Developing sustainable markets for the Woman's Condom

PROTECTION OPTIONS FOR WOMEN PRODUCT DEVELOPMENT PARTNERSHIP

POW PDP | 2011–2015

PATH

上海达华医疗器械有限公司
Shanghai Dahua Medical Apparatus Co., Ltd

The POW PDP Partners

The Protection Options for Women Product Development Partnership (POW PDP) was created to promote sexual and reproductive health, including the prevention of HIV/AIDS, by expanding access to the Woman's Condom. The POW PDP was supported by funding from the Netherlands Ministry of Foreign Affairs from 2011 to 2015.

PATH, an international nonprofit health organization, led decisions related to manufacturing, market development, and advocacy. Through PATH's country program offices in China and South Africa, PATH staff worked directly with country partners on market research, market tests of uptake and acceptability, and advocacy to raise awareness for female condoms in general, and for the Woman's Condom specifically.

Shanghai DAHUA Medical Apparatus Co., Ltd (DAHUA) in China led Woman's Condom manufacturing production scale-up activities. They also led market development activities for the private sector in China. PATH licensed the Woman's Condom to DAHUA for manufacturing and commercialization.

CONRAD is a United States–based nonprofit organization that facilitates rapid development of safe, acceptable, affordable products for contraception, HIV, and other sexually transmitted infections. CONRAD is the regulatory sponsor of the Woman's Condom and developed and implemented the clinical study, A Randomized Cross-Over Study of Vaginal Semen Exposure and Clinical Failure Comparing the PATH Woman's Condom and the FC2 Female Condom. This study was funded directly from the United States Agency for International Development (USAID) to CONRAD.

***Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)** is a health research agency within the US government. NICHD conducts and supports clinical trials and other types of research that explore health and the process of human development from conception to old age. NICHD developed and implemented the clinical study, A Multicenter, Open-Label, Non-Comparative Study of the Safety and Contraceptive Efficacy of the Woman's Condom. Data from this study will become part of the Woman's Condom technical dossier and will assist in regulatory submissions. This study was funded directly by the US government through NICHD.

Photos on cover: (left) iStock, (middle and right) PATH/Patrick McKern

Contents

The female condom challenge

Rates of unintended pregnancy, maternal mortality, and HIV and other sexually transmitted infections (STI) among women are unacceptably high around the world. An estimated 225 million women in developing countries have an unmet need for contraception, and women comprise 50 percent of adults living with HIV globally. Each year an estimated 500 million people become infected with a curable STI.

The female condom is the only woman-initiated technology available today that provides dual protection from both unintended pregnancy and sexually transmitted infections, including HIV. Female condoms also provide an option for women seeking contraceptive protection without hormones or side effects, they can be used only when needed and without seeing a health provider, and they can enhance communication and sexual pleasure for some couples. Female condoms also empower women with a tool to initiate safer sex.

While female condoms have been available for 20 years, availability and use of this lifesaving product around the world has remained low. Although global frameworks and national policies recognize female condoms as a vital component of family planning and STI/HIV prevention programming, country governments and donors have only partially implemented these policies—primarily due to limited funding, competing budget priorities, and lingering questions about the product category. Investment to support training, programming, and market development—including demand generation—has been insufficient. Female condoms have not yet been fully embraced by many family planning or STI/HIV prevention programs, which has hindered access and use.

Photos: (top left) PATH/Patrick McKern, (bottom and top right) PATH, (middle right) iStock/Susan Chiang

An evolving landscape for a maturing product

Despite these challenges, the female condom field has grown and matured over the past decade. New products are coming to market. International standards for research and manufacturing guidelines for testing product quality have been developed, which harmonize quality standards and strengthen the product category. At the same time, through support from international donors and a few key country governments, global distribution of female condoms has more than quadrupled, reaching a record high of more than 60 million units in 2012.

As a product, the female condom still has a long road to attain a market share equivalent to user need. Bringing a new medical device like the Woman's Condom to market while concurrently building supply is a complex and challenging process that requires a wide range of activities—from establishing manufacturing and production quality assurance, to completing clinical trials, to regulatory approvals and development of local and global markets. However, the commercial market for female condoms is still in its infancy, and most of the existing female condom market is rooted in public-sector procurement programs that secure and distribute the product through free public programs or social-marketing avenues that tend to be heavily subsidized. Within this challenging landscape, over the course of five years, the Protection Options for Women Product Development Partnership (POW PDP) accelerated access to the Woman's Condom, a new female condom designed for improved acceptability and use, and worked toward building a more sustainable female condom market overall by focusing on three key priorities:

building supply, evidence, and demand.

POW PDP and the Woman's Condom

A product development partnership to support options for women

In 2011, PATH received funding from the Netherlands Ministry of Foreign Affairs to support the Protection Options for Women Product Development Partnership (POW PDP). From 2011 through 2015, this global partnership applied total market approach strategies to create sustainable markets for the Woman's Condom. The project implemented a set of strategic, step-wise activities critical to introducing and building demand for this new product, including supporting production scale-up and regulatory applications, market research and market testing to prepare for early introduction and commercialization, building evidence through research, and advocacy at the global and country levels to strengthen the perception of female condoms in general—and the Woman's Condom specifically. Country-specific work focused on China and South Africa.

Placing users at the center of product development

The Woman's Condom was designed through a user-centered process to address consumers' desire for a product that provides protection and is simultaneously acceptable and pleasurable for both partners. The Woman's Condom's special design features enable easy insertion, secure fit during use, good sensation, and easy removal.

With funding from the United States Agency for International Development (USAID), PATH and its research partners developed the Woman's Condom over a six-year period (1998–2003) with input from women and couples on four continents. Engaging users as co-designers resulted in a female condom that meets the needs of women and men from diverse regions. Through formative research with women's groups, health care providers, and other stakeholders, PATH identified performance objectives required for a new female condom design that could address consumer needs for acceptability and ease of use. The performance objectives below set the benchmark against which prototype designs were evaluated by users:

- **Easy to handle and insert**
- **Easy to use (especially for new users)**
- **Feels good during sex**
- **Comfortable for both partners**
- **Does not slip or move during use**
- **Easy to remove**

Women and their partners and family planning providers from Mexico, South Africa, Thailand, and the United States were active participants in evaluating the Woman's Condom during the development phase. Their feedback throughout the process helped refine the product features to ensure we built acceptability into the product each step of the way. This user-centered process led to a product that is easy to use, has good acceptability, and performs well compared to other female condoms.

Engaging users as co-designers resulted in a female condom that meets the needs of women and men from diverse regions.

Photo: PATH

Photo: PATH

The Woman's Condom

The Woman's Condom, branded as the V Condom in South Africa and O'Lavie™* in China, is the PATH-developed female condom product that was tested, marketed, and distributed during the course of the POW PDP's work. Over the last ten years, a team of designers, researchers, and health experts have tested the Woman's Condom in multiple countries. This has ensured that the product is safe, acceptable, and easy to use and that it performs well during sex. The condom has unique features—designed through a user-centered development process—that allow for ease of use, acceptability, and good sensation for both partners. In comparative studies, some women and men have reported preferring the Woman's Condom over other female condom products because it is easy to use.

The Woman's Condom consists of a thin pouch, ring, and dissolving capsule that encloses four foam shapes. All parts of the Woman's Condom are made of medical-grade material that is safe and has been used in medical products for years. The product is for one-time use only. The Woman's Condom comes with a small sachet of water-based lubricant to be applied at point of use. This lets women and couples use the amount of lubricant that is right for them.

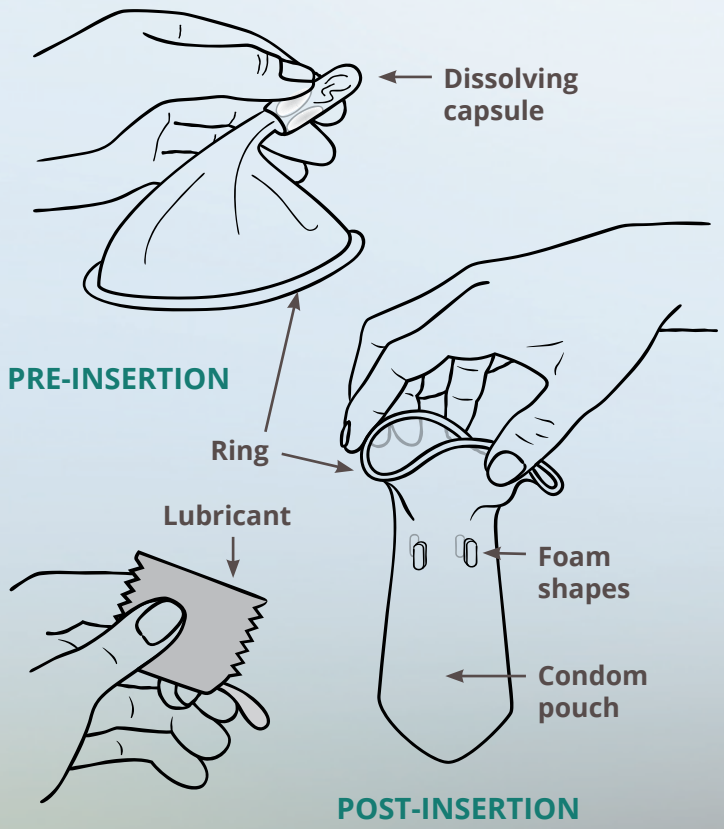

Illustration: PATH

** O'lavie is a trademark of the Shanghai Dahua Medical Apparatus Company*

POW PDP partners

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Building supply for the Woman's Condom

Increasing production capacity

In 2008, PATH began stabilizing and improving production capacity for the Woman's Condom by transferring production to Shanghai Dahua Medical Apparatus Co., Ltd (DAHUA), an important first step to increase supply. In 2011, with formation of the POW PDP, the partnership took another step forward, supporting DAHUA to accelerate production scale-up and optimization that would meet the production goals necessary to enter the international market. Thin-film polyurethane welding is difficult even at low-production volumes. Achieving quality high-volume manufacturing with thin-film welding adds complexity to this already challenging process.

By 2015, DAHUA had built, installed, and validated the new semi-automated production line with a capacity to manufacture nearly 2.5 million Woman's Condoms annually.

With POW PDP funding, DAHUA designed and developed unique manufacturing equipment that consolidated and automated several manufacturing steps. This new semi-automated production line allowed DAHUA to produce millions of Woman's Condoms annually while maintaining the quality required by international standards. DAHUA quickly had the opportunity to utilize its increased capacity for several purposes: producing the Woman's Condoms for clinical studies being implemented in China and South Africa, manufacturing product inventory for market tests, and manufacturing the product for commercialization efforts in private-sector markets.

By 2015, DAHUA had built, installed, and validated the new semi-automated production line with a capacity to manufacture nearly 2.5 million Woman's Condoms annually. By duplicating this production equipment, DAHUA's production capacity has the potential to reach 5 million units annually and beyond.

DAHUA's semi-automated pouch welding machine.

Worker removing pouches from semi-automated line after foam shapes and ring are heat welded.

DAHUA 3-in-1 packaging innovation has the lubricant and instructions within the foil pouch.

All photos: PATH

Watch Woman's Condom manufacturing at the DAHUA factory

As a final step toward building supply, DAHUA is currently completing additional stability testing of a new version of Woman's Condom packaging—a 3-in-1 package configuration where the lubricant and the instructions are placed inside the foil pack with the Woman's Condom to keep the three pieces together in one package This packaging innovation could improve supply chain logistics and potentially reduce product price.

DAHUA also is working with Chinese Government officials as part of an advisory committee that will draft a national testing standard for female condoms in China. This new standard will be based on the ISO Guideline and test requirements.

Meeting regulatory milestones to expand global success

UNFPA/WHO Prequalification

One of DAHUA's objectives during the POW PDP (2011–2015) was to achieve the regulatory approvals required to enter the international market, including achieving the critical UNFPA/WHO Prequalification. This internationally recognized certification ensures the quality of products procured by international agencies such as the United Nations. UNFPA/WHO Prequalification is often a tender requirement of country governments, including South Africa, that procure female condoms for use in government-supported sexual and reproductive health programs.

In 2011, DAHUA initiated the process for UNFPA/WHO Prequalification for the Woman's Condom by submitting their technical dossier detailing the manufacturing and quality testing of the Woman's Condom and all clinical data compiled to-date. In late 2015, DAHUA completed the required factory inspections for UNFPA/WHO Prequalification. DAHUA anticipates receiving UNFPA/WHO Prequalification in 2016. Achieving this certification will allow the Woman's Condom to be positioned to respond to global market opportunities.

Reducing US regulatory barriers to expand access to female condoms

The USFDA characterizes female condoms as a Class III medical device—the most stringent regulatory category, requiring the highest level of clinical evidence to gain market approval. Currently, only the FC2 female condom is approved for marketing by the USFDA. This classification was made 20 years ago, when they were a "new product category" and little clinical evidence existed about their safety and use.

In many other countries, female condoms are considered a Class II medical device, similar to male condoms, and regulatory authorities require data similar to what is required for male condom approval. Because achieving USFDA regulatory approval is such a high hurdle, many governments and agencies now rely on UNFPA/WHO Prequalification, plus approval by a stringent regulatory authority, before considering a female condom product as eligible for international procurement.

In 2014, sexual and reproductive health advocates in the United States, including PATH and the National Female Condom Coalition, launched a campaign urging the USFDA to consider reclassification of female condoms from a Class III to a Class II device, since a large body of evidence now confirms female condoms are safe. Also, international standards have been developed to ensure product quality and efficacy.

If successful, this reclassification effort could increase supply by educing the regulatory burden for new female condoms to enter the market in the USA thereby increasing access to new products.

The National Female Condom Coalition is leading the advocacy initiative to reclassify female condoms in the United States. If successful, this would reduce the regulatory requirements for female condoms and could lead to more female condoms being marketed in the United States.

Regulatory approvals

Before they can be marketed in a specific country, any female condom product requires regulatory approval from national regulatory authorities. The regulatory process shares some similarities across countries, but each country has its own specific requirements. For example, the CE mark—Europe's approval for a medical device—is very focused on safety and making sure that a device performs according to its intended use. USFDA approval—the US regulatory benchmark—places greater emphasis on evidence from human clinical studies. Some countries that do not have their own regulatory process rely on approvals from Europe or the United States or other stringent regulatory bodies before allowing product registration. Because of this, regulatory approvals in Europe and the United States are often seen as critical milestones for product access.

The status of regulatory approvals for the Woman's Condom is noted in the table to the right.

STATUS: COMPLETED	
CE technical dossier on production and QA/QC (*Submitted by DAHUA*)	CE mark obtained (2010)
USFDA Investigational Device Exemption (IDE) application (*Submitted by CONRAD*)	IDE granted (2010)
Shanghai FDA application (*Submitted by DAHUA*)	Chinese regulatory approval obtained (2011)
South African Bureau of Standards (SABS) (*Submitted by DAHUA*)	SABS certification mark obtained (2013)
Malawi and Zambia registrations (*Submitted through USAID-funded ECCO project*)	Registrations granted (2014)
STATUS: IN PROCESS	
UNFPA/WHO Prequalification (*Technical dossier submitted by DAHUA in 2011*)	WHO prequalification anticipated in 2016
Brazil ANVISA application (*Submitted in 2014*)	Approval expected in 2016
STATUS: FUTURE	
USFDA application for pre-market approval (PMA)	PMA not currently funded

Building evidence for the Woman's Condom

Over the last ten years, the Woman's Condom has been evaluated in **multiple clinical studies** by first validating the design, then assessing performance according to internationally agreed-upon standards and definitions. Overall, these studies have demonstrated that the Woman's Condom is safe, acceptable, easy to use, and performs well. In comparative studies, some women have reported preferring the Woman's Condom over other female condom products because it is easy to use.

Each study was designed to evaluate specific questions in the context of a specific population. For example, the design validation studies confirmed the Woman's Condom design met the performance objectives for this product based on data from couples from four distinct countries. The Phase I studies evaluated the Woman's Condom according to specific criteria to assess performance and failures. Each of these studies also collected safety and acceptability data to characterize use of the Woman's Condom in various populations. Data from each of these studies build evidence about Woman's Condom performance and are required for regulatory applications when applying for product approval.

Additional clinical studies

During 2011-2015 as DAHUA worked to scale up production and compile regulatory dossiers, POW PDP clinical partners CONRAD and *Eunice Kennedy Shriver* National Center for Child Health and Human Development (NICHD) began implementation of two clinical studies in the United States with separate funding. These studies were designed to provide additional clinical evidence for regulatory applications, including the dossier for the UNFPA/WHO Prequalification review and possibly a USFDA application. Once published, these data will become part of the Woman's Condom clinical dossier for further regulatory applications, as needed.

Photo: PATH/Patrick McKern

CONRAD clinical study

OVERVIEW

In this study, CONRAD evaluated the performance, safety, and acceptability of the Woman's Condom compared to the FC2 female condom. CONRAD also evaluated the potential of the biomarker prostate specific antigen (PSA) as a measure of barrier effectiveness.

PRIMARY OBJECTIVE

Compare self-reported acute failure of the Woman's Condom and FC2.

SECONDARY OBJECTIVES

- To compare the ability of the Woman's Condom and FC2 to prevent vaginal exposure to semen, as indicated by detection of PSA within the vagina
- To calculate the sensitivity and specificity of reported failures, using PSA as the reference standard
- To compare acceptability of the Woman's Condom and FC2

STUDY POPULATION

- Healthy heterosexual couples at least 18 years old and at low risk for pregnancy or STIs
- Study implemented at California Family Health Council, Los Angeles

METHOD

The study evaluated the performance of the Woman's Condom compared to the FC2 female condom in an open-label, two-period crossover study. Researchers collected data on functional performance, vaginal semen exposure as measured by vaginal PSA, safety, and acceptability of the two female condoms. Performance was assessed by self-reported total clinical failure and its components (clinical breakage, slippage, misdirection, and invagination).

A total of 490 couples were enrolled in the study, and 422 couples provided information on one or more study condoms. Couples were asked to use four condoms of each type. After accounting for condoms that were not used, data from a total of 1,577 Woman's Condoms and 1588 FC2 female condoms were available for analysis.

STATUS

Data analysis is completed and the study report has been finalized. CONRAD plans to develop a manuscript for submission to a peer-reviewed journal to share study results broadly.

CONRAD technical and research staff provide preclinical, clinical, and regulatory expertise.

Photos: (top) PATH, (bottom) CONRAD

NICHD clinical study

OVERVIEW

In this study, the NICHD evaluated the Woman's Condom through a Phase III contraceptive effectiveness study implemented through their Contraceptive Clinical Trials Network (CCTN) at 11 study sites in the United States. Women in this study used the Woman's Condom as their primary contraceptive for six months. When results are published, these NICHD data could support contraceptive labeling for the Woman's Condom. These data could have importance for the broader category of female condoms as well, since the only previous contraceptive effectiveness data submitted to USFDA were from a study using the Female Health Company's FC1 product, which was replaced by the FC2 in 2009.

PRIMARY OBJECTIVE

Determine contraceptive efficacy of the Woman's Condom when used as primary method of birth control for six months.

SECONDARY OBJECTIVES

- Evaluate safety of the Woman's Condom
- Determine incidence of urinary tract infections and symptomatic vaginal infection
- Evaluate acceptability of the Woman's Condom
- Assess performance by self-reported total failure
- Assess performance by vaginal detection of PSA

STUDY DESIGN

- Multicenter, open-label, non-comparative Phase III Device Trial for contraceptive efficacy and safety
- Enroll 500 healthy women (age 18–40)
- Substudy using PSA as a biomarker of semen exposure

METHOD

Researchers collected data on the efficacy, safety, and acceptability of the Woman's Condom as well as on the incidence of urinary tract infections, symptomatic vaginal infection, and acquisition of *Chlamydia trachomatis*, *Neisseria gonorrhea*, or *trichomoniasis*.

Performance of the Woman's Condom was assessed by self-reported total clinical failure and its components (clinical breakage, slippage, misdirection, and invagination). A subset of women assessed vaginal detection of PSA by self-collected swabs before and after intercourse.

STATUS

Data analysis is underway. Results are expected in 2016.

Photo: PATH/Patrick McKern

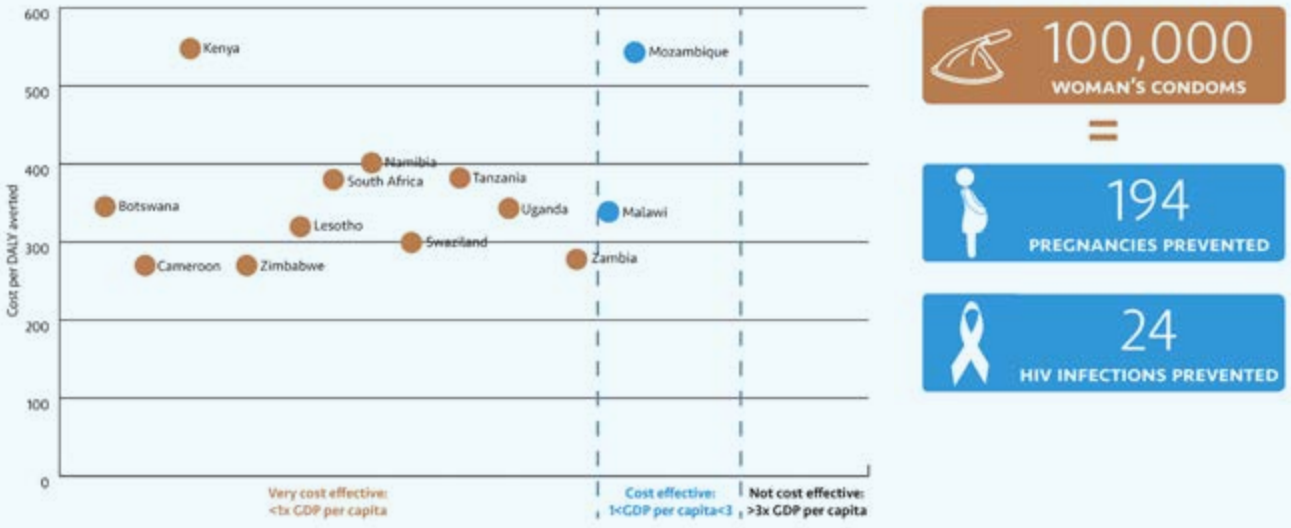
Cost-effectiveness is key

Policymakers and other stakeholders need cost-effectiveness information when considering purchasing and introducing a new product into their existing programs. Previous modeling analyses in South Africa and Brazil have indicated that female condoms can be a highly cost-effective public health intervention when compared to the costs of HIV treatment.[1,2] In the UnitesdStates, an economic evaluation of a female condom distribution program averted enough HIV infections in the first year alone to save more than US$8 million in future medical costs.[3]

However, additional benefits associated with female condoms—such as pregnancy prevention and prevention of mother-to-child transmission of HIV—were not previously quantified in reference models. To address this, the POW PDP conducted a cost-effectiveness study to estimate the health impact of the Woman's Condom attributable to its dual use as a family planning method and also as an HIV prevention method. Using two publicly available models, the study estimated the impact of 100,000 Woman's Condoms in 13 sub-Saharan African countries during a one-year period.

The Woman's Condom was found to be **very cost-effective in all 13 countries**. While the health impact is greater for use as an HIV prevention method, considering the dual protection of the Woman's Condom adds to the health impact and may help address stakeholder concerns about the cost-effectiveness of female condoms.[4]

COST-EFFECTIVENESS OF FEMALE CONDOMS[5]



[1] Dowdy DW, Sweat MD, Holtgrave D. Country-wide distribution of the nitrile female condom (FC2) in Brazil and South Africa: a cost effectiveness analysis. *AIDS*. 2006;20(16):2091-2098.

[2] Marseille E, Kahn JG, Billinghurst K, Saba J. Cost-effectiveness of the female condom in preventing HIV and STDs in commercial sex workers in rural South Africa. *Soc Sci Med*. 2001;52(1):135-148.

[3] Holtgrave DR, Maulsby C, Kharfen M, et al. Cost-utility analysis of a female condom promotion program in Washington DC. *AIDS Behav*. 2012;16(5):1115-1120.

[4] 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.

[5] Mvundura M, Nundy N, Kilbourne-Brook M, Coffey PS. Estimating the potential dual health impact and cost effectiveness of the woman's condom in selected sub-saharan african countries. Poster presented at: Third International Conference on Family Planning, November 12-15, 2103; Addis Ababa, Ethiopia.

Building demand: Market development opportunities and challenges

Over the past five years, the POW PDP assembled many of the critical building blocks necessary to prepare for widespread introduction of the Woman's Condom. Through this innovative partnership, DAHUA significantly increased manufacturing capacity and achieved regulatory approvals needed to expand market access. POW PDP partners implemented clinical studies generating key data about contraceptive effectiveness and performance. Consumer use studies that assessed acceptability and willingness to pay among target audiences not currently using female condoms provide a solid foundation for market segmentation and future marketing. Our first-of-its-kind economic analysis of the impact of the Woman's Condom for dual protection refines the value proposition for the product by identifying characteristics of countries where introduction is likely to be highly cost-effective. Creative and innovative global and national advocacy succeeded in bringing new participants to discussions and fostering action in support of sexual and reproductive health and rights in general. We shared results and lessons learned through presentations, conferences, and publications to raise awareness and generate demand for all female condoms including the Woman's Condom.

Despite these successes, the commercial viability of the Woman's Condom has not yet been proven. Building sustainable markets for female condoms, including the Woman's Condom, face challenges. Long-term reliance on public-sector procurement has left female condoms overly dependent on government and donor funding and public-sector distribution. Consequently, much of the awareness raising, training, and promotion of female condoms has focused on low-income women. Commercial-sector markets for female condoms are undeveloped at this time. It will require substantial investment and coordinated effort to mainstream the concept of female condoms as a consumer product for middle income consumers, which is what is required to build a more balanced market overall. In this regard, the commercial female condom market today is at a similar stage to where the male condom market was before the HIV/AIDS crisis. However, since the mid-1980s, male condoms have benefited from decades of investment on the part of governments, development agencies, the nongovernmental organization (NGO) sector and industry to normalize use of male condoms across a range of consumer groups and reduce the barriers to condom use for all audiences.

The POW PDP assembled many of the critical building blocks necessary to prepare for widespread introduction of the Woman's Condom.

Photos: PATH

Photo: PATH

Country-specific obstacles also exist. While China and sub-Saharan Africa still remain the most feasible areas for development of additonal markets, more work is needed to better understand country contexts and overcome market-related hurdles. Lessons learned from POW PDP activities in China and South Africa are important for future market development in these countries and may be relevant for partner organizations working on introduction of female condoms—including the Woman's Condom—to new markets.

Markets in China

Clinical and consumer use studies clearly demonstrated that current and potential Chinese users view the Woman's Condom as a stylish and high-quality product. High rates of abortion and increasing rates of STIs suggest that existing methods do not meet the needs of all consumers. Young people are interested in learning more about contraceptive options. They are interested in new products—especially those that are perceived as coming from "the West" (i.e., outside of China)—Education and promotion needs to focus on men as well as women. In formative research, more men than women expressed interest in purchasing and using the Woman's Condom. In consumer use studies, women were strongly influenced by male partner acceptance of the Woman's Condom to the degree that they did not think they could bring the Woman's Condom to the relationship unless the male partner agreed. There is a role for the Woman's Condom in public and commercial sectors in China, although additional work is needed to raise awareness and build demand for this new method among both women and men in China.

While opportunities for the Woman's Condom exist in China in both the private and public sectors, additional investment will be needed to develop both these market opportunities. While a centralized economy may appear to reduce barriers to market entry, public-sector engagement of the central government is require, which, in turn, requires multiple inputs at both central and provincial level.

In addition, China is a large country both in terms of geography and population. Sustained relationship-building with stakeholders at each level requires adequate resources and time. The POW PDP was successful at forging excellent relationships with Chinese government staff in Beijing and in some provinces to raise awareness about the Woman's Condom. Deepening these relationships to a level sufficient for sustained procurement will require additional time and resources in the future.

Public procurement standards in China set a high bar. To qualify, DAHUA must demonstrate that the product not only meets standards in the areas of reasonable price and sufficient production capacity, but also demonstrate strong sales in the private sector for a three-year period. Unlike in other countries, a robust private-sector presence in China is evaluated as one of the key criteria when considering a product for procurement by government programs. DAHUA's efforts to develop the private-sector market in China were hampered by low consumer awareness of female condoms in China, since this is a totally new product category for Chinese consumers to consider.

Despite the long road ahead, DAHUA is leveraging its reputation as an expert on female condoms in China and is collaborating with the government to develop a national standard for female condoms, which will benefit the female condom product category. Having a national standard for the product category will streamline future regulatory approvals and standardize quality testing for products in this category. DAHUA will also continue to foster relationships with national and provincial level stakeholders to continue to build the case for the Woman's Condom and will assess market opportunities for the Woman's Condom inside and outside the country.

Markets in sub-Saharan Africa

The POW PDP efforts in South Africa bring different and important lessons since South Africa is a country with one of the most well-developed female condom public-sector markets globally. Similar to China, data market tests, awareness raising, and market building in South Africa suggest that a potential market exists for the Woman's Condom. Consumers respond positively to the positioning of the Woman's Condom as an aspirational product. Consumers (both women and men) see the Woman's Condom as being high quality and distinct from other female condoms they have seen, heard of, or used. Also, they are willing to pay for the Woman's Condom. Since POW PDP sought to use Woman's Condom introduction to build toward a more sustainable market for female condoms overall, we developed a commercial-sector strategy for South African markets. Results from market research and consumer use studies confirm consumers in South Africa are willing to pay for the Woman's Condom at levels that approximate the cost of importing the product. From a perspective of assessing viability of a fully commercial market launch, this willingness to pay—while impressive—does not cover the additional costs required to develop markets for a new product, (i.e, promoting and building marketing and distribution for the Woman's Condom). Those additional expenses can add up to 100 to150 percent on top of the product cost. Going forward, additional resources will be needed to fully launch this product and develop commercial-sector markets.

Product introduction in South Africa was hampered by supply chain issues during the final years of the POW PDP; it took longer than DAHUA anticipated to fully validate the semi-automated production line, which impacted product availability and market introduction in South Africa. Heat welding of the very thin polymer film used in the condom pouch is technically challenging. DAHUA led the way by innovating a manufacturing process for thin film heat welding, and in 2015, achieved a semi-automated production line that combines three production steps into one machine. DAHUA plans additional innovation in the future to continue to increase production line yield, reduce the wastage rate, and bring down per-unit manufacturing costs. Delays in production scale up and validation of the new manufacturing line limited the available inventory of the Woman's Condom, which impacted not only the timing of market tests in South Africa but also the confidence of local distributors to generate demand for a product when the supply chain is still being developed.

New initiatives that show great promise include the USAID-funded Expanding Effective Contraceptive Options (EECO) project, which will introduce the Woman's Condom in Malawi and Zambia as a woman-initiated method to address unmet need for family planning. The EECO project—implemented by Woman Care Global and PSI—have branded the Woman's Condom as the Whisper Woman's Condom in Malawi and Maximum Diva Woman's Condom in Zambia. The Woman's Condom was introduced in Malawi in late 2015, and product launch in Zambia is scheduled for early 2016. Formative and market research from these two countries confirm significant interest in this new product.

Photos: (left and right) PATH, (middle) Doune Porter

Markets in Europe, the United States, and beyond

Other pathways for introduction may exist as supply and demand for the Woman's Condom evolves across various markets. Recently there has been significant interest from European distributors who market to middle- and higher-end consumers who access services and products from clinics and shops where they pay for products. Local distributors from countries such as Tanzania and Uganda have expressed interest in marketing the Woman's Condom. Some of these are waiting for UNFPA/WHO Prequalification to be achieved, while others are able to move forward more immediately. DAHUA has been working with a marketing and distribution company in Brazil for the past two years. In 2015, the Woman's Condom received ANVISA approval and the lubricant approval is pending. Once the Brazilian regulatory approvals are final, this will open the door to market introduction in Brazil.

In the United States, if USFDA decides to reclassify female condoms from Class III to Class II—thus reducing the regulatory hurdles—it may be more likely that a distribution partner who is willing to invest in the Woman's Condom will come forward. If this occurs, the Woman's Condom may be well-positioned to leverage existing awareness and create additional demand among key consumer groups there.

Overall, global market development for the Woman's Condom, especially in developing and emerging countries, hinges on UNFPA/WHO Prequalification. Once this quality assurance certification is achieved, the Woman's Condom could be procured by international agencies such as UNFPA and latent interest in developing countries may become more visible. However, given the price point of the product in its current specifications, it is unlikely that public-sector procurement orders could serve as the primary basis for Woman's Condom sales. It is possible that a public-sector opportunity may exist in potential split tenders, where the Woman's Condom might provide a small, yet significant, portion of a tender due to its high consumer acceptability and potential for consistent and correct use over time.

The Woman's Condom may be well-positioned to leverage existing awareness and create additional demand among key consumer groups.

Photos: PATH

Considerations and lessons learned from market development

The POW PDP aimed to explore and develop markets for the Woman's Condom to expand women's options for dual production, and thus improve reproductive health outcomes. Key considerations for building new markets for woman-initiated barrier methods include:

- Aligning production capacity and demand generation activities is critical to robust introduction.
- Optimizing production is a complex and ongoing process, which required more time than anticipated to achieve high-volume manufacturing. Systems and quality testing sufficient to produce a high-quality product at low production volumes needed to be strengthened and re-validated as production volumes increased.
- Building production capacity and scaling up manufacturing of the Woman's Condom to achieve international good manufacturing practice (GMP) standards required inputs from a multidisciplinary technical team including an international quality systems consultant. Cooperation on the part of DAHUA management and factory staff was critical in achieving these objectives.
- Market research and consumer acceptability assessments are critical to target new product introduction. It can be challenging to find appropriate strategies for collecting uptake and acceptability data of an approved consumer product. Due to local requirements, the market tests in China were implemented as clinical studies. This allowed greater opportunity for data collection but lacked the spontaneity of use outside of a study setting. In South Africa, the market tests successfully recruited consumers at locations where they worked or gathered socially, or at school. The South African questionnaires included only a limited number of questions so responding would not be too burdensome. This limited the amount of detail we were able to collect on each of these consumer groups.
- Given the sensitive and complex nature of woman-initiated barrier products within sexual relationships, it is imperative that consumers and stakeholders be given an opportunity to use the product through test-market and consumer-use scenarios to ensure success in the marketplace.
- Markets for new and underutilized products are small and will take time and significant resources to grow. We underestimated the financial resources and time required to launch and build demand for a new consumer product. Even though product launch and demand generation were not achieved, the market research, market testing, and advocacy laid the groundwork for market introduction. We did not include strategies to subsidize the Woman's Condom because of lack of sustainability of this approach coupled with budget constraints. This may have overly limited the potential market. Liberal use of free samples and subsidizing are important demand-generation tools for new products.
- Correctly identifying initial target audiences and distribution channels to build success can fuel future investments in developing markets to meet reproductive health needs of a wider audience.

Looking forward

The POW PDP was undertaken and inspired by PATH's vision that women and men should have access to a range of options to protect from unintended pregnancy and STIs, and that these options should be available, affordable, and accessible so they can live healthy and happy sexual lives.

Through this product development partnership, women and men have shown their support at country and global levels for expanded access to female condoms. Linking country and global-level advocacy with evidence building and market development can normalize the concept of female condoms as a protection option, and it can help make female condoms an acceptable product for women and men wherever and whenever they need protection. The POW PDP project team and its partners look forward to a world where female condom access and choice is a reality for all women and men who would benefit from using this life-saving multipurpose prevention technology.

Using the Woman's Condom to benefit the broader field of protection options

PATH has been the fortunate recipient of funding over the past two decades to design, develop, and launch the Woman's Condom, a second-generation female condom designed for improved acceptability and ease of use. PATH and its collaborators over the years are proud of the Woman's Condom and our patented innovations in the female condom space. We are now at a point when we realize that the greatest ongoing benefit to the populations that PATH serves will be to make the Woman's Condom innovations controlled by PATH available to others working in this space to support further advancements. In this way, all interested parties will be able to leverage PATH's work to enhance female condom products, thereby contributing to the growth of a sustainable global female condom market. For these reasons, PATH hereby pledges the free use of any of the Woman's Condom patents within its control for those who wish to use this technology in female condom products.

We thank the many funding organizations that have provided resources for this important work including USAID, the Andrew W. Mellon Foundation, the William and Flora Hewlett Foundation, the Lemelson Foundation, the Bill & Melinda Gates Foundation, the Overbrook Foundation, the David and Lucile Packard Foundation, Universal Access to Female Condoms (UAFC), and most recently the Netherlands Ministry of Foreign Affairs through support to PATH and its collaborators for the Protection Options for Women (POW) Product Development Partnership.

Read the related reports

Introducing O'Lavie Woman's Condom to China: Expanding dual protection options

http://www.path.org/publications/detail.php?i=2565

Introducing V Condom to South Africa: Expanding the female condom market

http://www.path.org/publications/detail.php?i=2566

Using innovative female condom advocacy to improve awareness and catalyze change

http://www.path.org/publications/detail.php?i=2563

Watch the related video

Watch the video of the DAHUA facility at:
https://www.youtube.com/watch?v=H6FvrEOmQjI

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