

# The Business Case For Female Condoms

Prepared by Sarah Thurston and Anna Forbes, Global Health Visions



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**Global Health Visions LLC**

[www.globalhealthvisions.com](http://www.globalhealthvisions.com)

[info@ghvisions.com](mailto:info@ghvisions.com)



**Address**

**138 Broadway Suite 1G**

**Brooklyn, NY 11211**

**Phone: +1 646.472.5870**

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Photo credits. All photos were taken by Ryan W. Daniels in Mozambique in May 2013 for UAFC, with the exception of variety of condoms pictures in Annex II, that UAFC obtained from the respective female condom manufacturers.

## List of Acronyms

ART	Anti-Retroviral Therapy
BCC	Behavior Change Communication
DALY	Disability Adjusted Life Year
FP	Family Planning
GDP	Gross Domestic Product
GNI	Gross National Income
HIV	Human Immunodeficiency Virus
MCH	Maternal and Child Health
MSM	Men who have Sex with Men
PMTCT	Prevention of Mother to Child Transmission
ROI	Return on Investment
STI	Sexually Transmitted Infections
UAFC	The Universal Access to Female Condoms Joint Programme
UNFPA	United Nations Family Planning Association
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization
WHO-CHOICE	World Health Organization – <i>CHO</i> osing Interventions that are Cost Effective

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## Executive Summary

**Female condoms are the only woman-initiated, dual STI/HIV and pregnancy protection method available today.** As such, female condoms occupy a unique position in the global marketplace where high unmet need for protection methods drives cooperation between governments, donors, and the private sector to reach new consumer groups.

Female condoms have been available for over 20 years, yet new product innovations and a strengthened global focus on women's health has led to a renewed interest in the method. Efforts are being championed by national governments, donors, and global health advocates including the Universal Access to Female Condoms Joint Programme (UAFC), a consortium of Rutgers WPF, Oxfam Novib, I+ Solutions, and the Netherlands Ministry of Foreign Affairs, working to decrease HIV prevalence and unintended pregnancies and promote women's empowerment.

At the same time, the global health community is thinking more strategically and shrewdly about investments in health. Needs greatly outweigh available resources, creating the impetus for careful evaluation of expected returns on investment in the form of immediate results and sustained impact. **As such, this business case for female condoms critically examines the evidence for investment in female condoms, offering new analysis of return on investment, cost effectiveness, and wider economic implications.** Using peer-reviewed, open-source modeling tools developed by leading international health organizations, this business case demonstrates that the economic gains to be realized from investment in female condoms far outweigh the costs of programming, especially in high HIV prevalence countries. Further, female condoms offer a competitive cost per DALY against WHO-CHOICE thresholds and in comparison with alternative interventions. Recognizing that the economic implications of female condom utilization are wider than the results of a single investment, this business case also reveals linkages with key social outcomes that spur growth, income equality, and economic development.

The global health community has coalesced around the business goal of **reducing unmet need and increasing utilization of family planning and HIV prevention methods. Female condoms offer the means to achieve this goal through efficient, market-based solutions.** Current market dynamics present a window of opportunity to invest in female condom programming, thereby unleashing a virtuous cycle of increased utilization, sustained demand, better health outcomes, and stronger economies. The future of the marketplace for products that address vast unmet need is being shaped by current decisions and actions. Investment in female condoms at this point in time offers a strategic opportunity to meet the needs of today's women and the needs of future generations.

The analysis presented in **this business case points to important takeaways and recommendations** for the global health community:

- **Investment in female condoms is strategic.** Female condoms offer excellent value for money and bring unquantifiable benefits to users and their wider communities.
- **Understand the gains made from female condom programming.** Experiences need to be documented and disseminated in order to replicate success in new contexts and bring pilot programs to scale.

- **Keep costs down by leveraging existing distribution channels** that currently bring other health products to last-mile consumers. Add female condoms into this product mix to vastly increase access.
- **Develop and communicate key messages to each target group**, covering broad STI/HIV prevention and family planning topics alongside the unique product attributes of female condoms.
- **Expand the female condom market** through focus on product innovations and the registration and prequalification processes that are essential to bringing new products to market. A broader mix of female condom products increases consumer choice and competition in the marketplace.

Unmet need for protection is vast, and sales of female condoms are steadily rising.<sup>1</sup> **Meeting this high demand requires effective solutions to complex challenges. Female condoms have an important role to play in delivering these solutions**, offering critical economic and social benefits for individual users and their wider economies.

## 1. Introduction & Background

### 1.1 The current state of female condoms

#### **Background**

In March 2012, female condoms were listed by the United Nations Commission on Life-saving Commodities for Women and Children as one of 13 high-impact, effective, but overlooked tools that “if more widely accessed and properly used, could save the lives of more than 6 million women and children”.<sup>2</sup>

The female condom is a user-friendly, dual protection tool, preventing both HIV and other STIs and unintended pregnancy. Its effectiveness is fully comparable to that of the male condom,<sup>3,4,5,6,7,8,9,10</sup> and it has shown high acceptability among both women and men.<sup>11,12</sup> **Designed for vaginal insertion, the female condom is the only dual protection method that women can initiate and use without their partner’s active participation, providing women with control over safer sex, their health, and the health of their families.** While other dual protection technologies, such as contraceptive microbicides, are under development and expected to reach the market within the next decade, female condoms are available now, at this critical juncture in global health and development.

#### **Current Market: The Supply Side**

Female condoms debuted more than 20 years ago and were introduced in developing countries in the mid-1990s.<sup>13</sup> By the mid-2000s, product innovations had begun to reshape the female condom market. Leading the way, the Female Health Company reintroduced their female condom product with a synthetic nitrile material (the FC2) at a lower price point. Several product innovations followed from other manufacturers eager to enter the market. As of March 2014, the FC2 and Cupid 1 are the only female condom products prequalified by the WHO, while several other products are at various stages of development: Cupid 2, HLL, VA w.o.w., Origami, Phoenurse, and Woman’s Condom. Some of these products are available in various countries through limited private sector distribution (see Annex II).

Products currently on the market may be rebranded by social marketers to appeal to specific markets, multiplying the variety of names by which they may be known. The basic models, however, are produced by five different manufacturers. Each offers slightly different attributes and price points. This variety brings greater choice for users and greater competition between brands, serving to strengthen the marketplace.

### ***Current Market: The Demand Side***

High unmet need in developing countries for STI/HIV and pregnancy protection is well documented. Limited data makes it challenging to quantify method-specific demand. However, it is clear that sales of female condoms are rising,<sup>14</sup> and countries that have invested in female condom programming are experiencing a sustained demand.<sup>15,16,17,18,19</sup> Therefore, ensuring access to female condoms within the context of broad method mix is critical. Not only does a broad method mix lead to higher rates of protected sex acts<sup>20,21,22</sup> - a key precursor of better health and economic outcomes - but choice among methods is an important individual right for women and men.

## **1.2 Defining the business goal**

Investments aimed at addressing key health priorities are driven by ethical imperatives but also economic considerations. While there is an obvious ethical imperative to meeting unmet need for family planning and HIV protection, especially in developing countries with high population growth rates, high HIV prevalence, and poor or uneven access to health care, there is also a clear economic rationale. Prospects for economic development are closely linked with a population's health status and fertility rate, both of which impact the level of resources available for infrastructure, education, and other growth-enabling institutions. Improving the health of a population and reducing disparities in health outcomes are critical for achieving pro-poor economic growth and reducing poverty. As such, governments and donors are eager to identify opportunities to respond to health needs through cost-effective solutions that drive economic objectives. A clear mapping of the business case for a particular intervention is necessary to understand the expected impact and return on investment.

The business goal can then be defined as a **reduction in unmet need and increase in utilization of family planning and HIV prevention methods through efficient, market-based solutions**. Through an analysis of economic and social factors, this business case lays out the rationale for investment in female condoms as an effective and efficient approach to achieving this business goal.

## **1.3 Methodology for assessing investment**

This business case includes an economic and social appraisal of female condoms. **Economic impact analysis** sheds light on the expected economic consequences of a particular intervention and provides a framework for analyzing an intervention's cost effectiveness. This provides investors with key data to assess return on investment, value for money, and the relative cost effectiveness of one intervention as compared with alternative interventions. However, the tools of health economics are concerned with resource maximization and do not offer guidance on important objectives such as expanding method choice, empowering women, and improving equity of health outcomes. As such, a **social impact analysis** broadens the evaluation by assessing the (macro) economic implications of social changes brought on by wider access to female condoms.

This business case discusses three key areas related to investing in female condoms: i) achieving a return on investment; ii) a cost effectiveness analysis; and iii) a review of the wider economic

implications. The following outlines key components of the methodology. (Please see Annex I for more on methodology.)

- 1. Return on investment:** A hypothetical number of 1,000,000 female condom units was selected. This quantity is assumed to be an achievable volume for one year of programming in a given country where programs are operating at scale. Four case study countries were selected – Cameroon, Kenya, Myanmar, and Nigeria – in order to show the effects of 1,000,000 female condoms in relation to real changes in population health status and set against variables in real economies.

This impact analysis uses peer-reviewed, open-source modeling tools developed by leading international health organizations, including Population Services International (PSI), Marie Stopes International (MSI), and Futures Institute. These models use data from case study countries' most recent Demographic Health Surveys (DHS) and other population surveys. The models incorporate average product usage rates, method failure rates, and average product wastage rates. For this analysis, the models are set to estimate the morbidity and mortality averted from provision of 1,000,000 female condoms. It is important to note that the impact results are *estimates* and assume that effective programming is taking place to enable successful distribution and uptake.

From the estimates of morbidity and mortality averted, the costs that the health system can save by not having to treat these cases, is calculated using average per-country treatment costs. In addition, the economic productivity of average working-age adults is calculated for each country along with reduced productivity on account of HIV infection (with access to ART) and maternal mortality. Economic benefits are expressed as productivity saved and health system costs saved by averting negative health outcomes through use of 1,000,000 female condoms in case study countries. Using actual per-country cost data from UAFC and PSI, enables comparison between programming costs and expected economic benefits for a return on investment analysis.

- 2. Cost Effectiveness Analysis of Health Outcomes:** Using the models' estimates of morbidity and mortality averted through provision of 1,000,000 female condoms as well as actual programming costs, the cost per DALY is calculated in case study countries. These metrics are compared against WHO-CHOICE cost effectiveness thresholds and against cost per DALY of alternative HIV prevention and treatment interventions in sub-Saharan Africa. This provides both a threshold and comparative cost effectiveness analysis.
- 3. Economic Implications Across Society:** Desk research and interviews were completed to further document the impact of female condoms on a society's prospects for economic growth and income equality. This included a review and synthesis of literature from health economics, public health, development studies, and sociology alongside insights from 14 key informant interviews with practitioners, policymakers, and donors in the FP and HIV/AIDS arenas. These findings were analyzed to draw out key social implications of greater female condom use, all of which have wide-reaching economic consequences.

## 2. Return on investment

### 2.1 Principles of strategic investing

The evidence-based link between better reproductive and maternal health outcomes and greater social and economic development has led many donors and governments to invest in programming for STI/HIV prevention and family planning. Yet greater access to protection methods is one of many high priorities in global health, and the need for investment outweighs the resources available.

These resource constraints motivate decision-makers to invest strategically – defined for the purposes of this business case as investment in interventions that are effective, efficient, and catalytic for wider societal benefits. Strategic investments yield returns in excess of the funds invested and accelerate market dynamics that attract further investment from the public or private sector.

For investments in health, ‘returns’ can be realized through **direct cost savings to health systems and increased economic productivity from workers who stay healthy and continue contributing to their countries’ economies**. Strategic investments also **address core social issues that have wide-reaching economic benefits and ignite virtuous cycles of better health and greater economic growth**.

The need to carefully evaluate return on investment (ROI) and comparative cost effectiveness has led to greater use of economic tools together with an increasing emphasis on standardized metrics and methodologies. The sum of these efforts has paved the way for a more strategic and evidence-based approach to social investing, a trend which brings greater transparency for taxpayers and donors and greater accountability to the women and men for whose benefit these investments are made.

### 2.2 Quantifying expected costs

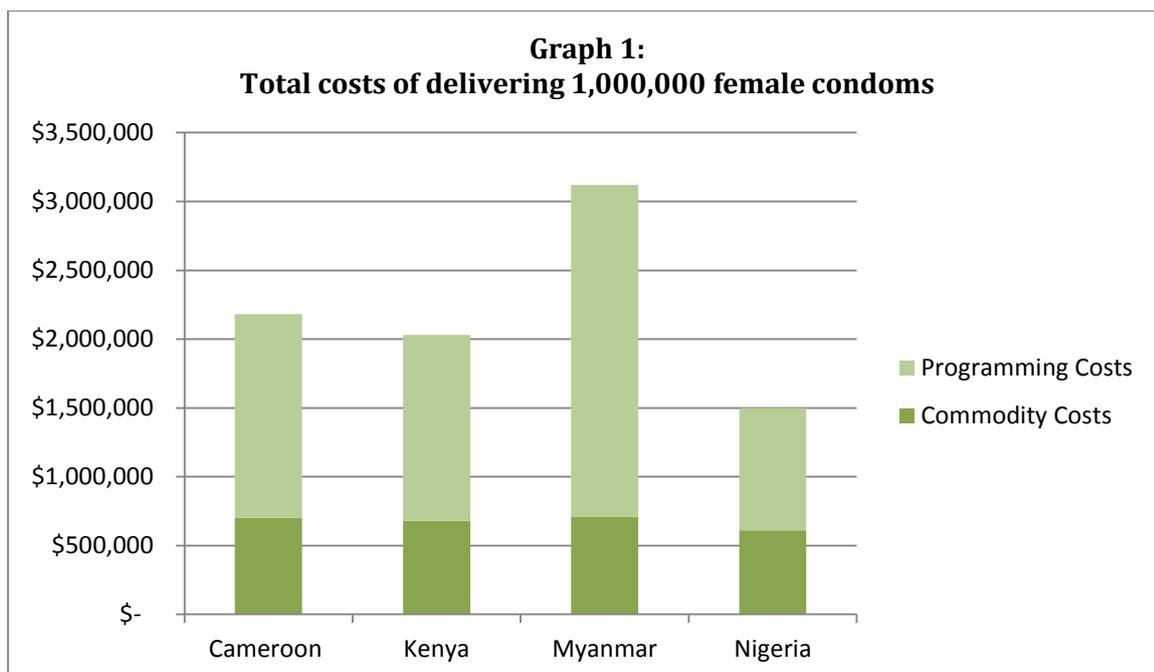
The first step in assessing the expected ROI on a health investment is to quantify the expected costs of the intervention. For this ROI analysis, actual cost data from female condom programs in Cameroon, Kenya,<sup>1</sup> Myanmar, and Nigeria is used. Costs vary by country, context, and the specific objectives of an intervention.

Programming costs for female condoms typically encompass intensive user awareness and behavior change communication (BCC). This is particularly necessary when marketing newer products that prospective users may not be familiar with. In some cases, communities may be suspicious of new products, increasing the importance of comprehensive information and education for users *and* key community stakeholders.

In addition to programming, commodity costs make up a significant proportion of expenditure. For the purposes of this analysis, a female condom cost of \$.55 per unit was used. This cost may be reduced depending on the brand, procurement volumes, and negotiation with the respective manufacturer.

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<sup>1</sup> Due to data limitations, the Kenya case study uses average costs for PSI female condom programs in eastern and southern Africa.



As shown in Graph 1, contrary to some opinion, **the main cost driver of female condoms is *not* the commodity costs**. Rather, programming accounts for a greater proportion of total costs. When female condoms are first introduced into a new market, as is the case for all new products, investment in marketing, user awareness, and community education is required. However, as evidence from Zimbabwe demonstrates, female condom programming costs decrease over time as community knowledge increases.<sup>23</sup>

Two key takeaways for governments and donors help reframe thinking on female condom costs. First, commodity costs do not drive overall costs, although female condoms are still more expensive than male condoms and efforts to decrease these costs through volume procurement, demand generation, and competition in the marketplace are ongoing. Second, the portion of programming costs associated with new market entry is an upfront investment that pays off and abates over time.

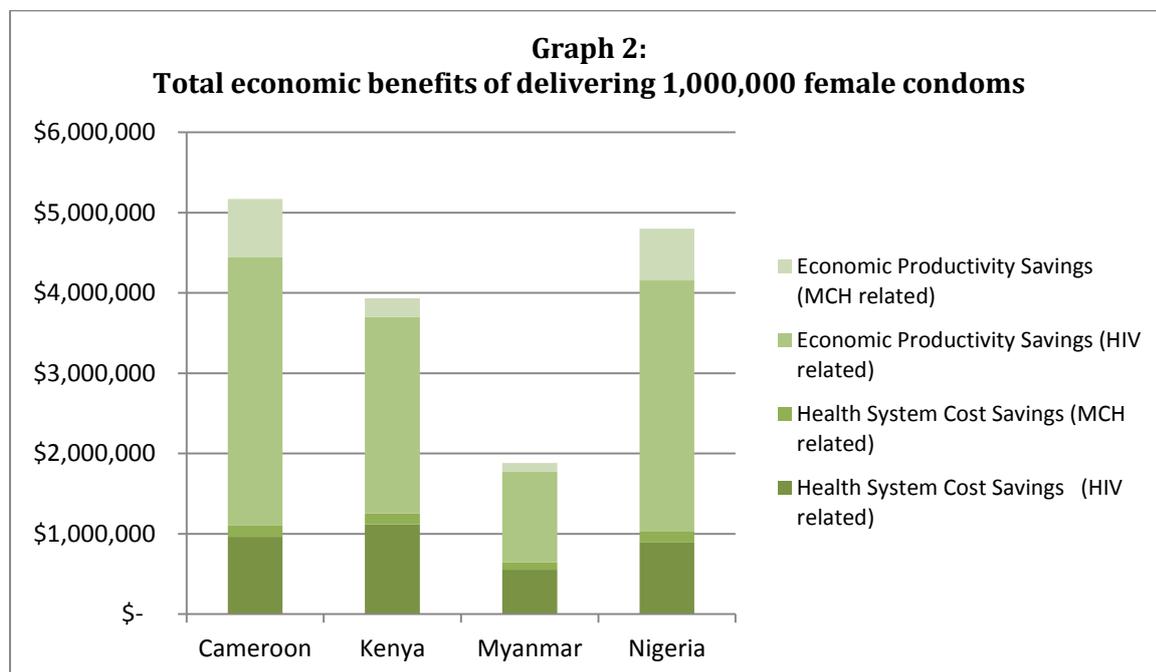
### 2.3 Quantifying expected economic benefits

The full economic benefit of improvements in a population's health status is complex and manifests over the long-run. For the purposes of this ROI analysis, economic benefits have been distilled into two key measures:

1. Cost savings to the health system realized through not needing to treat the HIV/AIDS and maternal morbidity cases averted through use of female condoms; and,
2. Economic productivity losses averted through the continued workforce participation of adults who avoid HIV infection and maternal mortality through use of female condoms.

These measures were chosen because of their direct relationship to the health outcomes generated by female condom use and the relatively short time frame within which benefits can be realized in the health system and wider country economies.<sup>24</sup>

As described in the methodology section and further in Annex I, models from PSI, MSI, and Futures Institute were used to calculate cost savings to the health system and economic productivity losses averted through distribution of 1,000,000 female condoms.<sup>25,26,27</sup>

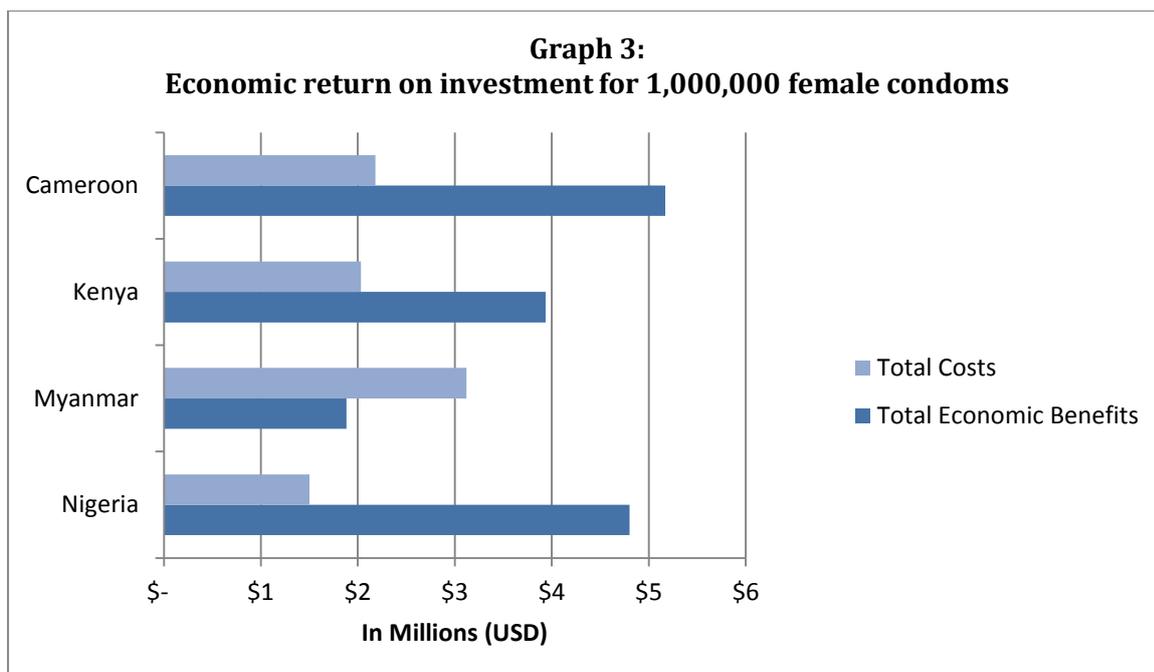


Graph 2 shows the total economic benefits of programming 1,000,000 female condoms in case study countries. Shown in the middle sections of the columns, economic productivity losses averted through a reduced number of HIV infections account for the greatest proportion of economic benefits. This analysis assumed full access and adherence to ART, allowing adults living with HIV and AIDS to continue participation in the workforce, albeit at a 25% reduction in productivity (see Annex I). In reality, ART does not reach the majority of adults living with AIDS who need it, meaning that many do not return to the workforce after falling ill. Therefore, this analysis is a *conservative* estimate of economic productivity losses averted.

The results in Graph 2 show clear economic benefits of investment in female condoms in the form of cost savings to the health system in intervention countries and direct productivity losses averted for countries' economies. For governments, this means that an investment now saves health budgets and economies many millions of dollars over the coming years. For donors, investment today reduces the level of support recipient countries will require in the future. For both sets of stakeholders, the economic benefits are clear.

## 2.4 Economic return on investment (ROI)

What level of return on investment can be expected from support for female condoms? Comparing total expected costs (programming + commodities) with total estimated economic benefits shows an excellent return on investment for female condoms in sub-Saharan Africa and a substantial benefit against costs in the southeast Asia case study country, Myanmar.



**In Cameroon the investment of \$1 offers \$2.37 return on investment to the country’s economy. In Kenya, the investment of \$1 offers \$1.94. In Myanmar, \$1 offers \$.61. And, in Nigeria, an investment of \$1 offers a \$3.20 return.**<sup>28,29</sup> When considered through the lens of an investor, these returns on investment offer excellent value for money in Cameroon, Kenya, and Nigeria, based on general population health indicators. In Myanmar, several factors contribute to a lower return on investment. Myanmar has a lower HIV prevalence rate, as compared to the sub-Saharan Africa case study countries, resulting in fewer HIV infections averted for the same level of female condom provision. In addition, PSI’s program in Myanmar specifically targets sex workers and other high-risk groups. Targeting high-risk groups can lead to higher programming costs. Lastly, Myanmar’s economy is affected by international sanctions, impacting the costs of conducting routine activities. Despite this, the ability to recoup over 60% of costs in the form of economic benefits is not a poor proposition for a social investor.

### 3. Cost effectiveness analysis of health outcomes

On their own merit, female condoms represent an effective, efficient solution to the business goal. Donors can expect clear return on investment in the form of economic benefits for intervention countries. However, any donor or national government investing in female condoms will want to understand how female condoms measure up against alternative uses of funds.

Using the same models from PSI and MSI, this section quantifies the estimated health outcomes resulting from programming 1,000,000 female condoms. Following this, a cost effectiveness analysis sheds light on whether female condoms represent a cost effective way to achieve these health outcomes as compared with alternative interventions.

#### 3.1 Estimating the health impact in case study countries

Distributing 1,000,000 female condoms through effective programming will deliver impressive health benefits in case study countries,<sup>30,3132</sup> which can be replicated in other countries. In real-time, these benefits are already underway in Cameroon and Nigeria, where UAFC is supporting female

condom programming that has already surpassed the 1,000,000 unit mark, and in Myanmar, where PSI has actively socially marketed female condoms to key populations since 2003.<sup>33</sup>

**Table 1: Estimated health outcomes from programming 1,000,000 female condoms**

<b>1,000,000 female condoms</b>	<b>Cameroon</b>	<b>Kenya</b>	<b>Myanmar</b>	<b>Nigeria</b>
# DALYs averted	9,292	9,713	4,122	9,488
# of unintended pregnancies averted <sup>2</sup>	1,939	1,939	1,939	1,939
# of HIV infections averted	108	125	62	100
# of maternal deaths averted	8	4	2	7
# of infant deaths averted <sup>3</sup>	53	39	14	77
# of unsafe abortions averted <sup>4</sup>	243	265	521	213

The ethical merit of improving access to health care is unquestionable. Each of these cases represents an individual whose life is better on account of these cases averted. In addition, these cases averted represent the chance for women and men to continue to contribute to their economy, consuming goods and services, and to reduce their utilization of the public health system for preventable diseases and conditions.

## 3.2 Cost effectiveness analysis

A key question for governments and donors is whether female condoms are a cost effective way to achieve these health outcomes. Could the same outcomes be more efficiently achieved through an alternative intervention? Cost effectiveness analysis helps answer these questions. It is an approach used by health economists to evaluate whether the costs of a health intervention are reasonable in light of pre-determined thresholds and in comparison to alternative interventions that may achieve similar outcomes.<sup>34,35</sup>

Comparing the costs and benefits of different health interventions requires a standardized ‘language’ of results. To meet this need, analysts have developed composite metrics like the disability-adjusted life-year (DALY), quantifying a ‘unit’ of health and allowing comparison between various interventions that produce ‘units’ of health.<sup>36</sup> The DALY combines years lived with a disability and years lost to early death. One DALY averted represents one year of healthy life.

### 3.2.1 WHO cost effectiveness thresholds

The first question that arises in a cost effectiveness analysis is: cost effective against what? For more standardized comparisons, the WHO-CHOICE project has issued recommended international

<sup>2</sup> The # of unintended pregnancies averted is expressed as a ‘comparison pregnancy rate,’ i.e. a method-specific failure rate compared with the average pregnancy rate without use of contraception. Although pregnancy rate will vary by country due to biological and behavioral differences, no studies exist to quantify these differences. Therefore, this metric expresses the # of unintended pregnancies averted through use of 1,000,000 female condoms in any country rather than in relation to country-specific variables. Hence, the same # of unintended pregnancies from use of 1,000,000 female condoms is seen across the four case study countries.

<sup>3</sup> Infant deaths averted is expressed as deaths averted due to improved birth spacing, i.e. increasing the previous birth interval (PBI)

<sup>4</sup> Unsafe abortions averted is expressed as the # of live births averted x the unsafe abortion ratio using WHO unsafe abortion estimates by sub-region from 2008. 1,000,000 female condoms prevent more unsafe abortions in Myanmar than in sub-Saharan Africa due to higher (unsafe) abortion rates in southeast Asia.

thresholds for cost effectiveness. A health intervention’s cost per DALY is classified within a three-tier scale: *highly cost effective*, *cost effective*, or *not cost effective*.<sup>37</sup>

**Table 2: WHO-CHOICE cost effectiveness thresholds**

Cost per DALY averted is:	
Highly cost effective	Less than the GDP per capita
Cost effective	Between one and three times the GDP per capita
Not cost effective	More than three times the GDP per capita

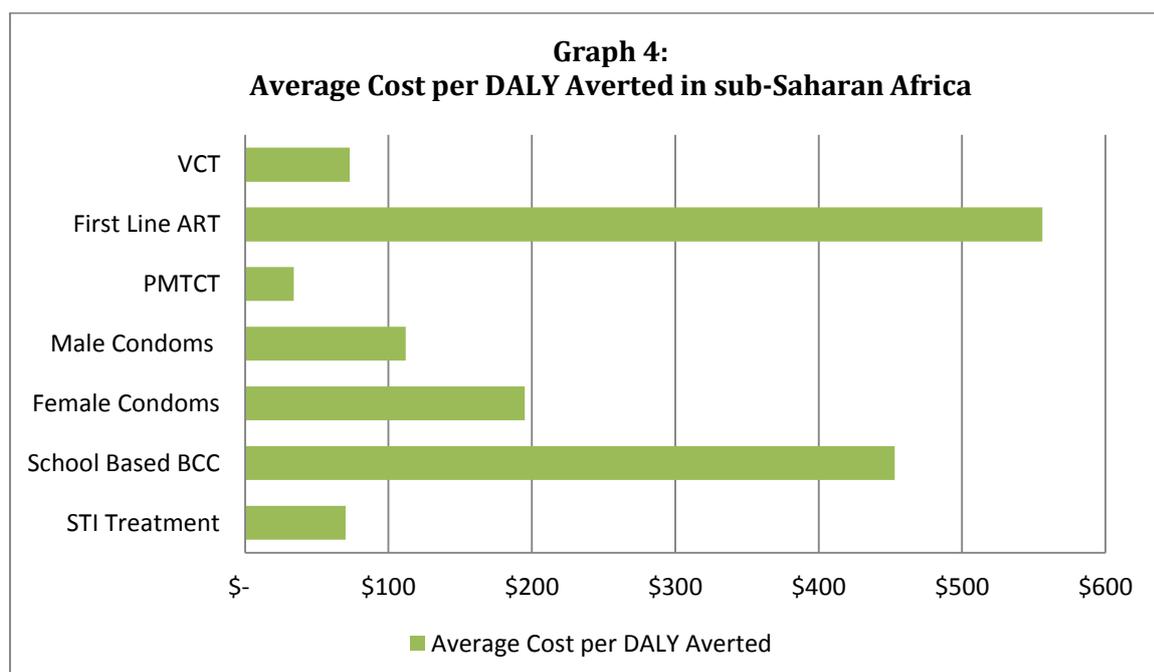
Framing cost effectiveness thresholds against country GDP per capita helps contextualize what spending levels are possible and reasonable for a given country’s resources. **In case study countries, cost per DALY for female condoms is highly cost effective against WHO-CHOICE thresholds.**

**Table 3: Female condoms’ cost effectiveness against WHO-CHOICE thresholds**

Cost per DALY of programming 1,000,000 female condoms	Cost per DALY	WHO Threshold	Rating
Cameroon	\$235	\$1,151	Highly cost effective
Kenya	\$209	\$862	Highly cost effective
Myanmar	\$757	\$1,200	Highly cost effective
Nigeria	\$158	\$1,555	Highly cost effective

### 3.2.2 Cost per DALY compared with other high priority interventions

In addition, comparative cost effectiveness analysis helps decision-makers understand how a given intervention measures up against alternative uses of funds. Using average cost per DALY available in the literature for both prevention and treatment interventions in sub-Saharan Africa,<sup>38,39</sup> Graph 4 demonstrates that female condoms offer a competitive cost per DALY when compared with other options for funding. This means that, **compared with alternative interventions, female condoms represent a competitive purchase price for one unit of health.**



## 4. Economic implications within the wider society

The results of the return on investment and cost effectiveness analysis in the previous sections demonstrate the potential of female condoms to achieve the business goal in an effective, efficient manner. But the economic implications of female condom programs are wider than the results of a single investment.

Broad macroeconomic benefits are associated with higher rates of protected sex acts, lower fertility, and reduced HIV prevalence, all achievable through greater access to a broad basket of contraceptive choice, including female condoms. The full economic impact of female condoms is complex, working through direct and indirect outcomes, over time, and across generations. This section focuses on three wide-reaching social benefits offered by female condoms. Each improves individual wellbeing and, in addition, directly contributes to the determinants of economic growth in developing countries.

### 4.1 Improving choice and coverage

Adding female condoms to the mix of available protection methods leads to increased rates of protected sex acts. For contraceptive needs, the evidence demonstrates that when more FP method choices are available, the rate of contraceptive utilization increases.<sup>40,41</sup> Further, studies show that, for HIV prevention, where both male and female condoms are available, the total number of protected sex acts increases as compared to situations where only male condoms are available.<sup>42,43,44,45,46</sup> **Positioning female condoms within the method mix improves method choice and coverage, resulting in fewer STI/HIV infections and fewer unintended pregnancies.**

Although male condoms are relatively inexpensive and widely available, data on male condom use indicates that a significant proportion of sex acts, including those considered high-risk, still go unprotected.<sup>47,48,49</sup> This suggests that male condoms alone do not adequately meet the needs of all couples requiring dual protection. Female condoms offer the same dual protection benefits but with different product attributes that studies have shown many men prefer, e.g. less constriction on the penis and possible to use without a full penile erection.<sup>50</sup> Female condoms are therefore a critical addition to the protection method mix for couples who do not, or find it difficult to consistently use male condoms, prefer the sensation of a female condom, or like to share the responsibility of initiating condom use.

**Female condoms increase STI/ HIV protection and contraceptive uptake, reducing disease burden and lowering fertility rates, indicators closely linked with better economic growth.** Representative of this dynamic, scenario modeling in Nigeria has shown that a reduction in the country's total fertility rate of one child per woman would result in a 13.2% increase in GDP per capita after 20 years, rising to a 25.4% increase after 50 years.<sup>51, 52</sup>

### 4.2 Supporting women's empowerment

Women's economic empowerment is positively correlated with poverty reduction and economic growth.<sup>53</sup> This evidence positions female empowerment – a broad concept encompassing access to education, workforce participation, sexual and reproductive health and rights, status and negotiating skills in the home, and financial agency – at the forefront of the global development agenda.

Higher rates of contraceptive uptake and HIV prevention are strongly linked with women's economic empowerment. At the household level, evidence from rural Bangladesh shows that, over time, women living in villages where contraceptives were available owned more economic assets than women in control group villages where FP programming was not implemented.<sup>54</sup> In Botswana, evidence demonstrates a robust positive correlation between women's economic independence and condom use at last sexual encounter.<sup>55</sup>

**Consistent access to a product that allows women to initiate dual protection supports mutually reinforcing goals: women's empowerment and better health outcomes.** In the short-term, female condoms provide women with a tool for their own protection, as well as their partners, providing expanded choices for women and couples to exercise the right to select a preferred method. Equally, the power to initiate dual protection and choose a preferred method supports structural improvement in women's status over the long-run.<sup>56</sup>

The causal relationship between women's economic empowerment and better health outcomes is difficult to disaggregate – empowerment leads to better health and better health supports empowerment. However, it is clear that catalyzing this virtuous cycle is critically important for women and their families. It is also evident that these positive outcomes have wide-reaching implications at the country level. **Women's economic empowerment is closely linked with higher per capita incomes and better rates of economic growth.**<sup>57</sup>

### 4.3 Increasing equity of health outcomes

Achieving higher per capita incomes is an important development goal, but the distribution of wealth within a population also impacts economic growth. Reducing health disparities between population groups improves income equality at the country level, leading to better rates of economic growth especially for poor countries.<sup>58</sup>

Reducing health disparities, i.e. increasing the equity of health outcomes, requires addressing the needs of disadvantaged and underserved groups. These groups include those who face financial or informational barriers to health services, as well as those who face stigma on account of their occupation or sexual orientation. Female condoms have a demonstrated success in providing additional protection to sex workers during commercial sex.<sup>59,60,61</sup> Men who have sex with men (MSM) and heterosexual couples having anal intercourse also benefit from female condom access.<sup>62,63,64</sup> Although no regulatory authority has yet evaluated or approved female condoms for anal sex, five public health departments in the US and Canada publicly endorse their use in this capacity.<sup>65</sup> As such, female condoms provide a critical tool to reduce health disparities for key disadvantaged groups.

Young women – a large and growing underserved cohort with a higher risk of STI/HIV and unsafe abortion – also stand to benefit from access to female condoms. Young people rely more heavily on short-acting contraceptive methods than older women and men do.<sup>66,67,68</sup> And, younger women may lack the confidence, maturity, and negotiating skills to convince partners to use male condoms. Therefore, ensuring access to female-initiated dual protection offers young women (and young men) the opportunity to better manage their reproductive lives.

**Addressing the health needs of disadvantaged women and men reduces health disparities within a country, facilitating the income equality associated with better rates of economic growth.** When

disadvantaged groups enjoy a more equal role in society and the labor market, higher rates of productivity, higher savings rates, and a broader tax base that allows national governments to invest in infrastructure, health, and education can be seen. Each of these trends represents a critical component of economic development.

## 5. Market dynamics and the future of female condoms

This business case has provided an evidence-based analysis of return on investment and cost effectiveness of female condoms alongside key economic implications of increased female condom access. Female condoms offer a proven and cost-effective platform for governments and donors to meet STI/HIV prevention and family planning goals. In the final section, broader market dynamics for the female condom are explored.

### 5.1 Investing at a critical juncture

Alongside steadily rising sales of female condoms,<sup>69</sup> new female condom products are entering the global marketplace (see Annex II). These innovations offer users more choice and offer purchasers more flexibility among products at different price points. Greater product choice may increase demand as users select a product that best meets their needs. The primary driver in a changing market is community-level awareness and aggregate demand for the method. Marketing and BCC for female condoms has proven highly effective in a number of countries including Brazil, South Africa, and Zimbabwe.<sup>70,71,72,73,74,75</sup> It is time to synthesize and replicate these lessons learned in new countries and contexts. With heightened global attention on the business goal – reducing unmet need and increasing utilization of family planning and HIV protection methods – now is the time to consolidate gains and capitalize on an important moment in the female condom market.

Unmet need for protection is vast. Over 222 million women in the developing world express an unmet need for contraception,<sup>76</sup> and the demand for HIV prevention is not fully met by male condoms. Ensuring access to female condoms, facilitated through comprehensive programming, is essential to ensuring a broad method mix to address this need across communities and countries.

Investment in female condoms offers governments and donors the opportunity to unleash a virtuous cycle of increased utilization, sustained demand, better health outcomes, and stronger economies populated by women and men with the purchasing power for the health products. Virtuous cycles like these, at the heart of economic and social development, attract private sector companies eager to participate in growing markets. **Investment in female condom programming now will leverage the market dynamics currently underway and realize the potential for sustained demand.**

### 5.2 Recommendations for action

In order to achieve the business goal and reduce unmet need for family planning and STI/HIV prevention methods, female condoms must be among the available interventions. However, timely action by stakeholders is needed. There are key areas for investment to better ensure access to female condoms, communicate their unique attributes, and expand the method mix for dual protection. Some critical recommended areas that are essential to greater female condom availability and access include:

- 1. Invest, Invest, Invest:** Resources and investments in female condoms are needed. Female condoms bring women unquantifiable benefits for their health and agency over safer sex. For investors, female condoms offer excellent value for money on their discrete investment and ignite social dynamics with wide-reaching economic benefits.
- 2. Understanding Gains with Female Condoms:** In order to better understand and replicate success in the current landscape, it is necessary to document and disseminate lessons learned in countries where female condom programming is being brought to scale and generating sustained demand. Rigorous costing studies can shed light on volume-driven efficiency gains as female condoms are made available to last-mile consumers.
- 3. Linkages to Current Distribution Channels:** In order to keep distribution costs down and create linkages in the minds of consumers, stakeholders should aim to leverage existing consumer health distribution channels. Men and women who may purchase anti-malarials, oral rehydration salts, or male condoms from a community-based vendor need the option to buy female condoms there as well. By piggy-backing on existing distribution channels and retail outlets, favorable cost savings and product associations in the minds of consumers can be leveraged.
- 4. Communication Pathways are Critical:** Investments in female condoms should be closely linked with consumer awareness and demand generation in order to clearly communicate the benefits of a newer product with which users may not yet be familiar. Messaging on STI/HIV prevention and contraception can coincide with marketing the unique product attributes of the female condom. Marketing within the general population is critical for broad-based support and sustained demand. At the same time, programmes targeting key disadvantaged groups are necessary, while being cautious not stigmatize female condoms. For each target group, an effective communication strategy, including context and target group specific messaging, should be designed.
- 5. Expand the Market:** Innovation is critical to ongoing progress. Resources must be used to continue to push the envelope with new female condom product innovations, opening new markets to the rising number of products through support for registration and prequalification. Competition among products drives innovation and directly benefits the consumer.

The future marketplace for the products that will improve the health of many millions of women and men is being shaped right now. The key question for investors is whether their current strategies are meeting needs while strategically influencing the market for the coming generations.

**The case is clear: investing in female condoms – a unique, life-saving commodity – is an effective and efficient use of resources.** Female condoms offer the opportunity for immediate results alongside sustained marketplace improvements, the results of which empower women, advance communities, and strengthen economies.

## Annex I – Methodology

The overarching methodological approach used in the business case is described in Section 1.3. In this Annex, further background is provided on the approaches, models, and sources used to calculate impact results displayed in Graphs 1,2,3, and 4.

### Graph 1

Graph 1 shows the total costs of delivering 1,000,000 female condoms in Cameroon, Kenya, Myanmar, and Nigeria. For this costing analysis, UAFC provided financial data from partners implementing female condoms programs in Cameroon and Nigeria. **The consultants independently reviewed financial data from programs’ audited annual accounts for 2010 and 2011. All direct and indirect in-country programming costs were included in the analysis.** The small amount of revenue from the portion of female condoms sold (socially marketed) was reinvested in programming and therefore netted off total costs. From the annual costs and female condom volumes distributed by each program, the cost per unit of programming 1,000,000 units was extrapolated. **For a conservative approach that is more representative of a typical female condom investment, the consultants used a per-unit commodity cost of \$.55,** even though UAFC had been able to negotiate a lower bulk per-unit price for its programming. For case study countries Kenya and Myanmar, the consultants utilized PSI programming cost data from 2008 published in Marseille and Kahn, 2008, extrapolating these programming costs to 1,000,000 units. The same \$.55 per-unit commodity cost was applied to Kenya and Myanmar case studies.

### Graph 2

Graph 2 shows the total economic benefits of delivering 1,000,000 female condoms. For this analysis, economic benefits fall into two categories. The first benefit is **cost savings to the health system** realized through not needing to treat the HIV and maternal morbidity cases averted through use of female condoms. To calculate this, the first step was to estimate how many morbidity cases were averted through distribution of 1,000,000 female condoms for each of the four case study countries (see Table 1). MSI’s *Impact 2* was used to estimate maternal morbidity cases averted and PSI’s *DALYs Calculator* was used to estimate HIV infections averted. Full methodologies for both models – which involve scenario modeling using DHS and other data sources – are available on the organizations’ respective websites.

The next step was to estimate what costs would have been incurred by the health system in treating these cases if they had they not been prevented through use of female condoms. To do this, MSI’s *Impact 2* was used. This model is pre-populated with average treatment costs per country for pregnancy-related and maternal morbidity cases. For HIV infections, cost savings were calculated using the Futures Institute’s *Future Cost of Anti-Retroviral Therapy* model. The model assumes that all adults requiring ART will require both first-line and second-line therapy. The consultants assumed that adults will initiate ART at a CD4 between 250 and 350. Costs reflected include ART, laboratory tests, and end-of-life care, but exclude the treatment of opportunistic infections, for an average total lifetime cost (with 3% discount rate) of \$8,935 per adult. **Average treatment costs for HIV and maternal morbidity are then multiplied by the number of cases averted through provision of 1,000,000 female condoms in each case study country – all with a 3% discount rate.** The key limiting caveat to this analysis – both for maternal health and HIV cases – is that it assumes full treatment, i.e. that women and men needing health care will be able to access it. Currently, many are unable to, saving the health system money but for the wrong reasons.

The second benefit is **economic productivity losses averted** through the continued workforce participation of adults who avoid HIV infection and maternal morbidity and mortality through use of female condoms. To calculate this, the consultants used an approach adopted from Resch et al, 'Economic Returns to Investment in AIDS Treatment in Low and Middle Income Countries' (2011). Reflecting the approach of Resch et al, each country's average GNI per working-age adult was used as a proxy for working-age adult economic productivity, defining 'working-age' as 18 and over. **A comparison was made, over a 22-year span, between the economic productivity of a healthy adult and the reduced productivity of a HIV-positive adult with access to ART.** It is assumed that, over 20 years, HIV-positive adults will achieve 75% of the productivity of their HIV-negative counterparts. For two additional years, it is assumed that this level will drop down to 10% of a HIV-negative productivity level. These two years at 10% productivity are the year that the patient falls ill enough to require ART and the final year of life. Demonstrating these calculations for Cameroon, the average GNI of working-age adults was \$4,691 in 2012. This means that over 20 years, a HIV-positive worker on ART would earn \$1,172 less per year than a healthy worker. For two years, this same individual would earn \$4,222 less per year during initial illness and end-of-life. Therefore, in Cameroon, averting one HIV infection equates to \$31,884 economic productivity losses averted, assuming access to ART. These per-case losses are multiplied by the number of HIV infections averted through provision of 1,000,000 female condoms – 108 in Cameroon – for a total of \$3,443,472 in productivity losses averted. Applying a 3% discount rate, the total losses averted are \$3,340,168. The same methodology is applied to Kenya, Myanmar, and Nigeria using 2012 average working-age adult GNI.

One limitation of this approach is that HIV disproportionately affects individuals in lower economic quintiles so that using average working-age adult GNI may overestimate average annual earnings of adults with HIV. However, because we have assumed full access and adherence to ART, and thus a boost back to 75% of pre-HIV productivity, the possible over-estimate of annual wages is off-set by the overly optimistic assumption that all patients will receive ART and return to the workforce with reasonably high productivity. On balance, it is believed that the productivity losses averted are a conservatively low estimate; in reality, losses will be greater due to limited access to ART.

To calculate economic productivity losses averted from maternal morbidity and mortality cases averted, a conservative approach is taken to focus exclusively on maternal mortality. This is due to data limitations of reasonable estimates for economic productivity losses from excess fertility, unsafe abortion, or child mortality. Again using the Cameroon example, it is assumed that maternal mortality cases occur at a conservatively high 38 years of age, reflecting the fact that older mothers run a higher risk of negative maternal outcomes. It is assumed that all women would be earning their per-working age adult GNI of \$4,691 per year from age 18 to 58. **If their life is cut short at age 38 by a preventable maternal death, the economy will lose 20 years of productivity from each woman.** This equates to \$93,820 productivity lost per maternal death. These losses are multiplied by the number of maternal deaths averted through provision of 1,000,000 female condoms – 8 in Cameroon – for a total of \$750,560 in productivity losses averted. Applying a 3% discount rate, total losses averted are \$728,043. The same methodology is applied to Kenya, Myanmar, and Nigeria.

### **Graph 3**

For Graph 3, total programming costs (data from Graph 1) is compared against total economic benefits (data from Graph 2).

#### **Graph 4**

For Graph 4, the **cost per DALY for female condoms – calculated using per-country total costs (data from Graph 1) divided by number of DALYs averted provided by the PSI *DALYs Calculator* – is compared against the cost per DALY for alternative interventions.** Information on average cost per DALY across regions varies, and insufficient data was available outside of sub-Saharan Africa for inclusion in this analysis. Data was drawn primarily from cost per DALY data available in cost effectiveness studies of HIV interventions in sub-Saharan Africa (please see References). It should be noted that most studies provided a range of cost per DALY per intervention. In these cases, an average was used.

## Annex II – Female Condom Products

The following female condoms products are currently on the market, widely or in limited distribution, or are in final stages of regulatory approval.

### Cupid 1®



- Manufactured by Cupid Ltd., India
- Regulatory Status: CE Marking, WHO Prequalified, USFDA registration process initiated
- Product attributes: Natural rubber latex, octagonal outer frame, medical grade sponge inside that facilitates insertion and holds condom in place. Pre-lubricated with silicon oil. Comes in transparent or pink color. Vanilla scented.
- Also branded as l'Amour® and Jeitosa®
- Available in India, Brazil, Indonesia, the Netherlands, South Africa, Mozambique, and Kyrgyz Republic

### FC2®



- Manufactured by Female Health Company, Malaysia
- Regulatory Status: CE Marking, WHO Prequalified, USFDA approved
- Product attributes: Nitrile (synthetic latex), flexible inner ring facilitates insertion and holds condom in place. Flexible outer ring protects genitals, pre-lubricated with silicon lubricant.
- Also branded as Femidom®, Protectiv®, Care® and many other names
- Available in over 140 countries

### HLL Female Condom



- Manufactured by Hindustan Lifecare Ltd. Regulatory Status: Preparing for WHO-prequalification submission.
- Product attributes: Natural rubber latex, flexible inner copolymer ring facilitates insertion and, with flexible outer ring, aids retention.
- Also branded as Velvet and Rani
- Available in India

### Origami Female Condom



- Developed by STRATA Various Product Design, USA
- Product attributes: Made of silicon, folded "origami style". Inserted by pushing the folded material into the vagina. A circular flange ensures outer retention. Pre-lubricated with water-based lubricant.
- Not yet commercially available

### Phoenurse®



- Manufactured by Tianjin Condobao Medical Polyurethane Tech. Co, Ltd., China
- Regulatory Status: CE Marking
- Product attributes: Polyurethane with flexible inner and outer rings. Sold with flexible stick that attaches to inner ring for insertion (use optional). Pre-lubricated with silicon lubricant
- Available in China, Brazil, Kenya, Mexico and Sri Lanka

### VA w.o.w.



- Manufactured by HLL (formerly Hindustan Latex Limited)
- Regulatory Status: CE Marking, approved by national regulatory authorities in India and Brazil
- Product attributes: Natural rubber latex with rounded triangular frame for outer retention. Polyurethane sponge facilitates insertion and holds condom in place. Pre-lubricated with silicone lubricant
- Available in India, Brazil, and Cameroon

### Woman's Condom



- Manufactured by Shanghai Dahua Medical Apparatus Company, China
- Regulatory Status: CE Marking, submitted for WHO Prequalification review, preparing for submission to USFDA
- Product attributes: Made of polyurethane. Tampon-like insertion capsule dissolves immediately after insertion. Tiny foam dots on outside ensure stability during sex. Flexible outer ring. Made of polyurethane. Tampon-like insertion capsule dissolves immediately after insertion. Tiny foam dots on outside ensure stability during sex. Flexible outer ring
- Also branded as O'lavie™ in China and V in South Africa
- O'lavie™ is in limited private-sector distribution in China. V is not yet commercially available.

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