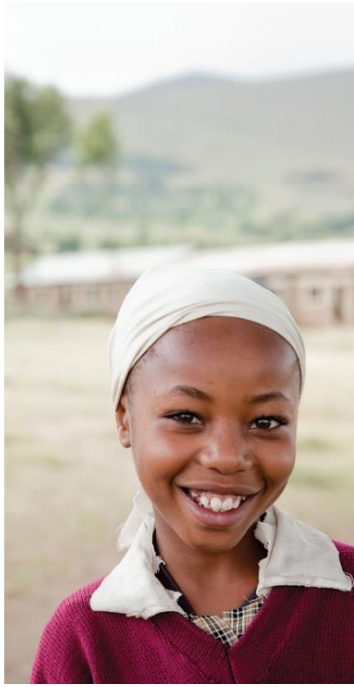
Nigeria

LNG-IUS Market Assessment & Service Delivery Evaluation

April 2018

FINAL REPORT



fhi360
THE SCIENCE OF IMPROVING LIVES

MARIE STOPES INTERNATIONAL
Children by choice, not chance

Table of Contents

Photo credit: Cecilia Schubert Photography, Nigeria

Background

In 2017, FHI 360 and Marie Stopes International (MSI) collaborated on a market assessment to explore potential demand for the levonorgestrel intrauterine system (LNG-IUS) and to assess initial service provision of the LNG-IUS through MSI clinics, franchises and outreach services and through a small number of public sector clinics.

Funding for this work was provided by the United States Agency for International Development (USAID) through MSI's Support for International Family Planning and Health Organizations (SIFPO-2) project, and by the Bill & Melinda Gates Foundation through FHI 360's Contraceptive Technology Innovation Initiative.

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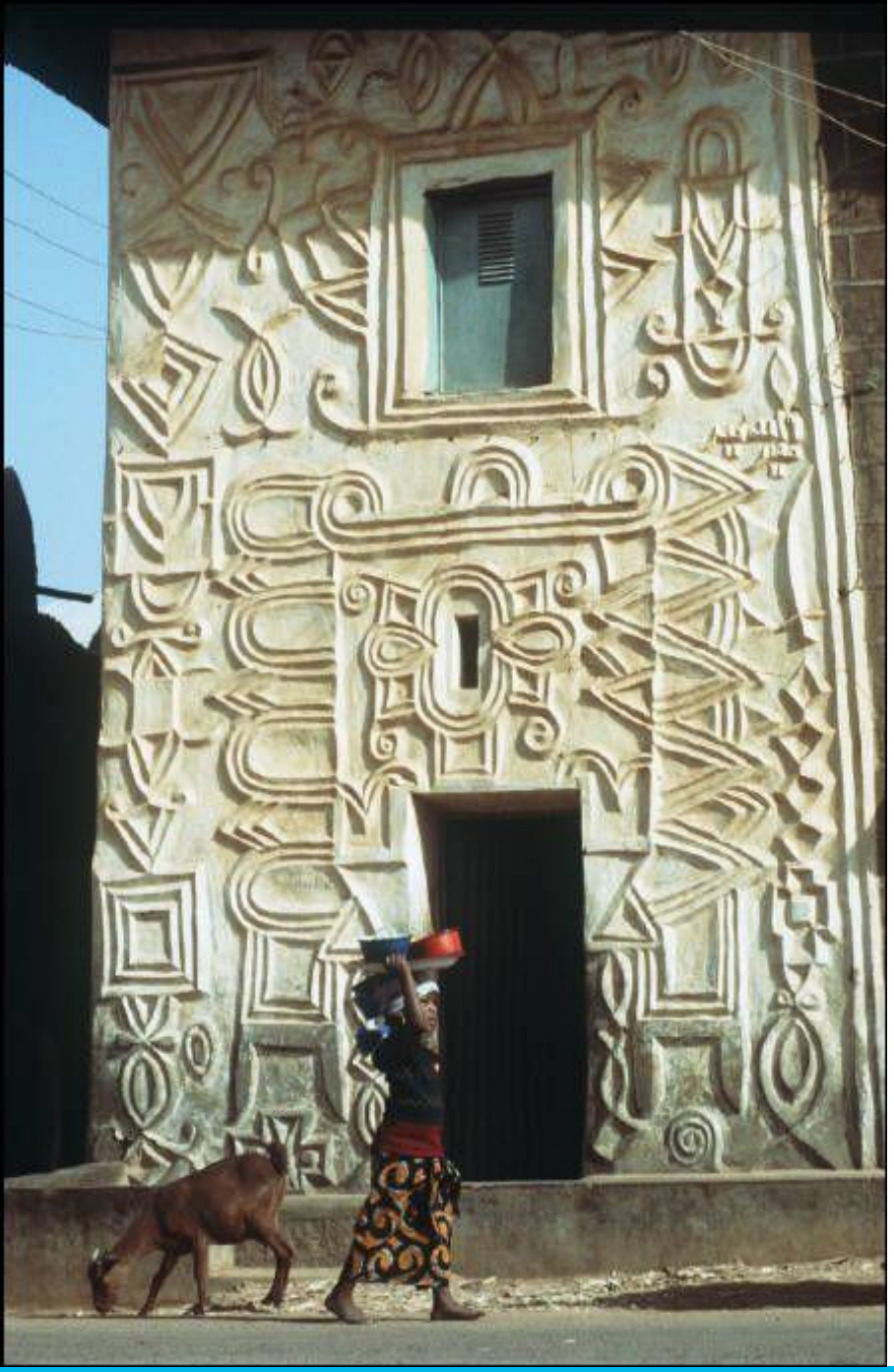


Family Planning Landscape in Nigeria

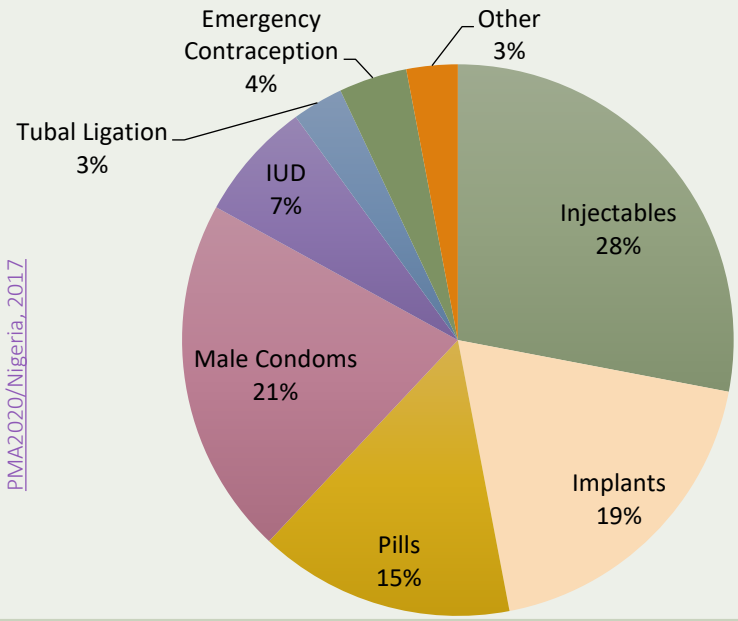
Photo credit: Bruno Barbey Photography, Nigeria

Family planning in Nigeria

Table 1. Family planning context in Nigeria among married women (15-49)

Total Fertility Rate*	Modern Contraceptive Prevalence Rate	Long-Acting/Permanent Contraceptive Prevalence Rate	Unmet Need for Contraception	Knowledge of contraceptive methods (IUDs)*	Public facilities providing IUDs**	Private facilities providing IUDs**
5.5*	16%	5%	25%	34%	65%	34%

Figure 2. Modern method mix among married contraceptive users aged 15-49



All data for married women (15-49) from the PMA 2020 Nigeria 2017 survey unless otherwise specified.
*Nigeria DHS 2013.
**Nigeria FP Blueprint 2014.

- According to the PMA 2017 Nigeria survey, 15% of all women and 16% of married women use a modern contraceptive method.
- Among married women (ages 15-49), 25% have an unmet need for family planning. Among those with unmet need, the majority desire contraception for spacing (18%) rather than limiting (8%) births.
- Relative to all women, married women more frequently use long acting or permanent contraceptive methods (3 vs. 5%).
- Currently, 7% of married contraceptive users have an intrauterine device (IUD).
- Whereas modern contraceptive use in the more rural, less prosperous, and less literate NE and NW states is <4%, levels are significantly higher in southern zones, particularly the SW where rates range from 21-32% (Shelton & Finkle, 2016).

National & Zonal FP Context

All data for married women (15-49) from NDHS 2013 unless otherwise specified.
* Data from Nigeria PMA 2017 Survey.

Nigeria
(National)

Median Age (1st Birth)	Mean # Children
20.2	6.3

Fertility Indicators

Total Fertility & Total Wanted Fertility Rates

TFR	TWFR
5.5	4.8

Unmet Need For Contraception*

Total	Spacing	Limiting
25%	18%	8%

Relationship Status

Married or living in union	72%
Never married	24%
Divorced/Separated/Widowed	4%

Wealth Quintiles

Lowest	Second	Middle	Fourth	Highest
18.3%	19.1%	19.2%	20.5%	22.9%

Highest Education Attended (38% no education)

Primary 17% | Secondary 36% | >Secondary 9%

South West
(Lagos, Ogun, Oyo)

Median Age (1st Birth)	22.7
Mean # Children	4.8
% of all women (ages 15-49) living in zone	16.2% (6,314)

Method Prevalence	
Pill	5%
Condom	8%
IUD	4%
Injectable	6%
Implant	<1%

Fertility Indicators

Total Fertility & Wanted Fertility Rates

TFR	TWFR
4.6	4.0

Unmet Need For Contraception

Total	Spacing	Limiting
15.4%	9%	6.5%

South East
(Abia, Anambra, Enugu)

Median Age (1st Birth)	23.7
Mean # Children	5.7
% of all women (ages 15-49) living in zone	11.5% (4,476)

Method Prevalence	
Pill	2%
Condom	4%
IUD	2%
Injectable	2%
Implant	<1%

Fertility Indicators

Total Fertility & Wanted Fertility Rates

TFR	TWFR
4.7	4.3

Unmet Need For Contraception

Total	Spacing	Limiting
12.5%	7.4%	5.1%

South South
(Delta, Edo)

Median Age (1st Birth)	21.8
Mean # Children	5.4
% of all women (ages 15-49) living in zone	12.7% (4,942)

Method Prevalence	
Pill	4%
Condom	3%
IUD	1%
Injectable	6%
Implant	<1%

Fertility Indicators

Total Fertility & Wanted Fertility Rates

TFR	TWFR
4.3	3.6

Unmet Need For Contraception

Total	Spacing	Limiting
22.2%	15%	7.3%

North Central
(Benue, Abuja)

Median Age (1st Birth)	20.6
Mean # Children	5.8
% of all women (ages 15-49) living in zone	14.3% (5,572)

Method Prevalence	
Pill	2%
Condom	2%
IUD	1%
Injectable	5%
Implant	<1%

Fertility Indicators

Total Fertility & Wanted Fertility Rates

TFR	TWFR
5.3	4.2

Unmet Need For Contraception

Total	Spacing	Limiting
24%	17%	7%

Service Delivery Context

Public Sector Services

- Constitutionally, Nigeria is divided into 36 states and one Federal Capital Territory (FCT). These are categorized into six major zones.
- Implementation of FP policies significantly depend on the support of state governors, who wield substantial political power. (MOH, Nigeria Family Planning Blueprint, 2014)
- Nigerian women seek FP services from a combination of both **public and private sector facilities.** The majority of IUDs are provided via the public sector.
- Roughly 30% of FP users access contraception through the public sector and 65% of IUDs are provided by public services (Nigeria DHS, 2013)
- Social Marketing Organizations (SMOs) also play an important role in providing IUDs in Nigeria. (Shelton & Finkle, 2016)
- FP is provided for free in public sector clinics which are under the jurisdiction of the Ministry of Health (MOH).

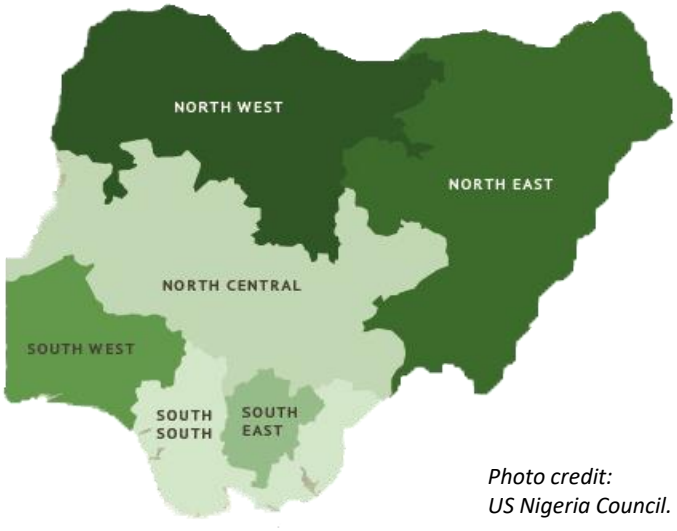
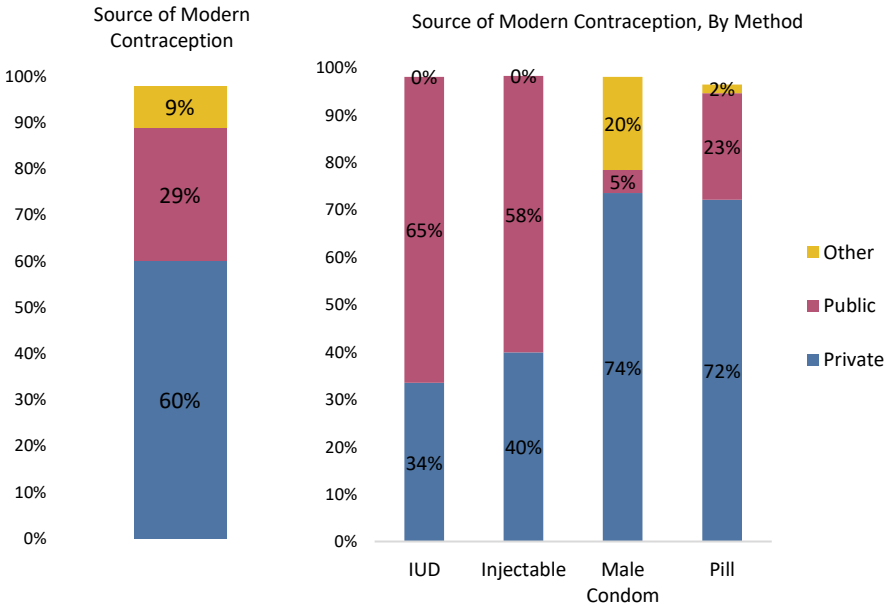


Photo credit: US Nigeria Council.

Figure: Sources of Modern Contraception (Source: Nigeria FP Blueprint, 2014)



Service Delivery Context continued

Public Sector Provision of LARCs

Challenges

- Lack of commodities and trained staff are major barriers to LARC provision (MOH, Nigeria FP Blueprint, 2014).
- According to the WHO Health Workforce Survey, Nigeria has approximately 0.4 doctors, 1.6 nurses, and 0.2 CHEWs per 1,000 people (Labiran, 2008).
- Skilled providers capable of providing FP services are scarce, particularly those providing injectables and LARCs. Implants were introduced on a larger scale in the public sector only in 2006, and it is possible that many trained providers no longer practice in the public system.
- High provider turnover persists - turnover can be as high as 40% in some areas of Nigeria (MOH, Nigeria FP Blueprint, 2014).

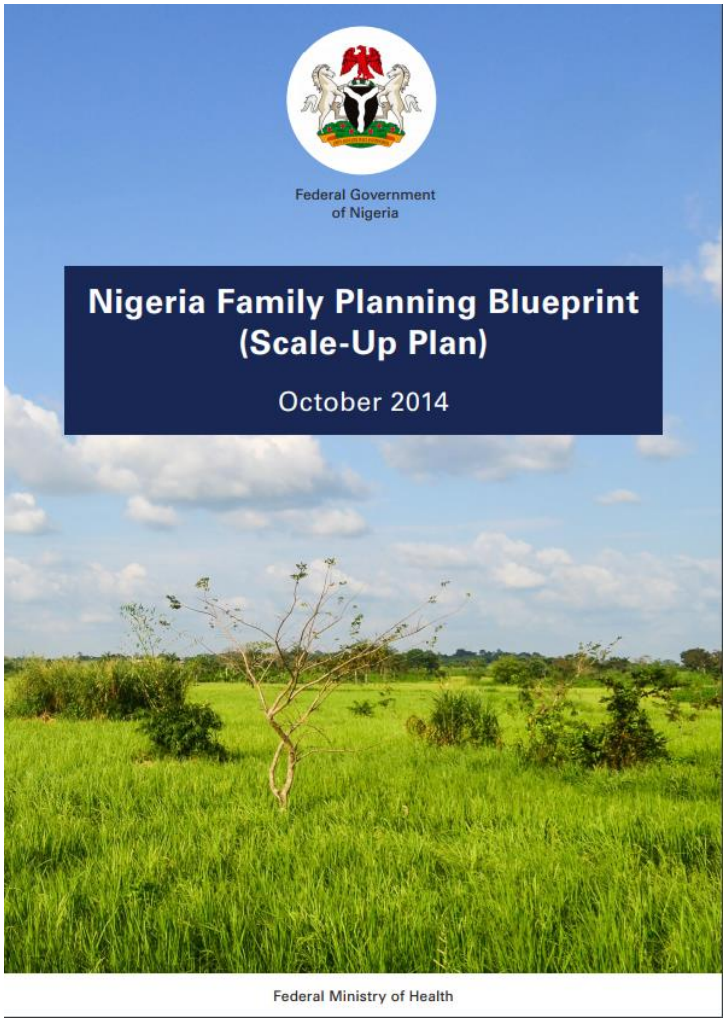
Successes

- Between 2008-2013, 6 states demonstrated gains of 5-12 percentage points in modern contraceptive use (Nigeria DHS, 2013).
- Contraceptive misconceptions declined markedly and intent to use contraception increased significantly in 4 urban areas between 2008-13, due to efforts led by the Nigerian Urban Reproductive Health Initiative (NURHI) (Shelton & Finkle, 2016; Krenn, 2014).
- Between 2016-17, over 334 health workers (CHEWs) have been trained LARC provision in 9 Nigerian states (Afolabi, 2016).
- Following the FP2020 summit in 2012, many states have composed costed implementation plans (CIPs) and enacted positive policy reforms (i.e. increasing CHEW training in LARC provision) (Shelton & Finkle, 2016).

Strategies to Increase LARC Use

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

- **Strengthen demand for FP services** by delivering accurate information to all key segments of the population.
- Create standard **budget** lines in federal, state, and local budgets to cover FP services.
- **Build capacity** of providers and training institutions.
- Increase coverage and access to integrated FP services through the **private sector and public health system**.
- Strengthen **coordination and monitoring** of all supply chain activities by efficiently using **innovative technologies**.
- Improve FP **knowledge** and performance management at all levels.



From: Nigeria's Integrated Family Planning Scale-up Plan

Programmatic Efforts to Increase LARC use

A range of programmatic approaches in both the private and public sector emphasizing access and quality have helped increase provision of LARCs in Nigeria. Examples of these efforts include:

Capacity Building

- SFH's Women's Health Project (WHP) focuses on building informed demand with clients by interpersonal communication and reducing biases, as well as by promoting behavior change communications among IUD providers. (Blumenthal et. al, 2013)

Task-Sharing

- In 2014, Nigeria created a new task-shifting and task-sharing policy that allows CHEWs to provide injectables and LARCs with an goal of increasing access in rural areas. In 2015, over 300 CHEWs were trained to provide LARCs in 9 Nigerian states.

Mobile Outreach

- Marie Stopes Nigeria deploys "mobile outreach" teams in the North. With only 8 outreach teams, they provided ~ 63,000 clients with LARCs in 2015 (Shelton & Finkle, 2016)

Postpartum Provision of LARCs

- There has been growing focus on providing LARCs during the postpartum period. For example, an initiative with private providers in southern Nigeria found that 41% of eligible women who delivered in those facilities accepted immediate insertion of an IUD. (Eluwa et. al, 2016)

Current Distribution & Use of the LNG-IUS in Nigeria

Photo credit: Susan Elden Photography, Nigeria

LNG-IUS Pricing— Facility Assessments in Abuja

Photo credit: The Guardian, Primary Health Care facility, Nigeria

Brief facility assessments were conducted at seven public and private healthcare facilities in Abuja. A convenience sample was used of private clinics and hospitals who provide FP services and who were identified by the technical team as sites that might stock either Mirena or Emily. Short interviews were conducted:

- 3 private hospitals provided Mirena
- 1 private hospital offered both Mirena and Emily
- 1 public hospital provided Mirena and the free ICA product
- 2 did not carry the LNG-IUS

Findings included:

- **The price of Mirena in the four private hospital ranged from N33,150 (USD$91) to N100,000 (USD $276).** This included the cost of insertion.
- **The price of Emily in the private hospital was N70,000 (USD $193)** and included the cost of insertion.
- At the public facility, the client either had to bring their own Mirena or were given the free LNG-IUS (ICA Foundation product) and **the cost of insertion was N1500 (USD $4.15).** In comparison **implants and copper IUDs are provided free of charge** in public facilities, though a **fee of between N200 and N500 (USD $0.55-$1.38) is charged to cover the cost of consumables.**

Mirena Distribution in Nigeria

MIRENA COIL (IUS) ₦85,000.00

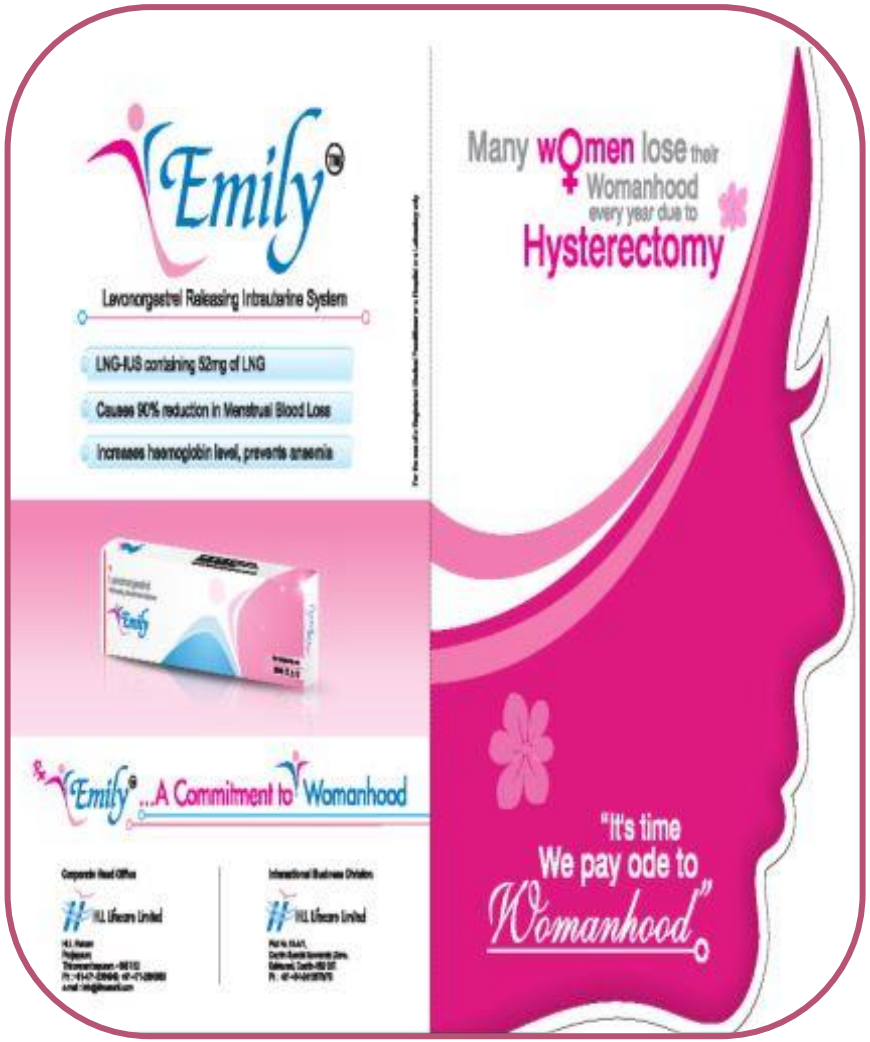
Location: Lagos
Condition: New
Price Negotiable: No
Phone No: 08052048893
Website: http://ipost247.com/
Type of Ad: Private Ad
Listed: March 16, 2016 4:34 pm
Expires: 5 days, 3 hours

- Mirena is manufactured by Bayer Healthcare and distributed in Nigeira by Assene-Laborex
- Mirena is marketed nationally by sales representatives based in different locations in Nigeria with a focus on urban areas
- Average price from distributor: N44,645 ($123) though often advertised at higher price (e.g. see advert to left – N85,000 (USD$239)

Eloira Distribution in Nigeria

- Eloira is manufactured by Pregna International Ltd, India and is currently being registered with NAFDAC
- DKT International will serve as the distributor
- Marketing material is targeted for both contraceptive use and non-contraceptive benefits associated with reduced menstrual blood loss
- Average price to providers N:20,0000 ($55)

Emily Distribution in Nigeria



- Emily manufactured by HLL Lifecare, India consists of a small white M-shaped frame from soft flexible plastic which contains levonorgestrel; it differs from the other LNG-IUS products which are T-shaped
- Registered with NADFAC since October 2014
- Marketed by Jawa International in Lagos which distributes the product across 8 states across Nigeria
- Jawa International has trained medical detailing team for marketing of the product through detailed product leaflets and insertion videos
- Promoted to gynaecologists, infertility specialists, and nurses in teaching hospitals trained in gynaecology, specialist hospitals and private nursing homes
- Average sales price N:15,0000 (USD$41)

Current Distribution of ICA Foundation's LNG-IUS in Nigeria

Service delivery channel where ICA LNG-IUS currently being introduced	Service delivery partners
Private sector (traditional for-profit; social franchises)	SFH, MSI
Mobile outreach	MSI
Public sector (limited basis)	MSI, Rotary

- MSI began distributing ICA Foundation units in 2010, and in 2016 received a large donation of 7500 units with planned distribution over approximately two years.
- PSI's local affiliate, Society for Family Health (SFH), began offering ICA Foundation units in 2016 and is providing ~2,000 units/year through 40 social franchise clinics in urban and peri-urban settings.
- Rotary International has been distributing ICA Foundation units since 2007 in the public sector
- Pathfinder International provided the ICA Foundation product in 2010 and 2014 with plans to re-introduce in their programs in the future
- University College Hospital Ibadan received their first donation of 700 units in 2012 which were integrated into services available to women receiving HIV//ARV testing services. A second donation was given to the hospital's FP clinics.

Key Opinion Leaders' Perspectives

Key Opinion Leaders (KOLs) were asked about their:

- Perspectives on current use of copper IUD
- Perspectives on current use of the LNG-IUS
- Potential demand for the LNG-IUS
  - Potential target markets
  - Method advantages and disadvantages
  - Strategies to increase access

Photo credit: AFROSAI WGEA, Abuja Nigeria

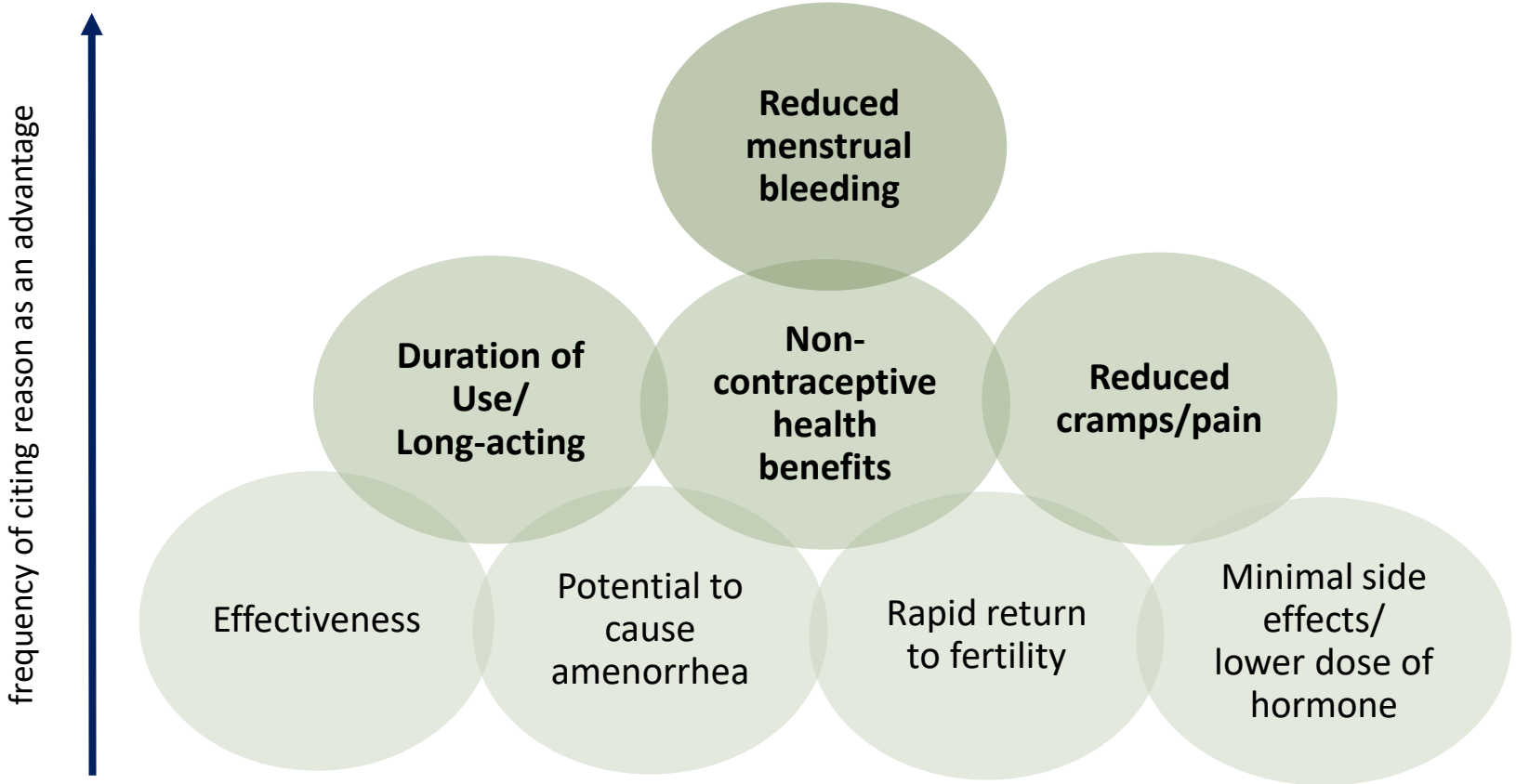
Key Opinion Leaders (KOLs)

- All KOLs were identified by peers as leaders in reproductive health
- 17 individuals were interviewed
- KOLs included representatives from government, NGOs, medical associations, academic institutions, and donor groups

Perceptions of LNG-IUS

All of the KOLs were aware of the LNG-IUS prior to interview

Perceived benefits of the LNG-IUS included:



I think you also need to highlight the fact that it can play a significant role in reducing menstrual blood flow which can be such a nuisance for many women.

Women that have heavy menses gave the feedback that their menstrual flow has much greatly improved…in terms of quantity and also in pain.

It would be more preferred among the younger and married women…Something that can prevent or limit the number of menstrual cycles they have in a year.

-KEY OPINION LEADERS

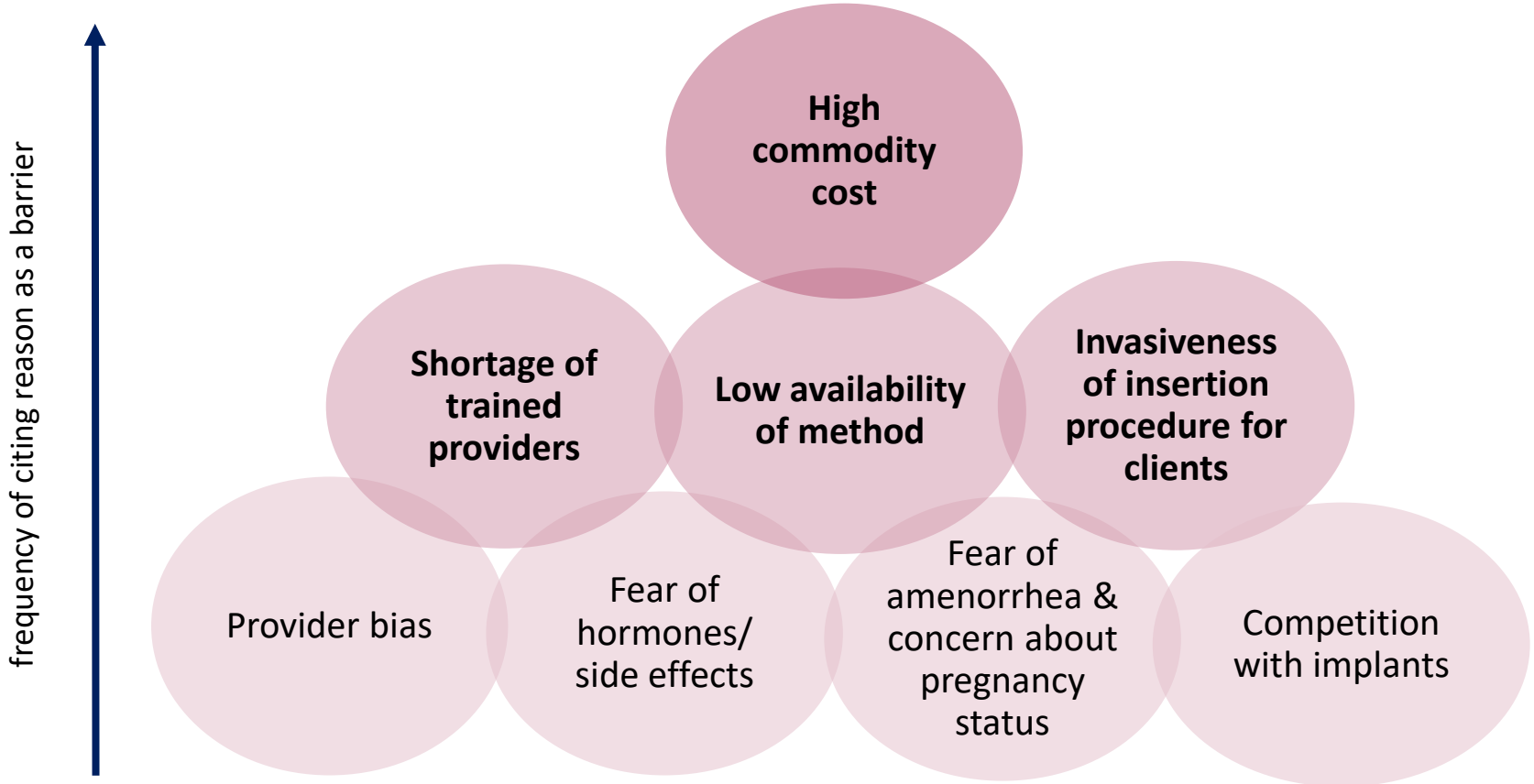
Well, the product has its advantages…giving women the choice to make both contraceptive and non-contraceptive choices at the same time—killing two birds with one stone.

-KEY OPINION LEADER

Perceptions of LNG-IUS

All of the KOLs were aware of the LNG-IUS prior to interview

Perceived barriers and disadvantages of the LNG-IUS included:



The insertion method through the vagina may not be acceptable to some groups of women, especially where there is the option of the 'less invasive' implants.

We have a particular challenge in Nigeria today which is a shift away from use of IUD in favor of implant…The problem…is that of provider bias.

-KEY OPINION LEADERS

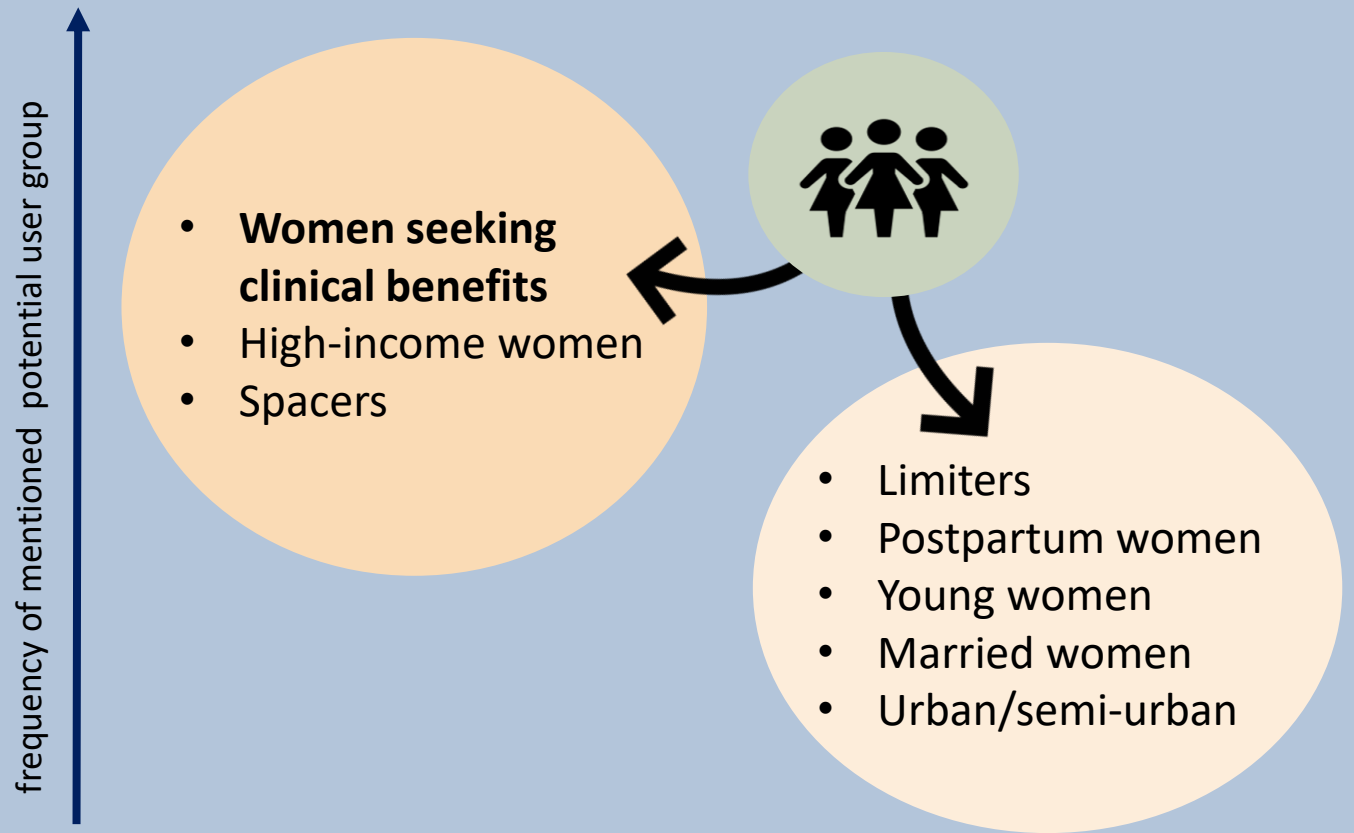
KOLs views on amenorrhea & potential user groups

Slightly more than half (N=8) said women would **LIKE** amenorrhea

Others (N=5) thought women would have a **MIXED** reaction to amenorrhea

A few said women would **NOT LIKE** amenorrhea

KOLS were asked: "If a new, more affordable LNG-IUS were available, what segments of the population do you feel would be the most likely users of the LNG-IUS?"



This could go either way as some women will feel anxious about the loss of bleeding – worrying both about the possibility of pregnancy and also a perception of losing their femininity. Awareness and assurance can overcome this.

-KEY OPINION LEADER

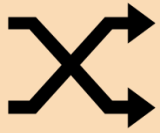
Strategies to Ensure Successful Scale-up if New, More Affordable Product(s) are Introduced

frequency of responses

Healthcare provider training

Marketing/education/ demand creation

Stakeholder engagement



Ensuring commodity security/supply chain

Educating providers/ reducing misconceptions

Including LNG-IUS in FP guidelines/policies

Male involvement

Regulatory approval & inclusion on national Essential Medicines List

Private sector engagement

We are eagerly waiting for it to be available so that it can increase the method mix and options for women.

The main barrier is the competition with copper IUD in terms of pricing.

If you use the total market approach, yes! It will thrive better in the private sector and social marketing sector – where women would want to pay for the services not necessarily where it is free….And then to get the consensus of the government to include it within the basket of commodities available in the public health facilities, it will help to increase access to it.

-KEY OPINION LEADERS

Providers' Perspectives on LNG-IUS Provision

Providers were asked about their:

- Perspectives on side effects of family planning, including bleeding changes
- Perspectives on clients' current experience using LNG-IUS
- Perspectives on community acceptability of LNG-IUS
- Perceived barriers to LNG-IUS uptake

Providers were trained on LNG-IUS in 2016
Total no. of providers interviewed = 32
State breakdown of providers: Oyo (n=6), Edo (n=5), Anambra (n=4), Ogun (n=4), Delta (n=3), Enugu (n=2), Lagos (n=2), Nassarawa (n=2), Abia (n=1), Benue (n=1), Abuja (n=1), and Plateau (n=1)

Photo credit: Marie Stopes International

Perceptions of LNG-IUS

Providers identified the following perceived advantages and disadvantages of the LNG-IUS based on their experience providing the method:

Advantages

- **Therapeutic/clinical benefits***
- **Contraceptive effectiveness**
- **Potential menstrual bleeding regulation**
- **Reduction of menstrual cramps**
- **Cost-effective over time**
- **Amenorrhea**
- Convenient
- Improved marital relations
- Rapid return to fertility
- No weight gain
- Reversibility
- Discreet nature
- Long-acting
- Fewer side effects

***For women with heavy menstrual bleeding or fibroids**

Disadvantages

- **None**
- **Expulsion of the method***
- **Spotting**
- **Up-front cost**
- **Amenorrhea**
- **Weight gain**
- **Certain health conditions preclude use of LNG-IUS**
- **Need for proper hygiene**
- Potential for LNG-IUS to perforate the uterus
- Cramps in initial months post-insertion

***Note: 4 providers reported expulsions**

Bold = reported by over half of respondents

The benefit is that is the long acting method, it's more convenient than the short method and it saves…the financial constraint there is reduced. You understand, like when you are on injectable, every three months, you take injection, you take injection. If you calculate it compared to this you say the financial cost is reduced.

-PROVIDER

I don't think there is any disadvantage over any other method. The only disadvantage is that people don't like us to go into this their thing, to view their uterus or their I don't know what they will call it now. Apart from that there is no disadvantage so far.

-PROVIDER

Opinions on women's response to reduced and/or irregular bleeding

Providers had contrasting perceptions of how women would respond to reduced and/or irregular bleeding.

- Most providers believed that women would respond positively to reduced bleeding
- However, some of these providers cautioned that women would be resistant to changes that result in total cessation of menstruation
- Providers, in a few cases, expressed confidence in their ability to counsel women seeking reassurance about amenorrhea as a side effect

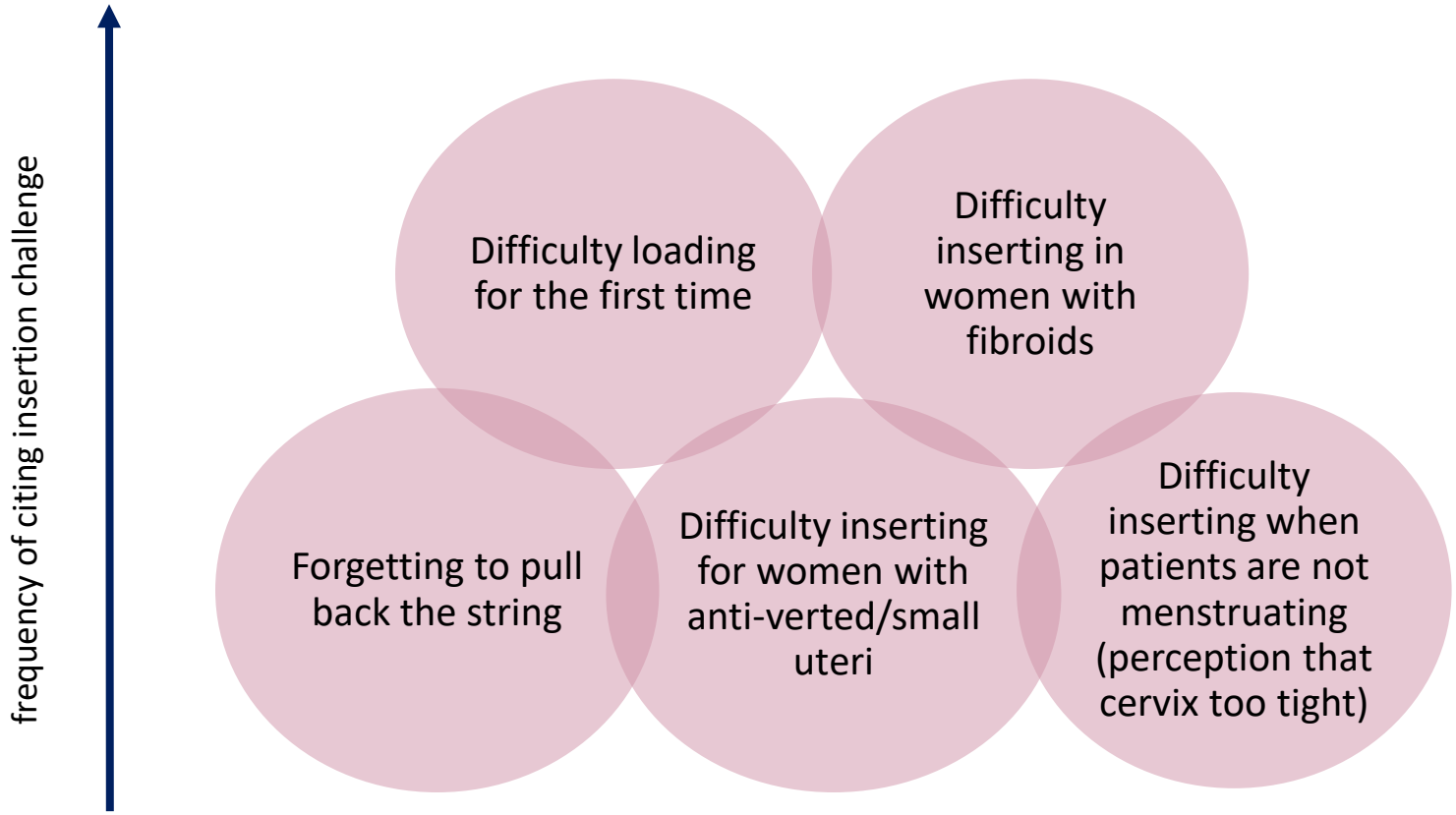
They demand it when they come, they say they want the one that will not make them bleed. When you explain to them, they will take it. Like the one I have just inserted says she doesn't want any method that will make her bleed.

-PROVIDER

Insertion challenges

Less than half (n=13) cited challenges inserting the LNG-IUS; challenges typically occurred during the provider's first insertion procedure

Frequently cited insertion challenges include:



Yeah, I had a challenge with some that had a huge uterine fibroid…my LNG-IUS couldn't sit in there so I had to send her for scanning…she ended up taking Jadelle. I wouldn't want to insert something that I wasn't confident of where I wanted it to be.

-PROVIDER

Perception of women's experience using LNG-IUS

Most providers reported positive experiences among their clients who selected the LNG-IUS, acknowledging that while clients experienced side effects in the initial months (n=19), side effects typically subsided

- Spotting was the most frequent side effect cited by providers, followed by cramping, and heavy bleeding
- Providers indicated that they were receptive to calls and follow-up visits from clients, often using these encounters to provide further counseling on expected side effects and/or to prescribe medication to address side effects
- Providers described the positive impact of the LNG-IUS on women who had previously suffered from heavy and/or painful menstruation
- 4 providers reported involuntary expulsion of the device

Initially, most of the initial reports I get are about cramping…there was a particular one that complained about a great vaginal discharge and then…that was all, plus the weight issue I had from one of my clients was dismissible, so I just dismissed it. Apart from that there is nothing else.

-PROVIDER

Does the current cost of the LNG-IUS discourage use among women?*

As noted previously, during the time of data collection, facilities were charging 2000-3000 Naira (US $6-8) for the LNG-IUS; 1000-2000 N for implants (US $3-6); and 500-1000 N for copper IUD (US $1.5-3).

MANY PROVIDERS FELT LNG-IUS PRICE TOO HIGH (n=18)

- LNG-IUS currently costs more than other long-acting methods (e.g., implant, cooper IUD)
- Some felt price prohibitive for very low-income women but is still affordable for professionals
- Some indicated 1000 Naira or less would be an acceptable amount to pay

SOME VIEWED PRICE AS AFFORDABLE (n=10)

- Some providers indicated that their clients had never complained about current cost
- A few did not think cost would discourage use but that misconceptions about the method would
- A few said cost was not an issue since they did not charge for the method

If they can reduce the price, so many people will like to take it. You know in our area here we have less privileged that they need money that they don't have money and they want to do it and there is nothing. I can only do the one that is very cheap for them but I cannot do LNG.

-PROVIDER

Providers' Views on their Colleagues' Perceptions of the LNG-IUS

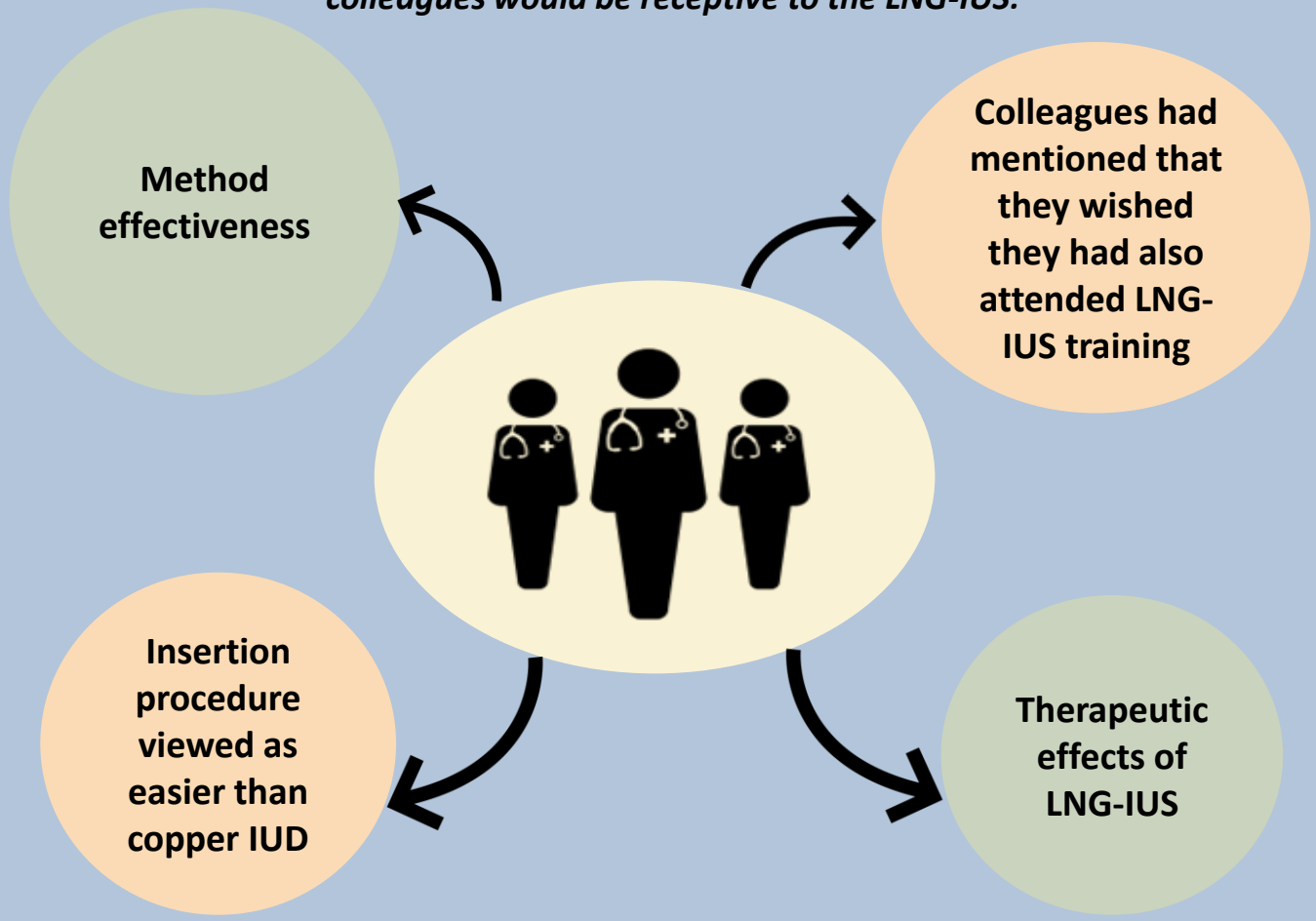
General Summary

Several (n=12) reported that colleagues had **POSITIVE** perceptions of the method (reasons depicted in center of slide)

Several (n=9) reported that their colleagues were still **UNAWARE** of the LNG-IUS

Three said that the prohibitively high cost of the LNG-IUS is a common topic of discussion among providers

Specific reasons cited by providers for why their colleagues would be receptive to the LNG-IUS:



Those of us that can do it, they are jealous of us…I will just advise if you can carry everybody along so that the work load will be reduced for some of that have the training because we are expert…but if they have the same experience, the same training, I think the work load will be less for us

-PROVIDER

Providers' perspectives on how to build awareness and drive demand for LNG-IUS

Community-based strategies

Faith-based institutions

Media outlets (TV and radio)

Markets, women's groups, and other community gatherings

Current users as advocates for LNG-IUS

Supply-side strategies

Train more providers on LNG-IUS insertion; newly trained providers would in turn be able to offer the LNG-IUS to clients at their respective clinics

Introduce LNG-IUS during ANC and child immunization visits

Mobilization efforts at primary health clinics thru community health workers

We have so many methods, we can go for advocacy, we go to the chiefs… then we go to the churches, the mosques around at the same time we should be youth friendly, we gather youth, we educate them, the importance and the advantages so we will have more clients.

-PROVIDER

Intentions to continue offering the LNG-IUS

All providers said they would continue offering the method

The **main reasons** cited for continued provision include:

- **Non-FP-related benefits of the method** (e.g., reduced bleeding and fibroids)
- **Fewer side effects** compared to other FP methods
- **Positive testimonies** from current users
- **Perceived ease of insertion** compared to copper IUD
- **Effectiveness** of the method

*Three providers voiced concern that the method was **prohibitively expensive** for clients*

If I have the commodity…to get the commodity is the problem. We were just privileged to be given [some]. Even I contacted some pharmacy if I can get it…we couldn't.

-PROVIDER

Clients' Perspectives On Use of LNG-IUS

Qualitative interviews were conducted with LNG-IUS users* who had used the method for 3 months duration

Users were asked about their:

- Reasons for choosing LNG-IUS
- Experience using LNG-IUS
- Community awareness and perception of LNG-IUS
- Cost of LNG-IUS

*Of the 33 female participants interviewed, 30 women were currently using the LNG-IUS method; 3 women were discontinuers

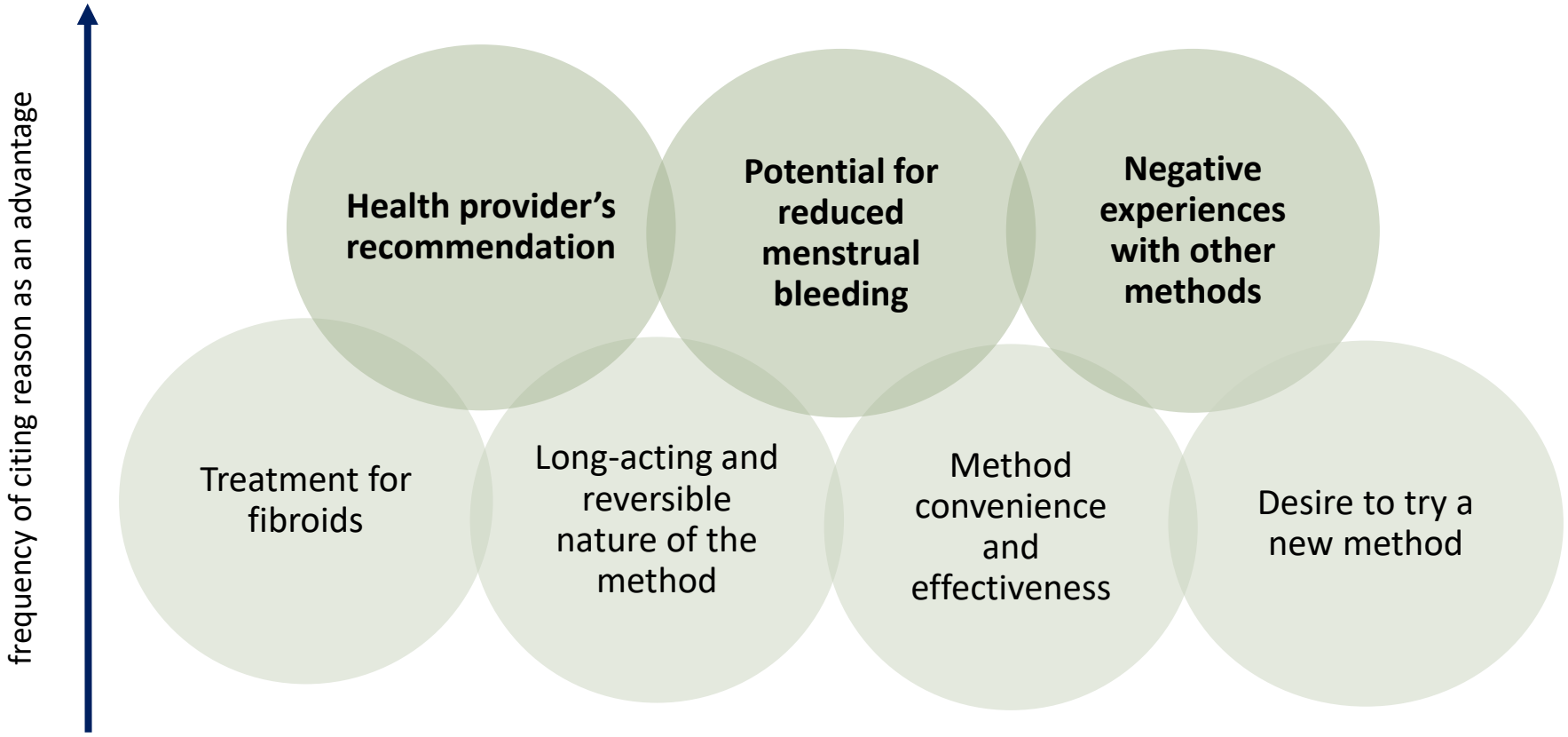
State breakdown of users: Oyo (n=11), Delta (n=5), Edo (n=3), Lagos (n=3), Ogun (n=3), Benue (n=3), Plateau (n=2), Abia (n=1), Nassarawa (n=1), and Abuja (n=1)

Photo credit: George Osodi Photography, Nigeria

Reasons for Choosing the LNG-IUS

Women often choose the LNG-IUS based on their health provider's recommendation.

Frequently cited reasons include:



They said it will work well with my body. I might forget to take the pills, and I don't like the injection. So, that's why I prefer it.

-CURRENT USER

LNG-IUS users' likes and dislikes

Almost all women (n=28) currently using the LNG-IUS reported positive experiences; majority said they would recommend the method to a friend

Most *participants reported positive experiences with the LNG-IUS.*

What users LIKED about the LNG-IUS

- **They did not experience any side effects**
- **The LNG-IUS regulated or reduced menstrual bleeding**
- **No pain with method use**
- Discreet nature of the method
- Improved sexual/marital relations
- Reversibility of the LNG-IUS
- Long-acting
- No weight gain

Many (n=21) women had nothing negative to say about the LNG-IUS.

What users DISLIKED about the LNG-IUS:

- **Initial spotting**
- **Sensation of the string**
- Irregular menstruation
- Continuous spotting
- Amenorrhea
- Abdominal pain

I am very okay with it. There is no excessive bleeding compared to the last one I did just like they told us. I am satisfied 100 percent.

-CURRENT USER

Users' perceptions of bleeding changes

Among women who reported reduced bleeding

Most of these women were comfortable with lighter periods.

In some cases, women clarified that while they were happy with reduced bleeding, they would have been opposed to the method had it resulted in amenorrhea.

Among women who reported amenorrhea

Most women mentioned that they were comfortable with amenorrhea.

Importantly, these women noted that they were either counseled about the possibility of no menses or preferred having no menstruation.

A few women disfavored amenorrhea.

Intentions to continue using the LNG-IUS

All current users (n=30) said they would continue using the method in the future*

The **main reasons** cited for continued use include:

- **Lack of side effects** compared to other FP methods
- **Pregnancy prevention**
- **Bleeding regulation**

**One user qualified that her continued use of the method would depend upon alleviation of side effects (irregular bleeding and abdominal pain). Another user said her continued use was contingent upon assurance from a provider that her side effects (e.g., reduced bleeding) were normal.*

When it's 5 years, it will be removed, and I will insert another one…it works for my body. If I take another one [method], it might not work for me.

-CURRENT USER

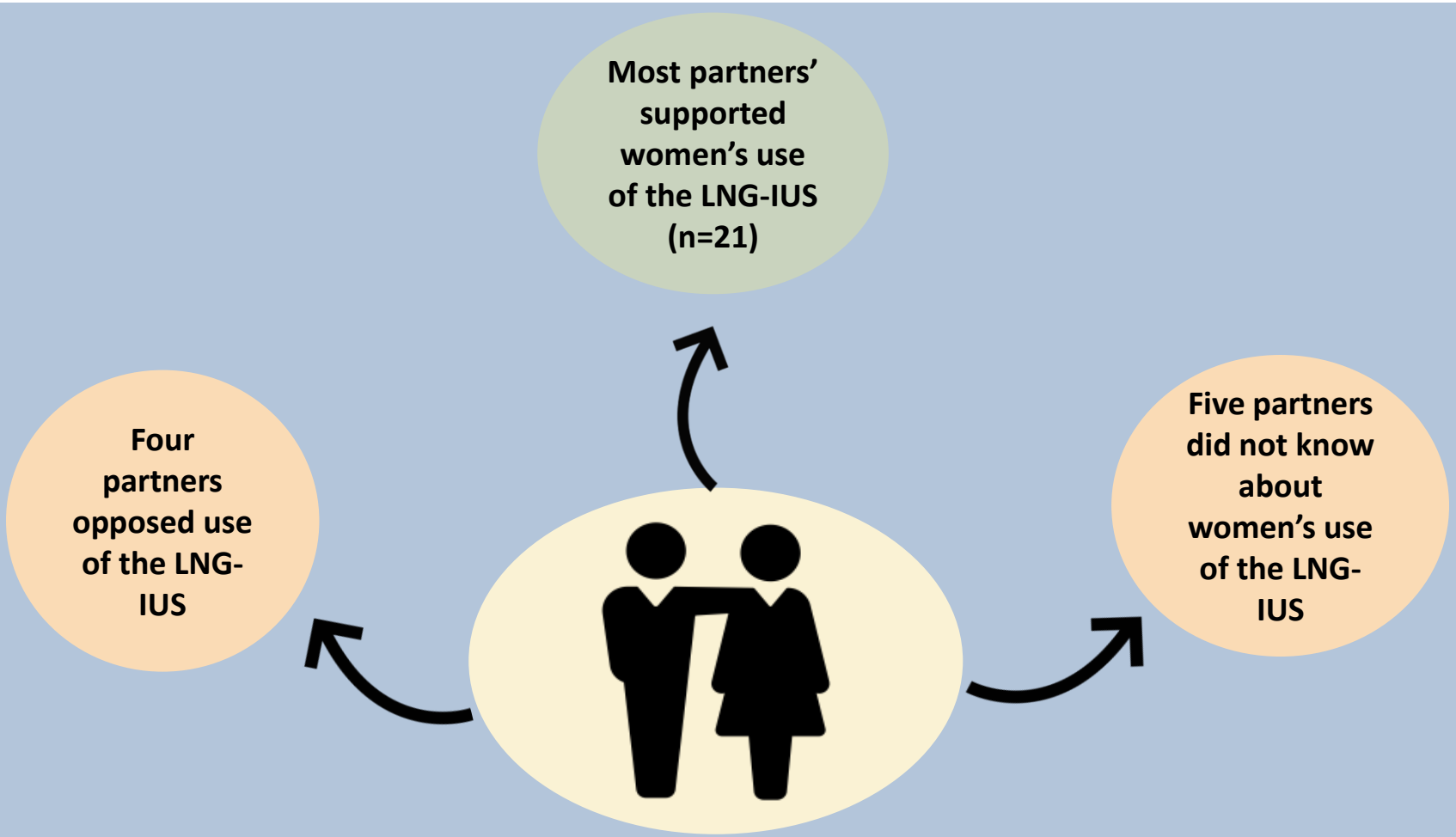
Reasons for discontinuation

Three women interviewed had discontinued use of the LNG-IUS

Reasons included:

- Two women did not choose to have the method removed but reported that it had become dislodged/displaced
- One woman had a range of symptoms (e.g., stomach pain, constant bleeding, blood in urine) for 2 months post-insertion and had the method removed

Husbands/Partners' perceptions of the LNG-IUS according to female clients

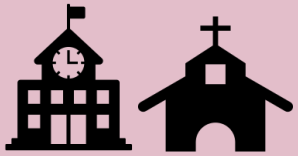


Users' perspectives on how to build awareness and drive demand for LNG-IUS

Community-based strategies

Media outlets (TV and radio)

Community mobilization, e.g., community meetings or large gatherings



Schools and faith-based institutions

Supply-side strategies

Marketing of method through health care providers / primary health care facilities/ hospitals

Introduce LNG-IUS during maternal & child health services (e.g., ANC and child immunization visits)

Clients' perspectives on information needed for community members to consider using the LNG-IUS

When asked what information women and men would need to consider using the LNG-IUS, users mentioned the following:

- **Outlining the benefits of the method to prospective users (n=18),** e.g., regulating menstrual bleeding, reducing fibroids, reversibility of the method, effectiveness at pregnancy prevention
- **Correcting misconceptions related to adverse side effects and the reversibility of the method (n=12)**
- **Testimonies from users about their experiences (n=5)**

The side effect, if they will make them to understand, if they will bring them one on one, talk to them [about] the side effect…because some of them are afraid. They say…I don't want something that will make me have cancer tomorrow, I don't want something that will make me like [have] tumor. Seat them one on one and talk to them.

-CURRENT USER

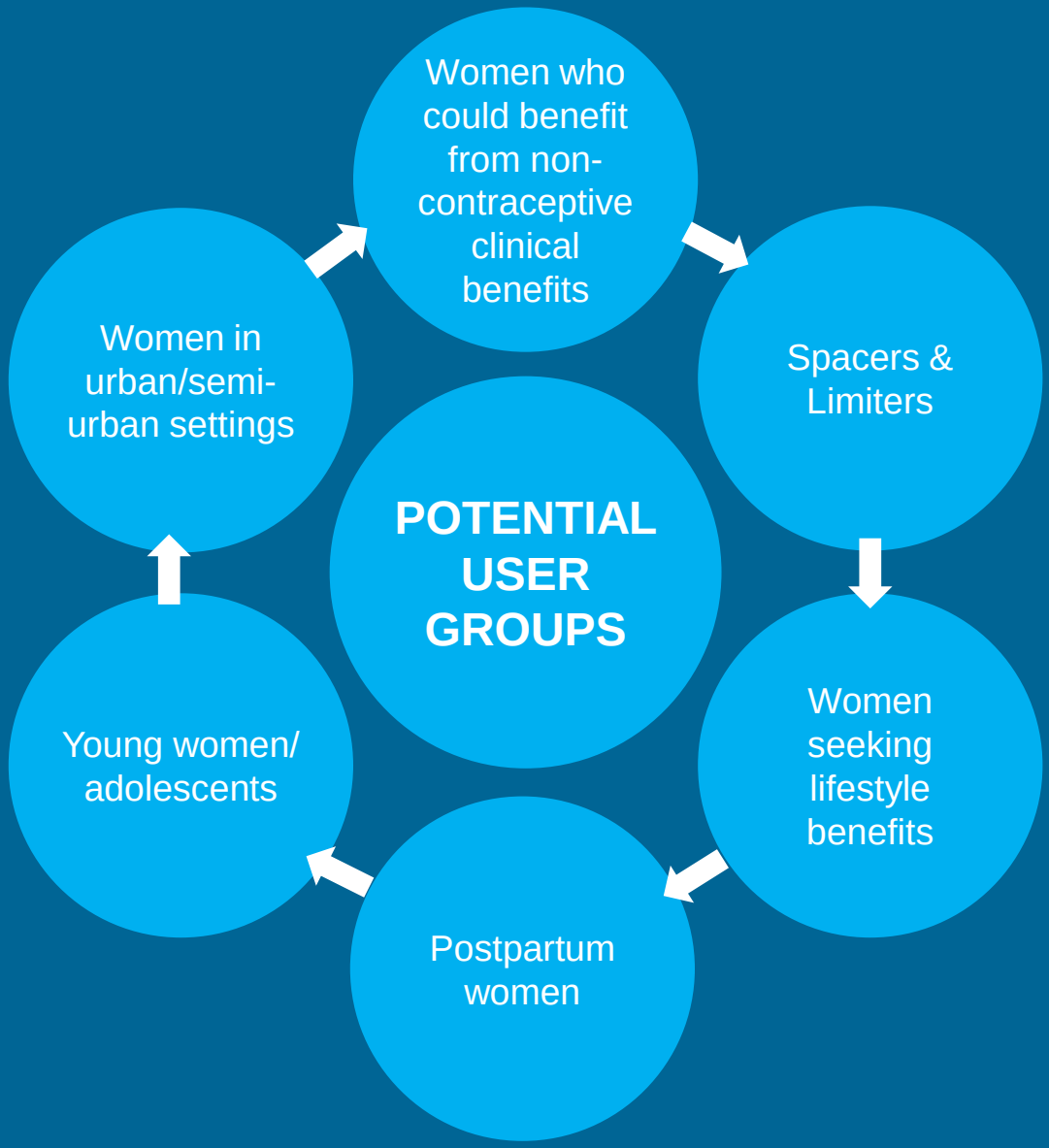
Clients' perspectives on LNG-IUS Pricing

When asked how much others in the community would be willing to pay for the LNG-IUS, participants cited a range of prices from "free" to 20,000 Naira (~ USD$55):

- Most women reported 1000 Naira (~USD$2.75) or under (n=14) would be best
- Others said between 1500 (~USD$4.15) and 3000 Naira (~USD$8.30) (n=13)
- Three women said 5000 Naira (~USD$13.85)
- Two women believed the best way to increase uptake of the method would be to offer it for free
- Some women were hesitant to indicate an exact amount

Potential User Groups

Photo credit: Jessica Scranton Photography, FHI 360



Based on the interviews and a review of secondary data sources, potential user groups of a more affordable LNG-IUS 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. Additional user segmentation analysis is needed.

Preliminary analysis: Potential User 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. Both Mirena and Eloira are being positioned as an effective treatment option for these women. Also, because the LNG-IUS may reduce anaemia in certain populations, women who are anaemic may find this product attractive.

Both Limiters & Spacers

KOLs agreed that both limiters and spacers would be attracted to the LNG-IUS. 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 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 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.

Women seeking lifestyle benefits

Responses from providers and early users of the LNG-IUS suggest that women may find non-contraceptive product attributes of the LNG-IUS 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 that amenorrhea may be less attractive needs to be addressed through education and demand creation activities.

Preliminary analysis: Potential User Groups

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. The LNG-IUS may be attractive to this group, particularly as it could extend amenorrhea without any interim resumption of menses. However, more education/demand creation would be needed to inform women that amenorrhea in the non-postpartum period does not cause negative health effects.

Young women/ adolescents

Young women/adolescents 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; reduced bleeding could help advance menstrual hygiene management.

Women in urban/semi-urban settings

Feedback from KOLs suggested that women in urban and semi-urban settings should be targeted for initial introduction of the LNG-IUS where access to healthcare is higher. In addition, focusing on introduction of the LNG-IUS in states where use of the copper IUD is currently higher could help drive awareness and use of a new hormonal product.

As a next step, **an in-depth segmentation analysis should be conducted** based on demographic and psychographic attributes and other pertinent dimensions to identify profiles of women who are most likely to become adopters of the LNG-IUS as well as those who are likely to reject or discontinue use of the method.

Regulatory Considerations

Photo credit: Bryn Pinzgauer Photography, Abuja, Nigeria

Regulatory Landscape

- All pharmaceutical products must be registered with the National Agency for Food and Drug Administration and Control (NAFDAC)
- Regulatory approval includes a full CTD dossier review, sample analysis and GMP inspection
- Recommendation is to have a strong local technical representative who can manage registration locally
- Average timeline 6 – 12 months
- Nigeria is part of the WHO Collaborative Procedure which allows for fast track registration for WHO prequalified products

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Support for International Family Planning and Health Organizations (SIFPO) 2: Sustainable networks is funded by the US Agency for International Development under Cooperative Agreement No. AID-OAA-A-14-00036 and is implemented by Marie Stopes International in partnership with EngenderHealth, Grameen Foundation and FHI 360

Support through the SIFPO-2 project is made possible by the support from the American People through the United States Agency for International Development (USAID). The contents are the responsibility of MSI and FHI 360 and do not necessary reflect the views of USAID or the United States Government.

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The Contraceptive Technology Innovation Initiative is funded by the Bill & Melinda Gates Foundation and implemented by FHI 360 in collaboration with partners including MSI

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