



KATHMANDU

25-28 MARCH 2019 / KATHMANDU, NEPAL

**19TH GENERAL MEMBERSHIP MEETING OF THE
REPRODUCTIVE HEALTH SUPPLIES COALITION**



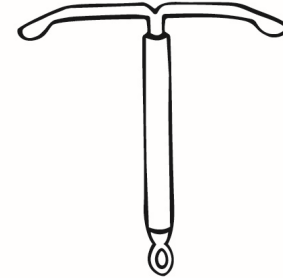
I-U-Me:

Building Markets for Copper IUDs and the LNG-IUS to Meet Diverse Needs

Presentations

- The Why and How of Shaping Markets to Add the LNG-IUS to the Method Mix
 - Ashley Jackson, PSI/WCG
 - Kate Rademacher, FHI 360

- ‘I don’t decide alone’: Understanding Decision-Making Pathways to IUCD Uptake Among Married Men and Women in Nepal
 - Raman Shrestha, MSI Nepal



LEVONORGESTREL
INTRAUTERINE SYSTEM



COPPER INTRAUTERINE
DEVICE



The Why and How of Shaping Markets to Add the LNG-IUS to the Method Mix

Ashley Jackson, Deputy Director of the
EECO Project for PSI/WCG

Kate Rademacher - Project Director,
LEAP LNG-IUS Initiative, FHI 360

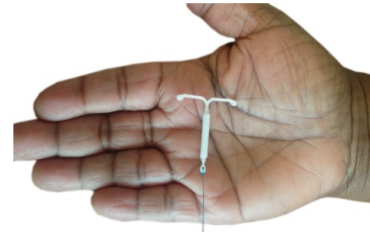
Overview of the levonorgestrel intrauterine system (LNG-IUS)

One of most effective methods; long-acting; rapid return to fertility

Additional non-contraceptive benefits

Popular in countries where available

In several pilots in FP2020 countries, high acceptability and continuation demonstrated



Overview of SRA-Approved LNG-IUS Products

BAYER HEALTHCARE:



Mirena

Mirena™ provided commercially through private healthcare clinics in some developing countries on a very limited basis. Pricing between ~US\$60-\$400 documented in recent market assessments.¹⁻³

ICA FOUNDATION:



LNG-IUS

Public-private partnership between Bayer HealthCare & Population Council. Provides free LNG-IUS product; donated over 125K units since 2005.

MEDICINES360:

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.¹

Overview of Additional LNG-IUS Products

Note: These products are not currently quality assured by a Stringent Regulatory Authority
No LNG-IUS product is currently WHO Prequalified

PREGNA:



Eloira

Pregna, located in India, manufactures the Eloira LNG-IUS. Being registered in several FP2020 countries outside of India.

APCOR R&M:



Femilis

APCOR Research & Manufacturing, located in Belgium, manufactures the Femilis LNG-IUS. Contains 60 mg of LNG with 28 and 24 mm long transverse retention arm. No current registrations.

Meril:



Fiona

Meril, based in India, manufactures the Erinna and Fiona LNG-IUS products (with different inserters). Currently only registered in India.

HLL LIFECARE:



Emily

HLL Lifecare, based in India manufactures the Emily LNG-IUS. The frame shape is modeled after Multiload, which differs from the frames of the other T-shaped LNG-IUS products. Being registered in several countries outside of India.



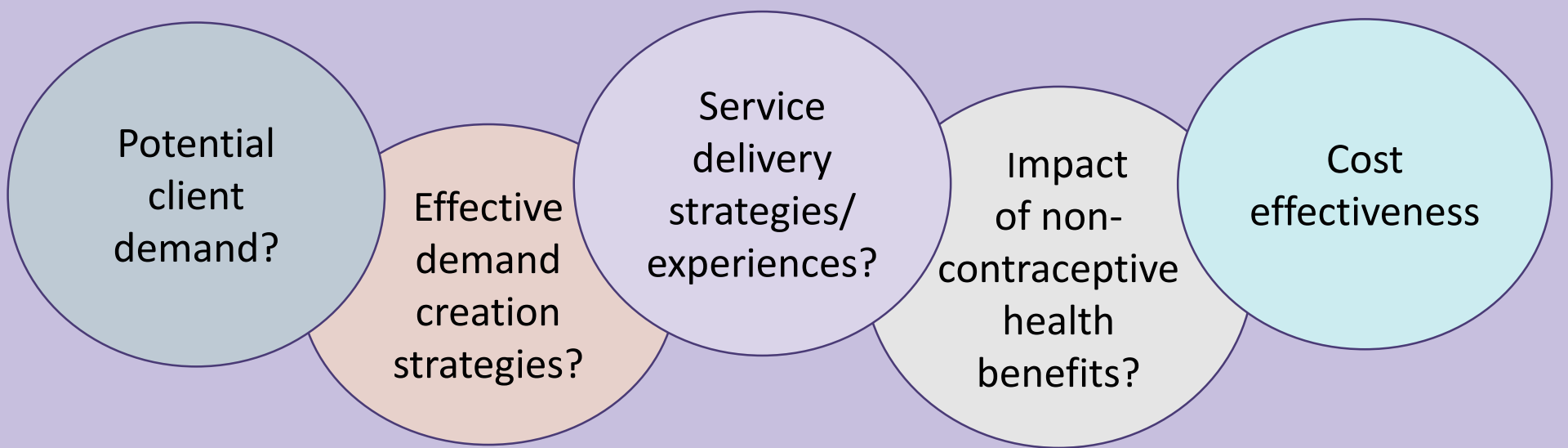
Key questions for the LNG-IUS

- What is the value proposition of adding this method in national family planning programs?
- What can potentially be done to increase the affordability and accessibility of the LNG-IUS for global procurers?



LNG-IUS Global Learning Agenda

- Interagency LNG-IUS Working Group convened by USAID
- Working Group allows for coordination, aligning research approaches, and developing shared learning agenda



Potential client demand?

Effective demand creation strategies?

Service delivery strategies/experiences?

Impact of non-contraceptive health benefits?

Cost effectiveness



EECO product introduction model



STAGE 1
Regulatory
Assessment &
Product Registration



STAGE 2
Consumer & Market
Research



STAGE 3
Procurement &
Quality Assurance



STAGE 4
Marketing,
Distribution &
Service Delivery



STAGE 5
Monitoring &
Learning



Family planning context in Madagascar

- Among modern contraceptive users, what percentage use injectables?
(TrackPF, 2017)
 - a) Nearly half
 - b) Nearly two-thirds

- Where do most copper IUD users access their method?
(DHS, 2009)
 - a) Public sector
 - b) Private/NGO sector



Avibela® LNG-IUS introduction Madagascar



STAGE 1
Regulatory
Assessment
& Product
Registration



In March 2018 through the EECO project, Madagascar became the first country in Africa to approve registration of AVIBELA



Photo credit: ©Evelyn Hockstein/Medicines360

AVIBELA is a registered trademark of Medicines360 in Algeria, Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Cote d'Ivoire, Democratic Republic of Congo, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, India, Kenya, Madagascar, Mali, Mauritania, Morocco, Niger, Nigeria, Pakistan, Senegal, Togo, and Zambia.

Key findings from market research



STAGE 2
Consumer
& Market
Research



1

Mirena available to wealthy clients for \$250

2

Side effects drive discontinuation of many methods

3

LNG-IUS side effect profile is attractive to many potential users

Product positioning



STAGE 2
Consumer
& Market
Research



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™

WCG psi
Management

AVIBELA

With reduced periods,
life is beautiful!

- My modern contraceptive
- My freedom
- My three years of peace
- The solution to my period problems

Procurement



STAGE 3
Procurement
& Quality
Assurance



Introduction model in Madagascar



STAGE 4
Marketing,
Distribution
& Service
Delivery



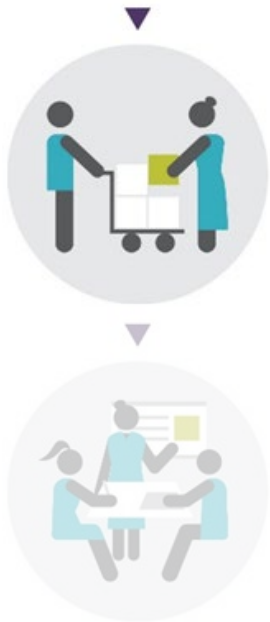
- **24** private providers in PSI's social franchise network
- **10** private providers outside of the franchise

PSI procures
AVIBELA for **\$16**
USD

Providers buy
AVIBELA for **\$15**
USD

Clients pay **\$20-30** USD or use
health insurance

Sales & distribution



STAGE 4
Marketing,
Distribution
& Service
Delivery



Photo credit: ©Evelyn Hockstein/Medicines360

From April 2018 - Mid-March 2019:

228 insertions within
the network

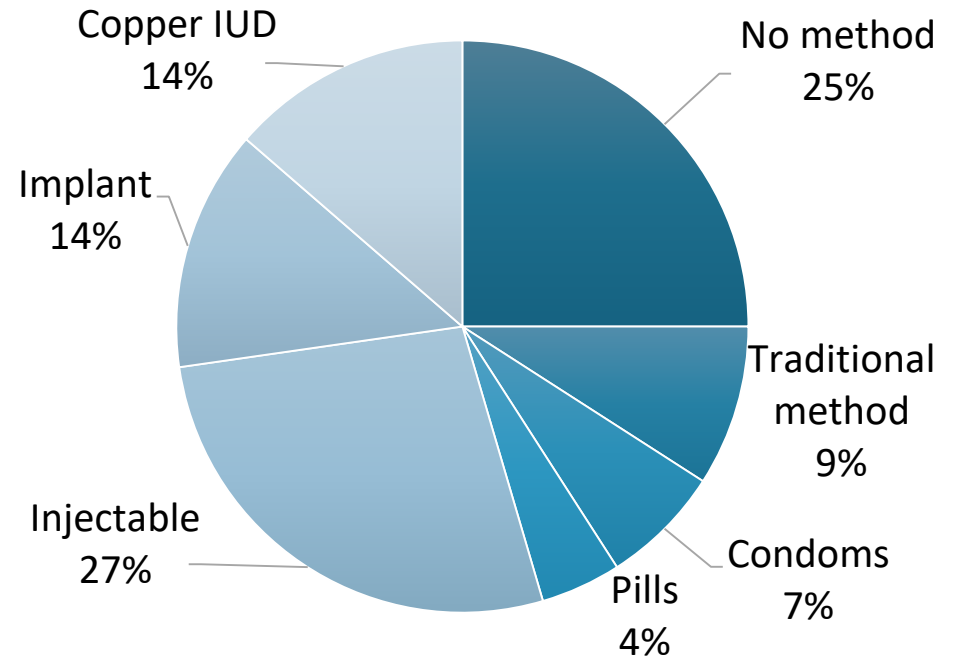
334 units sold to
providers or used
during training

Preliminary findings from client study

“What method would you have chosen if the IUS wasn’t available?” (n=44, one answer per client)

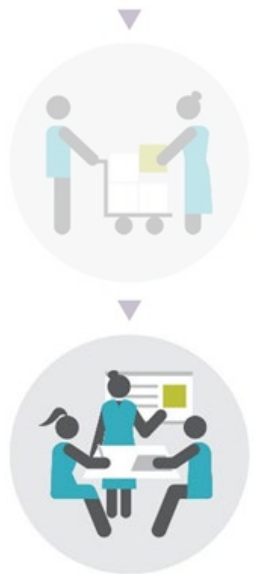


STAGE 5
Monitoring
& Learning



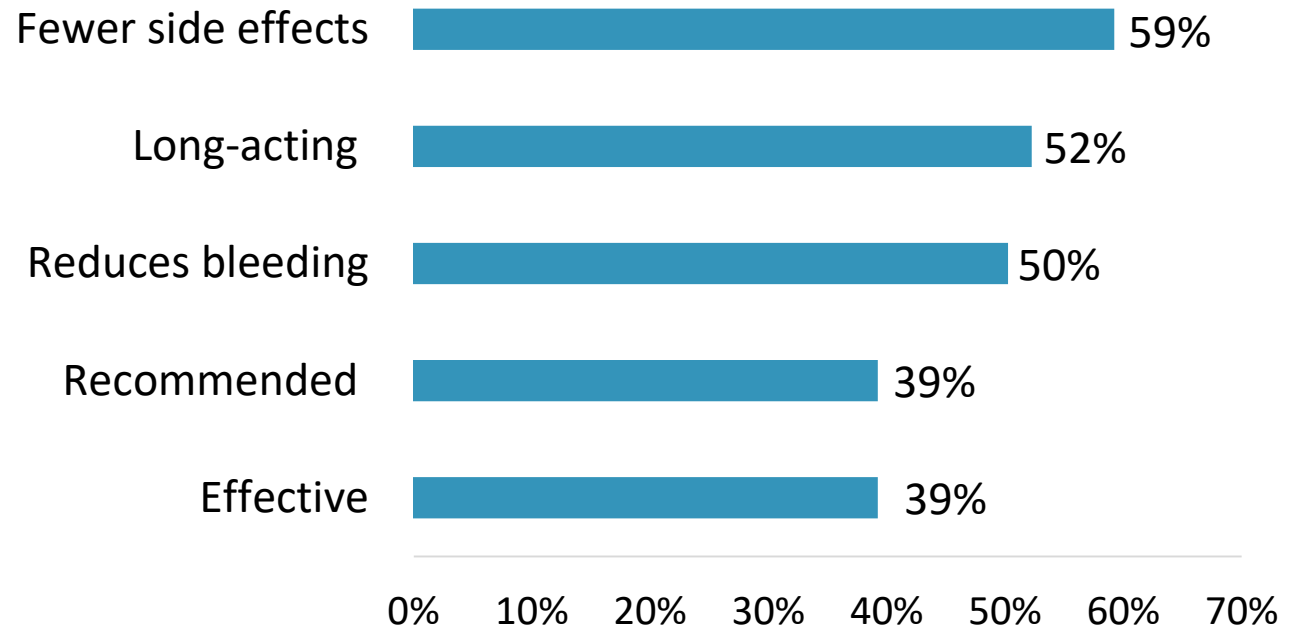
If AVIBELA had not been available on the day of service, **1/3** of users report that they would have chosen a traditional method or no method at all.

Preliminary findings from client study

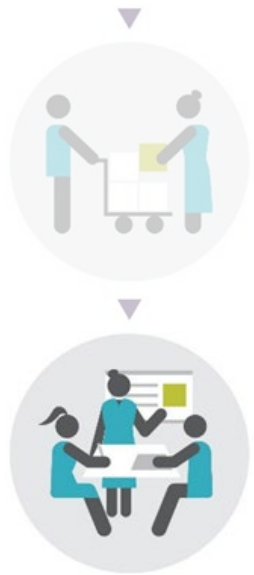


STAGE 5
Monitoring
& Learning

Top 5 responses to “Why did you choose the LNG-IUS?”
(n=44, multiple answers allowed)



Learning from pilot introduction



STAGE 5
Monitoring
& Learning

- Still adjusting the model to strike a balance between equity and sustainability.
- Value propositions that differentiate LNG-IUS from copper IUD and appear to resonate with clients:
 - Manageable side effects
 - Reduced bleeding

LNG-IUS Dashboard

Perspectives of LNG-IUS Users Across Introduction Programs

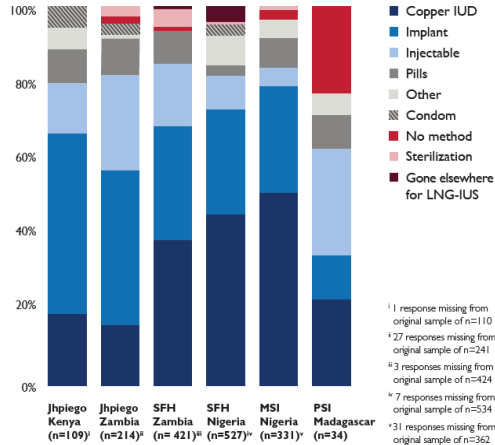
Q. IF THE LNG-IUS HAD NOT BEEN AVAILABLE TODAY, WHAT METHOD, IF ANY, WOULD YOU HAVE CHOSEN INSTEAD?

PILOT INTRODUCTIONS OF THE LEVONORGESTREL INTRAUTERINE SYSTEM (LNG-IUS)



M&E data included here for a sub-set of these countries.

Implementing partners with past or current USAID-funded pilots: MCSP/Jhpiego, Marie Stopes International, Population Services International/Society for Family Health, and WCG Cares. Data collection is ongoing for some programs; this dashboard will be updated periodically.



¹ 1 response missing from original sample of n=110
² 27 responses missing from original sample of n=241
³ 3 responses missing from original sample of n=424
⁴ 7 responses missing from original sample of n=534
⁵ 31 responses missing from original sample of n=342

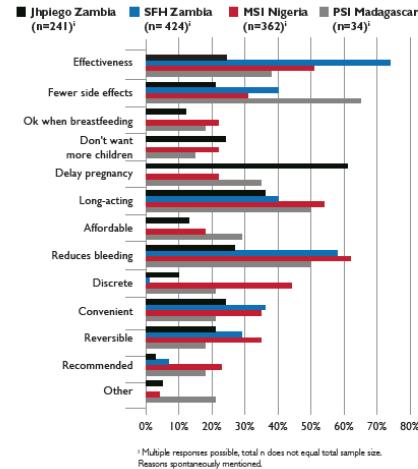
SEPTEMBER 2018



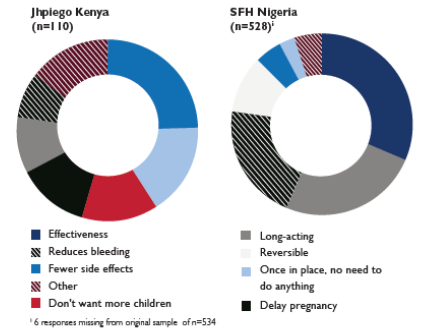
Across almost all countries, the majority of LNG-IUS users report that they would have used another long-acting reversible contraceptive (copper IUD or implants) if the LNG-IUS had not been available. However, a sizable portion in every country would have selected a shorter-acting, less effective method instead.

Q. WHAT REASONS DID YOU CHOSE AN LNG-IUS TODAY INSTEAD OF ANOTHER METHOD?

Q. WHAT WAS THE MAIN REASON YOU CHOSE AN LNG-IUS TODAY INSTEAD OF ANOTHER METHOD?



¹ Multiple responses possible, total n does not equal total sample size. Reasons spontaneously mentioned.



Across most countries, women's top reasons for choosing the LNG-IUS included its effectiveness, long-acting duration, reduced bleeding, and fewer side effects.

Questions were administered by providers to clients who selected the LNG-IUS at the time of provision. Due to challenges in getting all providers to collect the data, questions were only administered to a sub-sample of LNG-IUS users in most cases. As such, the number of respondents does not reflect the full number of LNG-IUS units provided.



Three questions administered across countries/programs:

- Can you briefly tell me the reasons you chose the LNG-IUS today instead of another method?
- If the LNG-IUS had not been available today, what method, if any, would you have chosen instead?
- How did you first find out about the LNG-IUS?



Key questions for the LNG-IUS

- What is the value proposition of adding this method in national family planning programs?
- What can potentially be done to increase the affordability and accessibility of the LNG-IUS for global procurers?



Assessing potential pathways to increase affordability and accessibility

**Goal: Decrease price barriers/ increase access
& evaluate impact**

1

Pathway 1:
Reduce Cost of
Goods Sold (COGS)

2

Pathway 2:
Support alternative supplier(s)
to achieve international QA &
lower COGS/prices

3

Pathway 3:
Incentivize QAed
manufacturer(s) to lower
price (e.g., through market
shaping intervention)

C

Complementary pathways: Increase impact of donated (free) product

LEAP LNG-IUS: Regulatory report



01 - Assessment of applicability of WHO Prequalification & the WHO-Supported Collaborative Procedures for an SRA-approved (US FDA) LNG-IUS product

02 - Assessment of Regional Harmonization Mechanisms

03 - National Regulatory Assessments



‘I don’t decide alone’: Understanding decision-making pathways to IUCD uptake in Nepal

Sabitri Sapkota¹; Deepika Bhatt²; Renu Lama²; Raman Shrestha²

¹ Marie Stopes International, UK; ² Sunaulo Parivar Nepal, Nepal



Background

Why IUCD?

- The 2016 National Demographic and Health Survey (DHS) in Nepal found that half of married Nepalese women and men aged 18 - 49 years did not want more children
- Despite the proven safety, efficacy and reversibility of IUCDs¹, the uptake of this contraceptive method is very low in Nepal, (1.4% according to the 2016 DHS).
- While men may play an important role in contraceptive use very little research to date has examined Nepali men's perspectives about IUCDs and their role in the decision-making process.



Why IUCD?

- Various barriers in IUCD uptake have been identified through quantitative surveys but little qualitative exploration of the decision making process.
- Husbands have an influential role in a couple's decision to use IUCDs (MSI Incite Study, 2014).
- Husbands in Nepal can be barrier to uptake of IUCD due to lack of action, discussion or husband's desire do not match that of the wife. (Kindsley, 2015)



Objectives

- To assess husband's knowledge, perceptions and attitude towards IUCD use.
- To explore the decision making pathway for IUCD uptake among women.
- To examine the role of husbands in IUCD uptake among married women in Nepal.



Methodology

Design: A qualitative formative study

Setting: Five selected districts in Nepal

Timeline: February 2017

Sample: 52 participants: 24 women who were current or previous users of IUCDs and 28 men whose wives were current or previous IUCD users. 12 men were the spouses of women interviewed

Data collection: Semi-structured in-depth interviews. All interviews were recorded and transcribed in Nepali. Transcriptions were later translated into English

Analysis: Thematic content analysis

Study Population and Sample Size

Characteristics of the Respondents	High IUCD District and Centre		Low IUCD District and Centre		Total
	Gangabu, KTM	Dumre, Tanahu	Birtamod, Jhapa	Illam, Illam	
IUCD user women (aged 18-49 years) and are continuing its use	3	3	3	3	12
Women (aged 18-49 years) who had used but removed IUCD [less than 3 months of use from the date of insertion] within last 6 months	3	3	3	3	12
Husband of IUCD users and are continuing its use	3	3	3	3	12
Husband of women (aged 18-49 years) who had used but removed IUCD [less than 3 months of use from the date of insertion] within last 6 months	3	3	3	3	12
Husband of those women who are using FP method other than IUCD	1	1	1	1	4
Total	13	13	13	13	52



Results

We identified an overarching theme of couples taking a ‘trial and error’ approach to finding the right contraceptive method.





Results

1. Building Acceptance

- Misconceptions about IUCDs among men and women
- Women expressed discomfort with pelvic examination
- Limited understanding and information of the method, particularly among men

“What I have heard that after using IUCD there is a chance of getting cancer (uterine). I am afraid of that type of cancer. I am not sure if this is only a rumor or if it will cause this type of cancer in reality” - Client using IUCD



Results

2. Trialing Methods

- Consultative approach between husband and wife (which extended to friends and family) prior to trialling an IUCD
- Often trialled 2–4 other methods before choosing to use an IUCD
- Men interested to know more about IUCDs

“We had used pills and pills didn't work properly for us We then used Depo (injectable) and because of that she got fat and also menstruation was not regular.then we used IUCD. After using IUCD most of things are good now and only a few things is not good”
- Husband of a woman using IUCD




Results

3. 'Challenges to Continuation'

- Longer periods of bleeding/spotting
- Longer period of exclusion from religious functions
- Compromised sexual pleasure as men talked about feeling IUCD thread during intercourse
- Men's concern for their wife's health

“In our Brahman community, women get pure after 4 days of menstruation. If bleeding is seen after 4th day then there will be difficulty to do puja (religious functions)”- Woman using IUCD

Next steps

- Both men's and women's concerns about IUCD usage must be addressed to build acceptance and address challenges to continuation of IUCD use.
- 
- Men's role in supporting women to make the right contraceptive choice for them from an initial stage of building acceptance can be facilitated by directing educational and counselling interventions towards women, men and couples.

Group discussion



In this session, we've explored potential supply-side and demand-side solutions to increasing access to both the LNG-IUS and the copper IUD.

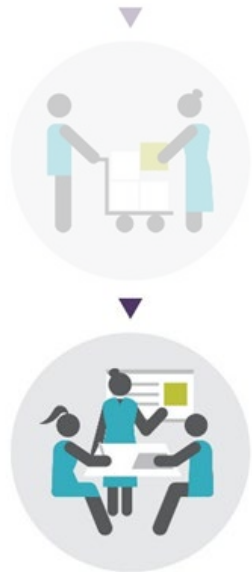
Questions:

- In the country or setting where you work, which of these potential solutions seem most relevant?
- What other strategies are needed to increase access, affordability and/or demand that were not addressed today?



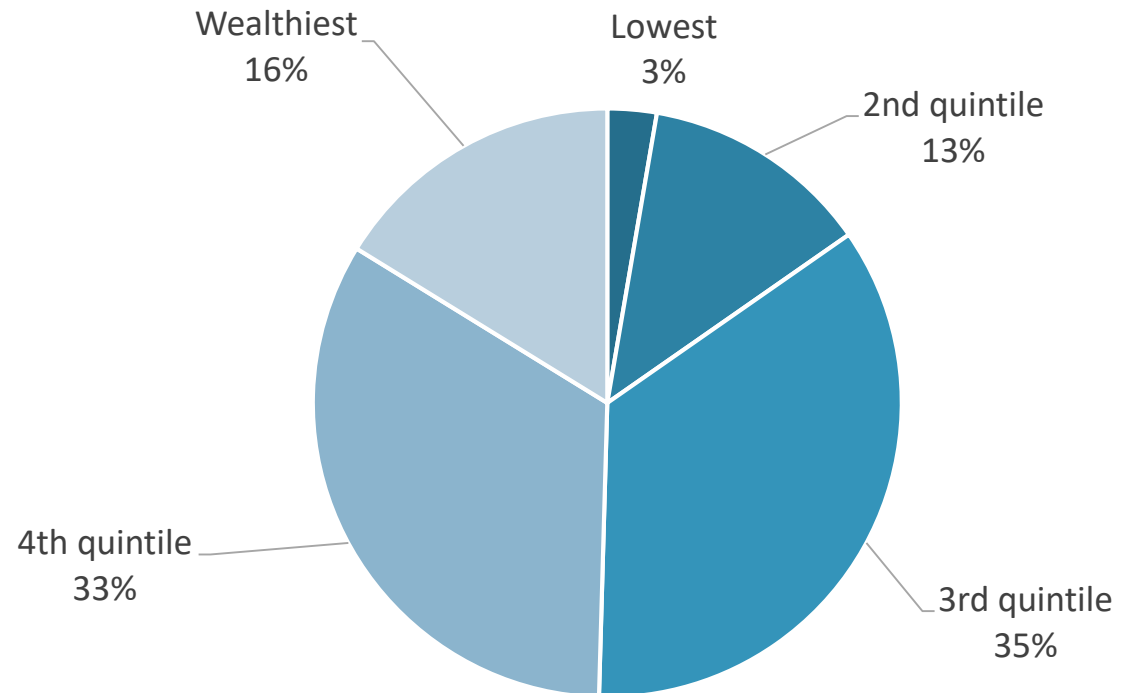
Additional optional slides to show
during Q&A if these topics arise

Preliminary findings from client study



STAGE 5
Monitoring
& Learning

Urban wealth quintiles of clients (n=44)



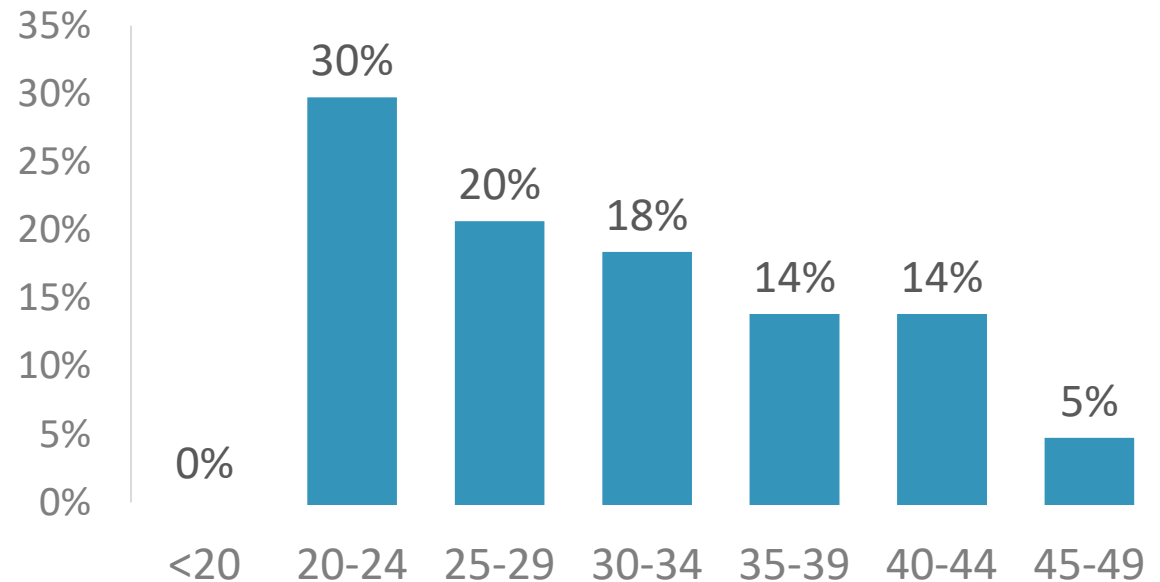
In addition, most clients have at least a secondary school education.
However, **25% have a primary school education or less.**

Preliminary findings from client study



STAGE 5
Monitoring
& Learning

Age distribution of LNG-IUS clients (n=44)



Of the study participants so far, **half have been under 30 years old.**