

# 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



GENERAL MEMBERSHIP MEETING

*of the*

REPRODUCTIVE HEALTH  
SUPPLIES COALITION

10-14 OCTOBER 2016

**#RHSUPPLIES2016**



Reproductive Health  
**SUPPLIES COALITION**

# Agenda

- Overview of the method/products
- Country Updates
  - Zambia
  - Madagascar
  - Kenya
  - Nigeria
  - Additional countries
  - 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/accessible
- ✓ 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

## Bayer HealthCare

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

## ICA Foundation

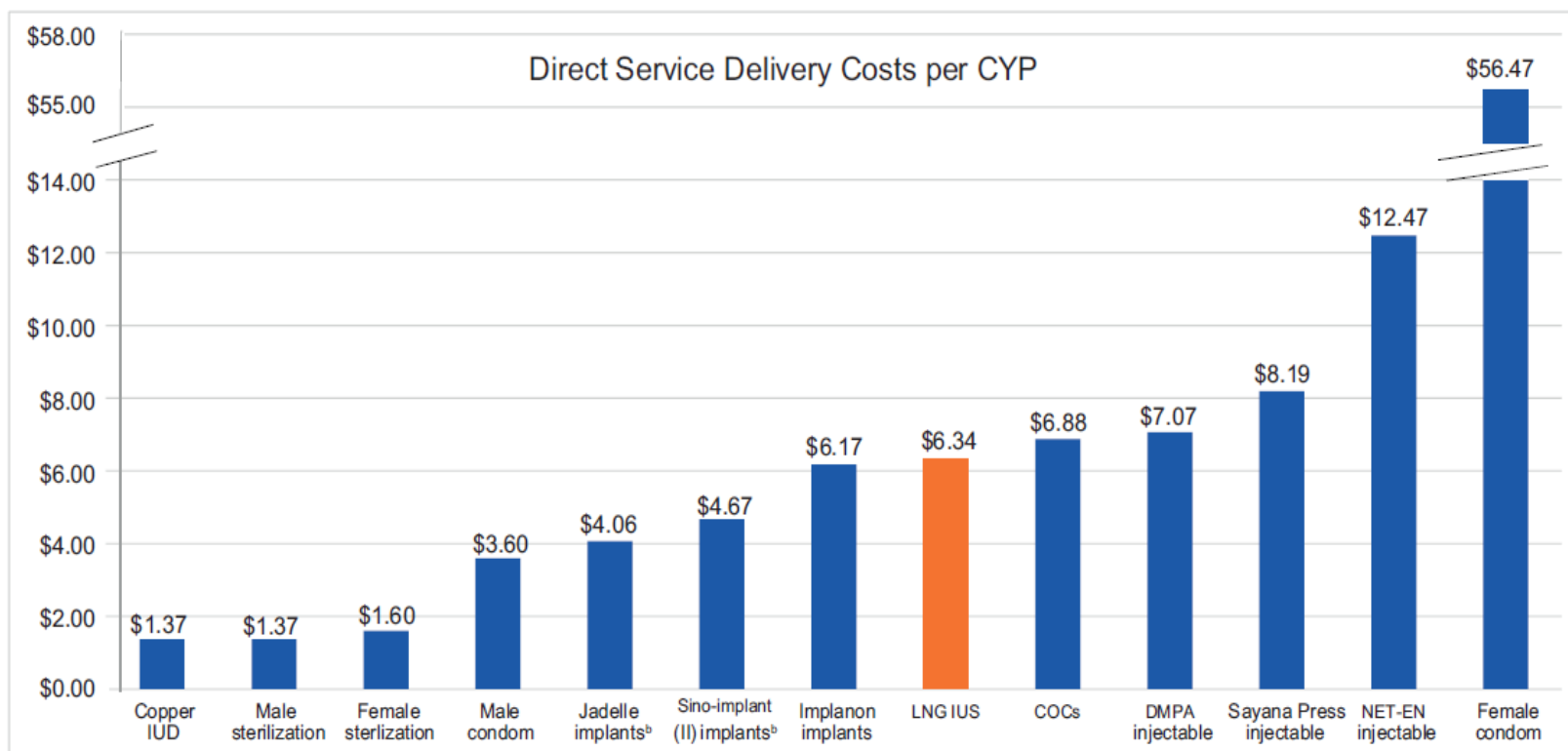
- Public-private partnership between Bayer Healthcare & Population Council. Provides free LNG-IUS product; donated 70K units in over 25 countries since 2005.

## Medicines360

- 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.

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

**FIGURE.** Direct Service Delivery Cost of the LNG IUS per CYP<sup>a</sup> 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.



# 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*



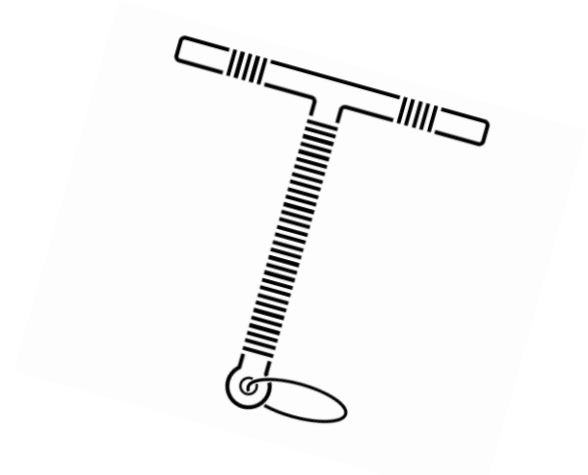
# Facilities offering IUCDs

- **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.*

”

**-KEY OPINION  
LEADER**

*Key Opinion Leaders*

# 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



## 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

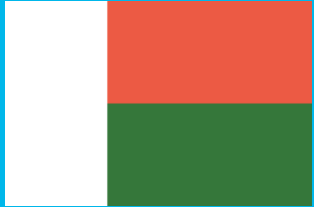


# Project team

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*





# Madagascar: LNG IUS Market Assessment 2016

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.



**USAID**  
FROM THE AMERICAN PEOPLE



Expanding Effective Contraceptive Options



# 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

Participants	Utilisatrices de MLD (Implant et DIU non-hormonal)		Ayant Abandonné la méthode PF pour une raison précise		Non utilisatrices de méthode contraceptive	
	Tamatave	Fianar	Tamatave	Fianar	Tamatave	Fianar
Femmes sexuellement actives de 18-24 ans	FGD (4 femmes)	FGD (4 femmes)	FGD (4 femmes)	FGD (4 femmes)	FGD (4 femmes)	1
Femmes sexuellement actives de 25-35 ans	FGD (4 femmes)	FGD (5 femmes)	FGD (5 femmes)	FGD (4 femmes)	FGD (4 femmes)	1
Prestataire Top Réseau	4 IIA	4 IIA	NA		NA	

# Reasons for Selecting a Method

### 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)

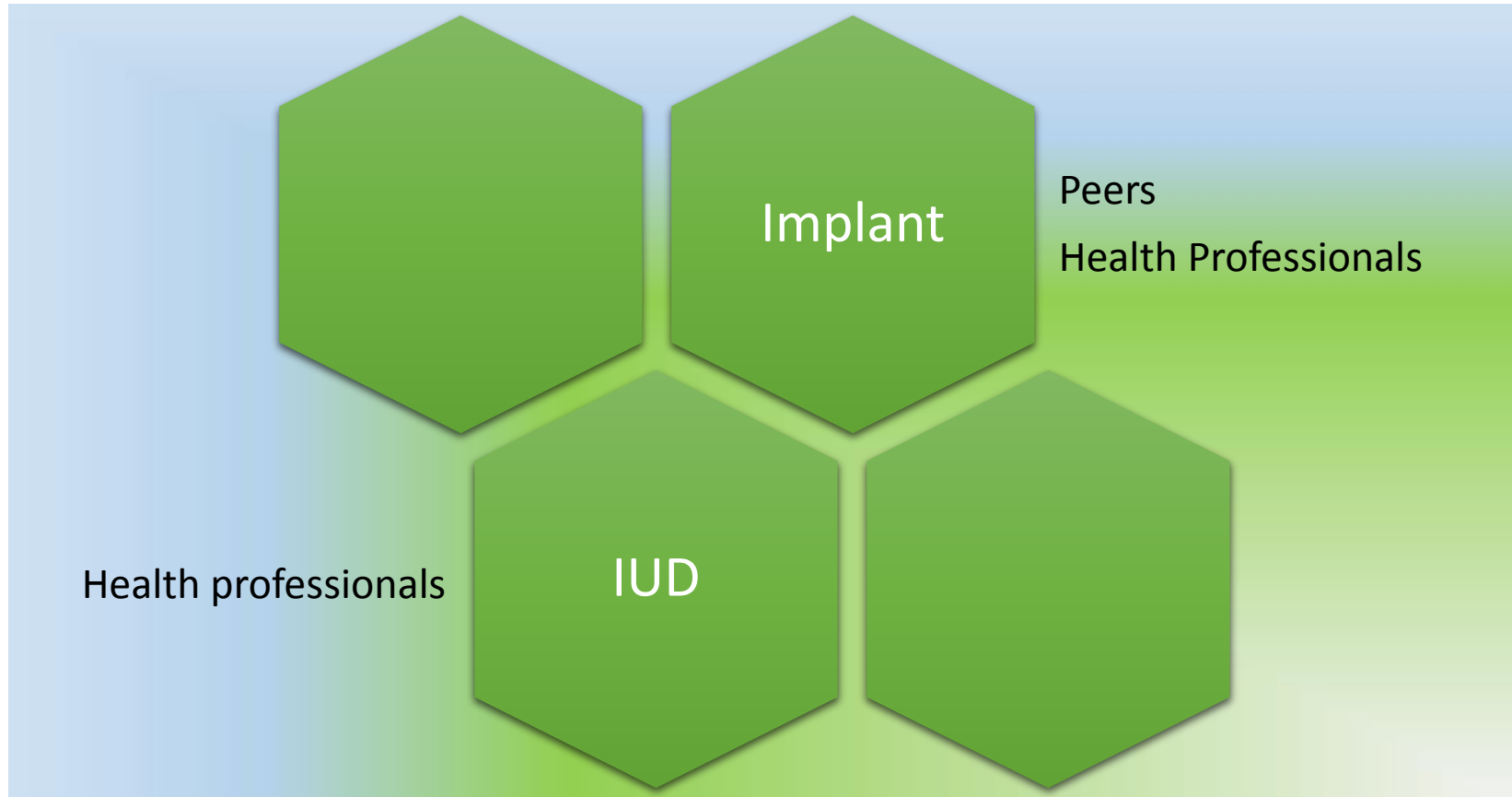
### Reasons for Abandoning a Method

- 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)



# Avibela Acceptability

## Providers

- Expands the method mix
- Appreciation for the non-contraceptive benefits (treatment of heavy bleeding)

## Clients

- Reversibility (no delay in return to fertility, no risk of malformation of the fetus)
- Appreciation for the non-contraceptive benefits (treatment of heavy bleeding)
- 3 year duration (shorter than copper IUD, good for spacing births)
- Use of the method during breast feeding
- New product (old methods less desirable ) (IUD, Implant)

## Barriers to Avibela Acceptability

### Providers

- Ineligibility of certain clients: (inverted uterus, unable to sound uterus)
- In their experience, hormonal products don't have any barriers
- Product may not be accepted by clients (hormone; absence of menses; weight gain; IUD poses risk of cervical cancer)

### Clients

- Presence of the strings: bothersome during sex, contact with the penis, can not be used secretly
- Concerns about hormones: uterine cancer; absence of menses; fertility issues
- IUD: fear of cervical cancer, partner refusal

## Madagascar

Have you experienced a change in menstruation while using a method of contraception?

Nearly all answered yes

Reduction in amount of bleeding

Irregularity in cycle

Prolonged bleeding

Change in color

## 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

---

**Side effects have a major impact on method choice and discontinuation**

**Less bleeding is a positive, but no bleeding seen as unnatural**

**At \$250, Mirena is not known by upper middle class women, only elites and some providers**

**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**

**Negative perceptions of IUDs and hormones mean Avibela should not be positioned as a "hormonal IUD"**

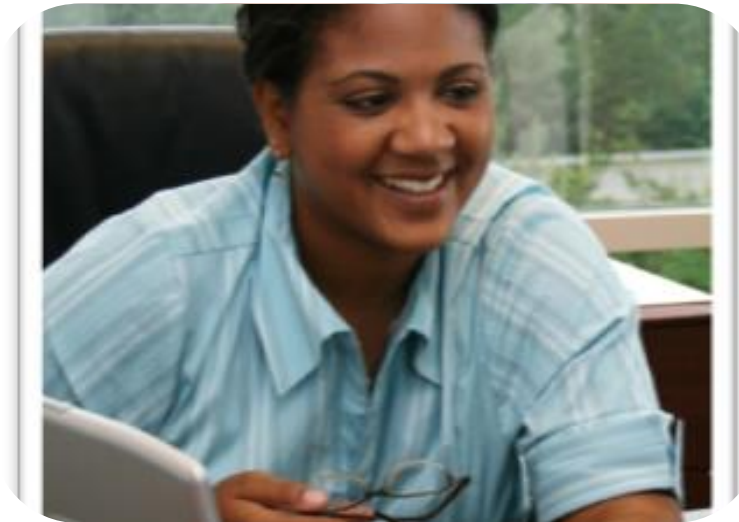
**There is high unmet need and traditional method use among urban, educated women, especially in the post-partum period**

## 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



**Kenya:** Building on market assessment completed in 2015 in partnership with Marie Stopes International, FHI 360 conducted qualitative interviews with Mirena clients and their male partners in 2016.

**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).



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



## 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
- Hormones are localized
- Leads to reduced bleeding
- Convenient (doesn't require daily action)
- Safe method
- Recommended for health benefits (e.g. treatment for fibroids)

“

*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

# 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
- Did not experience any side effects
- Longevity of the method
- Reduced periods
- Not feeling the method
- Effective in preventing pregnancy

## *DISLIKES*

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

# Mens' Views on Mirena: Likes and Dislikes



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

## *LIKES*

- **Partner did not experience any side effects**
- Longevity of the method
- Not feeling the method
- Flexibility of removing the method at any time

## *DISLIKES*

- **Some men (n=3) did not have anything negative to say**
- **Changes in partner's period**
- Cost of the method
- Infections
- Weight gain
- Discomfort during sex
- Hygiene issue due to location of method insertion



## *Mirena Users*



# 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*

## **Nigeria:** Project entitled, “Evaluating Provision of the LNG-IUS in Nigeria and Potential for Scale-Up of the Method”

Funding provided by the U.S. Agency for International Development (USAID) through MSI’s SIFPO 2 project and the Bill & Melinda Gates Foundation through FHI 360’s Contraceptive Technology Innovation Initiative. Collaboration between MSI and FHI 360.



**USAID**  
FROM THE AMERICAN PEOPLE



**MARIE STOPES  
NIGERIA**

Children by choice, not chance



**MARIE STOPES  
INTERNATIONAL**

Children by choice, not chance

**fhi360**

THE SCIENCE OF IMPROVING LIVES

# Nigeria

## 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



**USAID**  
FROM THE AMERICAN PEOPLE



**MARIE STOPES**  
**NIGERIA**  
Children by choice, not chance



**MARIE STOPES**  
**INTERNATIONAL**  
Children by choice, not chance

**fhi360**  
THE SCIENCE OF IMPROVING LIVES

# 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



**USAID**  
FROM THE AMERICAN PEOPLE



**MARIE STOPES**  
**NIGERIA**  
Children by choice, not chance



**MARIE STOPES**  
**INTERNATIONAL**  
Children by choice, not chance

**fhi360**  
THE SCIENCE OF IMPROVING LIVES

# 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.



**USAID**  
FROM THE AMERICAN PEOPLE



**MARIE STOPES**  
**NIGERIA**  
Children by choice, not chance



**MARIE STOPES**  
**INTERNATIONAL**  
Children by choice, not chance

**fhi360**  
THE SCIENCE OF IMPROVING LIVES

# Project team

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

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.

This presentation 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 FHI360 and do not necessary reflect the views of USAID or the United States Government.



**USAID**  
FROM THE AMERICAN PEOPLE





## **Additional country updates**

- Senegal
- Zimbabwe
- Uganda
- Burkina Faso

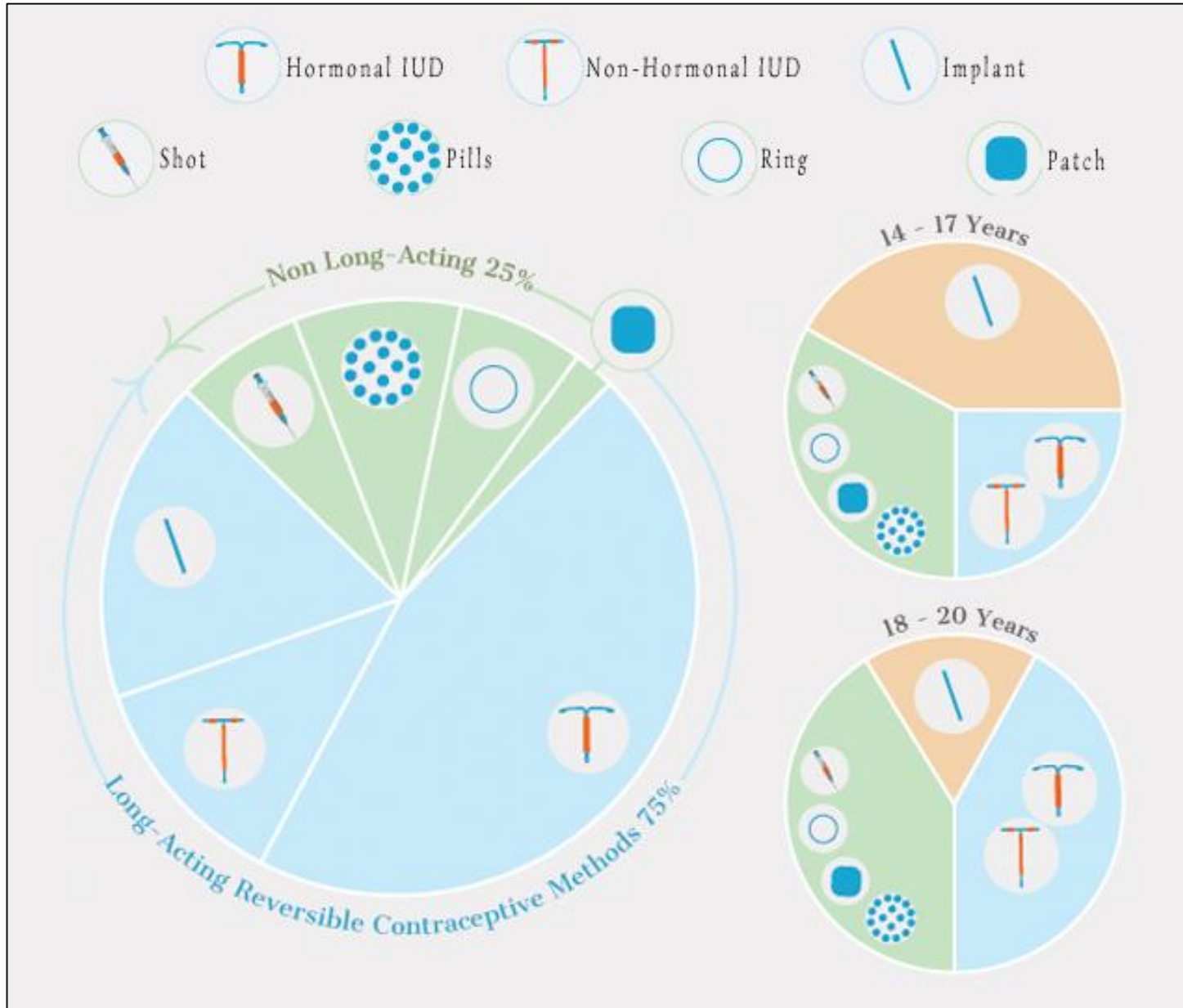
# What's Next with the LNG-IUS?

## 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