KENYA

Introduction of a New LNG-IUS: Summary of a Market Assessment

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Overview

In 2014, FHI 360 and Marie Stopes International (MSI)/Marie Stopes Kenya (MSK) conducted a market assessment which explored the potential demand for a new, more affordable levonorgestrel intrauterine system (LNG-IUS) in Kenya and identified key considerations for successful introduction and scale-up. This document provides a summary of the full market assessment that was completed. Funding for this work was provided by the Reproductive Health Supplies Coalition's Innovation Fund and the Bill & Melinda Gates Foundation through FHI 360's Contraceptive Technology Innovation Initiative. The three primary components of the market assessment were: 1) an **overview of the reproductive health landscape** in Kenya as of December 2014; 2) an **analysis of the market for Mirena®** in Kenya which was completed in August 2014, and 3) results from **interviews with Key Opinion Leaders (KOLs)** within Kenya which were completed in December 2014. This document also includes descriptions of key segments of the current and potential LNG-IUS market as well as considerations regarding successful launch of a new product. Key findings from the assessment include:

- **Early evidence suggests that introduction of a new, more affordable LNG-IUS would drive increased awareness, demand and uptake for such a product.** Use of non-hormonal IUDs has increased in Kenya over the past several years; IUDs currently represent 6% of the method mix compared to 4% in 2008-09. In a recent study of over 600 women who were offered a hormonal IUD as part of a diverse method mix, 16% chose the LNG-IUS. The Mirena®, which was introduced in Kenya in 2010, has been prohibitively expensive for most women, but it has been well-received among clients and providers when it is accessible. The KOLs who were interviewed overwhelmingly agreed that there is unmet demand for this method, and that potential users would be attracted to several product characteristics including the fact that the LNG-IUS is long-acting, convenient, can be used discreetly, and often leads to reduced menstrual bleeding and cramps.

- **Factors that have historically contributed to low uptake of IUDs in Kenya could impact scale-up of a new LNG-IUS.** Challenges have included persistent myths and misconceptions about IUDs among both providers and clients; inadequate training for providers; insufficient supplies and equipment; and a lack of motivation for providers to perform IUD insertions due to the extra time, space and counselling required. These barriers must be addressed to ensure successful large-scale introduction of a new LNG-IUS.

- **As a newer product with a more favourable side effect profile, the LNG-IUS has the potential to 'revitalize' the IUD market in Kenya.** Priority target user groups identified by KOLs and through a review of secondary data include women seeking clinical benefits from the product (e.g. relief from menorrhagia and severe dysmenorrhea), spacers, limiters, adolescents, postpartum women, and both high- and low-income women seeking the product's non-contraceptive benefits for lifestyle reasons. As a next step, it will be important to develop and evaluate client communication messages tailored for these different groups.

- **A more affordable LNG-IUS has the potential to increase access and choice for women in Kenya**. An analysis of the current market for Mirena® led by MSK revealed that the price of the product ranges from US$56 to US$194 in Kenya. Both the provider and KOL interviews indicated that price is currently a key barrier to access. It will be important to further refine the optimum pricing levels for a new LNG-IUS in both the public and private sectors through additional research with the identified user groups in order to maximize availability and uptake.

The findings from the market assessment as well as results from additional research in Kenya will help inform the development of a broader product introduction strategy.

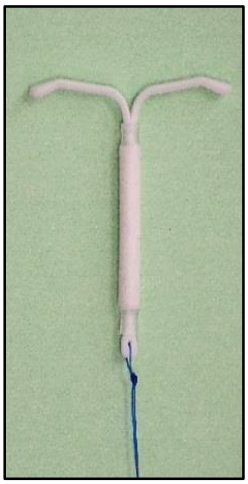
Background

The LNG-IUS is one of the most effective forms of reversible contraception available[1] and is increasingly popular among women worldwide. Mirena®, the innovator product manufactured by Bayer HealthCare,[2] offers a number of advantages including reduction of menstrual cramps and blood loss, fewer side effects compared to some other hormonal methods, and possible alleviation of anemia in some populations—all of which could provide substantial benefits to women in developing countries.[3] Recent assessments have indicated that in settings where unmet need for family planning is high, the LNG-IUS could play an important role in helping to reduce unintended pregnancies and improve maternal health.[4] However, the high cost of Mirena® has meant that its availability in developing countries has been extremely limited.

Medicines360, a nonprofit pharmaceutical company based in the U.S., in partnership with MSI, is poised to introduce a new, high quality, highly effective LNG-IUS in Kenya. Medicines360's mission is to expand access to medicines for women regardless of their socioeconomic status, insurance status, or geographic location. Recently, Kenya has seen an increase in political support for family planning[5] and a substantial growth in contraceptive prevalence including an increase in the number of women using non-hormonal intrauterine devices (IUDs).[6]

Description of the Product

The Medicines360 LNG-IUS is a T-shaped, intrauterine system loaded with 52 mg of levonorgestrel (LNG). It is designed to provide a steady, localized release of 20 mcg LNG per day. In Europe, approved indications include contraception (for up to five years of protection), menorrhagia, and hormone replacement therapy (not all approvals include all indications). In the United States, Medicines360 has been conducting a Phase III, randomized, multi-center open label study ("A Study of a Levonogestrel-Releasing Intrauterine System for Long-Term, Reversible Contraception") since 2009. The U.S. trial includes 1,751 women representing a broad range in parity, age, race, ethnicity, and BMI. Findings show that 98% of women in the U.S. study had a return to menses within three months of product removal.



Advantages of LNG-IUS products:

- ✓ One of most highly effective methods available[1,7]
- ✓ Very popular in many developed countries; helped kick-start the IUD revival in U.S. and elsewhere
- ✓ In small demonstration studies and introduction efforts in Kenya, LNG-IUS found to be highly acceptable[8]
- ✓ Offers important non-contraceptive health benefits including reduction of menstrual blood loss and possible alleviation of anemia in some populations[3,9]
- ✓ LNG-IUS introduction could help achieve goals of FP 2020 by reaching new users
    - Evidence shows that introduction of new methods can increase contraceptive prevalence rates[10]
    - Increasing equitable access aligns with a rights-based approach[11]

Overview of the Landscape in Kenya

In recent years, the Kenya government has strengthened its commitment to family planning, increasing its budgetary allocation from US $2.5 million in 2005-06 to US $6.6 million in 2012-13.[12] In addition, there has been a substantial increase in the modern contraceptive prevalence rate (mCPR) over the past five years. The mCPR, which was 39.4 percent among married women in 2008-09 according to Demographic and Health Survey (DHS) data,[13] increased to 55.4 percent among married women as of 2014, according to the Kenya Performance Monitoring and Accountability (PMA) 2014 survey.[6] The total fertility rate (TFR) also decreased from 4.6 in 2008-09,[13] to 3.5 in 2014.[6] Recent data also suggests that use of IUDs in Kenya is increasing. Non-hormonal IUDs now make up 6.2 percent of the modern method mix among married women, representing a 113% increase in prevalence since 2008-09 (see Table 1). Other than implants, copper IUDs experienced the most rapid growth in prevalence during this period, although injectables continue to dominate the market. The LNG-IUS use does not show up in national surveys because of the method's low prevalence to date; however, the positive trend in use of copper IUDs suggests that there may be an increasingly favorable landscape for large-scale introduction of a new, more affordable LNG-IUS product.

Table 1: Contraceptive use according to most recent DHS and PMA reports	**2008-2009 KDHS**			**PMA 2014**			**% change in prevalence**
	Proportion of method mix among MWRA	**Prevalence among MWRA**	**# of women***	**Proportion of method mix among MWRA**	**Prevalence among MWRA**	**# of women***	
All modern methods	**100.0%**	**39.4%**	**2,174,739**	**100.0%**	**55.4%**	**3,443,359**	**40.6%**
Injectables	54.8%	21.6%	1,192,242	52.6%	29.1%	1,808,696	34.7%
Pill	18.3%	7.2%	397,414	13.2%	7.3%	453,728	1.4%
Implant	4.8%	1.9%	104,873	20.1%	11.1%	689,915	484.2%
IUD	4.1%	1.6%	88,314	6.2%	3.4%	211,325	112.5%
Condom	4.6%	1.8%	99,354	3.2%	1.8%	111,878	0 %
Female sterilization	12.2%	4.8%	264,943	2.8%	1.6%	99,447	-66.7%
EC	0.0%	0.0%	0	0.8%	0.4%	24,862	n/a
Other modern	1.3%	0.5%	27,598	0.6%	0.3%	18,646	-40.0%

**From the UN estimate of the number of Married Women of Reproductive Age (MWRA) in 2009 and 2014*

Although progress has been made in decreasing unmet need for family planning in Kenya, 21 percent of married women still had an unmet need for family planning in 2014, with almost half (9.2 percent) being among "limiters," (women who do not want any additional children), and the rest being "spacers" (women who want to wait at least two years before having another child) (see Table 2). The LNG-IUS may be an attractive product to both of these groups, as reflected in responses from the KOL interviews (see below).

Table 2: Percent unmet need according to most recent DHS and PMA reports	**2008-2009 KDHS**	**PMA 2014**
Total unmet need among married women	25.7	20.9
For limiting	12.8	9.2
For spacing	12.9	11.7
Total unmet need among all women	16.3	15.9
For limiting	7.9	6.5
For spacing	8.4	9.4

Service delivery landscape

In 2013, the public sector healthcare delivery was decentralized, with training and services now coordinated and provided at the county level. At the national level, the Reproductive and Maternal Health Services Unit (formerly the Division of Reproductive Health) retains responsibility for setting policies and for resource mobilization. Public sector services are offered at six levels: 1) through community distribution; and at 2) dispensaries; 3) health centres; 4) sub-county hospitals (formerly district hospitals); 5) county hospitals; and 6) national hospitals (see Figure 1).[14] According to the 2008-09 DHS, 57% of family planning users obtain services in public sector facilities, while 36% of users access contraception through the private sector and 6% are accessed through other sources. The private sector includes privately owned, for-profit clinics as well as health centres run by religious organizations and NGOs.[13]

According to the PMA 2014 survey, 57% of the women interviewed (n=3815) reported that they had paid for family planning services. Among public sector facilities surveyed (N=200), 64% currently offer the IUD, while only 11.4% of private facilities do so. This low availability in the private sector represents a potential hurdle to introduction of a new LNG-IUS. In addition, there are a number of factors on the service delivery side that have historically contributed to low uptake of IUDs in Kenya and elsewhere in sub-Saharan Africa. These include provider misconceptions about the product including who can safely use it; a lack of supplies and equipment; inadequate training and competence among providers; and insufficient time and motivation for providers to perform the more lengthy procedure required for IUD insertion (compared to less intensive interventions required for shorter-acting methods).[15] Across the health system, these barriers will need to be addressed when scaling up a new LNG-IUS product.

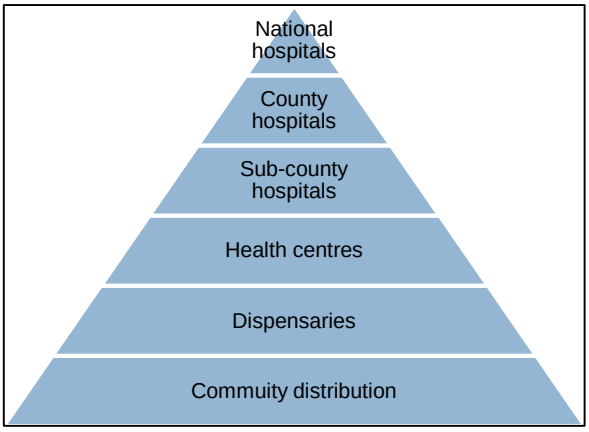


Figure 1: Public sector services are offered at six levels[14]

Past Experience with the LNG-IUS in Kenya

The LNG-IUS has not been widely available in Kenya to date. Table 3 shows the number of LNG-IUS units that have been donated by the International Contraceptive Access (ICA) since 2009 in Kenya compared to the number of copper IUDs procured, according to the RH Interchange. The ICA Foundation was established in 2003 and is a partnership between Bayer Healthcare and the Population Council. Over 65,000 units have been donated in more than 20 countries through the Foundation. In Kenya, recipients of the donations include MSI in

2009 and 2010, FHI 360 in 2011, Kenyatta National Hospital in 2011, and WomanCare Global/Maxim Pharmaceuticals Ltd. in 2013 and 2014 (although quantity of units may be underreported in the RH Interchange).

In general, data about acceptability and uptake of the LNG-IUS among women and providers in sub-Saharan Africa are limited. In contrast, recent experiences in Kenya with units donated by the ICA Foundation have been well documented and shed light on the potential demand for the product there:

	Copper IUD	LNG-IUS units donated by the ICA Foundation
2009	259,800	3,040
2010	6,540	1,000
2011	250,400	200
2012	122,700	100
2013	7,606	250
2014	190,100	250

Table 3: Units shipped to Kenya according to the RH Interchange

- **Research among postpartum women:** A recent study in Kenya led by FHI 360 showed high acceptability and uptake of the LNG-IUS. Among 671 postpartum women offered a range of short-acting and long-acting methods, 16% chose the LNG-IUS. Approximately one third of LNG-IUS users in the study indicated that if the product had not been available, they would have chosen a shorter-acting method; only 21% said they would have used a copper IUD, suggesting that the hormonal product can fill a niche in the market that is not currently filled by the copper device.[8] In a follow-up assessment of continuation rates, 89% of LNG-IUS users were still using the method after 1 year. Among seventy-nine LNG-IUS users, 87% reported being "very satisfied" with the method at 12 months, with 13% "somewhat satisfied"; none of the LNG-IUS users reported being dissatisfied with the method. Ninety-three percent of users reported that their menstrual pattern was either "highly acceptable" or "acceptable."[16] The 16% rate of uptake documented in this study and the high acceptability of the product suggest that the LNG-IUS will be well received if more widely accessible.

- **Distribution of ICA Units by MSK:** Between 2008 and 2011, MSK provided approximately 5,000 units of the LNG-IUS donated by the ICA Foundation. An assessment of 2011 service statistics showed that inclusion of the LNG-IUS did not lead to a statistically significant increase in IUD use; however, the assessment did reveal that all providers were enthusiastic about the method and a majority felt that the non-contraceptive health benefits were important to users.[17]

Analysis of Current Mirena Market

As a first step of the larger market assessment, MSK carried out an initial analysis of the current market for the Mirena® in Kenya. This included interviews with eleven private providers, eleven pharmacists, and five distributors as well as twenty-five mystery client visits to get a better understanding of the current awareness, distribution and usage of the Mirena® brand in Kenya.

From the provider perspective, the goal was to understand current knowledge of the Mirena®, how the product is viewed versus the copper IUD, its position in the market, and the typical Mirena® client profile/s. It was also important to understand how often and when the method is recommended to clients and the type of information that is provided to women. From the pharmacists' and distributors' perspective, the goal was to understand the sales and distribution strategy for the Mirena®.

The interviews were carried out in Nairobi, Kisumu, Nakuru, Mombasa, Thika, Ruiru and Juja. The mystery client visits took place in twenty-five facilities in Nairobi, Kisumu, Nakuru and Mombasa.

Bayer Healthcare launched Mirena® in Kenya in 2010; however, MSK's assessment demonstrated that the product has low awareness and limited distribution and uptake to date. MSK's main findings are summarized below.

Positioning

According to Bayer Healthcare marketing materials, the Mirena® is positioned as: ***"the convenient effective treatment option for heavy menstrual bleeding/menorrhagia that preserves fertility and provides contraception."***

It is registered for four indications:

- Contraception
- Treatment of idiopathic menorrhagia
- Treatment of dysmenorrhea
- Endometrial protection during oestrogen replacement therapy[18]

Product Description

"Mirena consists of a T-shaped polyethylene frame (the T-body) with a steroid reservoir (hormone elastomer core) around the vertical stem. The reservoir consists of a cylinder, made of a mixture of levonorgestrel and silicone (polydimethylsiloxane), containing a total of 52 mg levonorgestrel. The Mirena reservoir is covered by a silicone (polydimethylsiloxane) membrane. The T-body is 32 mm in both the horizontal and vertical directions. The polyethylene of the T-body is compounded with barium sulphate, which makes it radio-opaque. A monofilament brown polyethylene removal thread is attached to a loop at the end of the vertical stem of the T-body. Levonorgestrel is a well-established progestogen, used in both contraception and hormone replacement therapy."

-From Bayer HealthCare presentation at KOGS symposium, Oct 2014

Key Benefits and Audiences

Mirena® is positioned by Bayer Healthcare as a long-acting contraceptive and effective treatment option for menorrhagia. Key benefits include:

- It provides effective contraceptive protection for up to five years
- It is highly effective in reducing menstrual blood loss and is good alternative to surgery for the treatment of menorrhagia
- It contributes to the reduction of dysmenorrhea
- It preserves fertility; there is a rapid return to fertility on cessation of treatment
- It offers convenience and the majority of patients are highly satisfied with it

The key target audiences identified by Bayer Healthcare for the Mirena® include:

- Women seeking long-term contraception
- Women suffering from heavy and painful periods
- Women seeking an alternative to sterilization[19]

Current Sales Volumes and Pricing Strategy in Kenya

From the market analysis carried out by MSK in Kenya, it appears that Bayer Healthcare sells 100-200 units of Mirena® per month, hence 1,200-2,400 units annually. However, this number is regarded as a conservative estimate because additional intelligence suggests that the average hospital and clinic may insert up to 5 units per month. Mirena® is estimated to be available in over 100 hospitals and clinics across Kenya, so based on these assumptions, Mirena® sales could be up to 6,000 units per year.

Information gathered through the mystery client visits conducted by MSK demonstrates that the cost of Mirena® varies widely depending on location and service delivery setting. Table 4 illustrates that the price ranges from as low as US$56 up to US$194. Because the service cost is set by individual providers, prices will likely continue to vary significantly across sites.

Table 4: Prices of Mirena documented through mystery client visits (all prices in US dollars)			
Region	**Up-market***	**Central Business District (CBD)**	**Informal settlement***
Nairobi	US$111-$167 with a discount of $6-$11	$56-$111 with a discount of $6-$11	$56 and below with a negotiable discount
Nakuru	$133-$194 with a discount of $22	$78-$111 with a discount of $22	Not offered
Kisumu	$111-$167 with a discount of $22	$66.7-$111 with a discount of $22	Not offered
Mombasa	$111-$167 with a discount of $22	$56-$111 with a discount of $22	Not offered

***** "Up-market" is a region with primarily middle- and higher-income consumers. "Informal settlement" is generally comprised of low-income consumers. Discounts are negotiated by clients who cannot afford to pay the full price.

Distribution of Mirena in Kenya

Most service providers who offer Mirena® do not stock it but order it directly from Bayer through their detailers when they have a request from a client for the product. Mirena® is distributed through selected pharmacy outlets (retail and wholesalers), private clinics and hospitals and currently accessed only by medium- and high-income populations.

Bayer Healthcare distributes their products through two local distributors, Surgipharm (their exclusive distributor) and Laborex Kenya. Results from interviews suggest that little training or support materials are provided to distributors or pharmacists, which can leave them feeling less confident to sell the Mirena® than other methods.[19]

Training and Materials for Providers

Training is offered to healthcare providers in the form of one-day training courses, training videos and support materials. However, the degree of support provided depends on the size of the clinic, with hospitals having significantly more support than the individual private providers.

Bayer Healthcare holds round tables/dinner meetings with doctors/gynaecologists and also sponsors key symposia around Kenya where they focus predominantly on their portfolio of contraceptive pill products and implants. However, more recently they have started to focus more on the Mirena® brand and its benefits, specifically for the treatment of menorrhagia.[20]

Resources for Clients

The assessment found that Bayer seems to have concentrated most of their communication and support on providers, with limited IEC materials available for clients. When available, client resources tend to be in the form of informational leaflets. As a result, respondents reported that client awareness and understanding of the product is limited. Bayer Healthcare does use social media, e.g. Mirena® has a Facebook page but there is currently very limited activity.[19]

Stakeholder Engagement Activities

Bayer HealthCare partners with the Ministry of Health on a number of activities, but the LNG-IUS has not been a priority in terms of promotion until recently. Bayer is also an active participant in the national Family Planning Technical Working Group. They sponsored and held a symposium in October 2014 on the Mirena® at the Kenya Obstetrical and Gynaecological Society (KOGS) in Mombasa. Bayer also sponsors and participates in key professional scientific congresses such as the Kenya Medical Association, Pharmaceutical Society of Kenya, Kenya Clinical Officers Association and National Nurses Association of Kenya. They also support physicians presenting research papers at scientific congresses.[20]

Interviews with Key Opinion Leaders

In addition to the evaluation of the current market for the Mirena® in Kenya, FHI 360/Kenya and MSK staff interviewed Key Opinion Leaders (KOLs) as part of this market assessment. Thirteen interviews were conducted with KOLs in Kenya from a variety of organizations, including the Ministry of Health (N=2), NGOs (N=4), international donors and normative bodies (N=4), a private sector franchisee (N=1), a pharmaceutical distributor (N=1), and a member of national reproductive health society (N=1), to better understand the potential demand for a more affordable LNG-IUS in Kenya through the public, private and social marketing sectors. The list of KOLs was developed by the FHI 360/Kenya and MSK teams, and a standard questionnaire was used for all interviews (see Appendix 1). Respondents were asked about a variety of topics including their sources for information about reproductive health, their perception of the current and future landscape for IUDs, potential demand for a new LNG-IUS, and potential users' needs and preferences. All interviews were audio recorded and key themes that emerged are summarized below.

Key Sources of Information for KOLs

The stakeholders use a broad number of sources of information to stay up-to-date with the latest developments on sexual and reproductive health. They range from the DHS, K4Health, National Health Interview Surveys (NHIS), online clinicians' forums, and government sources such as the Technical Working Group and the Department of Health Information Systems (DHIS). Several references were also made to the WHO's Family Planning Handbook and FP2020 publications as key sources of information. In addition, knowledge is gathered through continuous professional development sessions, conferences and journals. Information is also received from pharmaceutical companies within the private sector on the latest product developments.

Potential to Increase the Prevalence of IUDs in Kenya

All stakeholders were in agreement that there is significant potential to increase the prevalence of IUD usage in Kenya. KOLs noted a trend in Kenya that women increasingly want to space and limit their children and are also demanding more choice of contraceptive methods, particularly for long-acting methods.

The KOLs identified different segments of the population who currently have limited access to family planning including the very poor and adolescents. The KOLs noted that many adolescent pregnancies could be averted if there was greater choice and better access to long-acting methods for youth.

Respondents noted that currently IUD usage is low— representing 6% of the method mix in contrast to the implants which have increased to 20% of the method mix according to the PMA 2014. As a result of a government effort to increase access to implants in recent years, awareness and acceptability of implants has significantly increased. The KOLs attributed the low usage of IUDs in comparison to other contraceptive methods to a general lack of knowledge and misconceptions associated with IUDs among both providers and clients which to date have been inadequately addressed. Misconceptions among clients included the belief that the IUD will either get lost in the body, fall out, or be implanted within their baby when they give birth. There is also often a belief that the IUD will impact sexual pleasure, with concerns that the husband will be able to feel the strings.

Key drivers behind low uptake of the copper IUD

The KOLs identified a number of reasons why uptake of the Copper IUD has historically been low in Kenya. These include:

- A lack of training and inadequate skills among providers
- For some providers, offering IUDs instead of other methods does not make commercial sense, given the length of time required versus the time required to administer injections, implants or pills
- One of the key side effects of the copper IUD is increased bleeding and cramps which have led to higher levels of discontinuation
- IUD insertion requires an gynaecological procedure that is perceived as invasive to some clients
- Misconceptions among clients persist including that the IUD can travel to the heart and brain and can cause infertility
- Concerns among women that the husband will feel the strings during sex. This is particularly concerning among those who do not have permission from their husbands to use contraception and who desire a discreet method.

Among some providers, there is a belief that an IUD can only be inserted in women who have already given birth, so often they will not recommend it as an appropriate method for nulliparous women. There is also confusion over when it can be inserted (e.g. after birth, only during menses etc.). Additional challenges include that many providers lack the necessary skills, insertion equipment and sufficient space within their clinics to be able to offer IUDs, resulting in reduced confidence and motivation. The KOLs noted that it is much quicker and easier to offer an injectable than an IUD, and so often providers do not offer the choice of a longer-acting method. Limited availability of IUD commodities was also cited by some as an issue.

Perceptions of and Experience with Mirena

Overall, almost all of the KOLs were familiar with the Mirena®, although only the medical doctors had practical experience with inserting or removing the LNG-IUS. Key advantages identified by the KOLs include that the product is highly effective, has a lack of systemic effects, and can lead to a reduction of heavy bleeding. In addition, the Mirena® was recognized as being a safe and effective treatment of dysmenorrhea, menorrhagia and uterine fibroids. The Mirena® was also seen as having a protective effect against endometrial cancer and as being suitable for breast-feeding women. Providers appreciate the fact that it offers a slightly shorter duration of protection versus the copper IUD, making it an ideal choice for women who are looking to space their children.

The KOLs reported that from the client perspective, the Mirena® has been well received among users in Kenya who have had access to the product with very low discontinuation rates. The respondents noted that the key barriers to uptake of the LNG-IUS have been both the lack of availability of the product and the high prices, of between 10,000 and 13,000 Kenyan shillings (US$111-$144) depending on the additional insertion cost added and where the product is sourced, with hospitals often being the most expensive service delivery points. Clients

will often buy the product from the pharmacy and take it to the clinic to be inserted, where the high service charge can be prohibitively expensive for many women.

There was an understanding among several of the KOLs that some providers want the LNG-IUS to remain at a premium price point so that they can continue to make a significant profit on the product.

According to the KOLs, the average current Mirena® user is educated and of a middle- to upper- socioeconomic background with a regular source of income. KOLs noted that Mirena® users are typically career women looking to space or delay the start of their family. Some users seek the method because they are suffering from severe dysmenorrhoea or menorrhagia. The core age range for users cited by stakeholders was between 25-35, although they recognized that the LNG-IUS is suitable for all women of reproductive age. Users of the Mirena® will sometimes have insurance coverage for family planning.

The KOLs noted that potential users may share similar concerns about the LNG-IUS as those associated with the copper IUD. There may also be concerns about hormonal side effects such as whether they will gain weight or whether it will affect their libido and cause acne.

Potential Demand for a More Affordable LNG-IUS

There was overwhelming agreement among respondents that introducing a more affordable LNG-IUS would increase uptake of the method.

Among the KOLs, there were generally two perspectives on where the biggest potential lies. Some felt that the greatest potential opportunity for increased uptake lies within the public sector, if the price was significantly reduced to be attractive and affordable to lower socioeconomic groups. In particular, interest may be high among women looking to space their children.

Others felt that the biggest opportunity lies within the private sector, recognizing the current Mirena® client profile. These respondents felt that users would continue to be urban, educated women, made up of a mix of spacers and limiters as well as women suffering from irregular menstruation, menorrhagia, severe dysmenorrhea, and those suffering from uterine fibroids and polycystic ovaries. In general, the KOLs agreed that a comprehensive introduction strategy should focus on both the public and private sectors.

Perceived Advantages of the LNG-IUS

In addition to the contraceptive benefits, key advantages of the LNG-IUS were seen as an improved quality of life, increased convenience and freedom, and a reduction in menstrual bleeding and associated pain/cramping. Some KOLs noted that there may also be cost benefits to women because of reduced need for sanitary protection. The groups identified as potentially most interested in reduced bleeding included sex workers, career women who travel frequently, and students. The product would also be attractive to women suffering from heavy menses or those who have had undesirable side effects with injectables, implants or the copper IUD. Finally, reduced bleeding would also be potentially appealing to women at risk of anaemia.

In addition to these advantages, past experience suggests that IUD users are attracted to the method because it is long-acting, safe, effective and can be hidden from their husbands, all of which may be seen as benefits of the LNG-IUS as well.

Key Considerations for the Successful Launch of a New LNG-IUS in Kenya

KOLs were asked if a more affordable LNG-IUS were to be introduced in Kenya, what key steps would need to be taken to ensure that the introduction is successful and uptake maximized. The KOLs agreed that a new LNG-IUS should be introduced not just within the private sector but within the public sector to achieve large-scale uptake. In addition, the KOLs noted several additional priorities:

- **Ensuring availability of the product:** It is important that the product is registered by the PPB (Pharmacy & Poisons Board of Kenya), stocks are consistently available, and the product meets quality standards. Some KOLs indicated that the product would need WHO prequalification before being procured for the public sector, and respondents agreed it should be added to the Essential Medicines List. The product should be positioned as a safe, high quality and effective product to ensure that it has the full endorsement of all key stakeholders.

- **Working with a broad coalition of stakeholders:** KOLs agreed that it is critical to collaborate with the government, NGOs, universities and other groups to develop an introduction strategy and to get the message out about the availability of a more affordable LNG-IUS.

- **Successfully engaging providers:** It will be critical to develop effective strategies to address existing myths and misconceptions among providers. Appropriate messages will need to be developed to position a new product and highlight the benefits of the LNG-IUS. Relevant training programs must be developed to enhance the knowledge and skills of the providers. Training should be carried out as a team and not just individually, and on-the-job training is important.

- **Successfully targeting new users:** It is imperative to ensure that relevant and effective messages are developed to address some of the misconceptions associated with IUDs, and to educate clients on the benefits of the LNG-IUS. Talking to women to get their perspective on IUDs will be essential so that relevant messaging can be developed to dispel some of the current myths and drive uptake of the LNG-IUS. Client testimonials should be developed. Key channels of communication identified as important for the dissemination of information include through mobile phones and through social media channels.

KOLs acknowledged that challenges to introduction of a more affordable product could include potential resistance from private sector providers due to their reduced profit margin.

As noted above, intensive training will be required to equip providers with the necessary skills and confidence. KOLs also noted a risk that competitors may potentially increase marketing efforts to discredit a new LNG-IUS, and may try to equate lower cost with 'inferior quality.' It will be important to reassure all key stakeholders of the safety and quality of a new product. There could also be resistance or confusion among clients about the side effect profile of a hormonal method; these will need to be addressed in communication and counseling messages.

Market Segmentation Assessment

Based on the KOL interviews, the assessment of the current market for the Mirena®, and a review of secondary data sources including the DHS and PMA 2014, profiles for potential user groups of a more affordable LNG-IUS were developed. Criteria from the *Market Segmentation Primer* developed by the RHSC's Market Development Approaches (MDA) Working Group were applied including that market segments must be: 1) measurable; 2) substantial; 3) accessible; 4) distinct; and 5) stable.[21] The following target groups reflect demographic, attitudinal, and behavioral variables; there will likely be some overlap between the groups.

Market Segment	Key Considerations
Middle- and high-income women: Women in the top three wealth quintiles	To date, this is the population that has been targeted for initial introduction of the Mirena® in Kenya. Given that the product has been well-received by this group, uptake is likely to increase as availability grows. The duration of use, convenience and reduced bleeding associated with this product may be of particular interest to this group.
Lower-income women: Women in the bottom two wealth quintiles	Although these women currently do not have access to the product because of cost barriers, this is an important target group for a new, more affordable LNG-IUS. Data from the PMA 2014 report indicate that unmet need is higher in this group than among wealthier women. Recent increases in implant use suggest that it is feasible to increase access to LARCs including among women in the lowest wealth quintiles. Product attributes that may be particularly attractive to this group include the ability to use the product discreetly and no need for regular resupply. These women may be accustomed to receiving family planning services for free, so additional assessments will be needed regarding ability-to-pay for commodities and/or services.
Spacers: Women who want to wait at least two years before having another child	Spacers may include women who want to wait before having children in order to establish their career and/or achieve financial security, or women who have one or more children already but want to delay additional pregnancies. Because the LNG-IUS is effective for up to five years of use, the product may be more attractive to spacers than the copper IUD which has a longer duration of effectiveness (i.e. users often perceive that they must use a product for its full duration of effectiveness).
Limiters: Women who do not want any additional children	KOLs agreed that limiters as well as spacers are likely to find the LNG-IUS attractive. Ongoing clinical research will evaluate whether the LNG-IUS is effective for a duration longer than 5 years; if the product is re-labeled for a longer duration at any point, this may also be of particular interest to limiters.
Postpartum women: Women in the extended postpartum period who are interested in birth spacing or limiting	In the first year after birth, many mothers experience a period of postpartum amenorrhea. The LNG-IUS may be attractive to this group, particularly as it could extend amenorrhea without any interim resumption of menses.
Adolescents: Young women ages 15-24	As the family planning community in Kenya continues to prioritize provision of youth-friendly services, adolescent girls will be an important target audience for the LNG-IUS. In the U.S., the American Academy of Pediatrics[22] recently issued recommendations that LARCs be the first choice of contraception for adolescents. These and similar recommendations may impact the service delivery landscape internationally including in Kenya. Adolescent girls may find the LNG-IUS attractive because it is long-acting which would facilitate school involvement and/or a focus on career. “Forgettable” contraception may also provide a sense of freedom. Adolescents may also be attracted to the side effect profile.
Users seeking lifestyle benefits:	Responses from the KOLs and recent research suggests that women in Kenya may find non-contraceptive product attributes of the LNG-IUS attractive including reduced

Women interested in non-contraceptive benefits of LNG-IUS including those who would welcome amenorrhea for lifestyle reasons	bleeding and/or amenorrhea. This product characteristic may be desirable because of health benefits, decreased pain/cramping, increased cost-savings (i.e. less sanitary pads to purchase), and increased freedom (i.e. to travel, engage in work/school activities).
Users seeking clinical benefits: Women who suffer from heavy periods and other medical conditions	This group includes women who are suffering from irregular menstruation and menorrhagia, uterine fibroids and polycystic ovaries. The Mirena® has been successfully positioned as an effective treatment option for these women, and the same can be achieved with a new LNG-IUS product. Also, because the LNG-IUS may reduce anaemia in certain populations, women who are anaemic may find this product attractive.
Switchers: Current contraceptive users who are seeking a new method	Another key audience for the LNG-IUS is women who are dissatisfied with their current contraceptive method. This may include short-term contraceptive users who are worried about forgetting daily contraception and want increased convenience. It may also include women who have had negative experiences with other mid- to-long acting methods, and are seeking another option with a somewhat different side effect profile.

Further research is needed to continue to refine and size the target groups, and to better understand their needs and motivations. Also, interviews with women will help identify sub-groups within these segments. For example, KOLs identified that female sex workers may be interested in the LNG-IUS because of its side effect profile. Follow-up market segmentation research will continue in Kenya as part of product introduction efforts.

Future Research and Next Steps

This market assessment was an important first step to better understand the potential demand for an LNG-IUS in Kenya and to help inform a product introduction strategy for both the private and public sectors. Because price is currently a key barrier to the uptake of the LNG-IUS in Kenya, a next step will be to conduct additional research to understand price sensitivities among the identified target client segments and to understand the potential demand more fully based on a set of different price points.

In addition, further qualitative research is needed to develop and test client communication messages (e.g. to tailor messages about product benefits to the target client segments). More in-depth research among providers is also needed to more fully understand current barriers to provision of IUDs and strategies to overcome them.

Results from additional research as well as the findings from this market assessment will inform the development of a broader product introduction strategy in Kenya.

Appendix 1: Interview Guide for Key Opinion Leaders

The following interview guide was used with Key Opinion Leaders (KOLs) to assess the acceptability and potential demand of a new LNG-IUS

Introduction: My name is _____ and I work at [FHI 360 or Marie Stopes Kenya]. As you may know, the availability and accessibility of hormonal IUDs in Kenya is quite limited at this point. FHI 360, MSI/MSK, and Medicines360 were recently awarded a grant from the Reproductive Health Supplies Coalition to evaluate the potential demand of a more affordable hormonal IUD through the public, private and social marketing sectors in Kenya. We are hoping to better understand potential users' needs and preferences, as well as potential demand for such a product. As part of the analysis, we are soliciting input from key experts such as yourself. Your participation in our brief interview is completely voluntary, and your answers will be kept confidential. Information that you provide during the interview may be used in publications (such as a final report or an article); however, neither your name nor your organizational affiliation will be included. Do you agree to participate?

General

1. Can you tell me what sources of information on sexual and reproductive health you access on a regular basis? For example, what websites, publications, forums or medical congresses do you find to be particularly useful?

2. In your opinion, do you see a realistic potential to increase the prevalence of IUD use in general in Kenya? If yes, what would this require? If no, why not?

3. Are you familiar with the IUD called the Mirena (also known as the "LNG-IUS" or the "hormonal IUD")? If yes, please describe your experience with the hormonal IUD and/or your knowledge of current use of this method in Kenya.

4. How do you think the hormonal IUD has been perceived to date among providers? Among clients?

User Groups

5. In your experience, who are current users of the hormonal IUD in Kenya? What are the socioeconomic background(s) and age(s) of current users?

6. What do you think is the potential demand for a more affordable hormonal IUD? In the public sector? In the private sector? Through social marketing organizations?

7. If a more affordable hormonal IUD were available, what segments of the population do you feel would be the most likely users of a hormonal IUD? Why do you think the product would appeal to these group(s)? *(Prompt, if needed: For example, what age groups? Women of which socioeconomic backgrounds? Would women who want to space births or have no more births be more interested? What about postpartum women? What about women suffering from menorrhagia? What other groups might be interested in this method?)*

8. The LNG-IUS generally reduces menstrual blood loss. Do you think some women would welcome reduced menstrual bleeding as a side effect for lifestyle reasons if they knew they were not pregnant? If yes, which group or groups of women would find this desirable? If not, why not?

Product characteristics

9. What do you think contributes to low uptake of the Copper IUD in Kenya? Do you think these issues would impact hormonal IUDs as well if they were more widely available?

10. Are you familiar with some of the common beliefs that women currently have about the hormonal IUD? What are the common beliefs that women have? Do you think these beliefs differ from beliefs about the Copper IUD in any way?

11. What characteristics of the hormonal IUD do you believe are most attractive and/or beneficial to women?

12. Are there any concerns that you or women themselves would have about a hormonal IUD?

13. The LNG-IUS may alleviate anemia in some populations. What is the likelihood that potential non-contraceptive benefits such as this would increase interest in this product among various groups?

Product Introduction

14. If a new, more affordable hormonal IUD (LNG-IUS) were to be introduced in Kenya, what key steps would need to be taken to ensure that introduction is successful and to maximize uptake? How could we best build awareness and drive uptake among providers and clients once such a product is launched?

15. What do you think would be the key challenges if a new, more affordable hormonal IUD were introduced? How could these be addressed?

16. [Optional question] In general, are you aware of new, innovative and/or successful efforts to increase IUD uptake in Kenya? If so, which approaches seem most promising?

Pricing

17. Are you familiar with prices charged to providers/clinics for the Mirena? Are you familiar with the prices charged to clients? (Note: If the respondent is not familiar with the price, please indicate that a recent assessment in Kenya showed that the price of the Mirena for clients is currently between 5,000 &15,000 KHS or $56 and $167)

18. If a hormonal IUD product became available that was more affordable than Mirena, do you think there would be an increased interest in this product among providers and clinic managers? Among clients?

19. [Question for policymakers and procurement experts only] What **procurement** price point would need to be achieved to increase interest in procurement and distribution through the public sector?

20. What price point **to clients** would need to be achieved to increase demand and uptake substantially within the private sector? In the social marketing sector?

Closing

21. In closing, can you recommend 2-3 additional experts or opinion leaders to whom we should talk about these issues?

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