

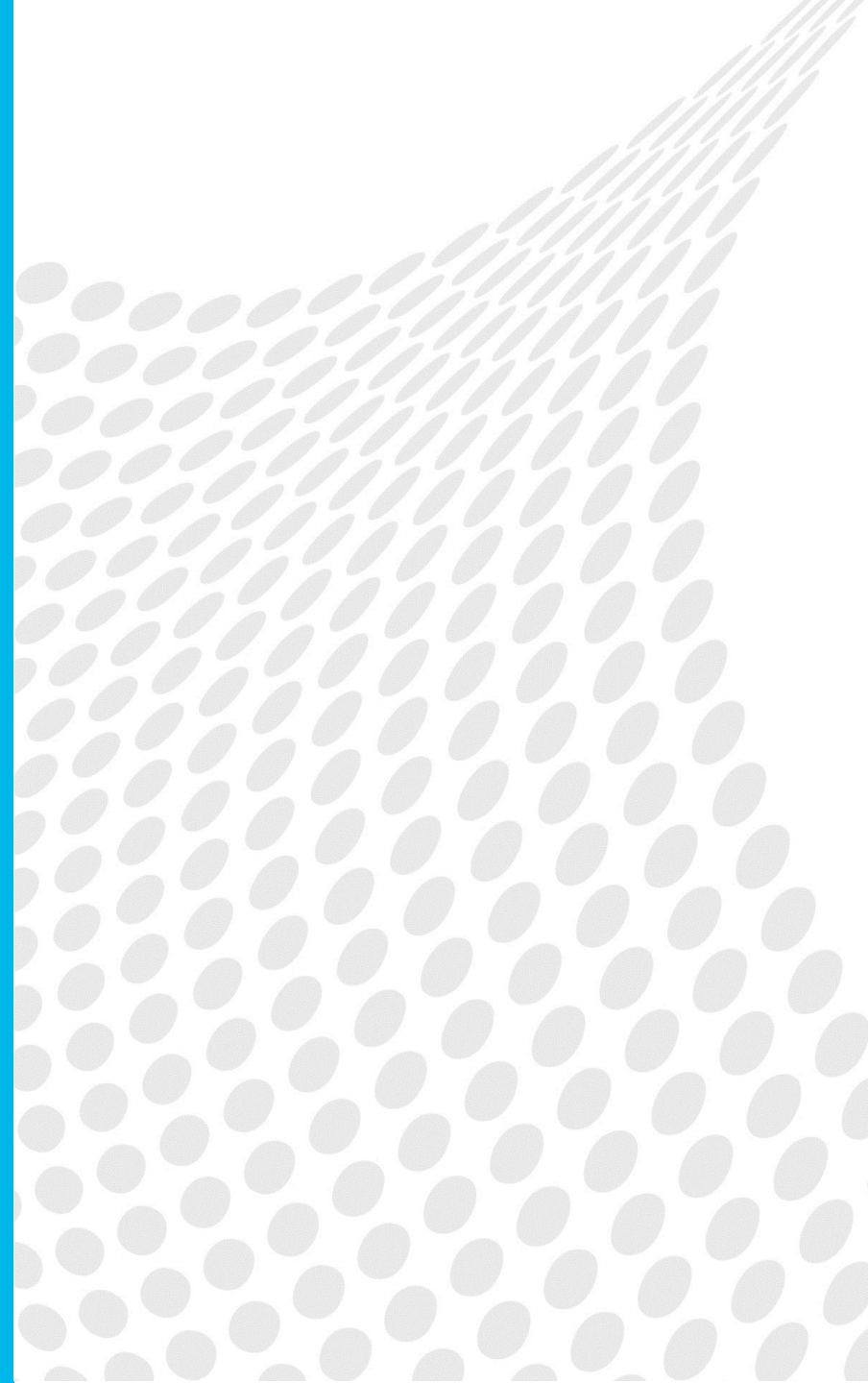
Final Report: Market Assessment for Potential Introduction of a New Hormonal IUCD in Zambia

DECEMBER 2016



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A group of people, including men and women, are gathered in a room, possibly a meeting or workshop. They are looking at documents or papers. The image is overlaid with a semi-transparent blue filter. The text is centered on the image.

In 2016, FHI 360, the Society for Family Health, PSI and WomanCare Global completed a market assessment to explore potential demand for a new, more affordable hormonal intrauterine contraceptive device (IUCD) in Zambia and to identify key considerations for introduction and scale-up.

Funding provided by the Bill & Melinda Gates Foundation through FHI 360's Contraceptive Technology Innovation Initiative

Executive Summary (1 of 5)

The hormonal IUCD (also known as the levonorgestrel intrauterine system or the LNG-IUS) is one of the most effective forms of reversible contraception and has helped revitalize the IUD market in countries where it is available. However, the high cost of existing products has meant that its availability and use in developing countries has been extremely limited.

As of 2016, the hormonal IUCD is not available in the public sector in Zambia and is only available on a very limited basis in the private sector. High quality, affordable LNG-IUS products are now being introduced in the global market. As a result, partners embarked on a national market assessment in Zambia.



Executive Summary (2 of 5)

The market assessment included three primary components:

- 1) An analysis of the current **reproductive health landscape in Zambia** including the **current market for IUDs**;
- 2) Interviews with **Key Opinion Leaders (KOLs), healthcare providers and potential users** including women currently using a short-acting family planning method, women currently using a long-acting family planning method, postpartum women and non-users of contraception; and
- 3) An assessment of the **regulatory landscape** and documentation of **partners' initial plans for introduction** of a new, more affordable, quality assured hormonal IUCD product.



Executive Summary (3 of 5)

Key findings from the assessment included:

- The majority of Key Opinion Leaders (KOLs) interviewed were familiar with the hormonal IUCD and perceived that it has important advantages including that it is a highly effective method with non-contraceptive health benefits.
- All healthcare providers interviewed indicated that based on what they had heard about the method, they would be willing to use the product in their practice. Both KOLs and providers agreed that myths and misconceptions are a major barrier to uptake of the copper IUCD and that education/demand creation are essential moving forward.

Continued next page



Executive Summary (4 of 5)

Key findings continued:

- Almost all of the potential users interviewed indicated that they would be willing to try the hormonal IUCD. Regarding bleeding changes associated with family planning methods, many potential users had the perception that ‘normal’ monthly menstruation is important for women and are concerned about methods that induce amenorrhea. Participants were generally more open to reduced bleeding.
- Key target markets identified for the hormonal IUCD include women who could benefit clinically from non-contraceptive benefits; young women/adolescents; spacers and limiters; postpartum women; and both rural and urban women.



Executive Summary (5 of 5)

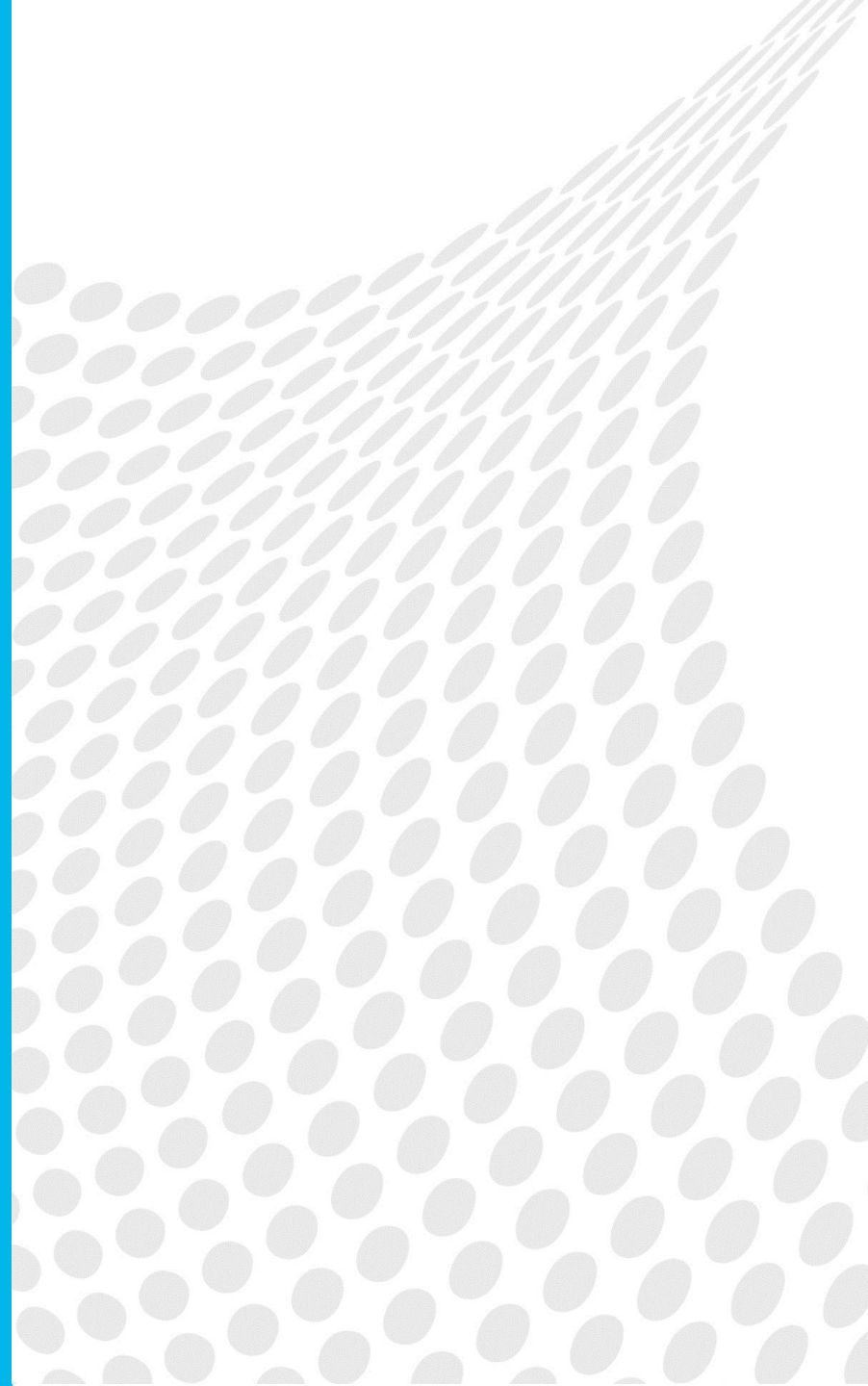
Next steps:

In August 2016, preliminary results of the market assessment were presented to the Family Planning Technical Working group which endorsed public sector introduction of the hormonal IUCD.

Starting in 2017 with USAID support, the Society for Family Health (SFH), PSI, WomanCare Global (WCG) and Jhpiego will introduce the hormonal IUCD in select public sector clinics. The partners will initially use donated product while WCG and SFH pursue registration of the Medicines360 product.



Background & Overview of Hormonal IUCDs



Background

- The hormonal IUCD—also known as the levonorgestrel intrauterine system or the LNG-IUS—is one of the most effective forms of reversible contraception available
- The high cost of Mirena® (the hormonal IUCD distributed by Bayer HealthCare) has created a barrier to access in many countries. The product is not available in the public sector in Zambia and only on very limited basis in the private sector
- The ICA Foundation has donated free units of the LNG-IUS on a limited basis in Zambia to date

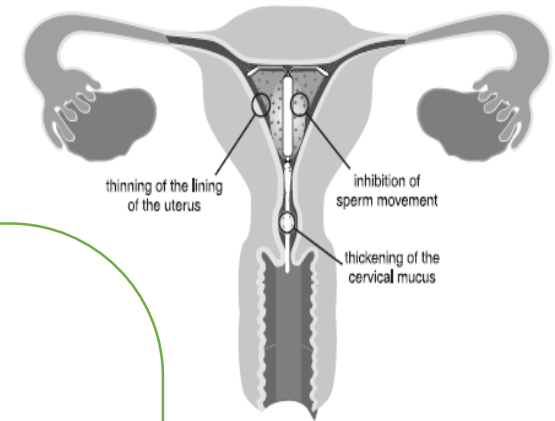
Why a market assessment now?

- Partners are evaluating opportunities to increase access to an **affordable, quality assured hormonal IUCD** including the potential to register and introduce Medicines360's new product



Overview of method

- The hormonal IUCD is a T-shaped, plastic, contraceptive intrauterine system
- The system contains 52 mg of the hormone levonorgestrel (LNG) and releases $\sim 20\mu\text{g}/24\text{h}$ in the uterus for up to five years of protection
- The hormonal IUCD prevents pregnancy by thickening the cervical mucus, inhibiting sperm mobility, and suppressing the growth of the lining of the uterus. Ovulation is also inhibited in a number of cycles.



Overview of method continued

- One of the most effective methods available
- Long-acting, reversible
- Rapid return to fertility after removal
- Additional health benefits:
 - Can make periods lighter, shorter and less painful; can lead to amenorrhea
 - Treatment option e.g. for women suffering from heavy menstrual bleeding
 - May reduce iron-deficiency anemia



- ✓ Very popular in countries where available/accessible
- ✓ Has helped revitalize the IUD market in some countries including the U.S.
- ✓ In early introduction efforts in Africa, high acceptability

Overview of Quality Assured Products

BAYER HEALTHCARE

Mirena™ priced at ~\$60-\$400 in developing countries. Provided commercially through private healthcare clinics in some developing countries on a very limited scale.

ICA FOUNDATION

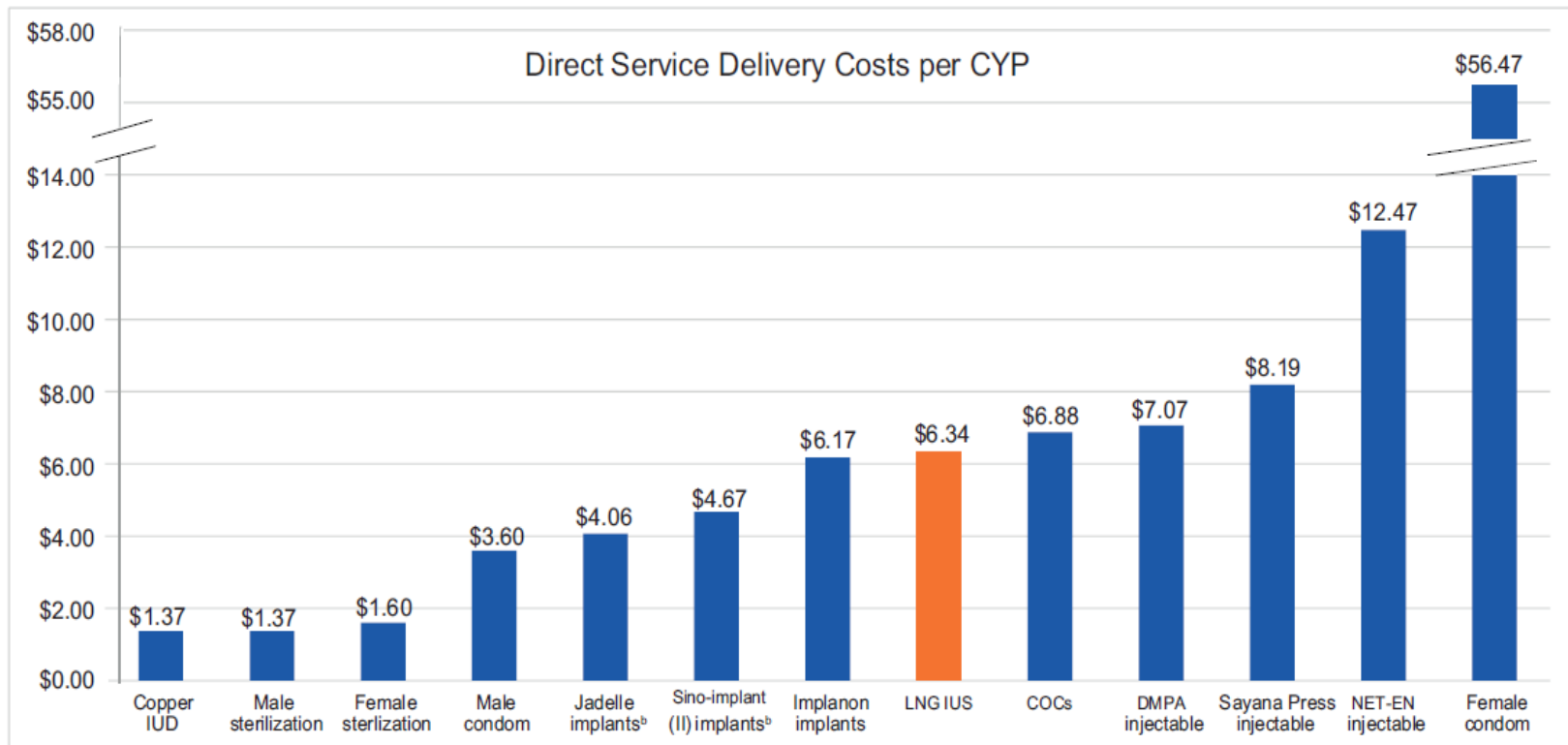
Public-private partnership between Bayer HealthCare & Population Council. Provides free LNG-IUS product; donated over 80K units in over 25 countries since 2005.

MEDICINES 360

Approved by the US FDA in 2015. Plans to register in African countries under the trade name “Avibela.” The public sector transfer price will vary by volume between US\$12-16; for an order of 100,000 units, public sector transfer price will be approximately \$15/unit.

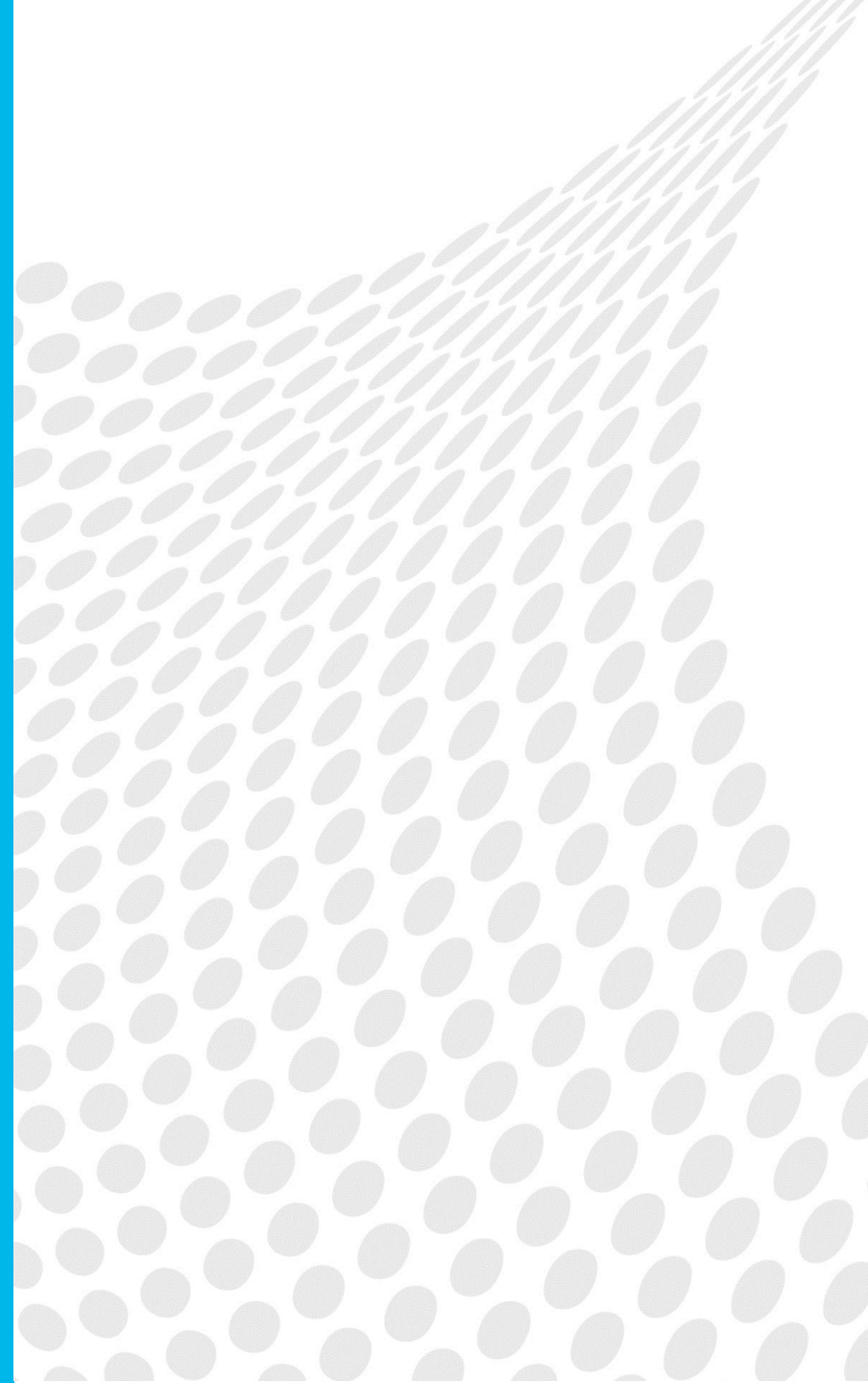
Direct Service Delivery Costs per CYP including LNG-IUS at \$15/unit

FIGURE. Direct Service Delivery Cost of the LNG IUS per CYP^a Compared With Cost per CYP of Other Contraceptive Methods (2015 US\$)



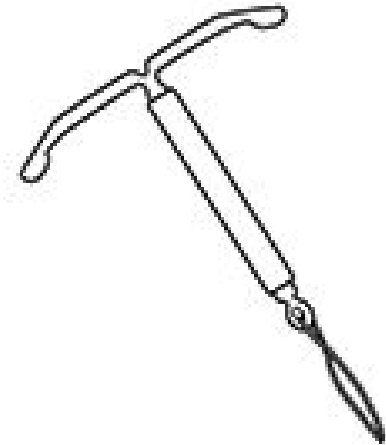
Rademacher KH, Solomon M, Brett T, et al. Expanding Access to a New, More Affordable Levonorgestrel Intrauterine System in Kenya: Service Delivery Costs Compared With Other Contraceptive Methods and Perspectives of Key Opinion Leaders. 2016

Market Assessment Methods

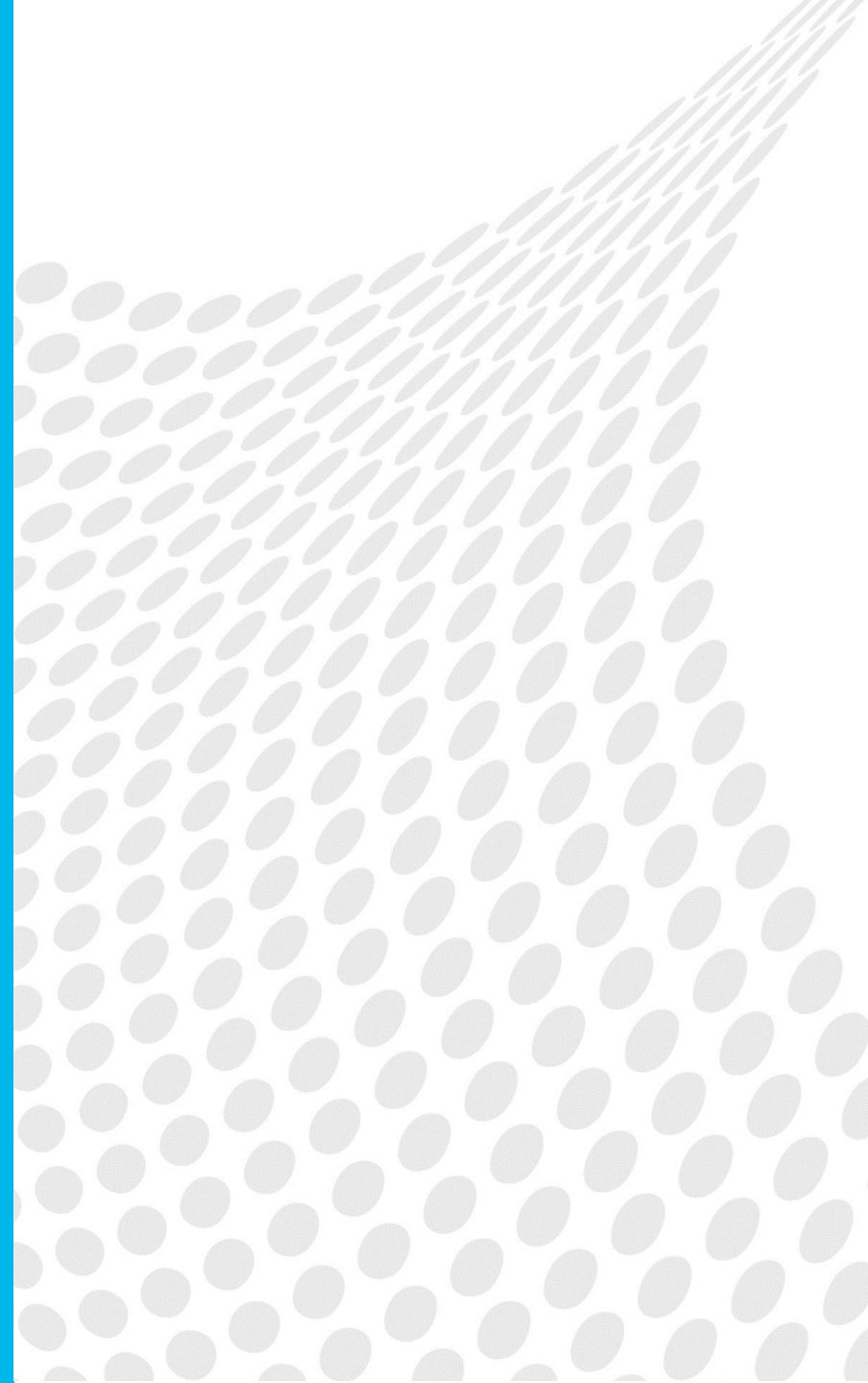


Market Assessment: Methods

- Desk review of service delivery landscape/ program experiences
- 34 rapid facility Assessments
- 18 interviews with Key Opinion Leaders
- 24 interviews with healthcare providers
- 6 Focus group discussions and 14 in-depth interviews were conducted with:
 - Postpartum women
 - Users of long-acting, reversible contraception
 - Users of short-acting methods
 - Non-users of contraception



Service Delivery Landscape



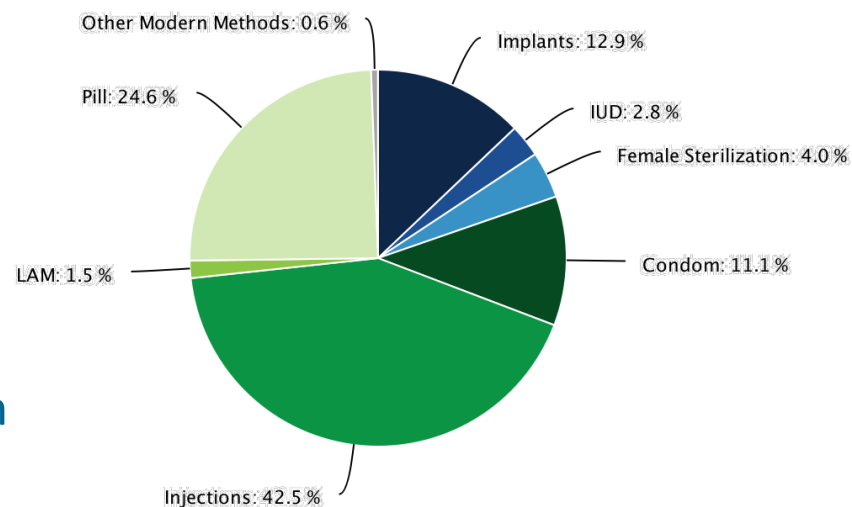
Family Planning in Zambia



Current Use:

- According to the 2013-14 DHS, 33% of all women and 45% of married women use a modern contraceptive method
- 21% of married women have an unmet need for family planning
 - 14% have a need for spacing births and 7% have a need for limiting birth
- 1.2% of married women currently use an IUCD

Modern Contraceptive Method Mix



Source: DHS 2013-14
Method mix
among all women

Government of Zambia FP2020 Commitments



A number of the commitments that the Government of Zambia made at the 2012 Family Planning (FP) Summit help create an enabling environment for the introduction of a new contraceptive methods. These include commitments to:

- Expand the method mix & increase access to FP
- Increase CPR for modern methods from 33% to 58%
- Commitment to double the budgetary allocation for FP commodities
- Address policy barriers to allow task shifting to Community Health Assistants (CHAs) and Community Health Workers (CHWs)

Service Delivery Context



Public Sector Services

- Zambia is divided into ten regions, which are further divided into 106 districts
- **FP is provided for free** in public sector clinics which are under the jurisdiction of the Ministry of Health (MOH)
- **82% of FP users** access services through the public sector and
- **90% of IUDs** are provided through public sector (DHS, 2013-14)
- Services provided through Health Posts (~250); Rural Health Centers (~1000); Urban Health Centers (~200); Level 1/District Hospitals (~70); Level 2 Hospitals (~16) and Level 3 Hospitals (~6). (MCDMCH, 2013)



Service Delivery Context cont.

Public Sector Provision of LARCs

- Lack of commodities and trained staff have been major barriers to LARC provision (MCDMCH, 2013)
- Recent progress includes **training of over 500 health workers in LARC provision** and development of a national database of trained providers. Currently, **40% of facilities have at least one person trained on LARCs** (IPPF, 2015; DHS, 2013-14).
- As highlighted in the Track 20 assessment, there is a need for further research on operational constraints to expand the method mix to include more effective methods of modern contraception including LARCs.



Strategies to Increase LARC Use

In Zambia's Integrated Family Planning Scale-up Plan, the following strategies were identified to increase access to LARCs:

- Increase knowledge of LARCS by raising public awareness & educating providers
- Strengthen pre-service clinical training of providers
- Provide cost effective in-service clinical training to a subset of strategically selected providers
- Modify the service delivery model of LARCS
- Improve local governance and management of FP services
- Improve availability of LARC commodities and consumables



Strategies to Increase LARC Use cont.

Past/current efforts to increase LARC provision include:

- **Use of dedicated providers:** Dedicated LARC providers were employed by SFH and seconded to public sector clinics starting in 2008. Evaluation showed over 30K clients served in 14-month period; successful at reaching young women and women of lower parity (Neukom et al., 2011). Program focus has since shifted; training/supportive supervision to public sector providers now continues under SFH's SARAI project.
- **Task-sharing:** There is growing support for task-sharing including potentially for LARCs. A technical working group on task-sharing of FP was recently established (includes Health Professionals Council of Zambia, University Teaching Hospital, USAID, MCDMCH, MoH, CAs). Recent pilot of tubal ligation provision by clinical officers showed early success (MSI, 2016). There was a recent policy change to allow CBD of injectables (FP2020, 2016).

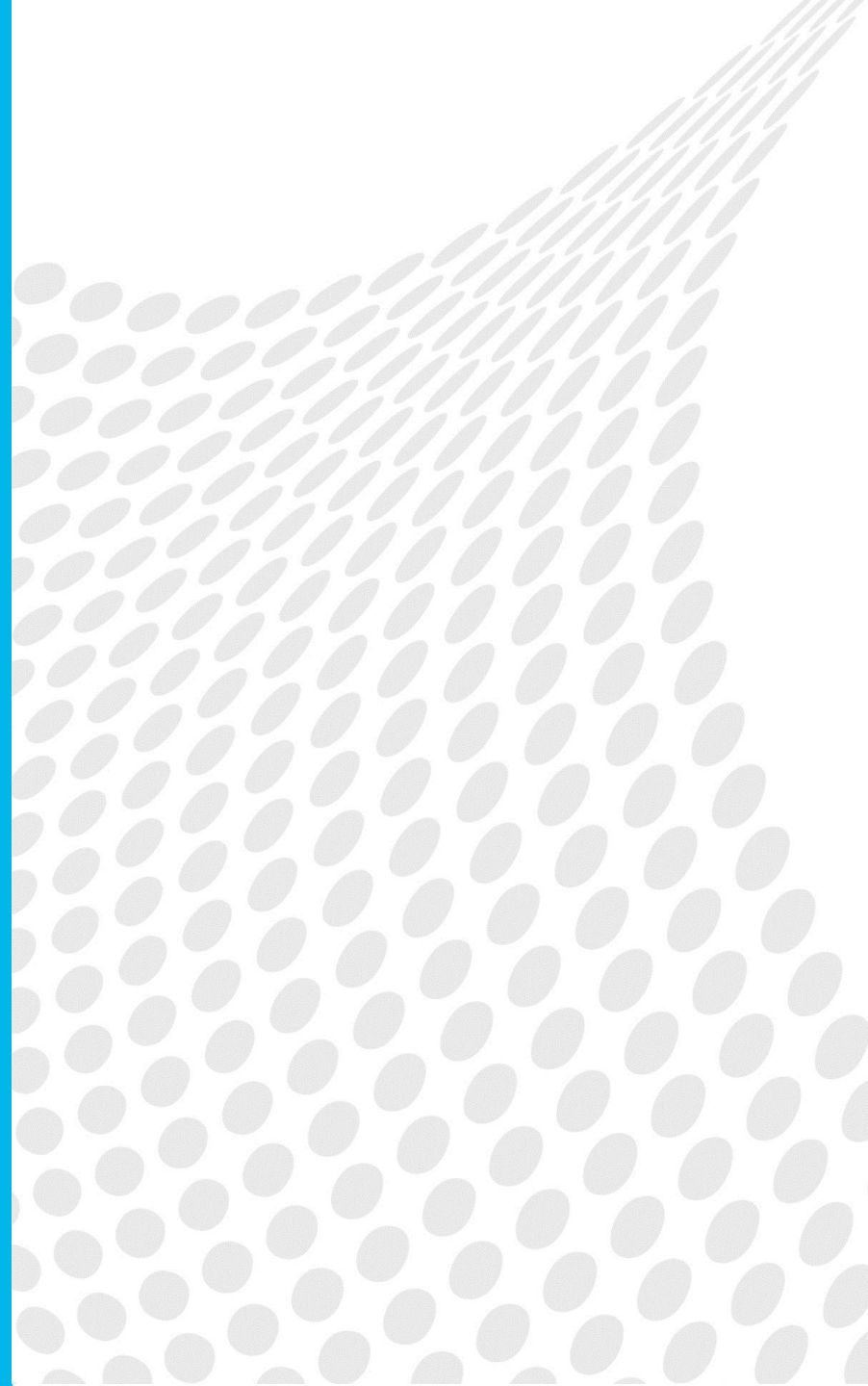


Strategies to Increase LARC Use cont.

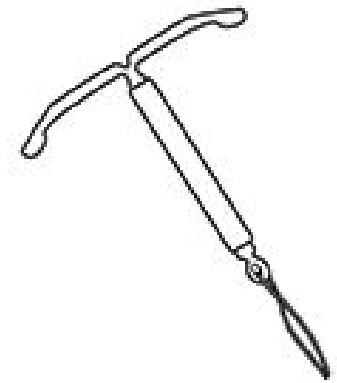
Past/current efforts to increase LARC provision includes:

- **Camping Approach:** Scaling Up Family Planning (SUFP) project launched in 2012 with focus on addressing both supply- and demand-side barriers in 26 districts. The Camping Approach is innovative outreach strategy that offers intensive technical assistance to district managers, providers, and community leaders over a 2-week period and then over shorter subsequent periods. There is interest from MOH in expanding to additional districts (Evidence Project, 2016; FP2020, 2016).
- **Postpartum IUD:** The Postpartum Family Planning Action Plan promotes the provision of post-placental and postpartum IUCDs (PPIUCDs). A pilot project was conducted in collaboration with the MOH to examine the feasibility of training nurse-midwives to perform PPIUD insertions in Lusaka. Nine nurse-midwives were trained using a competency-based didactic and practical curricula. Competency achieved by all nurse-midwives. (Prager, et al., 2012)

Current Use of Hormonal IUCDs in Zambia



Current use of hormonal IUCDS in Zambia



ICA donations of hormonal IUCDs

The ICA Foundation has provided donations of hormonal IUCDS to organizations in Zambia since 2011

- **The University Teaching Hospital (UTH) has received 600 units since 2011.** Along with community sensitization and demand-creation activities, UTH has integrated the hormonal IUCD into postpartum family planning services. In addition, the **Zambian Association of Obstetricians and Gynecologists (ZAGO)** received 200 units in 2015.
- **Marie Stopes Zambia received 200 units in 2014** for distribution throughout its service delivery network including outreach and static clinics.
- **WomanCare Global received 200 units in 2015.** WCG partnered with ZAGO to distribute the hormonal IUCD at Kitwe Central Hospital, Livingstone Central Hospital, Ndola Central Hospital, Kafue District Hospital and Chipata General Hospital. In January 2016, ZAGO held a LARC skills training for 20 providers, including OB/GYN residents and midwives.
- **Jhpiego received approval for an initial donation of 500 units** which will be shipped in January 2017. This will be via an existing UTH waiver, and commodities will be used at both UTH and Safe Motherhood 360+ sites.

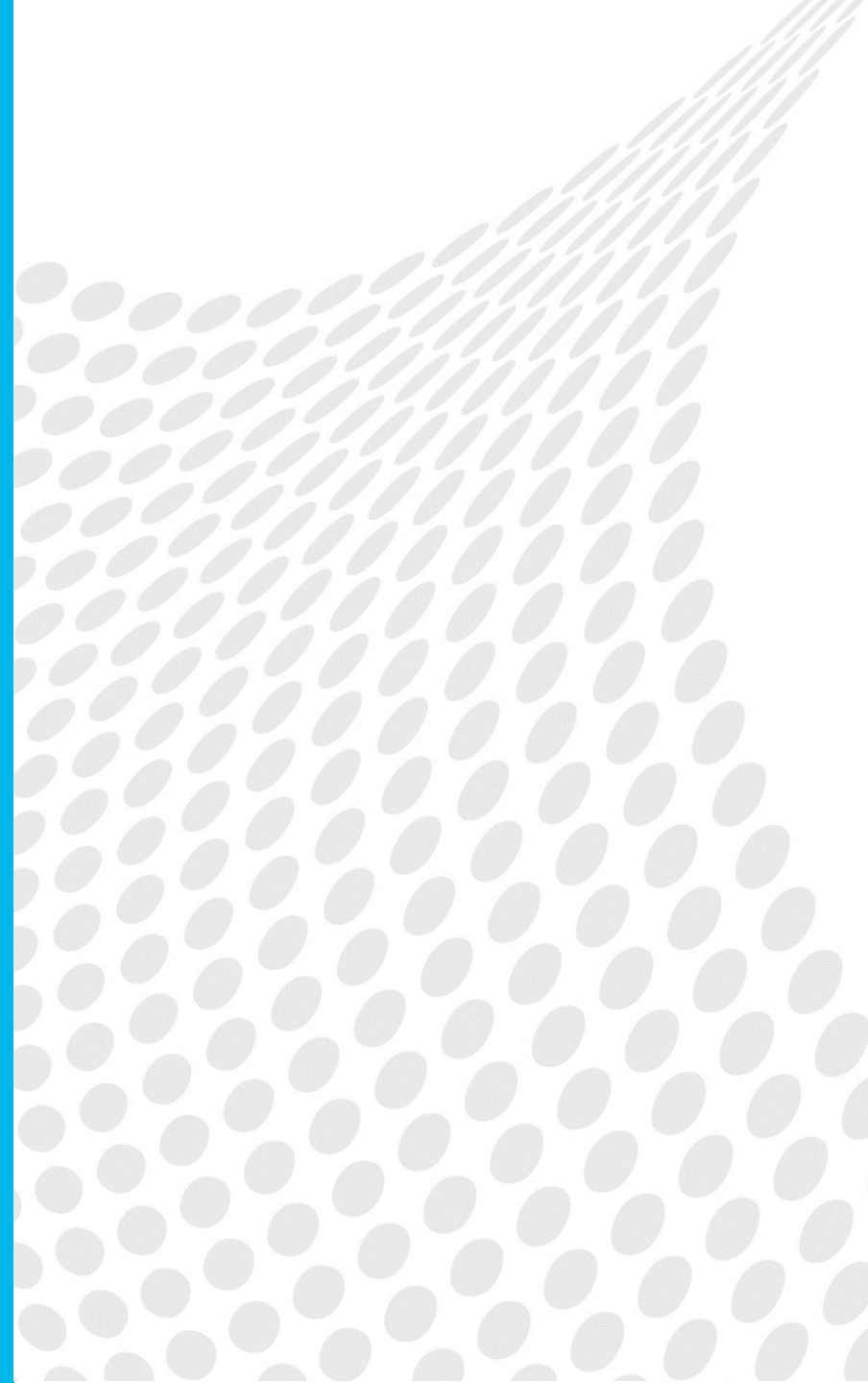


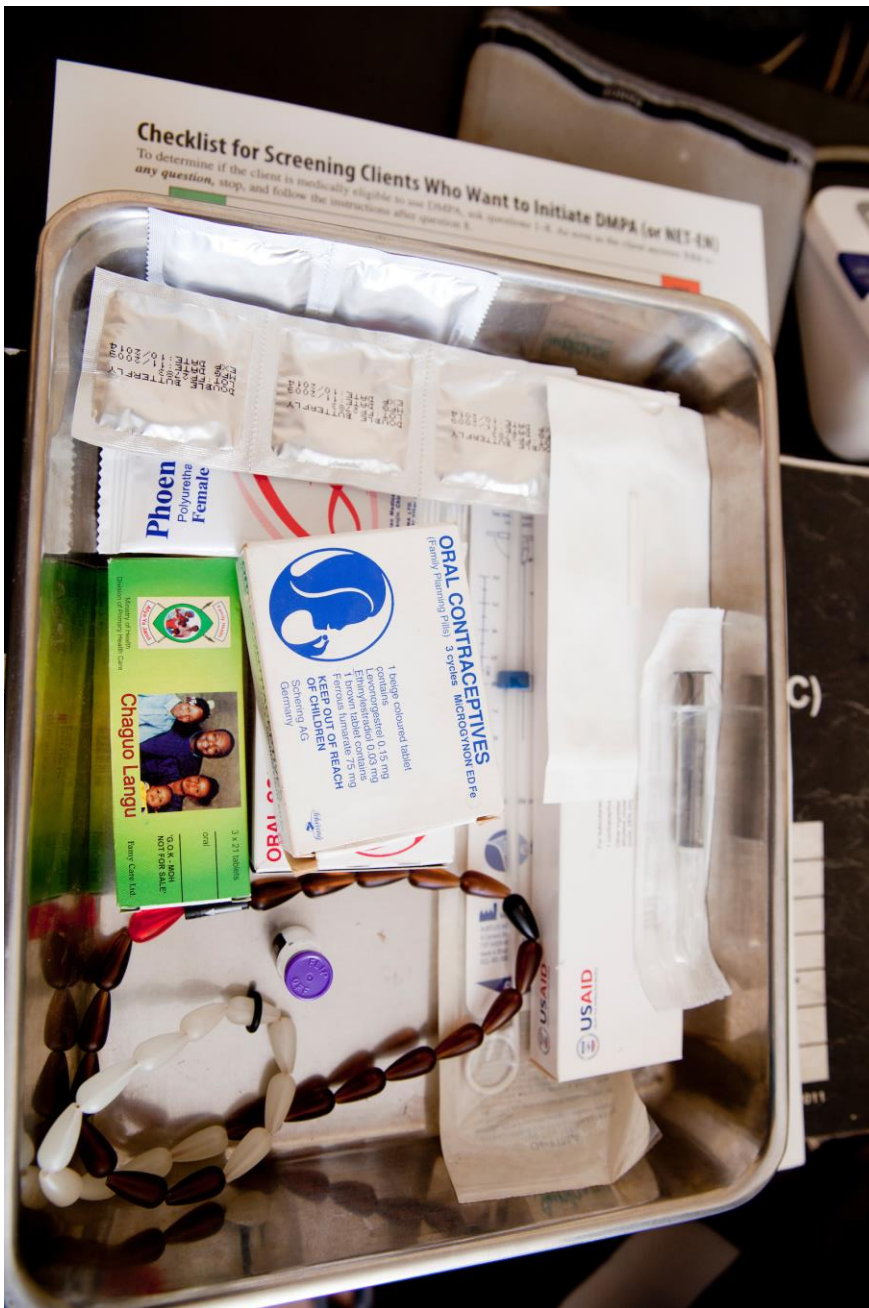
Facilities offering Hormonal IUCDs

- As part of the 2016 market assessment, **brief facility assessments were administered in 34 facilities in Lusaka and Ndola (24 public facilities, 10 private). Only 2 facilities offer insertions of the hormonal IUCD**
 - One privately owned, for-profit clinic offers insertion of Mirena; fee to client is K 4600 or US \$460 (K4000 for product; K600 for insertion fee)
 - One social franchise distributes free product provided by Marie Stopes (insertion fee is K 50 or US \$5)
- A private pharmacy chain sells Mirena for ~ K 3925 Or USD \$393



Market
Assessment:
**Perspectives of
Key Opinion
Leaders**





Perspectives of Key Opinion Leaders (KOLs)

KOLs were asked about their:

- Perspectives on current use of copper IUCD
- Perspectives on current use of hormonal IUCD
- Potential demand for hormonal IUCD
 - Potential target markets
 - Method characteristics
 - Strategies to increase access

KOLs were all identified as leaders in reproductive health including individuals from the government, NGOs, medical associations, academic institutions, and donor groups. All were based in Lusaka.

Perspectives on current use of copper IUCDs

For this and all subsequent slides, **orange** text indicates most common answers provided by respondents.

KOLs believed that uptake of copper IUDs is limited due to:

- **Myths and misconceptions among clients and providers**
- **Lack of provider training & skills**
- **Staff shortages/workload**
- **Insufficient awareness among public**
- Provider biases/poor counselling
- Insufficient commodities
- Lack of supplies/equipment
- Providers find other methods easier
- Lack of private space for insertion procedures
- Bleeding/side effects of copper IUD
- Women do not like exposing themselves –esp. to male provider

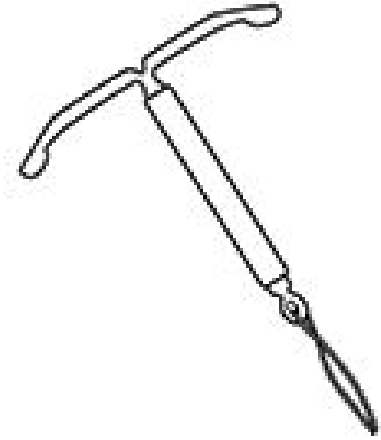
“

One of [the barriers] is skills... When family planning providers are trained, some of them do not grasp the skills properly... Sometimes they do not even have a lot of clients, so when they go back, they do not have skills because they haven't practiced enough.

”

**-KEY OPINION
LEADER**

Perceptions of Hormonal IUCDs



Over half of KOLs were aware of the hormonal IUCD prior to interview

Perceived benefits of the hormonal IUCD included:

- **Reduced menstrual bleeding**
- **Reduced cramps/pain from menses**
- **Highly effective contraception**
- **Non-contraceptive health benefits**
- Potential to lead to amenorrhea*
- Duration of use
- Rapid return to fertility after use
- Potential to reduce/treat anemia
- Reversible/can be removed at any time

*KOLs saw clinical and lifestyle advantages of amenorrhea but recognized potential resistance among some women and need for education

“

For a very long time, we have recognized the benefits of the hormonal releasing IUCD...But the accessibility has been very, very poor in the sense that there are cost implications.

”

-KEY OPINION
LEADER

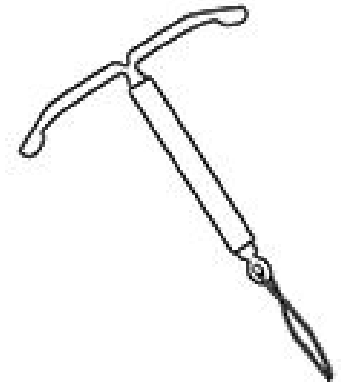
“

Yes, I am familiar [with the hormonal IUCD]. In fact I am a user....One of the advantages is that it reduces menstrual flow to the extent of having no periods at all, which I enjoy... Since you are not having the periods, there aren't cramps, the abdominal pain....For those with heavy flow it reduces anemia, and just that freedom to know that you are not going to buy any tampons, you are not going to buy pads. Yes, every day is Christmas!

”

KEY OPINION LEADER &
MIRENA USER

Strategies to Scale-Up Hormonal IUCDs



Potential target audiences identified included **women who could benefit clinically from non-contraceptive benefits; young women/adolescents***; spacers and limiters; postpartum women and both rural and urban women.

Key steps to ensure introduction and scale-up are successful:

- **Marketing/education/demand creation**
- **Provider training**
- **Stakeholder engagement & buy-in from the government**
- Ensuring adequate equipment
- Inclusion in FP guidelines
- Commodity security
- Engaging champions including at policy-level and providers
- Provider motivation
- Male involvement/community involvement

* Adolescents/young women mentioned frequently but some KOLs felt method not appropriate for this group

“

“Providers are the gatekeepers.”

“You need the government to get behind a program to ensure that long-acting and permanent methods have their rightful place in the method mix.”

“For clients, it’s giving them the information, the knowledge.”

”

**-KOLS ON PRODUCT
INTRODUCTION
STRATEGIES**

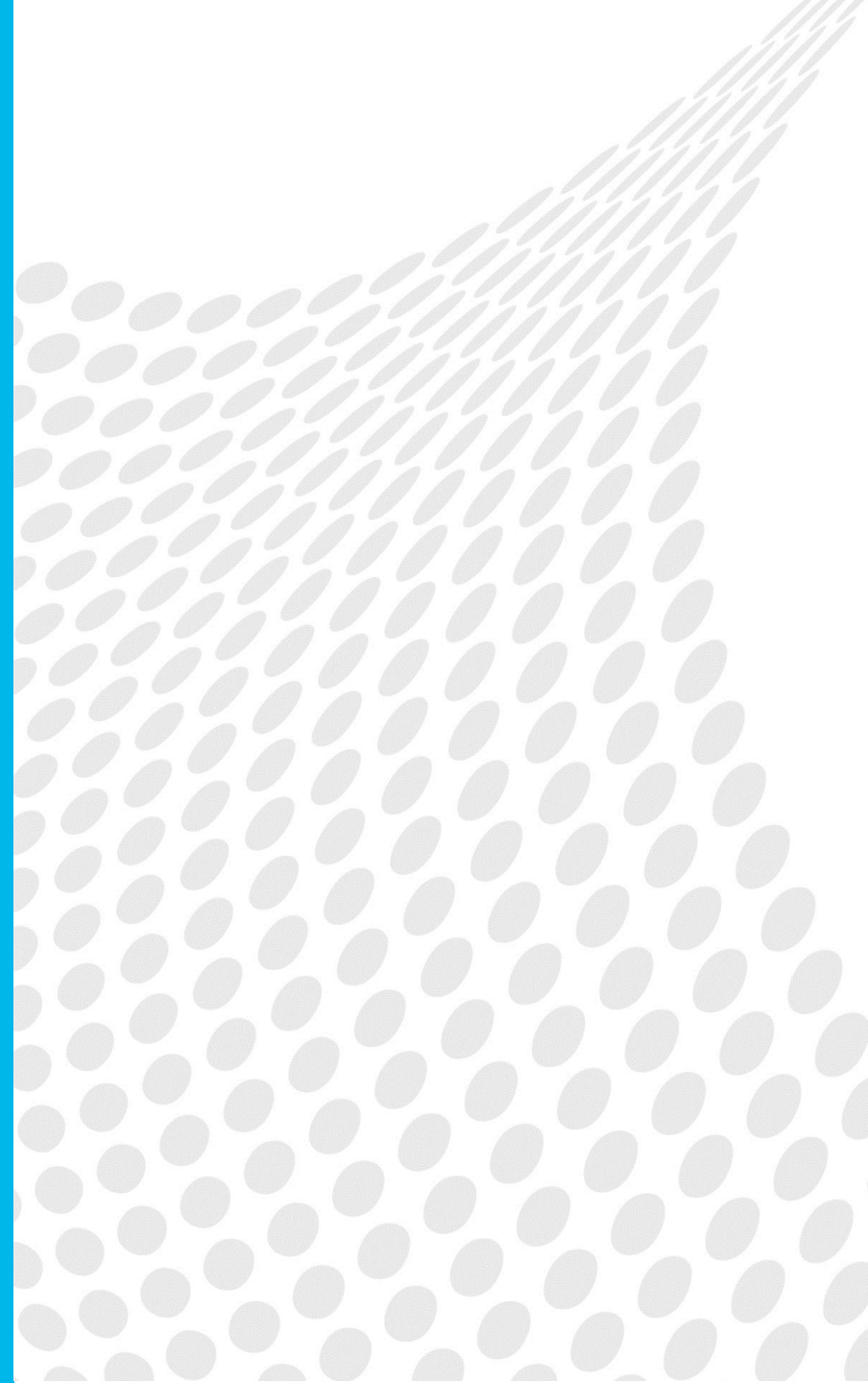
“

Because of the new advantages that are there, I think the IUCD can be given another chance... I think now that [the hormonal IUCD] has been there in the private sector, we need to move to the public sector.

”

**-KEY OPINION
LEADER**

Market
Assessment:
Perspectives of
Providers





Perspectives of Providers

Providers were asked about their:

- Perspectives on current use of copper IUCD
- Perspectives on side effects of family planning including bleeding changes
- Perspectives on potential introduction of hormonal IUCD

Almost all healthcare providers from public sector clinics. Half of providers were based in Lusaka; half based in Ndola.

Current challenges with LARC insertions and removals

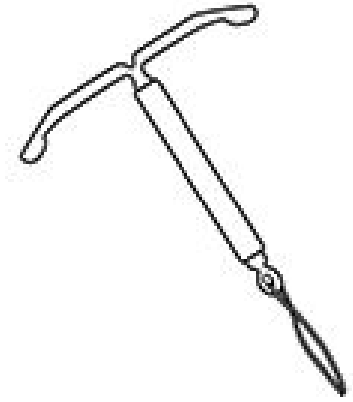


- **Myths and misconceptions among clients**
- **Lack of equipment/supplies**
- **Stock-outs of commodities**
- Staff shortage/workload
- Lack of exam space
- Lack of demand among clients

Very few providers mentioned a lack of training as a current barrier; this differs from KOLs' perspective

Perspectives on Bleeding Changes with Family Planning Methods

- **All providers indicated that the side effect associated with family planning methods that creates the biggest problem for women is bleeding changes** – e.g. heavier bleeding, prolonged bleeding, and spotting. Other problematic side effects included headaches, weight gain, mood swings.
- Almost all providers indicated that reduced bleeding or amenorrhea is an advantage for clients. A small minority mentioned that amenorrhea can be problematic for women.



Perception of hormonal IUCDs

Almost all of the providers had never heard of the hormonal IUCD

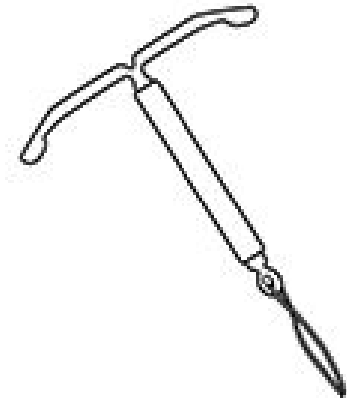
- Based on the description read to them, providers felt that advantages included **decreased bleeding, duration of effectiveness, rapid return to fertility, use in spacing/limiting, and the potential to reduce anemia.**
- **All felt that reduced bleeding associated with the hormonal IUCD would increase interest in the product.** However, some felt potential for amenorrhea would be a disadvantage.
- Other perceived disadvantages included pain for insertion and potential for “hormonal imbalance.”

“

I can say yes on that one when I compare it to the Jadelle. Because Jadelle is for five years and this one also is for five years and they are all hormonal. We receive a lot of women who complain of prolonged heavy bleeding. Now if they hear of this one which stops or reduces the bleeding, [I] am sure they may go for the one that reduces the bleeding.

”

**-HEALTHCARE
PROVIDER**



Perceptions of hormonal IUCDs continued

- **All providers indicated that – based on what they had heard – they would use this product in their practice**
- Almost all indicated that training is a priority to increase providers' knowledge/buy-in along with IEC materials to give to clients
- Almost all thought that demand among clients would increase if a more affordable hormonal IUCD were made available in Zambia

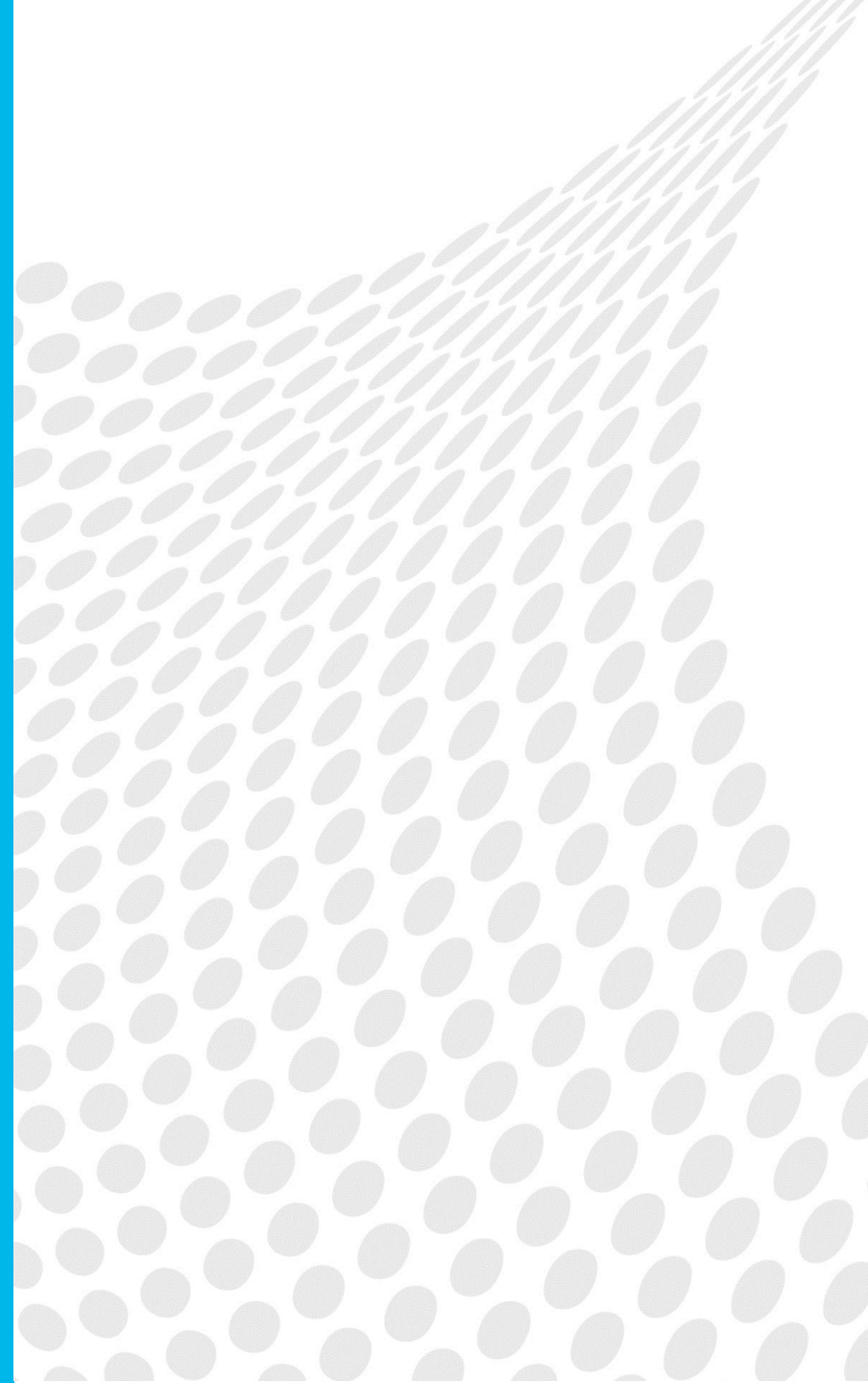
“

It depends on how we disseminate information to the women because information is power, so if we educate the women, explain properly, it will increase the number of women who may go after it as long as information is well given to the mothers.

”

**-HEALTHCARE
PROVIDER**

Market
Assessment:
**Perspectives of
Potential Users**





Perspectives of Potential Users

Women were asked about:

- Perspectives on current or previous method use
- Perceived side effects of contraception
- Perceptions of hormonal IUCDs
- Perspectives on potential use of hormonal IUCDs

Potential users included the following groups of women: LARC users, users of short-acting contraception, postpartum women, and non-users.

FGDs and IDIs – most conducted in Lusaka, small number in Ndola

Potential Users

Profiles of Potential Users, by Method Use

	LARC Users	Short-Acting FP Users	Postpartum* Women	Non-Users
18-24 YR OLDS	6 (1 FGD)	5 (1 FGD)	6 (1 FGD)	6 IDIs
25-49 YR OLDS	6 (5 in 1 FGD, 1 IDI)	5 (1 FGD)	6 (1 FGD)	7 IDIs

*Up to 12 months postpartum



Perspectives on Current or Previous Family Planning Method Use

Reasons for choosing among different FP methods:

- **To achieve desired birth spacing or limiting**
- **Wanted methods with fewer side effects**
- Method's effectiveness
- Rapid return to fertility after discontinuation
- Selected method based on what was advised by provider or available at clinic
- Avoided methods with specific side effects such as bleeding changes and/or weight gain

“

I use Jadelle because I never wanted to be pregnant. And the other thing is that people were promoting it, saying that it has less side effects. That is why I chose it.

-LARC USER

I was using oral contraceptives...I liked it because it didn't give me any side effects.

**-POSTPARTUM
WOMAN**

”



Perceived Negative Side Effects of Contraception

Women mentioned a range of negative side effects they associated with use of modern contraception:

- **Bleeding changes** such as heavier bleeding, prolonged bleeding, no bleeding, irregular bleeding, and spotting
- Painful periods
- Headaches
- Weight gain*
- Weakness
- Dizziness
- Backache or other body aches

*Some women perceived weight gain associated with a method as a positive attribute

“

Since I started this family planning method I have been having heavy bleeding and very painful such that sometimes I even fail to do house chores....And I don't enjoy heavy bleeding because am always conscious that maybe the pad that I am using is not enough and if I sit for a long time, I may mess up myself. So I feel very uncomfortable.

-COPPER IUD
USER

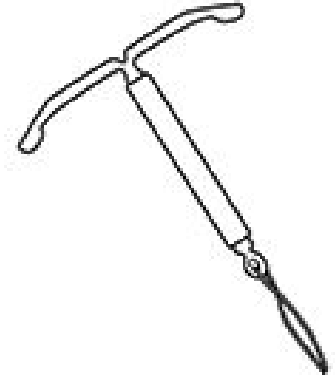
”

“

As for me, am very worried right now because am not seeing my periods anymore. Does it mean that am not ovulating anymore or what's the problem that I could have?...Am very scared and very concerned because I don't know what is happening. Maybe it will take long before I conceive again. I don't know to what extent this will happen.

”

-IMPLANT USER



Awareness of Hormonal IUCDs

Awareness of hormonal IUDs was very low among potential user groups

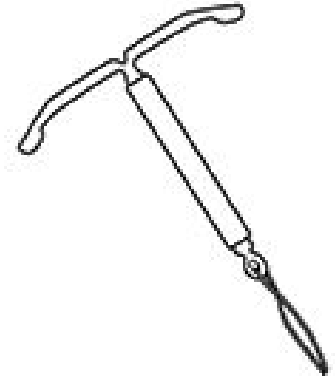
- The majority of participants were not familiar with the method, though two LARC users had heard of Mirena through a peer and international media source, respectively.

“

It was just a colleague at work. She mentioned that there's a new IUCD that they were going to introduce. I didn't know it was an IUCD because she was just mentioning another name, Mirena. I didn't know much about it.

- LARC USER

”



Perceptions of Hormonal IUCDs

Perceived Advantages

Based on the description of the method read to them, potential users identified perceived advantages of using the hormonal IUCD:

- The most commonly cited perceived advantage was **reduced blood flow and cycle length**.
- Common advantages also cited **were less painful periods, rapid return to fertility, and long duration of use with option to remove earlier**.
- Other advantages were the reduced risk of anemia, and that the method was highly effective.

“

If I want [the hormonal IUCD] to be removed, it can even be removed after two years and I can conceive immediately. It's unlike the...injections. After stopping using an injection you can stay another two months without conceiving because the medicine may still be effective in the body.

”

-SHORT-ACTING USER

“

Yes definitely. I have liked what you have said that it helps to reduce periods for those who have heavy periods and that it also reduces the pain. And that there's no delay in bringing back your fertility.

”

-LARC USER



Perceptions of Hormonal IUCDs

Perceived Disadvantages

- Based on the description of the method read to them, **the majority of participants did not perceive any disadvantages with use of the hormonal IUCD.**
- Among those that perceived disadvantages, **the main concern related to insertion of the device** in terms of potential discomfort and to a lesser extent, its location in the uterus.
- Other disadvantages were possible amenorrhea, weight gain associated with hormonal methods, and risk of the device moving/exiting the uterus without knowledge.

“

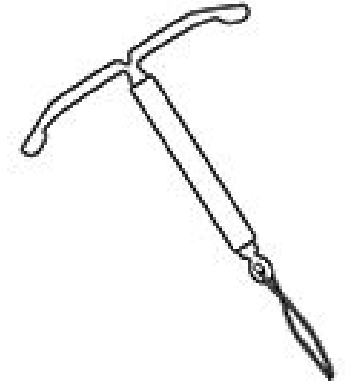
I did not like the idea of inserting it through the vagina. [chuckles] At least the Jadelle is put in the hand.

- NON-USER

What I didn't like is the discomfort that you said one may have after it's inserted. I don't know how long that discomfort can take and what help one can be given.

”

- SHORT-ACTING USER



Perspectives on Bleeding Side Effects – Amenorrhea

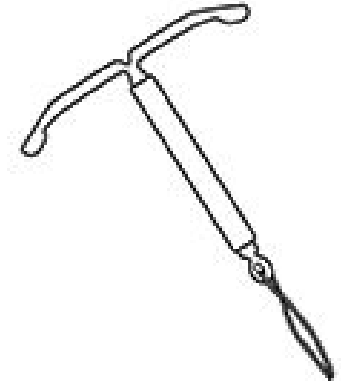
- **The majority of participants felt the absence of menses was not a desirable condition.**
 - The main reason cited was the **belief that bleeding was an important cleansing process** and source of ‘relief’ in the body, without which women risked discomfort and illness.
 - Participants also worried the absence of menstrual cycles might be mistaken for pregnancy and therefore a source of psychological stress.

“

Am also worried on the aspect of not bleeding at all. It would be better if one would bleed even just a little bit, you can feel relieved. It's not nice that it stops completely because when a woman bleeds, it cleanses the uterus. So it's not good that the periods stops completely.

”

-SHORT-ACTING USER



Perspectives on Bleeding Side Effects – Reduced Bleeding

- **Majority of women perceived reduced bleeding as an advantageous side effect.**
 - A number of participants complained of heavy monthly bleeding and said they would welcome a reduced blood flow for reasons including:
 - Lowered risk of anemia and associated symptoms (e.g., weakness/dizziness)
 - Improved ability to accomplish household tasks/chores
 - Less interruption to sexual relations and therefore improved marital/partner relations

“

I experience heavy bleeding. Sometimes I feel dizzy. And due to this excessive bleeding, I experience anemia. I would love to use this method so that it helps reduce bleeding. I'd truly feel relieved if bleeding were reduced.

”

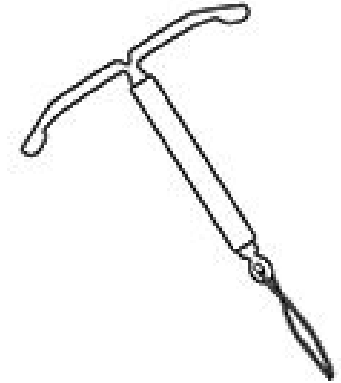
- LARC USER

“

It's a big disadvantage when you just continue bleeding heavily. It must give you time to breath because it brings many problems in marriage. You're just bleeding when you husband wants to have sex with you. If you just continue bleeding, your husband may start having sex outside marriage - just because of prolonged bleeding. But if you use a good method that helps to reduce bleeding for maybe four days, then there will be unity and peace in your marriage.

”

- LARC USER



Perspectives on Bleeding Side Effects – Postpartum Women

- **Most participants felt favorably about postpartum amenorrhea, citing desirable consequences including increased comfort and a reduced need for frequent bathing and sanitary products**
 - A smaller number expressed dislikes including the absence of physical and emotional relief they experience with their menses
- **When asked about the desirability of longer-term amenorrhea, none of the participants found the condition appealing**
 - Women of child-bearing age were perceived as ‘needing’ to bleed, to cleanse and relieve the body. Failure to do so was ‘unnatural’ and a potential catalyst for complications in the body.

“

A person needs to relieve herself per normal. I mean one needs to have monthly periods to relieve herself. Because if you miss your monthly periods, you can experience prolonged abdominal cramps.

- POSTPARTUM WOMAN

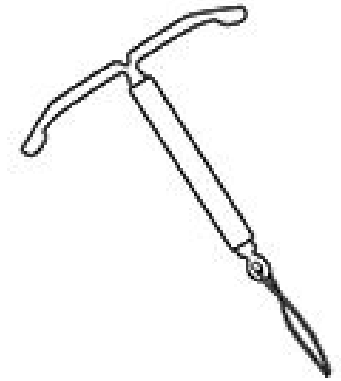
”

“

I can't like it to stay for a long time without having a period. It brings complications because the dirty is not coming out of the body. The other thing is that you may start wondering whether you are pregnant or maybe having other problems because of not having the periods. So it is important to have monthly periods.

”

- POSTPARTUM
WOMAN



Perspectives on Potential Use of Hormonal IUCDs

- **The majority of potential users indicated they would be willing to consider/try the hormonal IUCD**
 - Some participants qualified their inclination by saying that trying the method carried low risk because removal was easy if they experienced negative side effects
 - Several participants expressed a preference for others to use 'first' due to the newness of the product

“

I can love if someone else starts it rather than me so that I can see its advantages first.

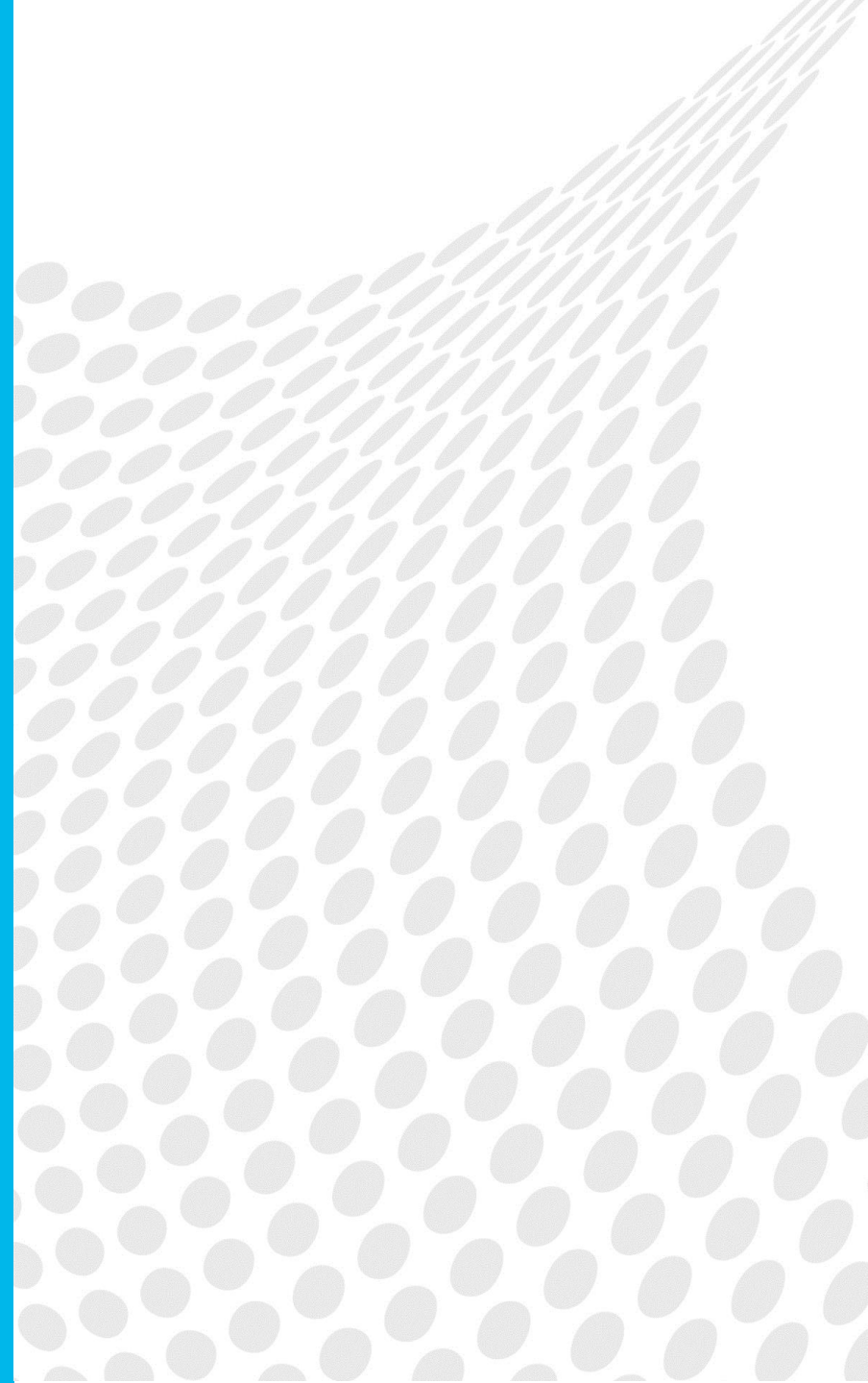
- POSTPARTUM WOMAN

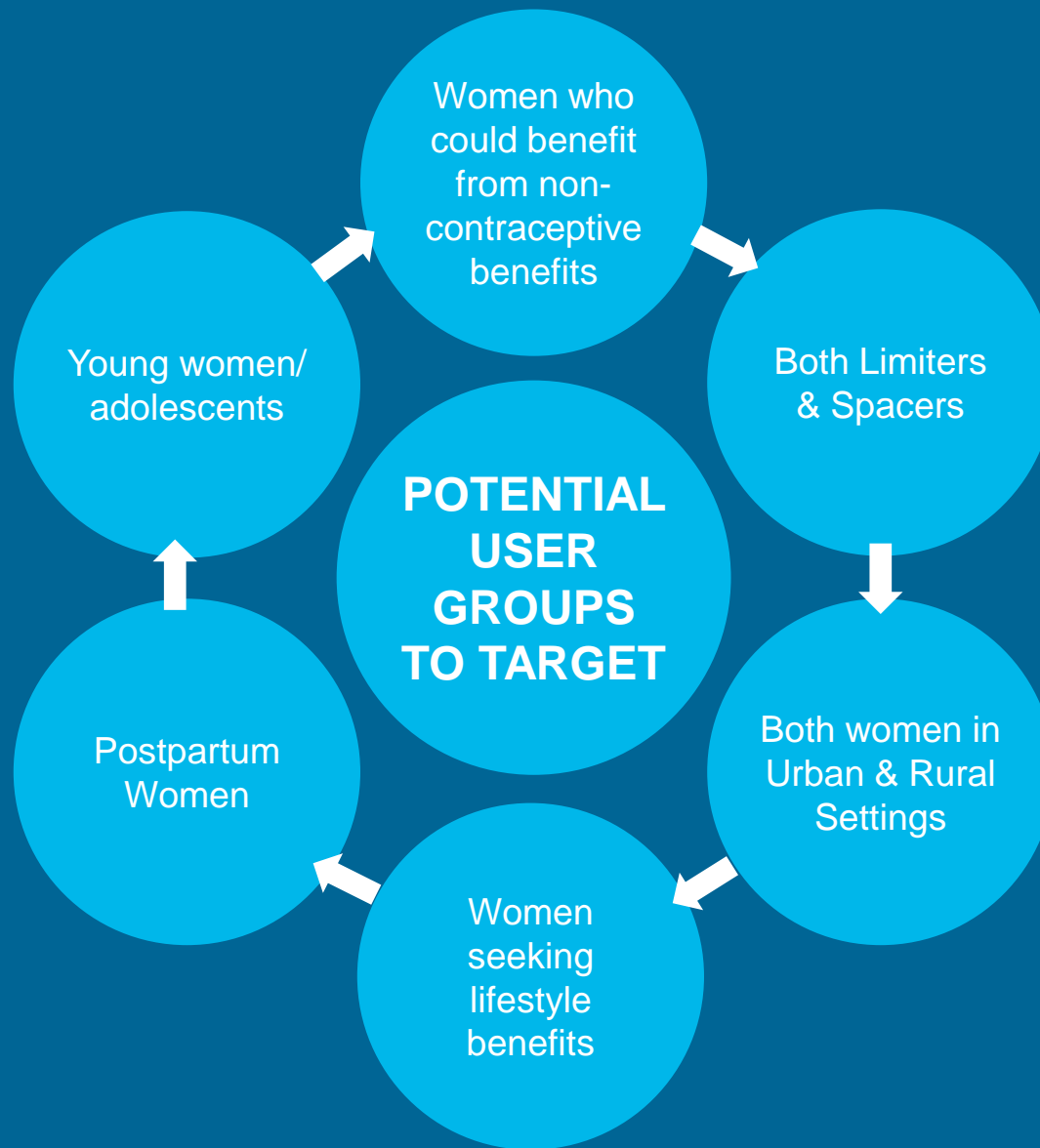
I can be interested in using it because as I have already mentioned, I bleed a lot. So I can love to use it so that the bleeding is reduced.

- SHORT-ACTING USER

”

Target Markets





Based on the KOL interviews and a review of secondary data sources including the DHS, profiles for potential user groups of a more affordable hormonal IUCD were developed. Criteria from the *Market Segmentation Primer* developed by RHSC were applied including that market segments must be: 1) measurable; 2) substantial; 3) accessible; 4) distinct; and 5) stable. The target groups reflect demographic, attitudinal, and behavioral variables; there will likely be some overlap between the groups.

Women who could benefit from non-contraceptive benefits


This group includes women who are suffering from irregular menstruation and menorrhagia, uterine fibroids and polycystic ovaries. In other settings, the Mirena has been successfully positioned as an effective treatment option for these women, and the same can be achieved with a new hormonal IUCD in Zambia. Also, because the hormonal IUCD may reduce anaemia in certain populations, women who are anemic may find this product attractive.

Both Limiters & Spacers

KOLs agreed that both limiters and spacers would be attracted to the hormonal IUCD. Spacers may include women who want to wait before having children in order pursue education or work and/or women who have one or more children already but want to delay additional pregnancies. Because the hormonal ICUD 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 incorrectly perceive that they must use a product for its full duration of effectiveness). That said, ongoing clinical research will evaluate whether the Medicines360 product 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.

Both women in Urban & Rural Settings

Unmet need is higher among rural women in Zambia, and long-acting methods including the hormonal IUCD are ideal for women with limited access to healthcare services because no regular resupply is needed. At the same time, focusing on introduction of a new hormonal IUCD in urban areas – where IUCD use is currently higher– could help drive awareness and use of the product.



Women
seeking
lifestyle
benefits

Responses from the KOLs and potential users suggest that women may find non-contraceptive product attributes of the hormonal IUCD attractive for lifestyle reasons including reduced bleeding. Reduced bleeding may be desirable because of 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, be sexually active, etc.) At the same time, feedback from women that amenorrhea is less attractive and can be alarming needs to be addressed through education and demand creation activities.



Postpartum
Women

Postpartum women are a group with high unmet need, and LARCs can be important to promote healthy timing and spacing of pregnancies. In the first year after birth, many mothers experience a period of postpartum amenorrhea; most women interviewed in the assessment found this desirable. The hormonal IUCD may be attractive to this group, particularly as it could extend amenorrhea without any interim resumption of menses. However, more education/demand creation is needed to inform women that amenorrhea in the non-postpartum period does not cause negative health effects.

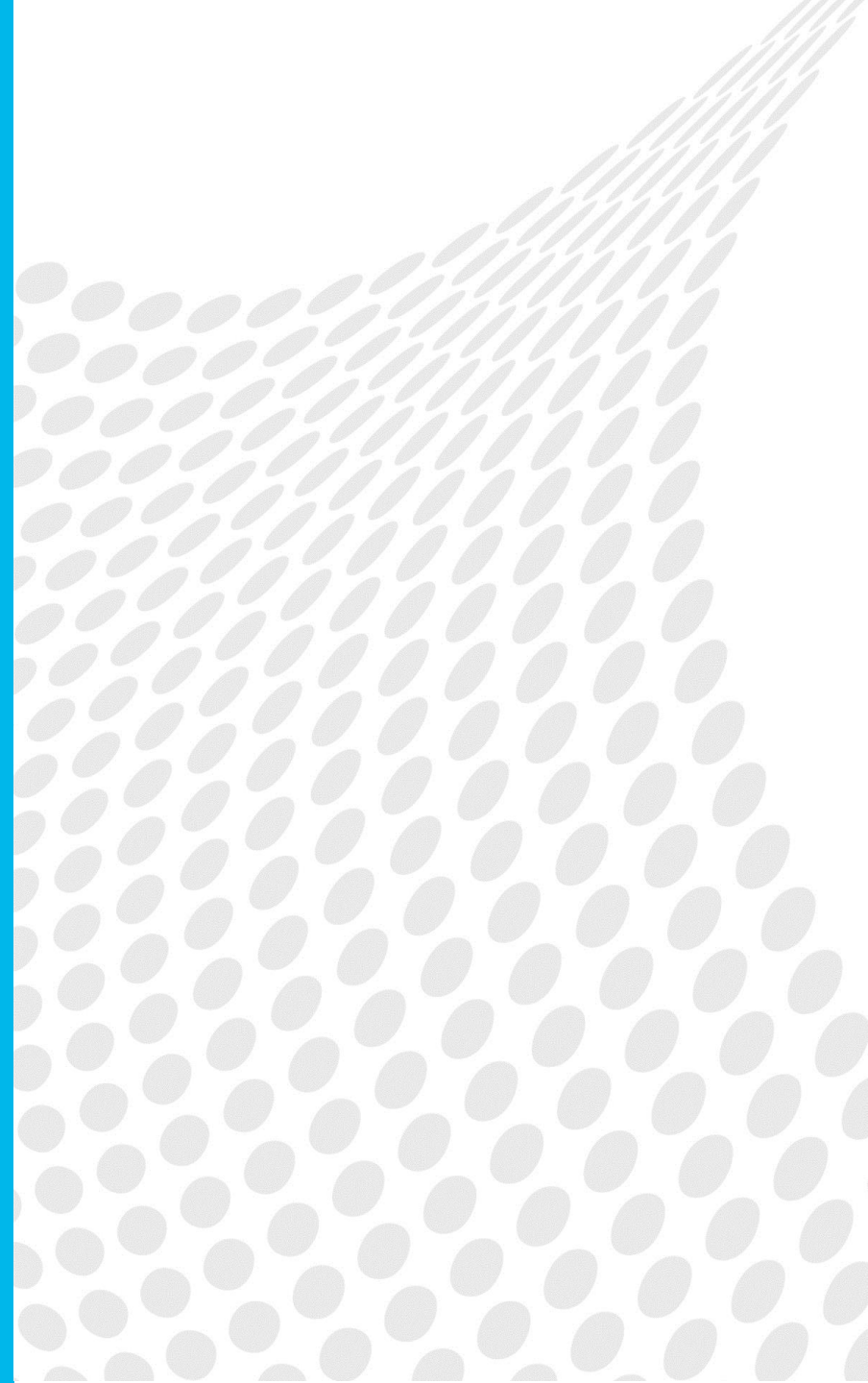


Young women/
adolescents

Adolescents/young women were mentioned frequently by KOLs as an important target market, though some felt the method is not appropriate for this group. Adolescent girls may find the hormonal IUCD 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; reduced bleeding could help advance menstrual hygiene management.

Product Introduction

- Regulatory considerations
- Distribution & service delivery
- Demand Creation
- Policy considerations & research



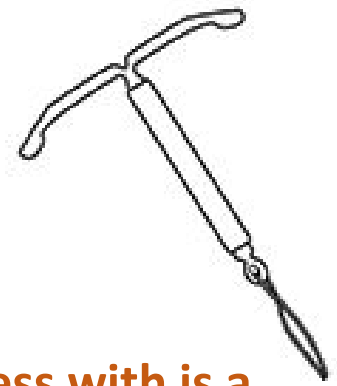
- In August 2016, preliminary results of the market assessment were presented to the Family Planning Technical Working group which **endorsed public sector introduction of the hormonal IUCD**
- SFH, PSI and WomanCare Global are planning introduction through the USAID-funded SARAI and EECO projects and Jhpiego plans to support introduction through the Safe Motherhood360 project. Initial introduction will involve distribution of ICA Foundation units while WCG and SFH pursue registration of the Medicines360 product





Regulatory considerations in Zambia

- **The Zambia Medicines Regulatory Authority (ZAMRA) is the national medical regulatory authority (NMRA) in Zambia that oversees all pharmaceutical and medical device regulatory approvals**
- ZAMRA has aligned their standards with global standards based on the International Conference on Harmonisation (ICH) guidelines and on the Technical Requirements for Registration of Human Medicines (ICH) guidelines in CTD format. A five module CTD dossier is required for submission of a new pharmaceutical product
- There is also a requirement for a pharmacovigilance plan to be submitted
- If all requirements are met, regulatory approval in Zambia can take up to 12 months. WCG and SFH will explore with ZAMRA potential pathways for expedited review and approval



Regulatory Harmonization: ZAZIBONA

ZAMRA is a member of ZAZIBONA collaborative regulatory process with is a collaboration between NMRAs in Zambia, Zimbabwe, Botswana and Namibia

- There is opportunity to streamline and fast track regional regulatory approvals through the ZAZIBONA where the participating NMRAs collaborate on assessments and inspections; however, final national registration decisions are the responsibility of individual participating authorities such as ZAMRA
- Any medicine meeting the criteria of being an essential medicine is invited for submission to be considered for registration via the ZAZIBONA collaborative process. Products registered by a Stringent Regulatory Authority (e.g. USFDA, MHRA) are eligible for abridged review process. This would be relevant to the Medicines360 LNG-IUS product.
- The projected timeline for approval is 11 months (210 days). Each NMRA will be required to finalize the registration process within a reasonable timeframe after the final recommendation from the collaborative process.

Distribution & Service Delivery



With USAID support, SFH, PSI and WomanCare Global will introduce the hormonal IUCD in select public sector clinics, initially using donated product.

- Starting in 2017, SFH will integrate the hormonal IUCD into 30 public sector clinics. Under the USAID-funded Sexual and Reproductive Health for All Initiative (SARAI), SFH works with public sector clinics in 15 districts in Copperbelt, Luapula and Muchinga provinces to improve access to and service delivery of LARCs. Under SARAI, 100 reproductive health providers have been trained in LARC provision, while 88 clinics are receiving on-going training, supportive supervision and FP demand creation support.
- SFH also uses the off-duty initiative wherein LARC-trained providers fill in at high volume facilities during their days off or while on annual leave from their primary place of employment.
- With support from USAID's Expanding Effective Contraceptive Options (EECO) project, SFH will integrate the hormonal IUCD into its on-going LARC work under SARAI. A subset of 30 clinics (2 providers per clinic; 60 providers total) will be selected for participation. All participating providers will already be certified in LARC provision and actively providing implants and copper IUDs. SFH aims to initially provide 1500 women per year with the hormonal IUCD.

Distribution & Service Delivery continued

With USAID support, Jhpiego will also support the introduction of the hormonal IUCD initially using donated product.

- Jhpiego intends to reach 2,000 women with the hormonal IUCD in 2017-18 (1,000 per year) through 40 high volume facilities (20 per year) in 16 Safe Motherhood 360+ implementing districts. The implementation in the first quarter of 2017 will be in 5 *Saving Mothers, Giving Life* (SMGL) districts in Luapula and Central Provinces.



Photo: Jhpiego SMGL

Product Introduction

Training, Coaching & Supportive Supervision

Currently IUD insertions can be performed by doctors, clinical officers, medical licentiates, midwives and LARC trained nurses

- SFH and JHPIEGO will provide training and on-going provider coaching and supportive supervision to FP providers in participating public sector clinics
- Training of Master Trainers: with USAID funding, SFH and JHPIEGO will support a training of MOH master trainers in Q1 2017
- SFH Quality Assurance Supervisors and Reproductive Health Officers will also be trained in Q1 2017 so as to integrate the hormonal IUCD into their provider mentorship and supervision activities under SARAI. Provider training in the three SARAI districts will also take place in Q1 2017.
- JHPIEGO will train mentors in LARC provision (including the hormonal IUCD) These mentors will integrate the hormonal IUCD into their mentorship activities (low dose, high frequency approach) to reach all healthcare providers in the 16 districts and the SM360+ supported health facilities.



Photo: Jhpiego SMGL

Demand Creation Strategies

The partners will promote the hormonal IUCD as both a long-acting contraceptive and a treatment for heavy menstrual bleeding

- Key messages will include: the long acting duration of the product; the reversibility of the product and rapid return to fertility; the localized release of hormones; and reduction in bleeding.
- SFH: With EECO support, the hormonal IUCD will be incorporated into SFH's SARAI FP demand creation activities. These include: use of community-based distribution agents who counsel women on FP methods, dispelling myths and misconceptions and referring clients to facilities for LARC provision.
- JHPIEGO: Demand creation will be through the one-on-one communication through CBDs and Safe Motherhood

Action Groups (SMAGS). Community radio stations will air messages on safe motherhood as well as the importance of family planning.



Photo: SFH

Policy Considerations & Research: Next Steps

Recommendations for next steps include:

- Add LNG-IUS to the Essential Medicines List
- Pursue registration of the Medicines360 product
- Document programmatic experiences and demand creation strategies along with client and provider perceptions of the product in early introduction sites
- Complete forecasting including potential demand among different market segments
- Address Learning Agenda questions identified by global LNG-IUS Working Group convened by USAID through research and/or M&E activities
- Advocate for MOH to consider adding the hormonal IUCD to the additional public sector sites if demand is demonstrated



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