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

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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

- 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
<table>
<thead>
<tr>
<th><strong>Overview of LNG-IUS products</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BAYER HEALTHCARE:</strong> Mirena, Skyla, Kyleena</td>
</tr>
<tr>
<td>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 &amp; Kyleena.</td>
</tr>
<tr>
<td><strong>ICA FOUNDATION:</strong> LNG-IUS</td>
</tr>
<tr>
<td>Public-private partnership between Bayer HealthCare &amp; Population Council. Provides free LNG-IUS product; donated over 100K units since 2005.</td>
</tr>
<tr>
<td><strong>MEDICINES 360:</strong> Liletta/Avibela</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>
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

- Impact of non-contraceptive health benefits?
- Cost effectiveness?
- Service delivery strategies/experiences?
- Effective demand creation strategies?
- User profiles? Potential demand?
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.
Nigeria: PSI and SFH
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Trainers trained</td>
<td>8</td>
</tr>
<tr>
<td>Private providers trained</td>
<td>40</td>
</tr>
<tr>
<td>Pilot sites</td>
<td>40</td>
</tr>
<tr>
<td>IUS insertions</td>
<td>651</td>
</tr>
<tr>
<td>IUS removals</td>
<td>4 (0.6%)</td>
</tr>
<tr>
<td>Reported expulsions</td>
<td>5 (0.8%)*</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>0</td>
</tr>
</tbody>
</table>

*Mirena expulsion rate = 2.9%
Previous method used (n=279)

- No method: 96
- Injectables: 42
- Implant: 39
- IUD: 32
- Pills: 28
- Condoms: 17
- Traditional: 12
- Other: 6
- SDM: 5
- EC: 1
- LAM: 1

- 34% No method
- 26% LARC
- 4% STM
- 2% Traditional
- 1% Unknown

[Graph showing the distribution of previous methods used with the number of each method and their percentages.]
Why did you choose the IUS? (only 1 response allowed, n=279)

- Effectiveness: 36%
- Long-acting: 24%
- Reduced/No bleeding: 18%
- Reversible: 10%
- Fewer side effects: 5%
- Recommended by trusted source: 3%
- Other: 4%
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)

- 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.

### Advantages

| 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) |
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
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 DÉS MAINTENANT À VOTRE MéDECIN SI VOUS ÊTES ADMISSIBLE À AVIBELA™

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

Perceived benefits of the LNG-IUS included:

- Reduced menstrual bleeding
- Non-contraceptive health benefits
- Reduced cramps/pain
- Duration of Use/Long-acting
- Potential to cause amenorrhea
- Rapid return to fertility
- Effectiveness
- Minimal side effects/lower dose of hormone
- Reduced menstrual bleeding
- Non-contraceptive health benefits
- Reduced cramps/pain
- Duration of Use/Long-acting
- Potential to cause amenorrhea
- Rapid return to fertility
- Effectiveness
- Minimal side effects/lower dose of hormone
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?”*

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

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

**What users DISLIKED about the LNG-IUS:**
- Initial spotting
- Sensation of the string
- Irregular menstruation
- Continuous spotting
- Amenorrhea
- Abdominal pain

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.
### Providers: Perceptions of LNG-IUS

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

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic/clinical benefits*</td>
<td>None</td>
</tr>
<tr>
<td>Contraceptive effectiveness</td>
<td>Expulsion of the method*</td>
</tr>
<tr>
<td>Potential menstrual bleeding regulation</td>
<td>Spotting</td>
</tr>
<tr>
<td>Reduction of menstrual cramps</td>
<td>Up-front cost</td>
</tr>
<tr>
<td>Cost-effective over time</td>
<td>Amenorrhea</td>
</tr>
<tr>
<td>Amenorrhea</td>
<td>Weight gain</td>
</tr>
<tr>
<td>Convenient</td>
<td>Certain health conditions preclude use of LNG-IUS</td>
</tr>
<tr>
<td>Improved marital relations</td>
<td>Need for proper hygiene</td>
</tr>
<tr>
<td>Rapid return to fertility</td>
<td>Potential for LNG-IUS to perforate the uterus</td>
</tr>
<tr>
<td>No weight gain</td>
<td>Cramps in initial months post-insertion</td>
</tr>
<tr>
<td>Reversibility</td>
<td></td>
</tr>
<tr>
<td>Discreet nature</td>
<td></td>
</tr>
<tr>
<td>Long-acting</td>
<td></td>
</tr>
<tr>
<td>Fewer side effects</td>
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*For women with heavy menstrual bleeding or fibroids
Cost & Pricing Considerations
Price reduction analysis

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?
New job aid: Bleeding changes are NORMAL

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.

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 each cycle. 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.

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.

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 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.

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

1 In addition to these points, provide methodspecific, information about potential changes to menses both before and after a client selects a hormonally contracepted method.

2 If applicable, inform your client that using equally risk avoidance (e.g., DHFR), 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 contraceptives, absence of menses can be a sign of pregnancy. Absence of menses during the first month after initiation of the implant or progesterone-only injectables may also be a sign of pregnancy (e.g., when the method was initiated as part of the QuickStart, 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 includes a 5-day course of leukoreduction or another NSAI (except aspirin) or a 21-day course of COCs or ethisterone tablets.

5 Treatment for bleeding associated with the copper IUD includes a 3-day course of tranexamic acid or NEADS (except aspirin). In most cases, however, providing supportive counseling and/or reassurance to clients is sufficient.

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?