



POUR ELLE

BRUSSELS | 20-22 MARCH 2018

**18TH GENERAL MEMBERSHIP MEETING OF THE
REPRODUCTIVE HEALTH SUPPLIES COALITION**

Accelerating Impact: Identifying Strategies to Increase Availability of the LNG-IUS

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Reproductive Health
SUPPLIES COALITION

#ITSABOUTSUPPLIES #RHSUPPLIES2018

Quiz!



1. Which country was the first to use the LNG-IUS and when?
2. How long is the LNG-IUS effective?
3. The LNG-IUS has not yet been approved by any regulatory body for the treatment of heavy or painful periods. True or false?

Levonorgestrel Intrauterine System (LNG-IUS)

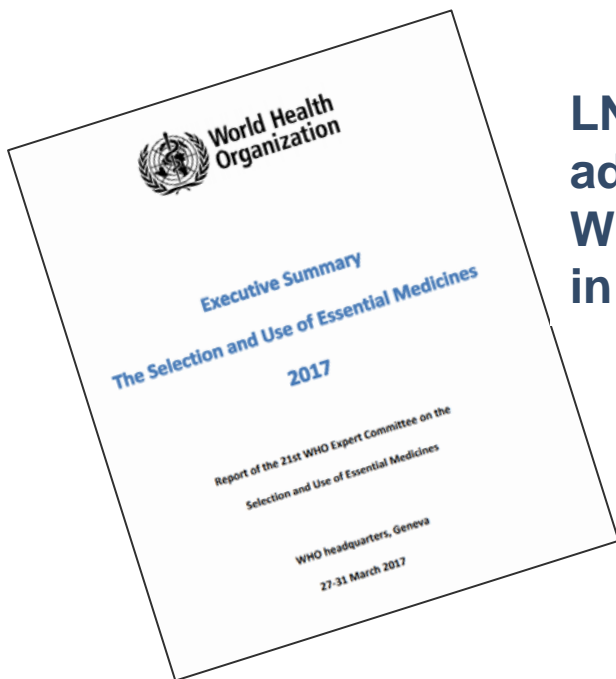


- **One of the most effective forms of reversible contraception available**
- **Long-acting, reversible, rapid return to fertility after removal**
- **Additional non-contraceptive benefits:**
 - Can make periods lighter/shorter, less painful; treatment for heavy menstrual bleeding
 - May reduce iron-deficiency anemia

✓ **Very popular in countries where available/accessible; helped revitalize the IUD market in some countries including U.S.**

✓ **In early introduction efforts in FP 2020 countries, high acceptability demonstrated**

Access to Method Remains Limited



LNG-IUS
added to
WHO EML
in 2015

FAMILY PLANNING 2020: RIGHTS AND EMPOWERMENT PRINCIPLES FOR FAMILY PLANNING

- Agency and autonomy
- Availability
- Accessibility
- Acceptability
- Quality
- Empowerment
- Equity and non-discrimination
- Informed choice
- Transparency and accountability
- Voice and participation

- ✓ First approved for use in 1990, the LNG-IUS has a nearly 30-year research-to-practice gap in FP 2020 countries
- ✓ Landscape may be changing as more affordable products become available

Overview of LNG-IUS products

BAYER HEALTHCARE:
Mirena, Skyla, Kyleena

Mirena™ priced at ~\$60-\$400 in developing countries. Provided commercially through private healthcare clinics in some developing countries on a very limited basis. Also manufacturers Skyla & Kyleena.

ICA FOUNDATION:
LNG-IUS

Public-private partnership between Bayer HealthCare & Population Council. Provides free LNG-IUS product; donated over 100K units since 2005.

MEDICINES 360:
Liletta/ Avibela

Approved by the US FDA in 2015 (Liletta). Registering in FP2020 countries under the trade name “Avibela.” The public sector price to distributors will vary by volume between US\$12-16; for an order of 100,000 units, public sector transfer price will be approximately \$15/unit.

Overview of LNG-IUS products continued

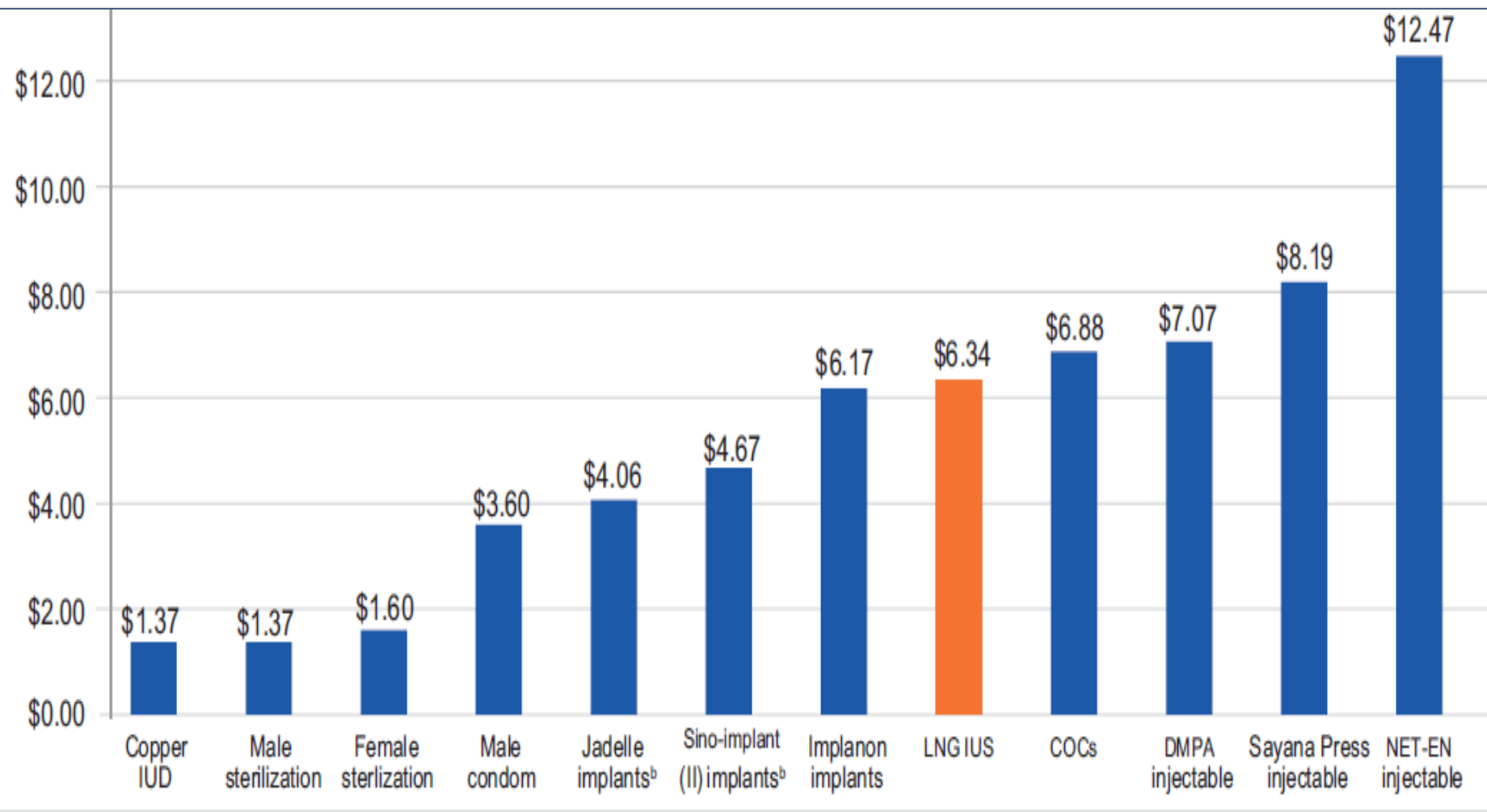
PREGNA:
Eloira

Pregna, based in India, manufacturers the Eloira LNG-IUS. Being registered in several countries in Africa.

HLL LIFECARE:
Emily

HLL Lifecare, based in India, manufacturers the Emily LNG-IUS. Has a small white M-shaped frame which differs from T-shape frame of other LNG-IUS products. Modeled after the Multi-load. Registered in several countries in Africa.

Direct Service Delivery Costs per CYP –with LNG-IUS at \$15/unit and 5-year duration



LNG-IUS Global Learning Agenda



- Interagency LNG-IUS Working Group convened by USAID comprised of donors, implementing agencies and manufacturers
- Allows for coordination, developing shared learning agenda, and aligning research approaches and M&E questions

User profiles?
Potential demand?

Effective demand creation strategies?

Service delivery strategies/
experiences?

Cost effectiveness?

Impact of non-contraceptive health benefits?

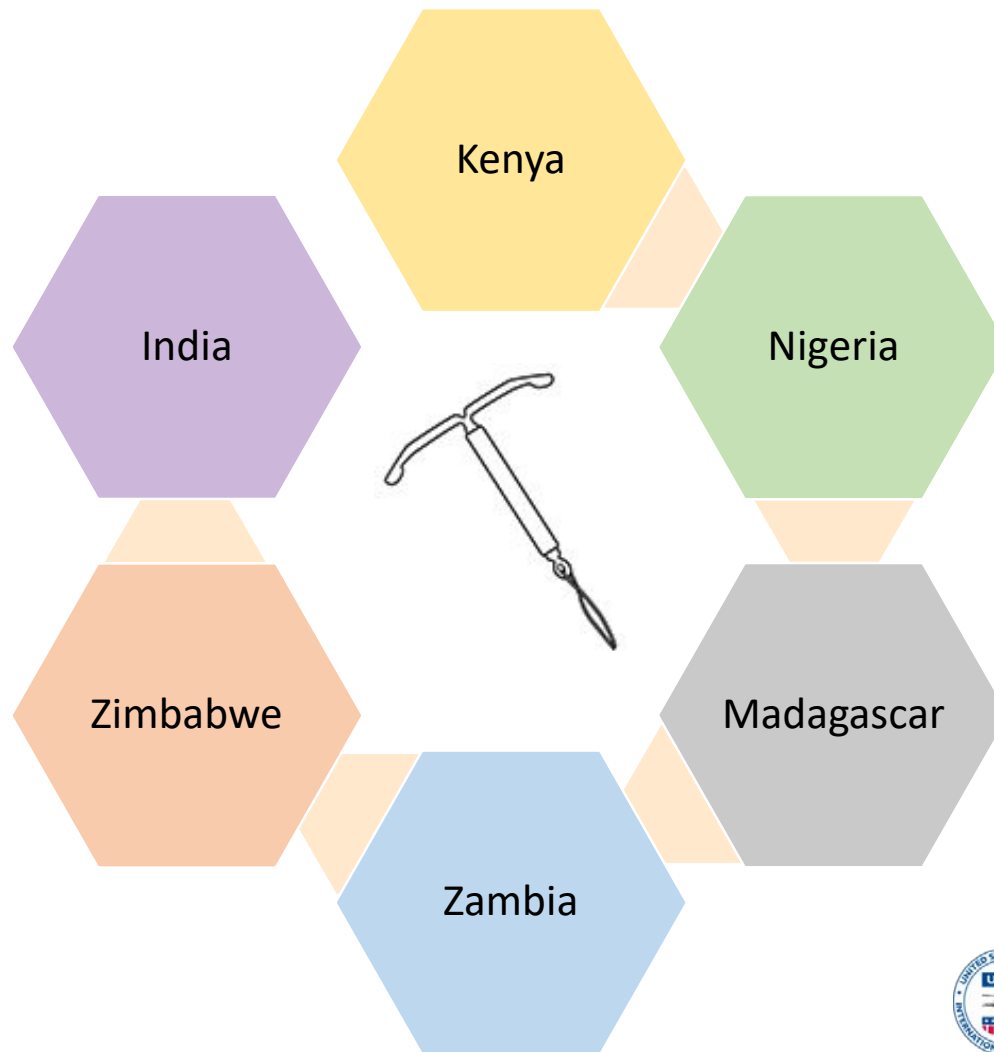
Pilot Introduction Efforts

Implementing partners with current USAID-funded pilots:

- MSI
- MCSP/Jhpiego
- PSI/Society for Family Health
- WCG

Additional organizations:

- DKT International
- Rotary
- Pathfinder
- Etc.



USAID
FROM THE AMERICAN PEOPLE



Nigeria: PSI and SFH



SFH Nigeria: Early IUS pilot results

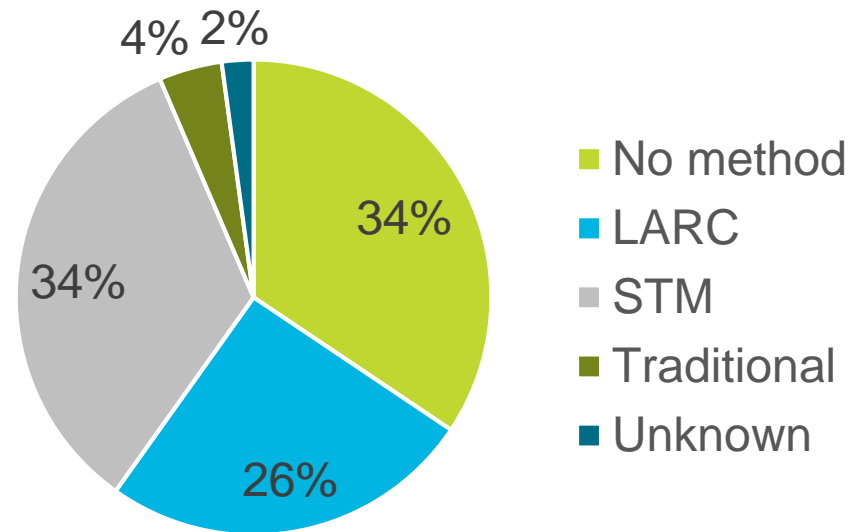
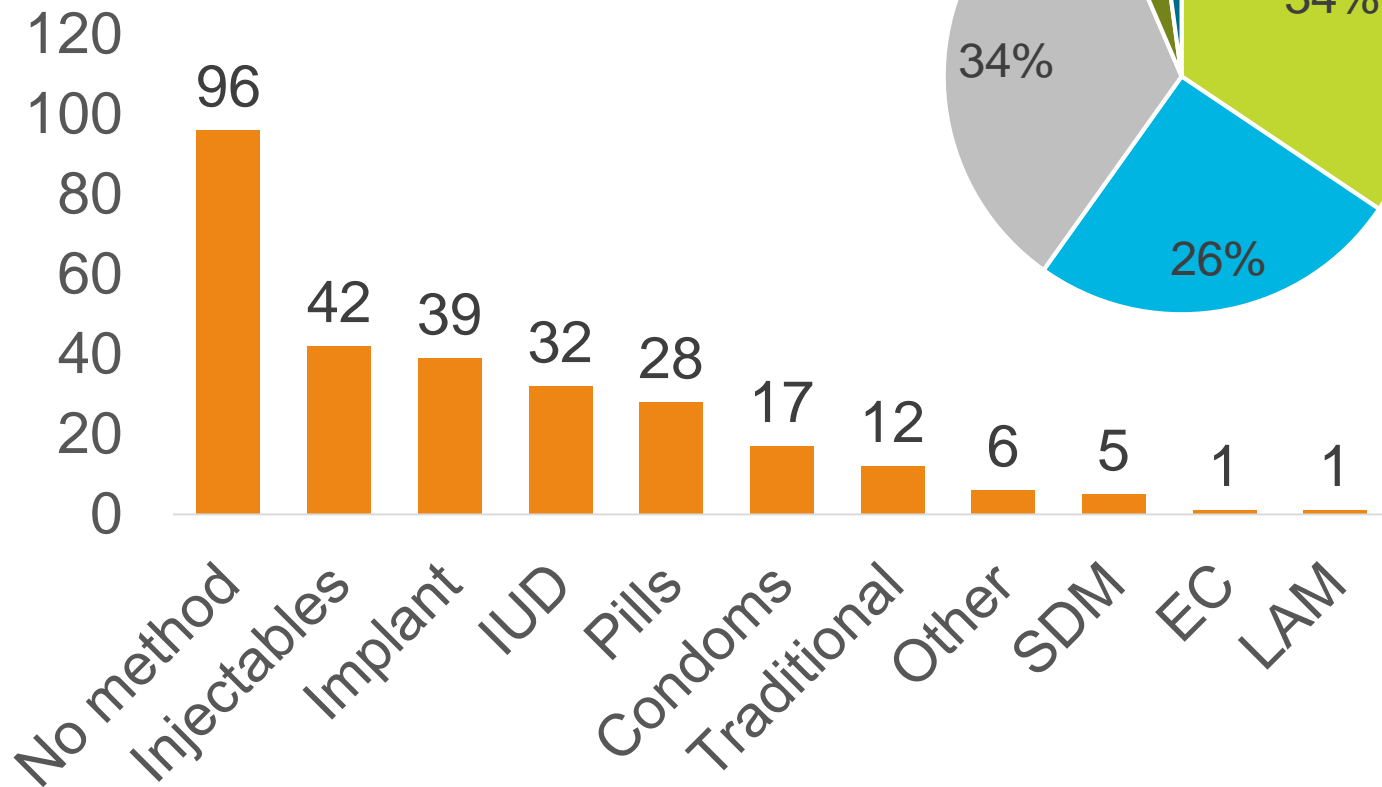


As of December 2017

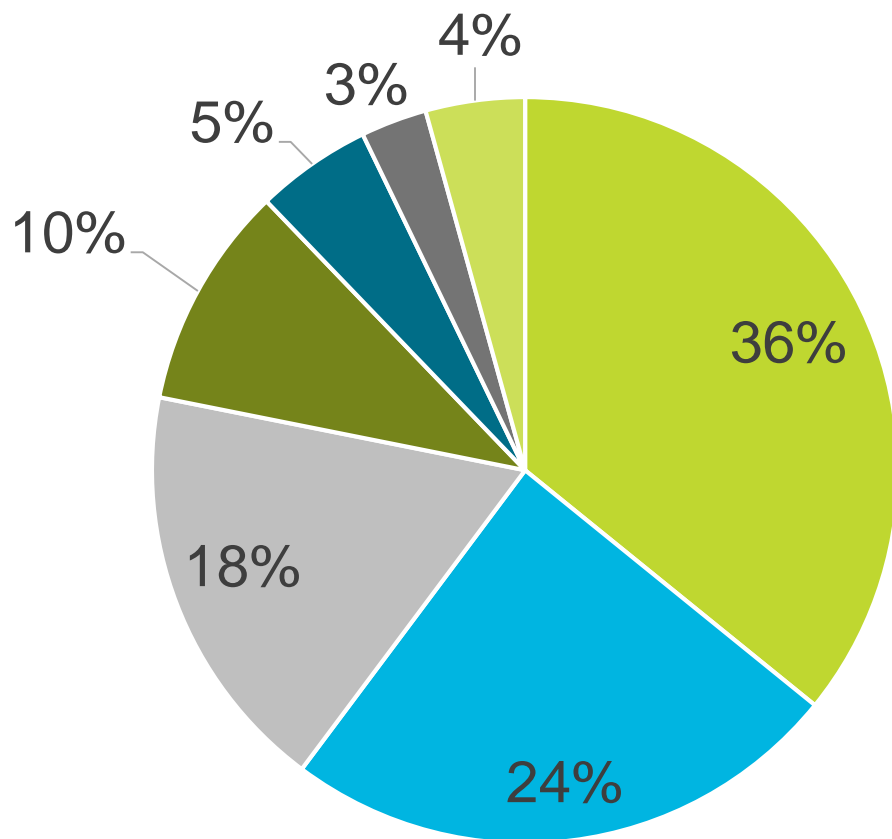
Trainers trained	8
Private providers trained	40
Pilot sites	40
IUS insertions	651
IUS removals	4 (0.6%)
Reported expulsions	5 (0.8%)*
Adverse Events	0

*Mirena expulsion rate = 2.9%

Previous method used (n=279)







Why did you choose the IUS? (only 1 response allowed, n=279)



- Effectiveness
- Long-acting
- Reduced/No bleeding
- Reversible
- Fewer side effects
- Recommended by trusted source
- Other

Provider study: Baseline results (April 2017)

40 providers surveyed before IUS training:

-  43% would recommend an IUD for a woman who has no children
-  90% reported that decreased or absent periods are not harmful to women using hormonal contraception
-  45% would prescribe the IUS to patients experiencing heavy bleeding
-  50% of providers report that the IUS would be most attractive to clients who currently use an IUD.

Lessons learned from review meetings (2017)

Advantages	Disadvantages
Providers found insertion of the IUS easier compared to IUDs	Common side effects noted are abdominal cramps and spotting
Some clients with heavy menstrual flow opted for the IUS after counseling	Price was a barrier for some clients (approx. US\$10)

- Providers are reaching out to friends and colleagues who are OB/GYNs to create awareness about the IUS, thereby getting referrals from them
- The MOH FP coordinators requested the extension of implementation to the public sector



Madagascar: WCG and PSI



Cost-recovery pricing model for long-term sustainability, higher-quintile target market



Target group: Professional Urban Spacers in 4 cities



Target group: 30 Private providers serving professional women

Client materials



Avibela™ 

Avec moins de règles,
la vie est belle!

-  Mon Contraceptif **moderne**
-  Ma **liberté**
-  Mes 3 années **de sérénité**
-  La **solution** à Mon problème de règles

DEMANDEZ DÈS MAINTENANT À VOTRE MÉDECIN SI VOUS ÊTES ADMISSIBLE À AVIBELA™



Avibela™ 

Avec moins de règles,
la vie est belle!

Avibela™ 

... pour les Utilisatrices

Avec moins de règles,
la vie est belle!

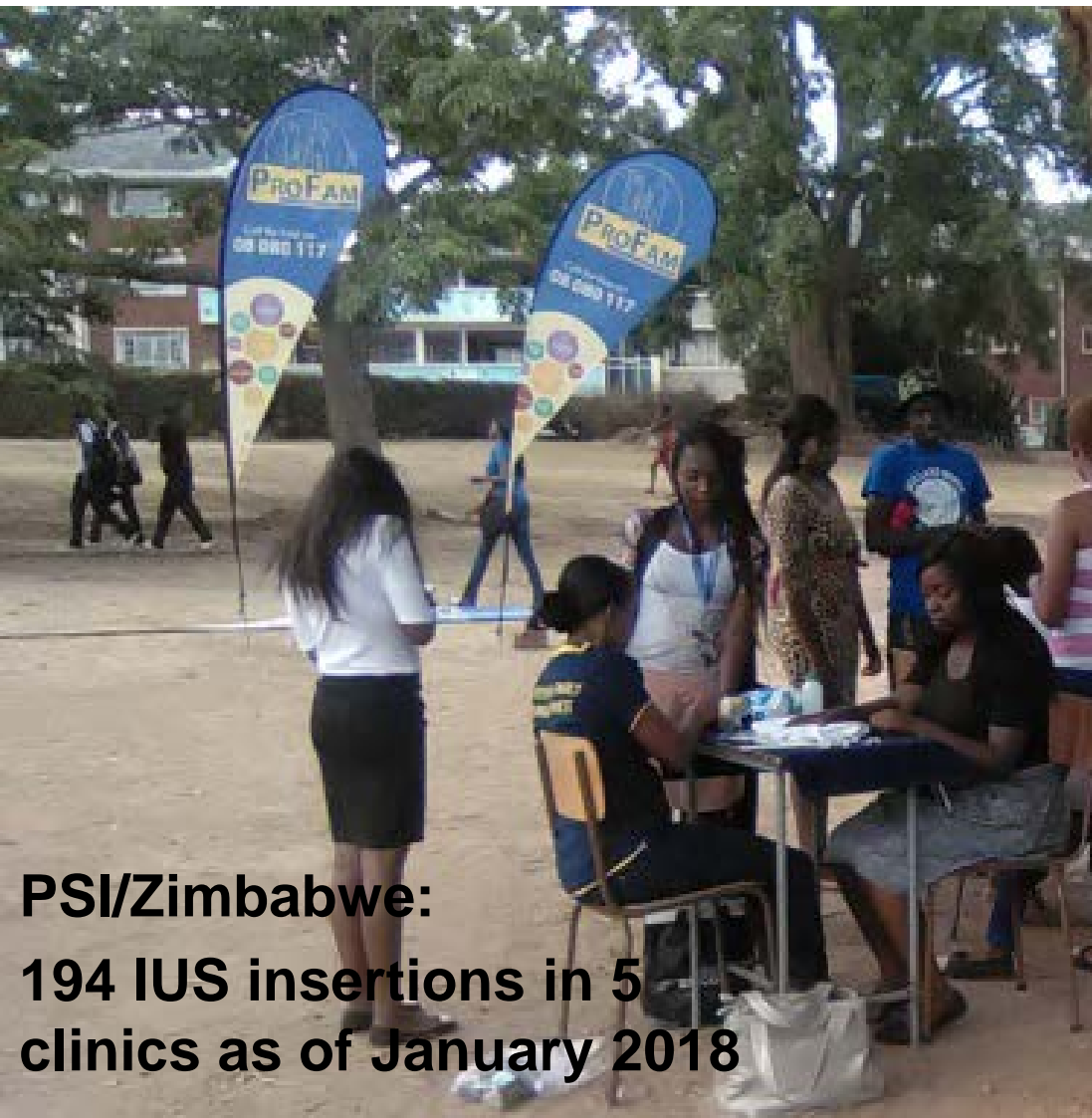
JUST ARRIVED

Avibela[®] 

Anticipated Launch: April 2018



Additional IUS pilots



**PSI/Zimbabwe:
194 IUS insertions in 5
clinics as of January 2018**



**WCG and SFH/Zambia:
236 IUS insertions in 8
public health facilities
as of January 2018**



Nigeria: MSI & FHI 360



Methods

- Desk review to document existing family planning landscape in Nigeria;
- Brief facility assessment to document existing use of LNG-IUS;
- Qualitative interviews with Key Opinion Leaders;
- Routine data collection among LNG-IUS clients at the point of service
- Qualitative interviews with LNG-IUS users
- Qualitative interviews with healthcare providers.

Service Delivery Sites

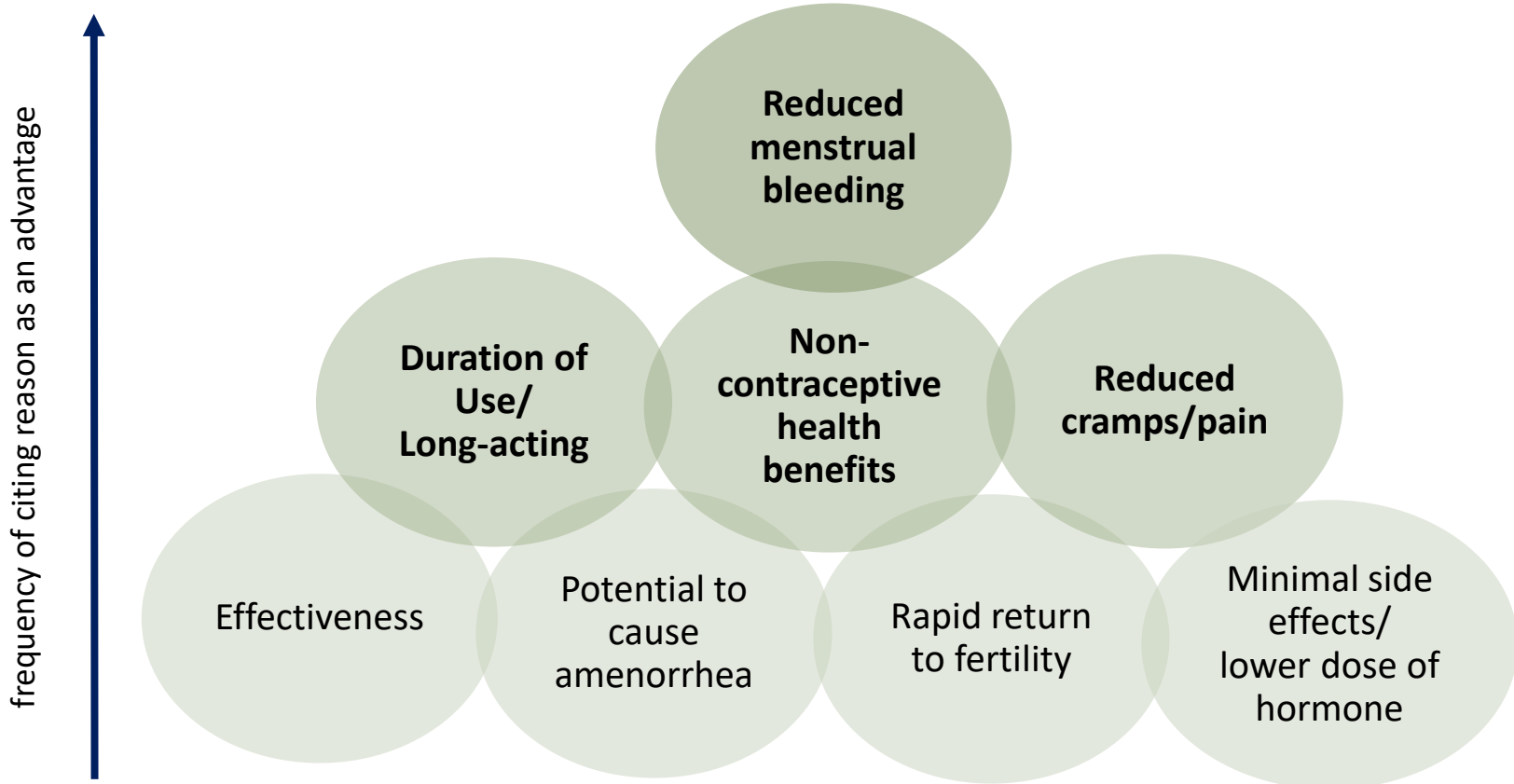
- MSI Nigeria Social Franchise clinics (Southern and North-Central Nigeria)
- MSI Nigeria Outreach teams (Northern Nigeria)
- Public sector facilities (Southern Nigeria)

Key Opinion Leaders' Views of LNG-IUS



All of the KOLs (n=17) were aware of the LNG-IUS

Perceived benefits of the LNG-IUS included:



Nigeria: “Enhanced” Routine M&E Questions – Clients’ reasons for choosing the LNG-IUS



“Can you briefly tell me the reasons you chose the LNG-IUS today instead of another method?”*

Reason	N
Reduced menstrual bleeding	198
It lasts for a long time	180
Effective	161
Nobody will know I’m using it	150
It is convenient/don’t need to do anything	120
Won’t affect future fertility	108
Few side effects	103
Want to delay pregnancy for at least 2 years	76
Recommended by friend or family	76
Don’t want more children	76
Can use while breastfeeding	74
Affordable here	59
Other	5

N=349

*Providers instructed not to read list aloud; mark all that apply

Nigeria: LNG-IUS Users – Qualitative interviews



Almost all women interviewed (n=28 out of 33) reported positive experiences with the LNG-IUS; 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
- Discrete 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

Providers: 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



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

**For women with heavy menstrual bleeding or fibroids*



Cost & Pricing Considerations



Evaluating potential pathways to increasing affordability & accessibility of the LNG-IUS



Goal: Decrease price barriers/ increase access

Reduce Cost of Goods Sold

Help additional manufacturer(s) achieve international QA

Incentivize existing manufacturer(s) to lower price e.g. market shaping intervention

Increase reach and impact of donated (free) product



Learning about Expanded Access and Potential of the LNG-IUS



- 2-year project
- Focus countries: Nigeria, Zambia & Kenya
- Partners: FHI 360, PSI, SFH/Nigeria, SFH/Zambia, WCG
- Funder: Bill & Melinda Gates Foundation



LEAP LNG-IUS: Learning Agenda



1. Estimate potential demand for the LNG-IUS in three countries;
2. Describe LNG-IUS acceptors and rejecters, including client profiles;
3. Measure continuation rates at 6 and 12 months and assess satisfaction compared to other LARCs;
4. Document incremental service delivery costs associated with introducing the LNG-IUS and evaluate the method's cost-effectiveness
5. Describe service delivery and demand barriers/facilitators; describe providers' and clients' experiences with method including perceptions of side effects and non-contraceptive health benefits;
6. Identify potential strategies to accelerate national regulatory approvals



Thank you

Questions?

MESSAGES TO CLIENTS USING CONTRACEPTION

Changes to Menses are **NORMAL**



Many women have misconceptions about changes to menses (periods) that occur with use of hormonal contraception or the copper IUD. Use this simple tool to help your clients understand that changes to their menses when they use a hormonal contraceptive method or the copper IUD are **NORMAL**. Provide your clients with evidence-based

information about method-specific changes that may occur. In addition, in each counseling session, reassure your clients about these changes and discuss the potential benefits of reduced bleeding and amenorrhea. Use the **NORMAL** acronym to address these points with them.

N O R M A L

NORMAL — Changes to your menses are **NORMAL** when you use a contraceptive method. With hormonal methods, menses could become heavier or lighter, occur more frequently or when you don't expect it, or you could have no menses at all. Changes to your menses may also be different over time.¹ With the copper IUD, menses could become longer and heavier, but remain regular; spotting could also occur during the first few months after IUD insertion.

OPPORTUNITIES — Lighter or no menses can provide **OPPORTUNITIES** that may benefit your health and personal life.

RETURN — Once you stop using a method, your menses will **RETURN** to your usual pattern, and your chances of getting pregnant will **RETURN** to normal.²

METHODS — Different contraceptive **METHODS** can lead to different bleeding changes. Let your provider know what types of bleeding changes you would find acceptable.

ABSENCE OF MENSES — If you are using a hormonal method, absence of menses does not mean that you are pregnant. If you have another symptom of pregnancy or if you missed your menses while using the copper IUD, talk to your health care provider or use a pregnancy test.³

LIMIT — If changes to your menses **LIMIT** your daily activities, there are simple treatments available. Talk to your provider.⁴

Illustration credit: Period emoji, Plan International UK. <https://plan-uk.org/act-for-girls/break-the-taboo-vote-for-your-favourite-period-emoji>

¹ In addition to these points, provide method-specific information about potential changes to menses both before and after a client selects a hormonal contraceptive method.

² If applicable, inform your client that when using injectable contraception (e.g., DMPA), return to fertility will likely be delayed after discontinuing the method. For other methods, return to fertility will be immediate.

³ If applicable, inform your client that when using oral contraceptive pills, absence of menses can be a sign of pregnancy. Absence of menses during the first month after initiation of the implant or progestin-only injectables may also be a sign of pregnancy (e.g., when the method was initiated as part of the Quick Start, without pregnancy being ruled out with reasonable certainty). Tell your client to return to the clinic if she is unsure of her pregnancy status.

⁴ Treatment for heavy/prolonged bleeding due to hormonal methods include a 5-day course of ibuprofen or another NSAID (except aspirin), or a 21-day course of COCs or ethinyl estradiol. Treatment for bleeding associated with the copper IUD includes a 5-day course of tranexamic acid or NSAIDs (except aspirin). In most cases, however, providing supportive counseling and/or reassurance to clients is sufficient.



New job aid for health care providers to counsel clients on **bleeding changes associated with the use of contraception**

Co-developed by FHI 360 and PSI



Discussion: Pricing considerations at country level

- **Additional costs** – beyond commodity costs— impact the final price point (e.g. in-country logistics; provider training/support, demand creation and marketing)
- **Product positioning affects pricing strategy:**
 - Should this be positioned as a premium product or should it be priced competitively relative to other LARCs?
 - Should additional subsidies be offered to price LNG-IUS lower than other LARCs to create initial demand/momentum?
 - What are the trade-offs on volume, client group reached, and provider attitudes towards the product for each of these approaches?

