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EXPANDING EFFECTIVE CONTRACEPTIVE OPTIONS:

Lessons Learned from the Woman's Condom Introduction in Zambia and Malawi



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Acronyms

CSL	Commodities Security and Logistics
E1M	Every1 Mobile
EECO	Expanding Effective Contraceptive Options
FP	Family Planning
FSW	Female Sex Workers
HIV	Human Immunodeficiency Virus
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICRW	International Center for Research on Women
IPC	Interpersonal Communication
IPA	Innovations for Poverty Action
IRB	Institutional Review Board
ISO	International Organization for Standardization
MAH	Marketing Authorization Holder
MOH	Ministry of Health
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PSI	Population Services International
SFH	Society for Family Health
STI	Sexually Transmitted Infection
TMA	Total Market Approach
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WCG	WCG Cares
WHO	World Health Organization
ZAMRA	Zambia Medicines and Regulatory Authority

ACKNOWLEDGEMENTS

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Expanding Effective Contraceptive Options

Expanding Effective Contraceptive Options (EECO) is a USAID-funded project that supports the introduction of new contraceptive and dual protection methods. Each product was designed to address one or more barriers to contraceptive use: some are non-hormonal, some are long-acting and reversible, and others are discreet or used only on-demand. In addition, there are several woman-initiated methods to help overcome provider-related access barriers, such as a limited number of skilled providers and provider biases that reduce women's uptake of contraception.

EECO relies on formative research and follow-up with consumers and providers to market products effectively. In the project planning phase, the EECO team analyzed research on both the emotional and physical needs of consumers, while assessing the contraceptive landscape in each of the target countries. Based on these analyses, project partners identified each product's most likely target audiences, its perceived positive and negative traits, the most promising distribution and communication channels, and the type of training and advocacy required. These approaches will be tested throughout the project, and the results can be extrapolated to scale up access to the products or expand introduction to additional countries.

By the project's end, EECO will have produced roadmaps for product introduction, including the generation of stakeholder support and consumer demand, for a variety of contraceptive and dual protection methods. Pilots in Zambia, Malawi, Madagascar, Nigeria, and Niger will provide women with more choices to prevent unplanned pregnancy and STIs such as HIV. The first of these pilots started in Malawi and Zambia in mid-2014 with the launch of the Woman's Condom.

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THE EECO TEAM

WCG Cares (WCG) leads the team, bridging the private sector and non-profit worlds, and linking upstream product developers/suppliers and downstream marketing and distribution partners. WCG leads regulatory and quality assurance efforts, intensive medical detailing and data collection.

Population Services International (PSI), the social marketing partner, works through existing service delivery and product distribution networks to market and distribute the EECO products.

Every1Mobile (E1M), the mHealth partner, creates mobile communities and uses

mobile social networking to increase awareness and drive demand for methods and products.

International Center for Research on Women (ICRW), the research and gender partner, conducts consumer and provider research, focusing on product acceptability and contraceptive decision-making.

Evoform, the biotechnology partner, develops and markets products that are woman-initiated, non-invasive, and rapidly reversible.



Introduction

UNDERSTANDING UNMET NEED FOR CONTRACEPTION AND HIV PREVENTION

The Expanding Effective Contraceptive Options (EECO) project, funded by the United States Agency for International Development (USAID), seeks to meet the needs of the 214 million women in developing countries who do not wish to become pregnant, yet are not using a modern method of family planning (FP).³ Many of these women also face a high risk of HIV acquisition, especially in Southern and East Africa. See Figure 1, right, for method-related reasons for non-use of modern contraceptives, which include: side effects, infrequent sex, breastfeeding, and a need for discreet methods.⁴ Studies suggest that the critical factors for meeting women's contraceptive needs are: access to a broad choice of methods, improvement in the quality of information and services available, a consistent supply of contraceptive products, and the reduction of social barriers to use. Women seeking protection from HIV have very few options, often only male condoms or abstinence – both of which can be difficult for women to negotiate with male partners. Female condoms are the only dual protection option that can be controlled by the woman herself without the need for action by her partner.

EECO PROCESS

Recognizing that the successful introduction of new products involves multiple players and an understanding of market dynamics, WCG assembled a team of organizations covering the entire product life cycle – from development to end use – to support the successful introduction of the Woman's Condom. EECO

Figure 1. METHOD-RELATED REASONS FOR NON-USE OF CONTRACEPTION

Of the women who cite method-related reasons for non-use of modern contraceptives:

Want methods that do not cause side effects

26%

Want methods appropriate for infrequent sex

24%

Need methods suitable to use while breastfeeding

20%

Need discreet methods

23%

determines how best to improve the value chain by coordinating market players (e.g., product developers, researchers, market analysts, and others), sharing information, and conducting stakeholder advocacy. This value chain approach, together with a focus on activities that are driven by consumer insights, can be applied to bring any new reproductive health product to market.

EECO product introduction takes place in five stages, resulting in pilot introduction programs in each country. This case study focuses on the lessons learned throughout each stage of the Woman's Condom introduction in Zambia and Malawi. The stages are outlined in Figure 2.

³ Adding It Up: The Costs and Benefits of Investing in Sexual and Reproductive Health 2017, fact sheet, New York: Guttmacher Institute, 2017, <https://www.guttmacher.org/fact-sheet/adding-it-up-contraception-mnh-2017>.

⁴Hussain R et al., Unmet Need for Contraception in Developing Countries: Examining Women's Reasons for Not Using a Method, New York: Guttmacher Institute, 2016, <http://www.guttmacher.org/report/unmet-need-for-contraception-in-developing-countries>.

Figure 2. **EECO PRODUCT INTRODUCTION STAGES**



STAGE 1

Regulatory Assessment & Product Registration

- Perform regulatory landscape assessment
- Engage stakeholders and meet with marketing authorities
- Support identification of a suitable market authorization holder
- Prepare the registration package, submit and support its lifecycle upon approval



STAGE 2

Consumer & Market Research

- Plan and conduct market research
- Complete market segmentation analysis
- Determine pricing and branding strategies



STAGE 3

Procurement & Quality Assurance

- Perform manufacturer audits
- Initiate pre-shipment inspection and testing of product
- Develop and initiate pharmacovigilance systems



STAGE 4

Marketing, Distribution & Service Delivery

- Launch product, with marketing and communications support
- Supply stock to commercial outlets and providers
- Deploy medical detailers to train and follow-up with providers

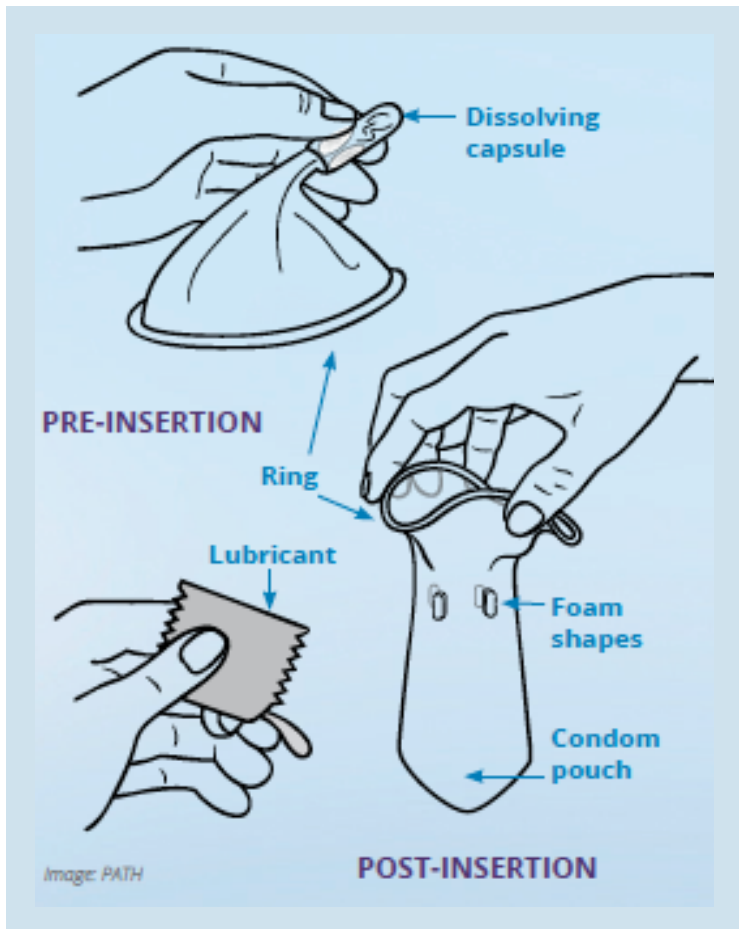


STAGE 5

Monitoring & Learning

- Monitor and course-correct
- Conduct baseline and endline evaluations
- Disseminate lessons learned



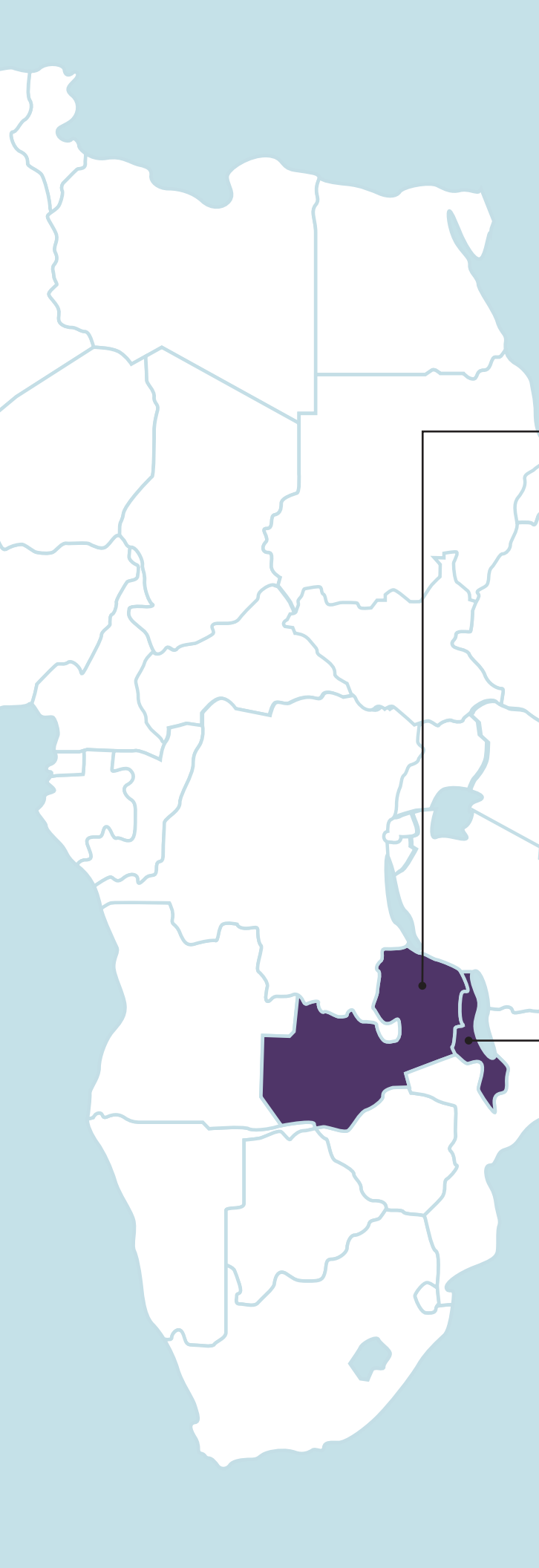


THE WOMAN'S CONDOM

The Woman's Condom, designed by PATH, was created following an iterative, human-centered design process to address women's concerns with the previous generation of female condoms. The Woman's Condom is made of a soft and thin material, and does not contain an inner ring. When inserted, the Woman's Condom adheres to the interior of the vagina using four small dots of soft, absorbent foam. These dots hold the condom securely in place during use and release from the vaginal walls for removal. To ease insertion, the Woman's Condom features a rounded capsule on the end of the condom. Upon insertion, the capsule dissolves in less than a minute. The Woman's Condom is non-hormonal and intended for one-time use.

In 2008, PATH transferred production of the Woman's Condom to the Shanghai Dahua Medical Apparatus Company of Shanghai, China. Shanghai Dahua has received approval to market the product in China, Europe, and South Africa. As part of the EECO project, the Woman's Condom was additionally registered in Zambia and Malawi. The Woman's Condom achieved World Health Organization (WHO)/United Nations Population Fund (UNFPA) prequalification in 2016, allowing the UN and other international purchasers to obtain the product for public-sector distribution.





COUNTRY CONTEXT

In both Zambia and Malawi, unmet need for FP is greatest among young women aged 15-19.

Zambia

HIV PREVALENCE: **14.3% AMONG WOMEN AGED 15-49**⁽¹⁾

MODERN CONTRACEPTIVE PREVALENCE: **32.5%**⁽²⁾

UNMET NEED FOR FP: **21%**⁽²⁾

Malawi

HIV PREVALENCE: **12.1% AMONG WOMEN AGED 15-49**⁽³⁾

MODERN CONTRACEPTIVE PREVALENCE: **45.2%**⁽⁴⁾

UNMET NEED FOR FP: **19%**⁽⁴⁾

Sources:

(1) Ministry of Health, Zambia. Zambia Population-based HIV Impact Assessment (ZAMPHIA) 2016: First Report. Zambia, Ministry of Health. December 2017.

(2) Central Statistical Office (CSO) [Zambia], Ministry of Health (MOH) [Zambia], and ICF International. 2014. Zambia Demographic and Health Survey 2013-14.

Rockville, Maryland, USA: Central Statistical Office, Ministry of Health, and ICF International.

(3) Ministry of Health, Malawi. Malawi Population-based HIV Impact Assessment (MPHIA) 2015-16: First Report. Lilongwe, Ministry of Health. November 2017.

(4) National Statistical Office (NSO) [Malawi] and ICF. 2017. Malawi Demographic and Health Survey 2015-16. Zomba, Malawi, and Rockville, Maryland, USA. NSO and ICF.





STAGE 1

Regulatory Assessment & Product Registration

As an initial step in the EECO regulatory strategy, WCG conducts a regulatory landscape assessment in the focus country to determine the most efficient pathway for product registration. During the assessment, WCG meets with the local regulatory authorities and identifies an appropriate partner to serve as the marketing authorization holder (MAH).

REGULATORY LANDSCAPE ASSESSMENT

The first step of the regulatory landscape assessment is to review online resources from the applicable country regulator, as well as the available global standards from the WHO and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Using information from the WHO and ICH, WCG develops a country-specific questionnaire for the in-country assessment. WCG then uses this questionnaire as a tool for data collection, interviewing regulatory authorities to confirm the regulatory requirements and process.

SELECTION OF MARKETING AUTHORIZATION HOLDER

To facilitate the selection of the MAH, WCG identifies potential local partners that meet the minimum requirements identified during the regulatory landscape assessment (e.g., mandatory registration or licensing specifications). WCG then meets with each of these potential partners to assess their interest and capacity to serve as the MAH, and requests that they complete a standardized questionnaire. Based on this series of meetings and responses to the questionnaire, EECO submits a recommendation for the MAH to the product manufacturer. Ultimately, the product manufacturer selects the MAH, and establishes a distribution agreement and procedures for adverse event reporting.

PSI served as the MAH for the Woman's Condom in Malawi. In Zambia, the MAH was PSI's Zambian network member, Society for Family Health (SFH).

ZAMBIA

The Woman's Condom was listed with the Zambia Medicines and Regulatory Authority (ZAMRA) in September 2014. The ZAMRA listing granted marketing authorization to SFH for a period of five years. Male and female condoms are considered pharmaceutical products in Zambia, and MAHs are therefore required to submit annual product retention fees to ZAMRA.

MALAWI

The Woman's Condom was approved for distribution in Malawi in July 2014. Male and female condoms are categorized as medical devices and are therefore not technically registered with the regulatory agency.⁵ Nevertheless, the EECO team submitted product samples and provided Malawian authorities with information on the product and its planned distribution.

In both Zambia and Malawi, the regulatory approval process for the Woman's Condom was relatively efficient. In-country regulatory assessments were key to understanding the correct pathway for registration or listing, and for making contacts within the regulatory agencies to support the product.

KEY STEPS TAKEN:

- Conducted regulatory landscape assessments to identify the most appropriate registration pathway for the new product and to generate support within the appropriate ministries.
- Recommended an MAH for each country to the manufacturer.

⁵ Medical devices, unlike pharmaceutical products, do not contain an active ingredient causing a therapeutic effect. However, guidelines for medical devices were not available at the time of listing in Zambia so the EECO team followed the listing process for pharmaceutical products instead.





STAGE 2

Consumer & Market Research

FORMATIVE RESEARCH

To better understand the needs and preferences of consumers, EECO partnered with the International Center for Research on Women (ICRW) to conduct a review of available literature related to female condoms, and in Zambia and Malawi in particular.

The literature review found that limited funding, competing budget priorities, and other questions about female condoms have contributed to low access and use in sub-Saharan Africa.⁶ In addition, women have cited concerns with specific design features of female condoms that affect ease of use and comfort. The review also identified some consumer-level insights related to female condom use, seen in Table 1, right. Additionally, EECO formative research conducted by ICRW together with PSI in Zambia and Malawi, highlighted that women were more concerned with pregnancy prevention than with prevention of sexually transmitted infections (STIs).

BRAND DEVELOPMENT

Custom market research in both countries included a proprietary tool to help assess users' emotional needs as they relate to the Woman's Condom. South Africa-based Kantar TNS, a custom market research agency, conducted "need states" research to connect consumers with the Woman's Condom and branding. The market research firm measured need states using a tool based on a psychological framework. The tool explores, measures, and analyzes functional drivers, emotions and perceptions of brands and products. This framework is based on the Jungian concept of archetypes, which are consistent patterns of behavior that are believed to exist in the unconscious of every person across all cultures. These archetypes can be used to help organizations identify how their brands should act and communicate to meet the emotional needs of consumers. Every archetype possesses its own

⁶ Murithi et al., Understanding the Social and Cultural Context of Gender Dynamics, Sexual Relationships, and Method Choice: Impact on Family Planning Use in Malawi and Zambia., Washington DC: International Center for Research on Women, 2016, <https://www.icrw.org/wp-content/uploads/2016/10/EECO-report-ICRW-2016.pdf>.

Table 1. **FORMATIVE RESEARCH FINDINGS**

<p>USERS</p>	<ul style="list-style-type: none"> • Younger women • Higher socio-economic status • Higher perceived risk of pregnancy/HIV • Use of condoms within marriage strained/stigmatized due to fear of accusations of marital infidelity
<p>POSITIVE ATTRIBUTES</p>	<ul style="list-style-type: none"> • Acceptability improves with use over time • Increased decision-making by women in sexual encounters • Absence of side effects • Enhanced sexual pleasure • Protection against HIV/STIs • Convenience (men) • Curiosity (men) • Enhanced sexual sensation (men) • Perception of better safety and comfort (men)
<p>BARRIERS</p>	<ul style="list-style-type: none"> • Generally low knowledge and practice of consistent and correct condom use • Due to years of targeting of female sex workers with female condoms, the product category may be stigmatized within the general population • Lack of familiarity (men) • Partner’s difficulties inserting method (men) • Concern about losing control over sexual encounters (men)

Need states research helps build a product’s long-lasting relationship with consumers by addressing their emotional needs for that product. While functional needs (e.g., price), are easy to identify, it is often harder to understand emotional needs. These needs are usually unconscious and tied to a range of psychological factors, such as social identities and personality drivers. A need states analysis is commonly used by commercial organizations to develop a deep understanding of their consumers and to position products accordingly.

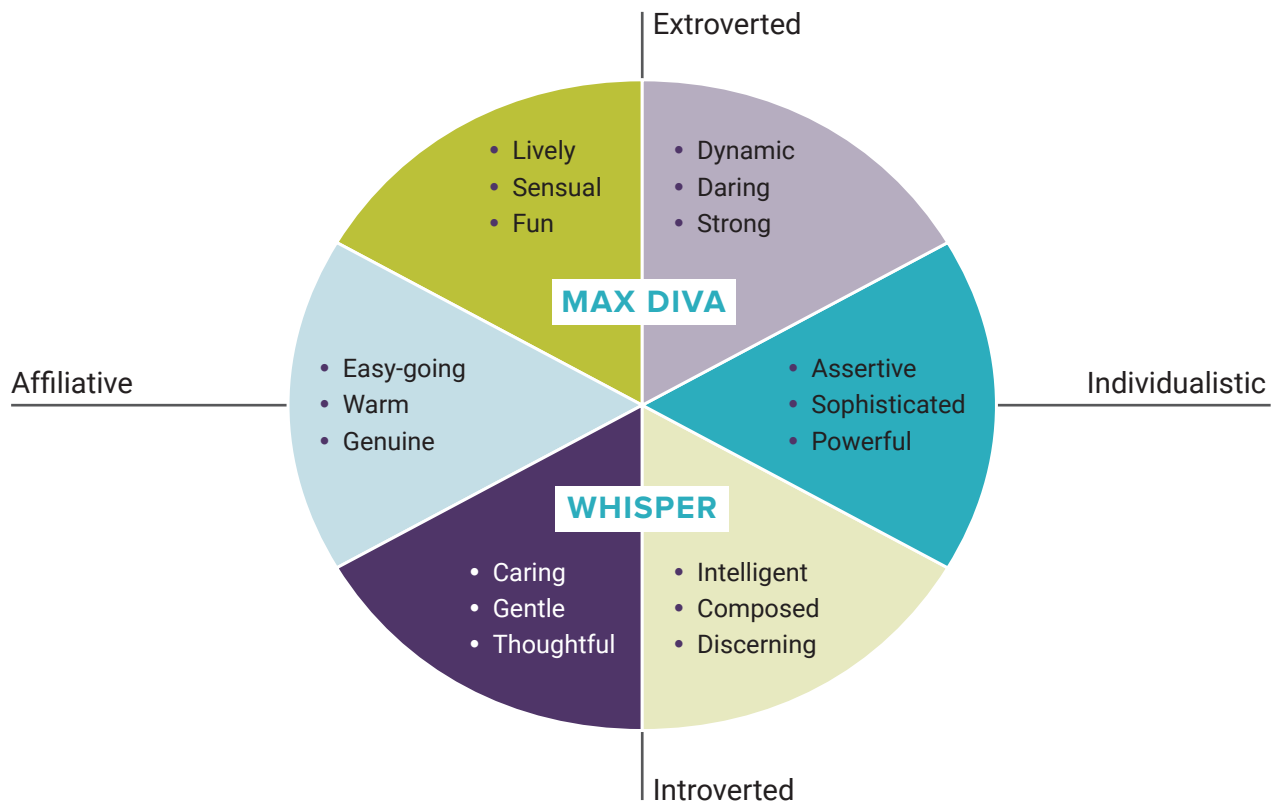


set of values, ambitions, behaviors and needs (see Figure 3 below).

In Zambia, the need states research placed the Woman's Condom in the "fun-loving" needs category. This category is associated with extroverted behaviors, suggesting that it might appeal to younger women who want to have fun without having to worry about consequences. In Malawi, the need states analysis indicated that men and women who used the Woman's Condom were more likely to fall into a 'practical' need state. This category is associated with introverted and hardworking young women who might be more apt to worry about their future. Women who fall into this category tend to be in steady relationships and may view sex as a necessary part of a relationship, perhaps even an obligation.

In addition to the needs states' analysis, formative research conducted by ICRW provided more information about the target audience, building out the foundation on which to create the EECO strategy. Alongside their extensive background literature review, ICRW also held focus group discussions and conducted key informant interviews and in-depth interviews with women in Zambia (N=57) and Malawi (N=50) about perceptions of female condoms, sexual norms and contraceptive behaviors. ICRW's research was approved by their Institutional Review Board (IRB) as well as Malawi's National Health Sciences Research Committee and the University of Zambia's Biomedical Research Ethics Committee. One of the key themes that emerged from ICRW's research was women's preference for non-hormonal contraceptive methods, a potentially enabling factor for

Figure 3. **WOMAN'S CONDOM AND NEED STATES IN MALAWI (WHISPER) AND ZAMBIA (MAXIMUM DIVA)**




uptake of the Woman's Condom. However, several barriers were also identified, including unequal gender roles and power in negotiating sexual activity as well as provider biases in recommending the Woman's Condom to consumers.

Building on this formative research, PSI used a proprietary "DELTA" process to identify target audiences and market segmentation strategies. The research identified the "4 Ps" in each country (Product, Promotion, Price, and Place), as well as key messages for both providers and consumers. The development of the 4 Ps culminated in archetype users, branding and promotion strategies, and branded products for Whisper (Malawi) and Maximum Diva (Zambia). For a description of this process and the resulting Woman's Condom marketing plans, see the case study "Expanding Effective Contraceptive Options: Understanding the Consumer."⁷

KEY STEPS TAKEN:

- Prior to product introduction, the EECO team conducted an intensive literature review as well as formative research to understand the perceptions that consumers and their partners had about the new product. A deeper understanding of gender norms, cultural context, and barriers that consumers face in using contraceptives was another key outcome of this activity.
- Successful marketing relies on an understanding of target consumers: their needs, wants, behaviors, and habits. The process to identify target audiences, create key messages for consumers/providers, and develop a market segmentation strategy was foundational to the introduction of the Woman's Condom. In an ideal scenario, the process should be repeated regularly to refine targeting strategies and to assess the impact of the selected approach.

 **Woman's Condom Providers:** Typically, the term "provider" is reserved for medically-trained personnel who interact with consumers. For the purposes of this case study, however, the term "provider" will be used to encompass clinic providers, pharmacists and pharmacy staff, and other retail vendors who carry condom products and interact with consumers.

⁷ Gomez A, Mann C, Cooley T, Miller N. Expanding Effective Contraceptive Options: Understanding the Consumer. <https://www.psi.org/publication/expanding-effective-contraceptive-options-in-zambia-and-malawi-understanding-the-consumer/>.





STAGE 3


Procurement & Quality Assurance

EECO introduces products that are new and thus have not yet been procured through the USAID Commodities Security and Logistics (CSL) system. As a result, these products must undergo independent quality assurance steps that mirror those of the CSL system to verify product safety and performance. Products are tested in accordance with an international product standard developed by a consortium such as the International Organization for Standardization (ISO), an independent, non-governmental organization that brings together subject-matter experts to share knowledge and develop voluntary, consensus-based international standards for product quality assurance.

The EECO team partnered with FHI360 Product Quality and Compliance, an ISO 17025-accredited⁸ laboratory partner, to verify compliance with product specification requirements. FHI360 conducted pre-acceptance testing of all Woman's Condom procurement lots with WCG, providing final review and release of acceptable products. In addition, EECO, FHI360, and the manufacturer, Shanghai Dahua, conducted a proficiency testing study to align testing methodology across the organizations, thus ensuring equivalency of reported test results from all parties.

In an effort to improve product release acceptance, WCG conducted annual quality assurance audits of Shanghai Dahua, which resulted in several recommendations for improvement. Most importantly, WCG recommended implementation of a lot traceability system to segregate and track any lots of the product that failed to conform to standards. Shanghai Dahua made improvements based on WCG's recommendations.

⁸ ISO 17025 is an international standard used to evaluate the competency of testing and calibration laboratories. ISO 17025 accreditation indicates that laboratories have demonstrated that they are technically competent and able to produce precise and accurate test and/or calibration data.



Pre-acceptance testing: Verification testing performed by a Third Party to confirm that product meets product/performance specifications prior to distribution release.

Proficiency testing: Testing to determine the proficiency of laboratories in identifying acceptable/unacceptable products; accuracy of laboratory results in identifying “known” acceptable/unacceptable samples.

Quality assurance for the Woman’s Condom was an intensive, multi-year process. Given that condom manufacturer Shanghai Dahua is relatively new to this market, and underwent a transfer from manual to automated production during EECO implementation, it was critical for the EECO team to provide technical assistance for Shanghai Dahua’s manufacturing operations to ensure consistent delivery of high-quality product. WCG hosted biweekly conference calls with partners Shanghai Dahua and PSI to address nonconforming quality issues identified during pre-shipment inspection, pre-acceptance testing activities, and supplier audits. These activities proved to be essential in improving Shanghai Dahua’s processes for sampling of quality control test samples (in-process and final release), batch traceability, and final inspection/testing of finished products.

KEY STEPS TAKEN:

- Performed supplier audits prior to procurement of first order to verify status of manufacturing operations.
- Evaluated manufacturer’s internal quality control testing processes against an independent, accredited third-party laboratory’s processes prior to procurement of first order.
- Established biweekly supplier conference calls that included an agenda and list of actions to address any procurement issues and ensure timely delivery of products (e.g., production delays, product quality issues, transport/customs issues, receipt of damaged product, etc.).





STAGE 4

Marketing, Distribution & Service Delivery

Following EECO's consumer and market research, the Maximum Diva and Whisper Woman's Condom brands were launched in Zambia and Malawi, respectively.

ZAMBIA: MAXIMUM DIVA WOMAN'S CONDOM

In Zambia, the Woman's Condom was marketed as a companion to the male condom brand Maximum, as Maximum Diva. The positioning statements for the brand reflected the benefits that differentiate the Woman's Condom from other methods available.

MALAWI: WHISPER WOMAN'S CONDOM

In Malawi, there was no clear fit for the Woman's Condom under an existing brand, so a new brand was developed. Market research revealed that potential consumers viewed the Woman's Condom as quieter and less intimidating to insert than other female condoms. They also suggested it would be less difficult to negotiate than the male condom and thus would be more discreet and easier to use. The team brainstormed several potential brand names related to this insight: Sensational, Whisper, Silk, and Softmate. These names were then tested with the target audience and assessed for fit with the chosen positioning. Ultimately, Whisper was chosen as the new brand name.

PRICING

EECO conducted willingness-to-pay research to determine an appropriate pricing strategy for the Woman's Condom in each country. In Malawi, the price was set at MWK 150 per condom (approximately \$0.20 USD). In Zambia, a pack of Maximum Diva, which includes two female condoms, retailed between ZMK 6–10 (approximately \$0.60-1 USD). Some providers chose to lower the price, thus earning fewer returns on the sale of the Maximum Diva Woman's Condom, to make the product more accessible to their customers.

DISTRIBUTION

The Woman’s Condom launched in Malawi in October 2015 and in Zambia in March 2016. By the end of each pilot, a total of 23,400 Woman’s Condoms had been sold in Malawi and more than 98,400 in Zambia (through June 2018). In Malawi, these sales figures were in line with distribution targets set out in EECO’s initial strategy for the product. In Zambia, the sales were much lower than

expected due to slow uptake at the provider level, as well as the end of SFH Zambia’s integrated social marketing project. EECO had originally planned to leverage that larger project to gain efficiencies — e.g., including multiple products in the portfolio of sales agents. Despite the lower than expected sales, Zambia saw a significant, steady increase in distribution as the program continued.

Table 2. **WHISPER & MAXIMUM DIVA DISTRIBUTION**

Average number of units purchased per order by facility type:

	PRIVATE/ SM CLINIC	PHARMACY	RETAILER/ KIOSK	BAR/ HAIR SALON	OTHER
Whisper Woman’s Condom (Malawi)	22 units	22 units	12 units	10 units	36 units
Maximum Diva Woman’s Condom (Zambia)	106 units	55 units	53 units	98 units	205 units

ENGAGING POTENTIAL USERS THROUGH PHONES AND COMPUTERS

Using the consumer and market research findings from Stage 2, the EECO mHealth partner, Every1Mobile (E1M), developed an online platform called smartChoices to provide young Zambians with essential information about HIV protection and voluntary contraception, including the Maximum Diva Woman’s Condom. Developed in concert with SFH Zambia and youth themselves, smartChoices was an interactive platform featuring expert advice from healthcare practitioners, “safe space” discussion forums, and learning modules. Promotional campaigns aimed to reach women, in particular, to address the gender divide in digital access to information. Between June 2015 and November 2017:

- More than 200,000 unique users opened the smartChoices site.
- More than 5,000 unique users registered with the smartChoices site.
- More than 1,000 “Ask the Expert” questions asked and answered on the site.
- Registered users spent an average of 28 minutes per visit on the site.
- Of the various digital promotion strategies used, Facebook was the most cost-effective way to drive traffic to the site.



Figure 4. HIGHLIGHTS OF THE WOMAN'S CONDOM MARKETING PLANS



MARKET SEGMENT:

Single women aged 19-24, lower socioeconomic status

KEY INSIGHT:

"I want to be protected from pregnancy and HIV. Sometimes using a condom compromises the pleasure of sex, and brings up issues of trust. I just want to have fun without having to worry."

POSITIONING:

"Using Maximum Diva allows me the freedom to explore life without worrying about the consequences."

PRICE:

The price to vendors for Maximum Diva was determined based on an analysis of a 'market basket' of consumer goods. The price of the Maximum male condom, which is sold in a three-pack, was also an important consideration.

Price to Consumers:

Maximum Diva Woman's Condom

ZMK 6-10 for 2 units

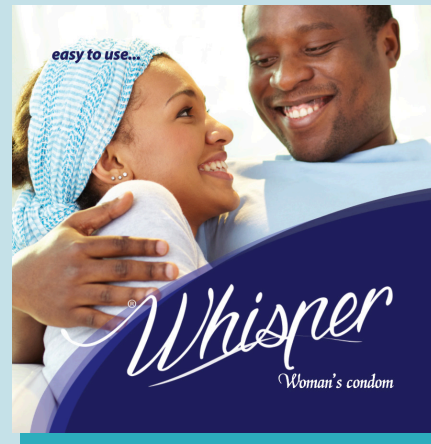
Maximum Male Condom

ZMK 5 for 3 units

FC2 Female Condom

Free

UNITS SOLD: 98,408



MARKET SEGMENT:

Unmarried urban females in relationships, aged 20-24

KEY INSIGHT:

"I know that in a few years I will have achieved all the successes I'm working for but now I'm not quite yet ready to settle down. Now is not the time to get pregnant. If I could discreetly find a quality method that doesn't cause side effects and allows me and my partner to enjoy sex, I'd be really happy."

POSITIONING:

"Whisper is the easy-to-use contraceptive choice that guarantees an intimate sexual experience free of fear of pregnancy and full of pleasure."

PRICE:

An important consideration for pricing Whisper was the positioning of the product as a "luxury" compared to FC2s. With the higher price, the team hoped to target a different segment of the condom market and to differentiate Whisper from previous generations of female condoms.

Price to Consumers:

Whisper Woman's Condom

MWK 150 for 1 unit

Care FC2 Female Condom

MWK 40 for 2 units

UNITS SOLD: 23,400

The Woman's Condom is a more expensive product than existing male and female condoms. However, the low level of uptake of previous generations of female condoms suggested that earlier products also suffered from user acceptability issues, in addition to price concerns.

The EECO team therefore took price concerns out of the equation, providing a high subsidy for the Woman's Condom. It focused instead on product acceptability. EECO tested the approach of introducing the Woman's Condom as a "luxury" product. The branding campaign focused on women living in urban areas who had some disposable income, rather than the lowest wealth quintiles. This segmentation approach was meant to determine whether a higher-end product could overcome past stigma and be attractive to users.

In Zambia, Maximum Diva was sold at outlets and venues frequented by young women aged 19-24 in Lusaka. These outlets included pharmacies (especially at large shopping malls), retail outlets such as supermarkets, and sporting and music events near college campuses. In Malawi, distribution took place in pharmacies, private clinics, and smaller retail kiosks. However, post-market research in Malawi revealed a potential lack of access to Whisper. In response, the team expanded distribution to bars and hair salons where the target audience of women and men ages 20-24 would be more likely to purchase condoms.

In both countries, distribution was slower than initially expected. While many providers were enticed by the high-quality packaging, branding and marketing support provided by EECO, as well as the targeted outreach to consumers to promote the product, the team still faced challenges in overcoming stigma against female condoms. Initial sales to providers required persistence, frequent values clarifications, and creative value propositions.

In Malawi, a dedicated team of medical detailers conducted frequent in-person visits with providers to encourage them to purchase Whisper.

In Zambia, there was no dedicated medical detailing team providing support for Maximum Diva sales, as the target venues were primarily through retail outlets. Given the slow start of sales, the EECO team later recruited dedicated sales agents in Zambia to focus on promotion of Maximum Diva. The dedicated sales team did show some success in moving stock to providers, despite continued challenges in finding new retail outlets.

KEY STEPS TAKEN:

- Considered a Total Market Approach (TMA) to contraceptives and HIV/STI prevention in determining price points for new products. Rather than introducing a product to the entire population, the EECO team conducted market and consumer research to develop an evidence-based market segmentation strategy.
- Conducted willingness-to-pay research with consumers to identify an appropriate price for both providers' desired profit margin as well as consumers' ability to pay. Ensured that the pricing strategy aligned with a TMA approach for contraception and HIV/STI prevention (i.e., that customers who are willing to pay do pay and those who cannot afford to pay do not have to pay).
- Invested resources in a dedicated education/promotion team to perform values clarification exercises with consumers and providers, which is particularly important for the Woman's Condom and other products that face a high level of stigma. In Malawi, this took the form of medical detailers who conducted in-person visits with pharmacists, clinicians, and retail outlet owners. In Zambia, this took the form of dedicated sales agents who worked with providers at retail outlets.





STAGE 5

Monitoring & Learning

POST-MARKET RESEARCH IN MALAWI

The EECO team conducted post-market research in Malawi in February 2017 to monitor the consumer and provider experience with Whisper. The consumer questionnaire sought to understand the consumer experience regarding the attractiveness and acceptance of the branding and packaging, experience with use of the product, the price point, market availability and access to the product. The provider research evaluated provider views on the product, their experience selling the product, and the attractiveness of the price margins and promotions.

This was a descriptive market assessment that was approved by the PSI Research & Ethics Board as well as the Malawian National Health Sciences Research Committee. The primary data collection methods for this study were one-on-one in-depth interviews with consumers of Whisper Woman's Condom as well as providers from clinics, pharmacies, and other retail outlets either stocking or not stocking the product.

CONSUMER INSIGHTS

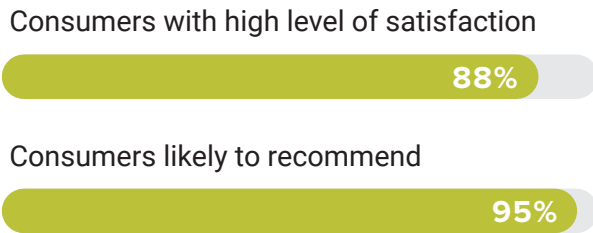
Consumers were recruited from a roster of participants who received Woman's Condom education and outreach through PSI's brand promotion team. The outreach program used interpersonal communication (IPC) techniques to raise awareness about the availability and use of Whisper, and to connect potential users with points-of-sale. Of those surveyed, 40% had purchased Whisper at least once, with 5 out of 41 respondents reporting that they had purchased Whisper three times or more. Consumers who had used the product stated that they did so because they were interested in a new product (69%), were attracted to the features of Whisper such as the ease of insertion and the lubricant sachet (31%), desired dual protection against HIV/STIs and pregnancy (13%), and were attracted to the packaging (13%). Overall, the consumers that used Whisper reported a high level of satisfaction and willingness to recommend the product.

Table 3. **CONSUMER & RETAILER DEMOGRAPHICS IN MALAWI**

CONSUMERS	N=41	RETAILERS	N=40
Age	18-48 (avg 27)	Facility type	
Female (%)	54%	Clinic	41%
Location		Pharmacy	53%
Blantyre	39%	Retail/Wholesale/ Other	6%
Mzuzu	34%	Retailer position	
Lilongwe	27%	Clinician	13%
Number of times purchasing Whisper		Nurse	23%
Zero	61%	Owner	13%
1-2	27%	Sales Agent/Cashier	25%
3+	12%	Manager	20%
Is Whisper available where you live?		Other Employee	6%
Yes	44%	Currently stocking Whisper?	
No	41%	Yes, currently stocking	63%
Don't Know	15%	Previously stocked	12%
Where did you purchase Whisper?		Never stocked	25%
Clinic	31%		
Pharmacy	69%		

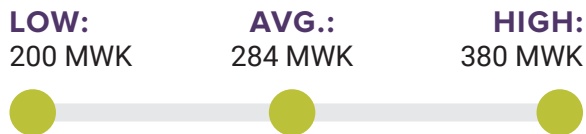


Figure 5. **WHISPER CONSUMER FEEDBACK**



Consumers paid an average price of 284 MWK for one unit of Whisper, which equates to approximately 0.50 USD.⁹ The range of prices that consumers reported was from 200 MWK (0.36 USD) to 380 MWK (0.70 USD). The range of prices suggests that there is flexibility in the market for providers to set price points based on their clients' ability to pay.

Figure 6. **PRICE PAID FOR WHISPER (PER CONDOM)**



The research showed that there was a low level of awareness among consumers about the availability of Whisper, with 56% of consumers stating that they did not know a source where they could purchase Whisper. In line with the findings of the formative research, there was a high level of stigma among consumers associated with purchasing female condoms, specifically for women; 40% of consumers said that shyness, embarrassment, or fear may be a barrier for purchasing Whisper. Interestingly, male consumers appeared to be more interested than female consumers in purchasing and trying Whisper.

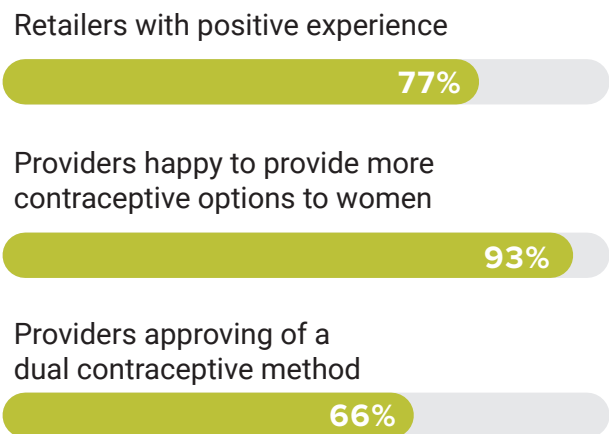
PROVIDER INSIGHTS

Providers were randomly selected from a list of facilities where at least one employee had

been trained on Whisper by the WCG Medical Detailing team in the last six months. Not all providers were currently stocking Whisper, as an important question posed by this research was why some may not be interested in the product. The final sample included providers who currently had Whisper in stock (63%), who had previously stocked Whisper but currently did not (12%), and those who had never stocked Whisper (24%). There were a variety of reasons for not having Whisper in stock offered by those who had either never stocked Whisper or were currently not stocking, including wanting to see client demand before purchasing (39%), out of stock or sold out (28%), discouraged by previous experiences stocking female condoms (22%) and a lack of information about the product (17%).

For those who were currently stocking or had previously stocked Whisper, the majority said that they had a positive experience with the product. However, the providers also highlighted some negative aspects of stocking Whisper, including low demand for the product and a lack of returning clients. Providers were concerned that their customers may experience barriers to purchasing Whisper including negative experiences with other female condoms (57%), inability to afford Whisper due to its higher price point (43%), embarrassment or stigma (41%), and spouse/partner disapproval (41%).

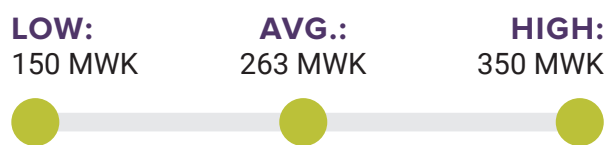
Figure 7. **WHISPER PROVIDER FEEDBACK**



⁹ Prices in USD based on USD/Kwacha exchange rate at the time of research.

Providers in the study sold Whisper at an average price of 263 MWK, which is approximately 0.47 USD. The prices reported ranged from 150 MWK to 350 MWK. As the product is sold wholesale to providers at 150 MWK, this suggests that some providers were selling Whisper “at cost” with no additional margin, while others were able to sell the product at a 230% markup.

Figure 8. **PRICE CHARGED FOR WHISPER (PER CONDOM)**



The EECO team learned several key lessons from the provider survey. To begin, convincing providers to purchase Whisper for the first time is a major challenge; many want to see client demand before they will stock a new product. In response to this challenge, the EECO team implemented facility-based promotion days, where brand promoters would conduct IPC activities in the area surrounding specific facilities. In this way, the EECO team was able to more efficiently link interested consumers with a product source and to show providers that consumer interest existed. A second key lesson was that both consumers and providers were concerned about the stigma associated with purchasing female condoms. In response to this, the EECO team integrated additional training materials in the medical detailing program to support providers in creating welcoming and safe environments for young women and their partners to purchase Whisper.

IMPACT EVALUATION IN ZAMBIA

Between November 2015 and April 2017, the EECO project partnered with Innovations for Poverty Action (IPA) to conduct an impact evaluation for the Maximum Diva Woman’s Condom in Lusaka, Zambia. Using a cluster randomized study design, IPA aimed to

understand the effect of IPC – one of EECO’s primary demand-generation strategies – on knowledge, acceptability and uptake of the Maximum Diva Woman’s Condom in urban and peri-urban areas of Lusaka.¹⁰ The research study protocol was approved by IPA’s IRB as well as Zambia’s Excellence in Research Ethics and Science (ERES) Converge.

The Maximum Diva Woman’s Condom was introduced in 40 urban wards within Lusaka Province. All wards were exposed to the Maximum Diva Woman’s Condom mass media campaign, which included billboards, promotional activities and a social media presence. Half of the wards were also exposed to IPC through peer-led small group sessions focusing on the Maximum Diva Woman’s Condom product. These sessions focused on myths and misconceptions, safety and use, partner communication and condom negotiation. IPA administered cross-sectional surveys at baseline (n=2,364 participants) and endline (n=2,430 participants) focusing on knowledge, acceptability and uptake in all 40 wards.

At the community level, the results were mixed: participants exposed to IPC had higher odds of accurately identifying female condoms, but not discussing or using female condoms with partners. Low IPC coverage in the intervention wards, as well as spillover effects, may explain the lack of significant results at the community level. However, at the individual level, IPA’s analyses showed that participants who attended IPC sessions were four times more likely to discuss contraceptives with their partner (OR=4.32; 95% CI [2.26, 17.13]), five times more likely to be able to identify a female condom (OR=5.22; 95% CI [3.01, 12.69]), and five times more likely to have used a female condom in the last six months (OR= 4.94; 95% CI [1.11, 9.39]). These results suggest that IPC sessions may have positive effects on individual-level knowledge, acceptability and uptake of the Maximum Diva Woman’s Condom.

¹⁰ Pinchoff et al. (2018). The impact of a peer-led interpersonal communication intervention on knowledge, attitudes and uptake of the new Woman’s Condom among urban, young adults in urban Lusaka: A cluster randomized evaluation. Manuscript submitted for publication.



Conclusions & Next Steps

EECO's value chain approach to product introduction incorporates the entire product life cycle – from development to end use – thus creating a roadmap for bringing the Woman's Condom to market. This roadmap can be applied and adjusted for the introduction of other reproductive health products in varying contexts.

One of the primary takeaways from the Woman's Condom introduction experience is the need to engage a coordinated set of market players and stakeholders to build ongoing support for the product launch and ongoing distribution. Securing the support of key stakeholders, like the Ministry of Health (MOH), ensured speedy product registration and import. In particular, identifying a champion within the Ministry was helpful in understanding and navigating the roles of different market players, and incorporating female condoms into national HIV prevention efforts. In Malawi, for example, Dr. Owen Chikhwaza, Deputy Director in the Directorate of Reproductive Health, advocated for the Woman's Condom from within the MOH.

Similarly, capacity-building efforts with the manufacturer were necessary to assure the quality of the product for the pilot and prepare the manufacturer for the future. Quality assurance capacity building is likely to be needed for other new manufacturers. Considerable time should be allotted to ensure that manufacturers can adequately meet acceptable performance specification and product workmanship. EECO recommends

planning for 6-12 months of this support prior to product procurement. Recommended steps include:

- conducting a supplier audit for the manufacturer with specific attention to inspection and final testing procedures to determine adequacy of manufacturer's processes;
- conducting proficiency studies between manufacturer and third-party laboratory to ensure alignment of testing results; and
- evaluation of market history and post-market surveillance to determine product experience of manufacturer.

Taking these steps during the pilot period allows for monitoring of product quality as well as opportunities for improvement of manufacturer operations.

Early on, EECO invested in in-depth consumer and market research to better understand their target audiences, including their cultural contexts and potential barriers to use. Employing market segmentation, EECO positioned the Woman's Condom as a high-end product for young women in Zambia and Malawi who wanted to prevent pregnancy and avoid HIV and STIs while using a non-hormonal method. Branding and pricing strategies reflected this positioning.

Demand-generation activities used a variety of creative means to reach consumers – from mobile and social platforms, billboards and branded activities, to IPC and community-

based roadshows featuring music, Woman's Condom demos and Q&A sessions. Given low historical demand for female condoms coupled with a high level of stigma, ongoing demand-generation efforts were fundamental to building a consumer base and attracting new users. In Malawi, medical detailers dedicated considerable effort to engaging providers to combat stigma and encouraging them to stock the Whisper Woman's Condom.

EECO employed distinct strategies for providers and potential consumers to combat stigma against female condoms due to their historical association with commercial sex work. For potential consumers in Malawi and Zambia, EECO focused on responding to their practical and emotional needs. For example, marketing materials placed a greater emphasis on the use of the Woman's Condom

for contraception due to formative research results showing that women were more concerned about pregnancy prevention than the prevention of HIV and STIs. Furthermore, promotional messaging aimed to address barriers to use of female condoms more generally, like ease of use and comfort. Lastly, the Woman's Condom was marketed as an aspirational product and sold at a higher price than other female condoms in hopes of attracting a different segment of the population.

Moving forward, the EECO team plans to undertake a TMA assessment for female condoms in both Malawi and Zambia. This assessment aims to better understand the total markets for female condoms, and the potential for the market to grow as well as become more sustainable and equitable.

WHAT'S NEXT FOR THE WOMAN'S CONDOM?

MALAWI

The MOH in Malawi, with support from UNFPA, plans to place an initial order of the Woman's Condom for distribution in the private sector to gauge interest before a potential public-sector launch.

ZAMBIA

Society for Family Health will continue to distribute existing Woman's Condom stock in Zambia. Discussions are underway with USAID and advocates in Zambia with regard to the future of the Woman's Condom.



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