What’s Next with the LNG-IUS? Updates on Country Activities

Kate H. Rademacher, FHI 360
Temple Cooley, PSI/WomanCare Global

Moderator: Frederiek Chatfield, Marie Stopes International

14 October 2016
Agenda

• Overview of the method/products

• Country Updates
  o Zambia
  o Madagascar
  o Kenya
  o Nigeria
  o Additional countries
  o Discussion
LNG-IUS

Method Overview

- Contains 52 mg of levonorgestrel
- One of the most effective methods
- 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/accessibe
- In early introduction efforts in Africa, high acceptability
- High cost of existing products has meant that availability has been very limited in low-resource settings
- Goal is to increase access and choice
### Overview of Quality Assured Products

<table>
<thead>
<tr>
<th>Organization</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bayer HealthCare</strong></td>
<td>• Mirena™ priced at ~$60-$400 in developing countries. Provided commercially through private healthcare clinics in some countries on very limited scale.</td>
</tr>
<tr>
<td><strong>ICA Foundation</strong></td>
<td>• Public-private partnership between Bayer Healthcare &amp; Population Council. Provides free LNG-IUS product; donated 70K units in over 25 countries since 2005.</td>
</tr>
<tr>
<td><strong>Medicines360</strong></td>
<td>• Approved by 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.</td>
</tr>
</tbody>
</table>
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$)

Zambia: Market assessment conducted in 2016

Objective: To explore potential demand for a new, more affordable LNG-IUS (hormonal IUCD) and identify key considerations for introduction and scale-up

Funding provided by the Bill & Melinda Gates Foundation through FHI 360’s Contraceptive Technology Innovation Initiative. Collaboration between FHI 360, Society for Family Health, PSI and WomanCare Global.
Zambia

Market Assessment: Methods

- Landscaping—desk review of literature/program experiences
- 34 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
Facility assessments

Facilities offering IUCDs

- Brief facility assessment 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 hormonal IUCD if client brings own Mirena; fee to client is K 4600 or US $460 (K4000 for product; K600 for insertion fee)

  - Other is social franchise; distributes free product provided by Marie Stopes (insertion fee is K 50 or USD $5)

- Private pharmacy sells Mirena for ~ K 3925 or USD $393
Key Opinion Leaders

Perspectives on current use of copper IUCDs

Uptake of copper IUDs 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.
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 isn’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
Healthcare Providers

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.

- All providers indicated that – based on what they had heard – they would use this product in their practice.
Potential Users

Perceptions of Hormonal IUCDs

The large majority of women interviewed were not familiar with the method, although a small number of LARC users had heard of Mirena.

- Based on the description read to them, potential users identified advantages including **reduced blood flow**, **less painful periods**, **rapid return to fertility**, **long duration of use** with option to remove earlier.

- Many participants had the perception that ‘normal’ monthly periods are important though some participants would be okay with having lighter periods.

- The overwhelming majority of potential users indicated they would be willing to consider/try the hormonal IUCD.
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... What’s the problem that I could have?... Am very scared and very concerned because I don’t know what is happening.

-IMPLANT USER
“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
Zambia: What’s next?

- In August, results presented to the Family Planning Technical Working group; the group endorsed public sector introduction of the LNG-IUS

- SFH planning introduction through the USAID-funded SARAI and EECO projects and Jhpiego plans to support introduction through the Safe Motherhood360 project

- Monitoring & evaluation efforts will help address global learning agenda questions
Project team

Tracey Brett
Temple Cooley
Prisca Kasonde
Anna Lawton
Namuunda Mutombo
Mary Namukoko
Geeta Nanda
Towela Ndhlema
Namakau Nyambe
Kate Rademacher
Esther Sakala
Jill Sergison
Markus Steiner

Final report is forthcoming
Objective: To explore potential demand for a new, more affordable LNG IUS and better understand provider and consumer barriers and motivations to use the product.

Funding provided by USAID via the Expanding Effective Contraceptive Options (EECO) project. The project is primed by WomanCare Global and implemented in collaboration with Population Services International.
Madagascar
Landscape

• 0.3% IUD prevalence in the 2008-2009 Madagascar DHS, 1% in PSI’s 2015 survey

• PSI/Madagascar added IUDs to their portfolio in 2006
  • Distributed 175k IUDs in the past 10 years
  • Inserted 163k IUDs in the Top Reseau network of private clinics

• Marie Stopes Madagascar also offers IUDs, as does the public sector

• Mirena is available in select pharmacies for about US$250, low awareness and low volumes
Madagascar

Methods

- 8 interviews with private sector healthcare providers
- 10 focus group discussions and 2 in-depth interviews with women between the ages of 18 and 35 who were:
  - Users of long-acting, reversible contraception
  - Discontinuers of short or long acting contraception
  - Non-users of contraception

<table>
<thead>
<tr>
<th>Participants</th>
<th>Utilisatrices de MLD (Implant et DIU non-hormonal)</th>
<th>Ayant Abandonné la méthode PF pour une raison précise</th>
<th>Non utilisatrices de méthode contraceptive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tamatave</td>
<td>Fianar</td>
<td></td>
</tr>
<tr>
<td>Femmes sexuellement actives de 18-24 ans</td>
<td>FGD (4 femmes)</td>
<td>FGD (4 femmes)</td>
<td></td>
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<tr>
<td></td>
<td>Fianar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Femmes sexuellement actives de 25-35 ans</td>
<td>FGD (4 femmes)</td>
<td>FGD (5 femmes)</td>
<td></td>
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<tr>
<td></td>
<td>Fianar</td>
<td></td>
<td></td>
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<tr>
<td>Prestataire Top Réseau</td>
<td>4 IIA</td>
<td>4 IIA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

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- 10 focus group discussions and 2 in-depth interviews with women between the ages of 18 and 35 who were:
  - Users of long-acting, reversible contraception
  - Discontinuers of short or long acting contraception
  - Non-users of contraception
Reasons for Selecting a Method

• Ability to pursue a personal long-term project (IUD, Implant)
• Limited side effects (injectable, IUD)
• Doctor recommendation (pills)
• Positive experience of peers (pills, injectable)

Reasons for Abandoning a Method

• Decided to have a child
• Noted physiological changes (absence of or irregularity of menses, weight gain, fatigue)
• Experienced an illness and associated it with the method (stomach aches, hair loss)
• Began to worry about irreversibility and infertility
Madagascar
Source of Information (for LARC users)

Implant
Peers
Health Professionals

IUD
Health professionals
## Madagascar

### Avibela Acceptability

<table>
<thead>
<tr>
<th>Providers</th>
<th>Clients</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Expands the method mix</td>
<td>- Reversibility (no delay in return to fertility, no risk of malformation of the fetus)</td>
</tr>
<tr>
<td>- Appreciation for the non-contraceptive benefits (treatment of heavy bleeding)</td>
<td>- Appreciation for the non-contraceptive benefits (treatment of heavy bleeding)</td>
</tr>
<tr>
<td></td>
<td>- 3 year duration (shorter than copper IUD, good for spacing births)</td>
</tr>
<tr>
<td></td>
<td>- Use of the method during breast feeding</td>
</tr>
<tr>
<td></td>
<td>- New product (old methods less desirable) (IUD, Implant)</td>
</tr>
</tbody>
</table>
## Barriers to Avibela Acceptability

<table>
<thead>
<tr>
<th>Providers</th>
<th>Clients</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Ineligibility of certain clients: (inverted uterus, unable to sound uterus)</td>
<td>▪ Presence of the strings: bothersome during sex, contact with the penis, can not be used secretly</td>
</tr>
<tr>
<td>▪ In their experience, hormonal products don’t have any barriers</td>
<td>▪ Concerns about hormones: uterine cancer; absence of menses; fertility issues</td>
</tr>
<tr>
<td>▪ Product may not be accepted by clients (hormone; absence of menses; weight gain; IUD poses risk of cervical cancer)</td>
<td>▪ IUD: fear of cervical cancer, partner refusal</td>
</tr>
</tbody>
</table>
Madagascar
Have you experienced a change in menstruation while using a method of contraception?

<table>
<thead>
<tr>
<th>Nearly all answered yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in amount of bleeding</td>
</tr>
<tr>
<td>Irregularity in cycle</td>
</tr>
<tr>
<td>Prolonged bleeding</td>
</tr>
<tr>
<td>Change in color</td>
</tr>
</tbody>
</table>
Madagascar

Interest in reduction of bleeding and cramps

**Interest**

- Have experienced heavy menstruation with a previous method
- Less Expense
- Physical and Psychological Well-Being (possibly to keep working)
- Possible to have sex

**Not interested**

Lack of bleeding signifies an abnormal state of health (sickness, pregnancy)
### Key Learnings from Market Research

<table>
<thead>
<tr>
<th>Side effects have a major impact on method choice and discontinuation</th>
<th>Less bleeding is a positive, but no bleeding seen as unnatural</th>
<th>At $250, Mirena is not known by upper middle class women, only elites and some providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-year duration of IUD leads women to think of it as a method for limiting, whereas a 3 year product is seen as ideal for spacing</td>
<td>Negative perceptions of IUDs and hormones mean Avibela should <strong>not</strong> be positioned as a &quot;hormonal IUD&quot;</td>
<td>There is high unmet need and traditional method use among urban, educated women, especially in the post-partum period</td>
</tr>
</tbody>
</table>
Madagascar

Target Audiences

Target group: Urban Spacers
Strategic Segment: Post-Partum
Desired Behavior:
Ask their provider about Avibela

Target group: Providers serving professional women
Strategic segment: OB/GYN opinion leaders
Desired Behavior: Propose Avibela to their eligible clients and peers
Madagascar: What’s next?

- MOH signed off on registration application; application filed with regulatory body
- PSI/Madagascar has designed an introduction strategy for the private sector:
  - Create an integrated communications campaign to introduce Avibela
  - Advocate among opinion leaders in medical community to support Avibela
  - Introduce Avibela via Top Reseau and assure service quality there
  - Sell Avibela to additional private sector OB/GYN clinics
- JHPIEGO may pilot in the public sector
- M&E efforts will help address global learning agenda questions
Project team

Bakoly Rahaivondrafahitra
Jacky Raharinjatovo
Francia Rasoanirina
Jimmy Ramahavory
Noah Tarukerekera
Laura Glish
Temple Cooley
Nora Miller

Objective: To examine attitudes regarding product-related acceptability and attributes, including the non-contraceptives benefits of the product.

Funding provided by the Bill & Melinda Gates Foundation through FHI 360’s Contraceptive Technology Innovation Initiative. Collaboration between FHI 360 and Family Health Options Kenya (FHOK)
Kenya
Methods & Demographics

- Qualitative interviews were carried out with Mirena users/recent users (N=29), and a subset of their husbands/partners (N=9).

<table>
<thead>
<tr>
<th></th>
<th>Women (N=29)</th>
<th>Men (N=9)</th>
<th>Total (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (average)</td>
<td>38.3</td>
<td>38.7</td>
<td>38.4</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Married</td>
<td>26</td>
<td>9</td>
<td>35</td>
</tr>
<tr>
<td>In Union/living together</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Widowed</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td># Children (average)</td>
<td>2.3</td>
<td>2</td>
<td>2.2</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed primary</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Some secondary</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Completed secondary</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Post-secondary</td>
<td>24</td>
<td>9</td>
<td>33</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Professional/Technical / Managerial</td>
<td>22</td>
<td>8</td>
<td>30</td>
</tr>
<tr>
<td>Other</td>
<td>7</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Currently using Mirena</td>
<td>23</td>
<td>6</td>
<td>29</td>
</tr>
<tr>
<td>Removed Mirena</td>
<td>6</td>
<td>3</td>
<td>9</td>
</tr>
</tbody>
</table>
Mirena Users

Reasons for Choosing Mirena

Most common reason why women opted for Mirena as their FP method was perception that method had less side effects (N=12)

Other reasons mentioned included:

- Long-acting method
- Recommended by friends and providers
- Desire for IUD but not “the coil” (i.e. the copper IUD)
- Highly effective method
- Leads to reduced bleeding
- Convenient (doesn’t require daily action)
- Safe method
- Recommended for health benefits (e.g. treatment for fibroids)
- Hormones are localized
Even though hormones are involved it is at a very minimal level.... It is something I don’t have to pop into the mouth every day. And it is something that keeps me going for about 5 years then that made all the sense to me.

- MIRENA USER
Mirena Users

Participants’ Views on Mirena: Likes and Dislikes

Almost all women currently using Mirena reported positive experiences; majority said would recommend to a friend and will continue use of the method.

**LIKES**
- Convenience of method and not having to worry
- Reduced periods
- Not feeling the method
- Effective in preventing pregnancy
- Did not experience any side effects
- Longevity of the method

**DISLIKES**
- Feeling the string
- Bleeding, cramping
- Some women (n=16) did not have anything negative to say
- Insertion procedure
- Cost of the method

1 woman said she didn’t like not having regular periods
“The spotting bit was the first few months. I liked [the method] because I didn’t have my periods and I didn’t have to stress about that.”

“It is 5 years. For all these 5 years I don’t have to worry about pregnancy. I have not heard anybody say it has failed. It empowers a woman.”

“I dislike the price and the fact that maybe the trained people to handle Mirena are not as many.”

-MIRENA USERS ON LIKES AND DISLIKES
Male Partners of Mirena Users

Mens’ Views on Mirena: Likes and Dislikes

Almost all men were very positive about their partner’s use of Mirena.

<table>
<thead>
<tr>
<th>LIKES</th>
<th>DISLIKES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partner did not experience any side effects</td>
<td>Some men (n=3) did not have anything negative to say</td>
</tr>
<tr>
<td>Longevity of the method</td>
<td>Infections</td>
</tr>
<tr>
<td>Not feeling the method</td>
<td>Weight gain</td>
</tr>
<tr>
<td>Flexibility of removing the method at any time</td>
<td>Discomfort during sex</td>
</tr>
<tr>
<td></td>
<td>Hygiene issue due to location of method insertion</td>
</tr>
</tbody>
</table>
Community Awareness and Barriers to Use

- Most women felt that awareness of the method is low. The most commonly mentioned barriers to greater use was cost (n=14) and lack of knowledge (n=9).

- Women felt if more people could afford the method, the more people would be using it because of the benefits it provides such as it’s a long-acting method, the lack of side effects, minimal bleeding, and pregnancy prevention.
Kenya: What’s next?

- Results will be shared with MSI, Jhpeigo and other service delivery partners to help inform development of the demand creation and/or communication strategies.

- ICA Foundation product is registered; MSI is seeking registration of Medicines360 product (Avibela).

- Based on market research, MSK refining launch strategy following development of initial draft in 2016.
Project team

Tracey Brett
Sarah Mercer
Rose Masaba
Geeta Nanda
Rose Njoki Ngahu
Kate Rademacher
Jill Sergison
Marsden Solomon
Markus Steiner
James Namanywa Wawire
Eunice Were

Final publication is forthcoming

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Objectives

Goal: To strengthen existing service delivery and ultimately to expand access and contraceptive choice for women in Nigeria.

1) To document uptake of LNG-IUS and assess perceptions and experiences with the method among both clients and healthcare providers

2) Document programmatic experiences and costs with the provision of the LNG-IUS in Nigeria

3) Conduct a landscaping exercise regarding current distribution and use of the method and document perceptions of Key Opinion Leaders regarding opportunities and challenges associated with further scale-up of the method
Nigeria

Methods

- Desk review of existing data on provision of long-acting reversible contraceptive methods

- Brief, quantitative questions as part of client intake forms

- Qualitative interviews with clients who accepted LNG-IUS at private and public facilities at 3, 6, and/or 12 months

- Brief quantitative questions as well as qualitative interviews with clients who discontinue the LNG-IUS

- Qualitative interviews with healthcare providers at private and public facilities

- Qualitative interviews with Key Opinion Leaders
Nigeria: What’s next?

- ICA Foundation product will be offered through MSION social franchise clinics and mobile outreach as well as public sector clinics; refresher training of providers being conducted

- IRB review underway for assessment

- Knowledge gained will be used to strengthen service delivery and to assess the potential for further scale-up of the method.
Project team

Tracey Brett
Ellen Clancy
George Eluwa
Gillian Eva
Geeta Nanda
Lucky Palmer
Kate Rademacher
Mariya Saleh
Jill Sergison
Markus Steiner

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Additional country updates

• Senegal
• Zimbabwe
• Uganda
• Burkina Faso
What’s Next with the LNG-IUS?

DISCUSSION
Back-up Slides
The CHOICE Study

**Key Opinion Leaders**

**Strategies to Scale-Up Hormonal IUCDs**

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