectations then innovators should explore alternative go-to-market strategies to reach intended clients, adapt the product or deprioritize further development.



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