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EXPANDING EFFECTIVE CONTRACEPTIVE OPTIONS:

Lessons Learned from the Introduction of the Levonorgestrel Intrauterine System (LNG-IUS) in Zambia and Madagascar

USAID FROM THE AMERICAN PEOPLE

EECO Expanding Effective Contraceptive Options

WCG EMPOWER EDUCATE ENABLE

psi Healthy lives. Measurable results.

SFH zambia Society for Family Health Better Choices. Healthier Lives.

Acronyms

CBD	Community-based distributor
CSL	Commodities Security and Logistics
CYP	Couple Years of Protection
E1M	Every1Mobile
EECO	Expanding Effective Contraceptive Options
FP	Family Planning
FSW	Female Sex Workers
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICRW	International Center for Research on Women
IPC	Interpersonal Communication
IPA	Innovations for Poverty Action
IRB	Institutional Review Board
ISO	International Organization for Standardization
IUD	Intrauterine Device
KOL	Key Opinion Leader
LARC	Long-Acting Reversible Contraception
LNG-IUS	Levonorgestrel Intrauterine System
MAH	Marketing Authorization Holder
MOH	Ministry of Health
OC	Oral Contraceptive
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PSI	Population Services International
QA	Quality Assurance
SFH	Society for Family Health
SRA	Stringent Regulatory Authority
STI	Sexually Transmitted Infection
TMA	Total Market Approach
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WCG	WCG Cares
WHO	World Health Organization
ZAMRA	Zambia Medicines Regulatory Authority

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Introduction

UNMET NEED FOR CONTRACEPTION

214 million women in developing countries do not wish to become pregnant yet are not using a modern method of family planning (FP).[i] Top method-related reasons for non-use of modern contraceptives include contraceptive side effects, infrequent sex, a need for discreet methods and methods compatible with breastfeeding. Studies suggest that the critical factors for meeting women's contraceptive needs are access to a broad choice of methods, improvement in the quality of information and services available, a consistent supply of contraceptive products, and the reduction of social barriers to use.[ii]

EXPANDING EFFECTIVE CONTRACEPTIVE OPTIONS (EECO)

Expanding Effective Contraceptive Options (EECO) is a USAID project with funding from 2013-2022 that supports the introduction of new contraceptive options, like the SILCS diaphragm, and dual protection methods, like the women's condom. Each product in the EECO portfolio is designed to address one or more method-related reasons for non-use of contraception. Among these methods is the Levonorgestrel Intrauterine System (LNG-IUS)[5], a contraceptive option with a side effect profile that differs from other methods and may appeal to women seeking reduced menstrual bleeding.

EECO conducts pilot introductions of new contraceptive products, like the LNG-IUS, in countries that have high levels of unmet need for contraception such as Madagascar, Malawi, Niger, Nigeria, and Zambia. By the project's end, EECO will have produced step-by-step roadmaps for product introduction which can be used to scale up access to the products or expand introduction to additional countries.

This program brief focuses on the lessons learned through each stage of the project's pilot introductions of the LNG-IUS in Zambia and Madagascar from 2016 to 2018.

THE EECO TEAM SUPPORTING LNG-IUS INTRODUCTIONS

WCG Cares (WCG) leads the team, bridging the private sector and non-profit worlds, and linking upstream product developers/suppliers and downstream marketing and distribution partners. WCG leads regulatory and quality assurance efforts, intensive medical detailing and data collection.

Population Services International (PSI), the social marketing and service delivery partner, works through existing healthcare and product distribution networks to market EECO products. In Zambia, PSI works through its local network member, the **Society for Family Health**.

EECO PROCESS

EECO introduces new and innovative contraceptive products by collaborating with market players along the supply chain from product manufacturers to providers and clients, as well as the stakeholders who influence the policy environment for FP. EECO product introduction takes place in five stages, which are outlined in Figure 1.

[5] For the purposes of this program brief, "LNG-IUS" refers specifically to the 52 mg LNG-IUS product, such as Mirena™, Liletta™ and Avibela™. Other products exist that are also levonorgestrel releasing intrauterine devices, such as Skyla™, which contains 13.5 mg of levonorgestrel, however these products are not being discussed in this paper.

Figure 1. **EECO PRODUCT INTRODUCTION STAGES**

STAGE 1

Regulatory Assessment & Product Registration

- Perform regulatory landscape assessment
- Engage stakeholders and meet with regulatory authorities
- Support identification of a suitable market authorization holder
- Prepare the registration package, submit and support its lifecycle upon approval

STAGE 2

Consumer & Market Research

- Plan and conduct market research
- Complete market segmentation analysis
- Determine pricing and branding strategies

STAGE 3

Procurement & Quality Assurance

- Perform manufacturer audits
- Initiate pre-shipment inspection and testing of product
- Develop and initiate pharmacovigilance systems

STAGE 4

Marketing, Distribution & Service Delivery

- Launch product, with marketing and communications support
- Supply stock to commercial outlets and providers
- Deploy medical detailers to train and follow-up with providers

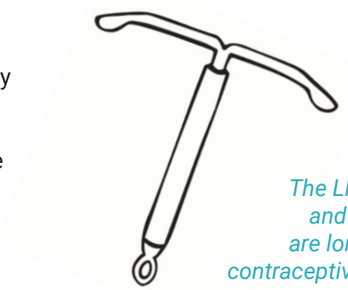
STAGE 5

Monitoring & Learning

- Monitor and course-correct
- Conduct baseline and endline evaluations
- Disseminate lessons learned

The Levonorgestrel Intrauterine System (LNG-IUS)[6]

The LNG-IUS is a small, T-shaped device that, like the copper IUD, is inserted into the uterus by a trained healthcare provider. However, unlike the copper intrauterine device (IUD), the LNG-IUS releases a low, steady dose of the hormone levonorgestrel (LNG) directly into the uterus. LNG is a progestin hormone also used in some contraceptive implants and oral contraceptive (OC) pills.



The LNG-IUS, copper IUD, and hormonal implants are long-acting reversible contraceptive (LARC) methods.

CHARACTERISTICS OF THE LNG-IUS

- **Highly effective**
  - Fewer than 1 pregnancy per 100 women using an LNG-IUS over the first year (2 per 1,000 women).[iii]
- **Long-acting**
  - LNG-IUS is approved for up to 5 years of use (depending on the country), and there is evidence that it could be effective for up to 7 years.[iv]
- **Reversible at any time,** with no delay in the return of fertility[v]
  - However, a client should not discontinue use of the LNG-IUS or any Long-Acting Reversible Contraception (LARC) on her own; the method should be removed by a trained provider.
- **High rates of user satisfaction and continuation**[vi]
- **Safe for women** living with HIV, breastfeeding women, nulliparous women, and adolescents[vii]
- **Easy to maintain,** requiring no routine action by the client
- Menstrual bleeding changes are common and safe, and may be viewed as a **benefit by the user**
  - Typically, women experience lighter and fewer days of bleeding, or infrequent or irregular bleeding. At least 15% of women will experience amenorrhea (the absence of 3 menstrual periods in a row). Likelihood of amenorrhea varies depending on several factors, including the heaviness of the user's menstrual bleeding prior to insertion.[viii]

The LNG-IUS delivers a small but steady dose of LNG directly into the uterus. This lower dose leads to fewer peaks in the hormone levels in a woman's system. For some women, **lower levels of hormones** can make the side effects of the LNG-IUS easier to tolerate than those of other hormonal methods.[ix]

The LNG-IUS also has therapeutic indications, meaning it can be provided for women who are seeking non-contraceptive health benefits in addition to contraception (see below). At the same time, the LNG-IUS is a contraceptive product that must be inserted into the uterus and removed by a trained healthcare provider. Figure 2 summarizes the known health benefits and risks associated with the LNG-IUS.

[6] Drawing not to scale.

Figure 2. **KNOWN HEALTH BENEFITS AND KNOWN HEALTH RISKS OF THE LNG-IUS**

KNOWN HEALTH BENEFITS	KNOWN HEALTH RISKS
Helps protect against: • Risks of Pregnancy • Iron Deficiency Anemia **May help protect against:** • Endometrial cancer • Cervical cancer **Reduces:** • Menstrual cramps • Heavy monthly bleeding • Symptoms of endometriosis (pelvic pain, irregular bleeding) • Risk of ectopic pregnancy	Expulsion of the LNG-IUS, if not detected, could leave the user unprotected from pregnancy. **Rare:** • In the short term, Pelvic Inflammatory Disease may occur if the woman has gonorrhea or chlamydia at the time of insertion. • If inserted incorrectly, the LNG-IUS or an insertion instrument may puncture (or perforate) the wall of the uterus. Puncture/ perforation usually heals without treatment.

KEY LEARNING QUESTIONS FOR LNG-IUS PILOT

Introduction of the LNG-IUS has been shown to reinvigorate interest in intrauterine methods of contraception in the United States market, in part due to high customer satisfaction rates and the product's appeal to new and different users (like youth and nulliparous women) who may be attracted to both the contraceptive efficacy and therapeutic benefits.[x] It is worthwhile to explore whether introduction of the product could have the same effect in developing markets, where method choice for women is much narrower and access is lacking. With limited access to regular care, the convenience, ease of use, and efficacy may be particularly important to women in low-resource settings.

There are clear challenges to the introduction of the LNG-IUS in these target markets, including the high cost of the method relative to the non-hormonal copper IUD, service delivery barriers that affect the uptake of provider-dependent methods, and the need for tailored demand creation to address misconceptions and concerns.[xi] It is important to explore how the introduction of the LNG-IUS might overcome these barriers and help to reinvigorate the approach to demand creation among clients and providers.

The EECO pilots, along with similar studies being carried out in Nigeria and Zimbabwe with funding from USAID, aim to answer the following key questions:

- What are the profiles of women who choose this method?
- Why are women choosing the LNG-IUS method over other available contraceptive options?
- What is the user experience with the LNG-IUS in these contexts?
- What are the continuation and satisfaction rates with the LNG-IUS in these contexts?
- If this LNG-IUS were not available, what would women choose instead?
- What are provider perceptions of the LNG-IUS in these contexts, and how do these change over time?

More on the EECO service delivery pilots and research methodology will be discussed later, in the descriptions of Stages 4 and 5.

LNG-IUS PRODUCTS WITH INTERNATIONAL DISTRIBUTION

Of the various LNG-IUS products that exist with approval from a Stringent Regulatory Authority (SRA)[7], three currently have the potential for international market development through USAID programs. Several other LNG-IUS products exist and are available outside the US, however, these do not yet have approval by an SRA, which is required for procurement by USAID and the United Nations Population Fund (UNFPA).

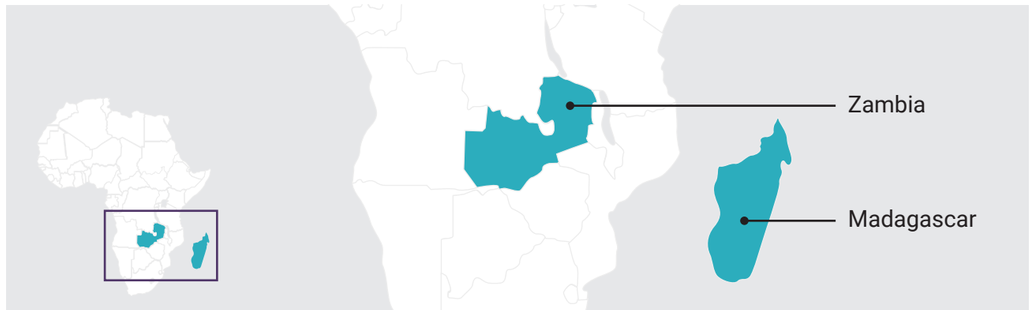
Figure 3. **LNG-IUS PRODUCTS WITH APPROVAL BY AN SRA**

Supplier	Product/ Brand	Price and availability in developing markets
Bayer Healthcare *A private pharmaceutical company that supplies LNG-IUS products to the US and global markets*	Mirena®	Currently available in some developing country markets for a price that can range from $60-400.[xii, xiii, xiv, xv]
International Contraceptive Access (ICA) Foundation: *A public-private partnership between Bayer Healthcare and the Population Council*	Unbranded LNG-IUS	Over 120,000 units of the LNG-IUS have been donated to recipients in over 35 countries. The product is free and cannot be sold to clients.[8] The product is made available upon request by a service delivery organization.
Allergan and Medicines360: *A nonprofit pharmaceutical company which brings the LNG-IUS product to market in areas where women lack access*	Liletta® /Avibela®[9]	In the U.S., LILETTA is available for $50 for clinics enrolled in the 340B Drug Pricing Program and has a current wholesale acquisition cost of $684.38. The product is approved in 30 other countries under various trade names.[10] Medicines360 has exclusive marketing and distribution rights to this product (under the trade name AVIBELA) in 88 countries throughout Africa, Central America, and Asia, including in 22 out of 24 USAID FP priority countries (including Madagascar and Zambia).

Though the commercially available LNG-IUS products above have a higher upfront cost to the client and the provider, a cost analysis by FHI 360 in Kenya showed that, with the LNG-IUS at a price point of $15, the direct service delivery cost per couple years protection (CYP) compares favorably with that of other contraceptive methods such as OC pills and injectable contraceptives.[xvi] Though the upfront cost of the product and service delivery is generally higher than other methods, the method is equally if not more cost effective over time than other methods that are commonly used in these contexts.

[7] e.g. the U.S. Food & Drug Administration or the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA)
[8] Providers are allowed to charge up to $10 USD for costs associated with insertion and removal, such as the cost of consumables.
[9] 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.
[10] Levosert®, Mireffik™, Benilexa™, Donasert™, Levonortis™, and Tresovelle™

Focus Country Context



ZAMBIA[xvii]

Modern Contraceptive Prevalence Rate (all women).....**32.5%**

Unmet need (all women of reproductive age).....**21%**

Demand met with modern contraception.....**64%**

MADAGASCAR[xviii]

Modern Contraceptive Prevalence Rate (all women).....**33%**

Unmet need (all women of reproductive age).....**16%**

Demand met with modern contraception.....**61%**[xix]

Figure 4. **MODERN CONTRACEPTIVE USE AND NEED**

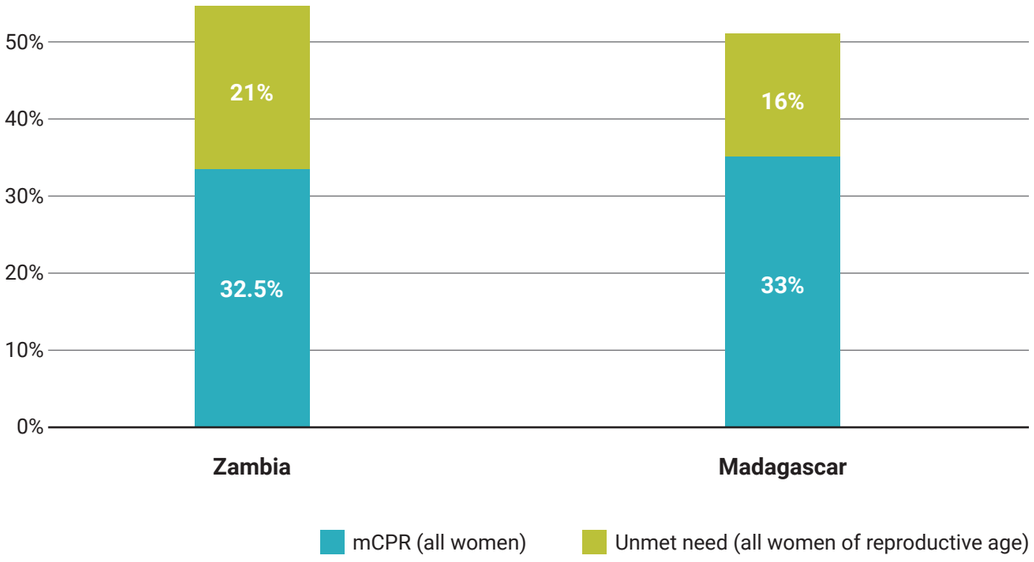


Figure 5. **METHOD MIX IN ZAMBIA**

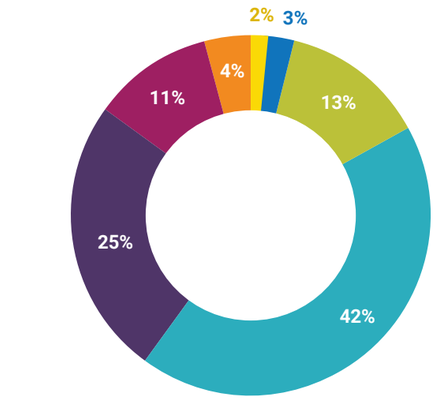
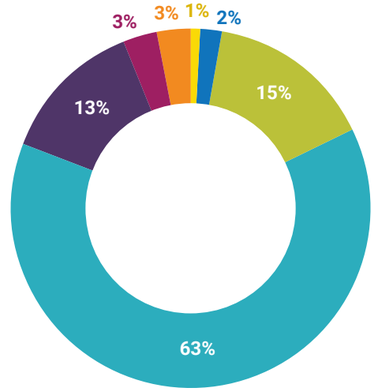


Figure 6. **METHOD MIX IN MADAGASCAR**



LAM IUD Implant Injection Pills Condoms Sterilization

Injectables are the most common method of contraception in both countries.

LNG-IUS PRODUCTS INTRODUCED THROUGH EECO

Zambia

In Zambia, the EECO project makes the LNG-IUS available through the public sector which is the largest source of contraceptive access in the country. The ICA Foundation has donated its generic product to EECO-supported facilities since 2017. In 2018, EECO worked with Medicines360, which offers the lowest cost SRA-approved LNG-IUS that can be commercialized, to register AVIBELA LNG-IUS in Zambia. EECO is procuring AVIBELA directly from Medicines360 since this product is not yet in the catalog for donations by USAID or UNFPA.

EECO-supported public facilities in Zambia will begin offering AVIBELA in early 2019. EECO will offer on-site training on AVIBELA to providers already trained and certified to offer the ICA Foundation product. The two products offer the same contraceptive and therapeutic benefits, and with similar insertion procedures for each product, it is simple for providers trained in LNG-IUS insertion and removal to offer either the ICA foundation product or AVIBELA. The introduction of AVIBELA will contribute to a consistent supply of the LNG-IUS in Zambia over the long term without a need for special import permits. In the future, private facilities that charge clients a fee for products could also offer AVIBELA in Zambia as part of a total market approach.

Madagascar

In Madagascar, EECO offers the AVIBELA LNG-IUS through the private sector. EECO is testing a partial cost recovery strategy that may facilitate the development of a financially sustainable market for this product.

Five Stages of LNG-IUS Introduction

STAGE 1
Regulatory Assessment & Product Registration

The objective for the first stage of the EECO road-map is to register the new product in each focus country.

LNG-IUS REGISTRATION HIGHLIGHTS

- EECO supported Medicines360 to register their AVIBELA LNG-IUS in both Madagascar and Zambia in 2017, with approvals granted in 2018. These were the first two registrations of Medicines360's product in Africa.
- The ICA Foundation product is not intended for large-scale product introduction, and it does not register its LNG-IUS product with national regulatory authorities unless required and supported by the ICA Foundation and Bayer. Instead, a waiver must be secured prior to each importation. EECO's regulatory team secured waivers for two donations of the ICA Foundation LNG-IUS in Zambia through the Zambia Medicines Regulatory Authority (ZAMRA).

REGULATORY LANDSCAPE ASSESSMENT

Although the regulatory process in the U.S. is complex, information is readily available. In developing countries, however, regulatory policies and guidelines can be difficult to obtain from online resources, challenging to navigate, and vary from one country to the next. WCG led a regulatory landscape assessment in Zambia and Madagascar to determine:

- the most efficient pathway for product registration of AVIBELA in these countries,
- the steps and documents required to complete the product registration,
- an appropriate partner to serve as the Marketing Authorization Holder (MAH),
- possible distributors of the product.

Figure 7. **EECO REGISTRATION STEPS**

First, WCG conducted a desk review of resources available from the country regulatory authorities. Using this, as well as the available global standards, WCG developed country-specific questionnaires.

Next, WCG used the questionnaire to guide interviews with authorities and other stakeholders in each country. Interview participants included, among others:

- National Regulatory Authority,
- other stakeholders at the Ministry of Health (MoH),
- national associations of obstetricians and gynecologists.

WCG then wrote a landscape assessment report based on information from each country and submitted it to the AVIBELA product supplier, Medicines360. WCG and Medicines360 collaborated to develop the registration package and submit it for approval by the National Regulatory Authority.

SELECTION OF THE MARKETING AUTHORIZATION HOLDER (MAH)

The local regulatory body grants the MAH (i.e., the product license holder) approval to market a medicinal product for a given period (five years in Zambia and Madagascar). In some countries, the MAH must be a local entity while in others, it can be a foreign supplier or manufacturer. The MAH is responsible for compliance with the conditions of the market authorization, including pharmacovigilance and documentation of adverse events within the legislative framework of the registration. To facilitate the selection of the MAH, WCG identifies potential local partners that meet the minimum requirements identified during the regulatory landscape assessment (i.e., mandatory registration or licensing specifications). WCG then meets with each of these potential partners to assess their interest and capacity to serve as the MAH, and requests that they complete a standardized questionnaire. Based on this series of meetings and responses to the questionnaire, EECO submits a recommendation for the MAH to the product supplier. Ultimately, the supplier selects the MAH and establishes a distribution agreement and procedures for adverse event reporting.

Medicines360 selected PSI/Madagascar as the MAH and distributor for AVIBELA in Madagascar and PSI's local affiliate, the Society for Family Health (SFH), as the MAH and distributor of AVIBELA in Zambia.

A regulatory challenge with the LNG-IUS is that the method is considered a "combination product" (both a medical device and a drug). Determining the appropriate classification of the product required research and consultation with the National Regulatory Authority in each country. In the case of Zambia and Madagascar, the landscape assessments revealed that it should be registered as a pharmaceutical product (drug).

REGISTRATION TIMELINES

Zambia

- Date of AVIBELA registration approval: April 2018
- Length of time from initiating regulatory assessment to securing approval: 15 months
  - *Note: EECO worked on other stages of introduction concurrently.*
- Indications for use approved in this country: contraception and treatment of menorrhagia (heavy menstrual bleeding) for up to three years

Madagascar

- Date of AVIBELA registration approval: March 2018
- Length of time from initiating regulatory assessment to securing approval: 13 months
  - *Note: EECO worked on other stages of introduction concurrently.*
- Indications for use approved in this country: contraception and treatment of menorrhagia for up to three years

STAGE 2

Consumer & Market Research

To better understand consumer needs and perceptions of a new product, the EECO team carries out consumer and market research in focus countries. This research allows the team to develop strategic priorities and marketing plans as well as identify potential barriers to a successful introduction.

ZAMBIA

In Zambia, in collaboration with FHI 360 under their Contraceptive Technology Innovation Initiative, a preliminary market assessment for the LNG-IUS was carried out in 2016. By analyzing the reproductive health landscape, including the current market for copper IUDs as well as interviews with key opinion leaders (KOLs) and potential users, the market assessment found:[xx]

- Menstrual changes matter to women for multiple reasons—from misconceptions and concerns to preferences and needs.
  - Many potential users had the perception that normal monthly bleeding is important for women and were concerned about methods like the LNG-IUS that can cause amenorrhea.
  - Providers also identified that bleeding changes were among the side effects that women sometimes found problematic.
  - Despite these concerns around bleeding changes, providers still identified "decreased bleeding" as being among the main advantages of this method for women.
  - Providers and KOLs agreed that myths and misconceptions are a major barrier to uptake of the copper IUD and that demand creation/ education is essential.
- KOLs were familiar with the LNG-IUS and perceived that it has important advantages, including that it is a highly effective method with additional non-contraceptive benefits.
  - All providers indicated that they would be willing to offer the product.
  - Providers expected to see demand if the product were affordable.

SFH's programmatic experience showed that voluntary uptake of contraception among young women and women of lower parity increases through dedicated provider strategies.[11, xxi]

MADAGASCAR

EECO carried out formative research in Madagascar through focus group discussions with potential users and interviews with potential providers. Highlights of the formative market assessment included:[xxii]

- There is high unmet need for FP in Madagascar among urban, educated women.
  - Madagascar DHS data show that, contrary to what might be expected, women with a higher level of education seem less likely than their less educated counterparts to use a modern method of contraception.[xxiii]
  - Side effects have a major impact on method choice and discontinuation.
  - Women are choosing methods that offer limited side effects, or they are discontinuing a method because they are dissatisfied with the side effects (such as reported stomach pain or hair loss).
- While less bleeding is considered a positive, no bleeding can be seen as unnatural.
  - Women who responded that less bleeding would be positive cited the expense associated with menstrual products, ability to return to work, and regular sexual activity not being interrupted by menstruation as reasons they found this product appealing.
  - Women are concerned about using a hormonal method of contraception.
    - Respondents report fear of uterine cancer, unnatural bleeding patterns, and changes in their fertility.
- At an average price of $250 per insertion, the cost is so great that even women of a higher socio-economic status were not aware of MIRENA.
- The three-year duration of AVIBELA[12] is seen as ideal for spacing births, as opposed to limiting future pregnancies.
- Providers were enthusiastic about adding AVIBELA to expand the method mix for their clients.

As a result of this assessment, the EECO team chose to focus on reaching urban, educated, professional women in Madagascar for the launch of AVIBELA. These women not only have a high unmet need, but also expressed a willingness to pay for the method that would allow EECO to pilot a partial cost recovery strategy. In Zambia, where the product will be provided for free in the public sector, demand generation will target urban spacers.

In both Zambia and Madagascar, these preliminary findings informed EECO's strategic priorities for marketing and service delivery. The research helped to segment clients and frame the key messages for clients in each context. The marketing and service delivery strategies for both countries are discussed in Stage 4.

[11] Dedicated LARC providers were employed by SFH and seconded to public sector clinics starting in 2008. Evaluation showed over 30K clients served in a 14-month period; successful at reaching young women and women of lower parity.
[12] Indicated duration of use in Zambia and Madagascar will be updated as the data from the Medicines 360 clinical trial is available.

STAGE 3
Procurement & Quality Assurance

From 2017-2018, EECO received donations of the ICA Foundation LNG-IUS for Zambia and procured the AVIBELA LNG-IUS for both Madagascar and Zambia.

EECO LNG-IUS PROCUREMENT: 2017-2018

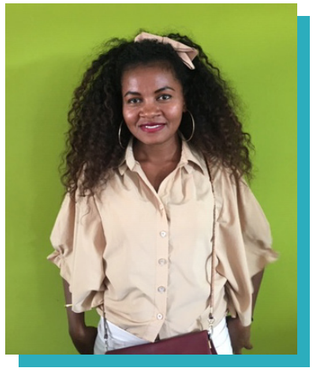
- Over 1000 units of the ICA Foundation LNG-IUS received for SFH Zambia
- 1600 units of AVIBELA procured for Zambia, for 2019 delivery
- 3500 units of AVIBELA procured for Madagascar

In 2018, WCG conducted a successful quality assurance (QA) audit of the AVIBELA manufacturing site, Odyssea, to confirm compliance with Good Manufacturing Practices (GMP). The audit is an evaluation of the effectiveness of the manufacturer's quality management system as well as their procedures and records and involves a sampling of relevant areas including manufacturing procedures, storage, release, and distribution of the product. No major observations were found, and WCG verified that Odyssea has established a GMP-compliant quality management system. WCG conducts QA activities to verify that any manufactured product provided through EECO is safe and effective for use. For AVIBELA, WCG reviews inspection reports from the U.S. FDA and the regulatory authority in Belgium, where the product is manufactured. WCG receives analytical testing results (Certificate of Analysis) and a Certificate of Compliance from the manufacturer before approving the QA release. This process is required before the supplier can ship the product to the MAH in each country.

In developing country markets, there are QA risks to mitigate that are less of a concern when registering a product in the US. In Madagascar, for example, there are concerns that counterfeit products with false labeling that imitates the labels of quality assured products will be sold, and also concerns about alteration of labeling of genuine products (e.g., false extension of expiration dating). WCG was asked by the national regulatory authority to ensure the integrity of the labeling during the registration

process in Madagascar, showing that the ink used on the label of AVIBELA is non-soluble and, therefore, cannot be erased from the packaging.

Stage 3, from the initiation of a purchase order to the receipt of AVIBELA in country, took approximately 7 months in Madagascar for the project's first order. Medicines360 is working with the manufacturer to shorten the time needed for procurement for the project's future orders.



The stories of real, individual clients can help us make sense of these numbers. This is Honorina, a young Malagasy woman studying to become a seamstress. Honorina wants to protect herself from getting pregnant until she is ready. Honorina stopped using injectables because it was too tough to make it to the clinic every three months. She used the rhythm method but worried that the method didn't provide enough protection. Honorina tried using implants too but was dissatisfied because the method prolonged her menstrual bleeding.

In August, a family planning educator told her about the range of methods and described how AVIBELA can address heavy periods, which attracted Honorina to the method. "At first I was afraid to have something inside of my uterus, but now my period is regular again and I feel healthier," she said. Now, Honorina can continue her studies without the stress of getting pregnant.

Approval was provided for the use of all photographs, stories, and names in this paper.

STAGE 4
Marketing, Distribution & Service Delivery

EECO introduced the LNG-IUS in Zambia and Madagascar through PSI's existing service delivery networks. PSI/Madagascar and SFH Zambia trained providers in high quality LNG-IUS counseling and services, within the context of broad FP method choice, and supported them with mentoring to achieve MoH certification in the insertion and removal of the LNG-IUS. To achieve certification, providers must demonstrate competency and must perform a minimum number of successful insertions, generally between 3-5, under supervision by an expert. After certification, providers continue to receive regular supervision to assure the quality of services. Interpersonal Communication (IPC) Agents generate demand for services in communities around these providers' facilities. PSI's local network members act as the product distributor, assisting providers to forecast their product needs and ensuring consistent supply is available.

ZAMBIA

In Zambia, PSI's network member SFH has offered the generic ICA Foundation LNG-IUS since mid-2017 through the public sector. The public facilities selected for the EECO LNG-IUS pilot also receive broader FP technical assistance from SFH through the USAID bilateral project, the Sexual and Reproductive Health for All Initiative (SARAI).

While registering AVIBELA in Zambia, EECO initiated LNG-IUS services with the unbranded product donated by the ICA Foundation. Once AVIBELA registration was completed, EECO placed an order that is expected to arrive in Zambia in early 2019. At the public facilities involved in EECO, all contraceptive methods are provided for free to the consumer, as will be AVIBELA, with the costs of the product currently borne by the donor.

As of September 2018, SFH trained 65 providers at 30 facilities to add LNG-IUS services to the range of FP methods available. These facilities were chosen based on the existing client load and the competency of providers to deliver other high quality LARC services. The team identified providers who were already competent and confident in IUD provision to help mitigate the risk of provider-linked service delivery barriers. SFH is also employing a model where additional dedicated IUS providers are seconded to facilities to meet increased demand.

From May 2017 through October 2018, SFH Zambia distributed 773 LNG-IUS products to facilities. Of those, 698 have been provided to clients.

105 Number of providers trained*

30 Number of facilities offering the LNG-IUS

698 Number of LNG-IUS inserted at EECO facilities

** In 2017, EECO trained 65 providers. Due to provider attrition (14 moving to different parts of the country), EECO trained an additional 40 providers in 2018.*

In Zambia, Community-based Distributors (CBDs) supported by the MOH provide health education and some short-term FP methods to communities. SFH in Zambia has trained CBDs around facilities that offer the LNG-IUS to offer comprehensive FP education and referrals to trained providers. Radio programs and printed materials also raise awareness about the full range of FP methods available at these facilities and introduce potential users to the LNG-IUS.

As reported by the local EECO team, the top service delivery challenges that have arisen are:

- The MoH relocated 14 of the 65 providers initially trained in LNG-IUS provision, moving them away from facilities that the project supports with LNG-IUS stock and quality assurance. With fewer providers now offering the LNG-IUS, EECO has seen lower service delivery numbers than projected. The project trained 40 new providers to make up for this shift.
- Furthermore, the project has faced facility-level stock-outs of the LNG-IUS due to the small amount of stock donated in each shipment from the ICA Foundation. To compensate, SFH has shifted stock from one region to another and borrowed stock from other organizations offering the LNG-IUS in Zambia. EECO expects that procurement of AVIBELA may help to prevent stockouts by making an additional source of LNG-IUS available in country.

MADAGASCAR

In Madagascar, EECO introduced the AVIBELA LNG-IUS in 2018 through two types of private providers:

- 23 providers in PSI/Madagascar's Top Reseau social franchise network
- 9 providers operating outside of the social franchise

The social franchise network is similar to a commercial franchising model, but with the goal of achieving social impact while recovering all costs, in order to operate sustainably. The social franchise creates a network of providers who are supported not only with materials and training, but also with opportunities for continuing education to meet the changing needs of their local market. Providers and sites were selected for inclusion in the EECO project for their high client load, volume of existing LARC service delivery, and high quality of existing services. The EECO team believes that these attributes are likely to contribute to their success in introducing a new LARC method like the LNG-IUS.

Both types of providers purchase AVIBELA from PSI for $15 USD per unit and sell it to clients for between $20 and $30 USD to cover the costs of their time, facilities, supplies and equipment.

Some providers are also working with employment-linked health insurance plans, some of which cover AVIBELA, thereby increasing the potential of the product to become a sustainable option in Madagascar for the small but growing segment of clients with health insurance.

Demand generation in Madagascar is carried out through Brand Ambassadors, who conduct FP education sessions with women of reproductive age in the catchment area of the private clinics offering the product. Brand Ambassadors are women who speak about FP with individuals and small groups at office workplaces, shopping malls, massage salons, and other places where they can find middle- to high-income women who are more likely to be able and willing to pay the relatively high cost of AVIBELA. The Brand Ambassadors provide information and make referrals for a full range of contraceptive options, including AVIBELA.

Lower and middle-income women have expressed a strong interest in the product, and some have accessed it through insurance, saving up, or purchasing from providers who offer the product on a sliding scale. However, it remains a challenge for Brand Ambassadors to locate and reach women who can afford the full price of AVIBELA. PSI is exploring solutions, including tiered pricing, where it could increase the price for private clinics that reach wealthier women, while lowering the price for clinics in the social franchise.

From April through September 2018, PSI/Madagascar has sold 189 units of the product to providers within and outside of the Top Reseau network. EECO tracks the number of insertions only within the franchise network; as of October, providers within the network had provided 101 LNG-IUS insertions.

32 Number of providers trained

27 Number of facilities offering AVIBELA

189 Number of AVIBELA sold to providers

101 Number of AVIBELA inserted in Top Reseau facilities (including those provided during trainings)

AVIBELA Brand Ambassadors (pictured here) raise awareness of the new method and make referrals within the context of informed choice in Madagascar. They go to locations like this shopping mall to seek out women who may have an ability to pay for the method or health insurance that would cover it.

WHY DOES EECO WORK IN THE PRIVATE SECTOR IN MADAGASCAR?

- Building up FP services in the private sector contributes to a healthier, more sustainable market by offering alternatives to those with the ability to pay for services, so that they do not access subsidy that is intended for those who cannot afford to pay.
- Many women across wealth quintiles seek health services in the private sector.[xxiv]
- In the short term, the sales of AVIBELA to providers at partial cost recovery prices allow EECO to generate program income, which the project will use to advance AVIBELA access. For example, this may enable offering the product at a lower price on a needs-based sliding scale, thus allowing subsidies to go further and reach more people.
- In the long term, full cost recovery may allow sustained access to the LNG-IUS after donor funding ends.

Navalona first gave birth at 18 years old and at 39 she now has three children. She works for a local cosmetics distributor. One day a family planning educator came to her home and spoke about different methods available. The educator handed her a flyer about AVIBELA and Navalona says she was immediately interested. Navalona had tried many family planning methods over the years—oral contraceptives, injectables, condoms, a Copper IUD. She was never quite happy with these other methods.

Navalona has been using AVIBELA for three months and she is very impressed by the positive effects she has experienced. She used to have a heavy period, but now her monthly period is very light, and she does not have as much pain from cramps. She is so happy with AVIBELA that she says she will not change methods again. "I have friends that ask me about the family planning method I use, and I tell them how much I love AVIBELA."

MESSAGING ON MENSTRUAL CHANGES AS A CONTRACEPTIVE SIDE EFFECT

An essential part of contraceptive counseling and communication is the discussion of side effects, including any changes that a method may cause to a woman's monthly menstrual bleeding. All contraceptive methods come with bleeding changes; these are summarized in Figure 8.

Women's perceptions and attitudes toward changes to their menses are highly varied across geographies. In some cultures, it is common for women to see lighter or absent menstrual periods as a benefit. For other women and their partners, including many in Madagascar and Zambia, changes to menstruation or complete amenorrhea are unwelcome. Misconceptions about bleeding changes are common, with many women and men believing that such changes indicate a permanent loss of fertility or a sign of poor health. For some clients, the preference for regular periods is based on tradition or a desire to track periods as reassurance that the client is not pregnant. It is important to note that while some women report concerns about potential bleeding changes in Zambia and Madagascar, injectables like DMPA are still by far the most popular method in these contexts despite the fact that they are more likely to cause amenorrhea than the LNG-IUS. Counseling women on what they should expect, especially addressing their personal feelings regarding changes in their bleeding, is a critical step in ensuring a client understands her choice and is satisfied with her method. Job aids like the NORMAL tool, developed through a partnership of PSI and FHI 360, are valuable in helping providers counsel women effectively (see page 24 to view the tool).[xxv]

The way the LNG-IUS is marketed to women also influences method choice. In Madagascar, EECO's messaging around the LNG-IUS targets professional, urban women and emphasizes the method's effects on menstrual bleeding as a reason why some women choose it. PSI's AVIBELA posters in Madagascar include the tagline, "With reduced periods, life is beautiful!" The French word for "periods" also means "rules" so PSI used this dual meaning to position AVIBELA as a method desired by women seeking freedom from both heavy menstrual periods and other types of constraints.

Early data from PSI's study of AVIBELA users in Madagascar shows that "reduced menstrual bleeding" and "fewer side effects" are the top reasons why women are choosing the method. (See Monitoring and Learning section on page 25). In this case, messaging on the therapeutic benefits of the product have, so far, been successful.

Figure 8. **COMMON BLEEDING CHANGES BY CONTRACEPTIVE METHOD**

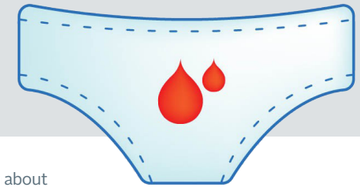
LNG-IUS	Lighter and fewer days of bleeding, or infrequent, irregular bleeding is expected. Irregular bleeding common in the first few months. At least 15% experience amenorrhea after one year.[xxvi]
Copper IUD	Irregular bleeding or longer, heavier bleeding is common. Amenorrhea is rare.[xxvii]
Implant (Implanon)	Typically prolonged, irregular bleeding over the first year and then lighter, more regular bleeding, infrequent bleeding or no bleeding. 22% experience amenorrhea, while 18% experience prolonged bleeding.[xxviii]
Injectables	Irregular and prolonged bleeding at first, then infrequent or irregular bleeding, or amenorrhea is common. 40% of users have no monthly bleeding after one year.[xxix]
OC Pills	Typically irregular bleeding for the first few months. Lighter and more regular bleeding likely with continued use.

Translation:
Avibela™
With Reduced Periods, Life is Beautiful!

- My Modern Contraceptive
- My Freedom
- My 3 Years of Peace
- The Solution to My Period Problems

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 — **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.

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

R — **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]

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

A — **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]

L — **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 ethynyl 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.

This job aid was developed with funding provided by the United States Agency for International Development (USAID) to FHI 360 through the *Envision FP* project and to PSI through the Support for International Family Planning and Health Organizations (SIFPO) project.

DECEMBER 2017

STAGE 5
Monitoring & Learning

The EECO team conducts regular monitoring and evaluation activities and works closely with other implementing agencies, partners, and donors in this space to share program data and collaborate on research through the LNG-IUS Working Group, a multi-organization coordination platform for introduction of the product. These partners share a global learning agenda focused on realizing the potential for the LNG-IUS in new markets. The group works together to understand potential client demand in different contexts, define successful marketing approaches of the contraceptive and non-contraceptive benefits of the product, and guide service delivery standards through various channels, looking at cost-effectiveness and willingness to pay.

ENHANCED MONITORING AND INFORMATION SYSTEM (MIS)

An effort by these partners, including PSI, FHI360, MSI, and Jhpiego, to harmonize data collection for comparison across projects and countries led to the creation of three MIS questions for LNG-IUS users and discontinuers. These questions provide a regular update on introduction efforts that can be presented to funders, researchers, manufacturers, policy makers, and implementers who are learning from LNG-IUS introductions. Across all implementing countries and lead organizations, the following questions are asked of clients who choose the LNG-IUS:

1. What reason did you choose an LNG-IUS today instead of another method?
2. If the LNG-IUS had not been available today, what method, if any, would you have chosen?
3. What FP method were you previously using?

Across countries, implementing partners are able to compare and contrast clients' responses, and analyze what contextual or programmatic changes may be influencing different trends.

EECO RESEARCH

The EECO team is carrying out research in both Zambia and Madagascar that includes longitudinal follow-up surveys of LNG-IUS users at 3 and 12 months after adoption of the method. The research also includes provider baseline surveys before

LNG-IUS training, and follow-up surveys with providers after 9 months. This study mirrors similar research that PSI is carrying out in Zimbabwe and Nigeria with funding from USAID through the Support for International Family Planning Organizations project (SIFPO2). The LNG-IUS research studies will continue collecting data through 2019.

Figure 9. **OBJECTIVES OF EECO LNG-IUS PILOT STUDIES**

Follow-up with users after 3 and 12 months	• Understand and define user profiles • Understand satisfaction and experience with LNG-IUS • Understand continuation rates
Baseline and follow-up provider surveys after 9 months	• Test LNG-IUS knowledge and experience • Understand perceptions of LNG-IUS and side effects • Understand demand creation strategies

REGULAR PROGRAM MONITORING

Monitoring of programs through regular meetings and site visits with program staff and providers allows the EECO team to evaluate progress and challenges, and to course-correct quickly. The most valuable insights are gleaned directly from providers and IPC agents, as they interact personally and most frequently with consumers. Through conversations with Brand Ambassadors in Madagascar, for example, the team learned of entrenched stigma and misconceptions around hormonal contraceptives held especially by the educated, urban women who are EECO's intended beneficiaries in this country. Through interviews with EECO providers, the program team can understand the challenges they are facing and find solutions that can be implemented right away, such as providing a refresher training on communication and messaging techniques to build the Brand Ambassadors' skills in this area.

REACHING NEW AND DIFFERENT USERS

The method characteristics of the LNG-IUS make it potentially more attractive to different user groups, compared to other contraceptives. For example, preliminary data shows that many women who receive the IUS report that if this method had not been available on the day of their service they would have left with either a short-acting method, or no method at all (see figures 10 and 12). This suggests that the LNG-IUS offers an option for women who want a highly effective and long-acting method of contraception, but do not find the characteristics of other LARCs to be acceptable. This implies that the majority of women interviewed to-date do not seem to see the LNG-IUS as being interchangeable with other methods like the IUD. Preliminary data indicate that a high percentage of women who may not otherwise be drawn to a LARC method are finding the characteristics of the LNG-IUS desirable and are choosing this method over other options that are less effective. EECO providers chosen for the introduction were already experienced in providing IUDs and therefore learned how to offer the LNG-IUS easily, since the techniques used for the two methods are similar. Because these providers can offer clients a wide range of method choices, the project is able to study why some clients choose the LNG-IUS over other LARCs and whether they are willing to pay more for the LNG-IUS at a site with multiple LARC options available (see figures 11 and 13).

Figure 10.[13] **WOMEN'S RESPONSES TO WHICH METHOD THEY WOULD HAVE CHOSEN, IF THE LNG-IUS HAD NOT BEEN AVAILABLE IN ZAMBIA**

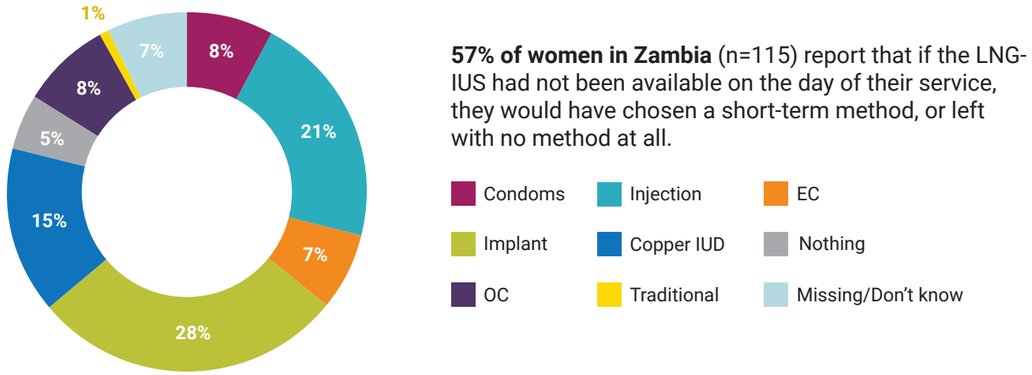
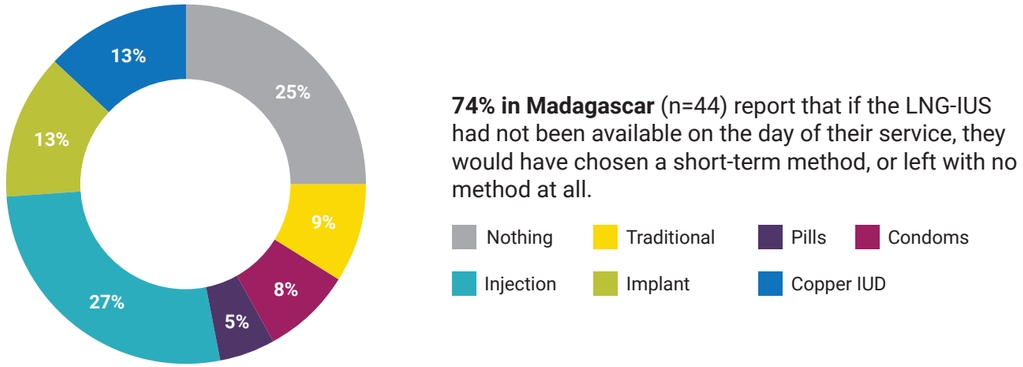


Figure 11. **REASONS WOMEN IN ZAMBIA REPORT CHOOSING THE LNG-IUS**

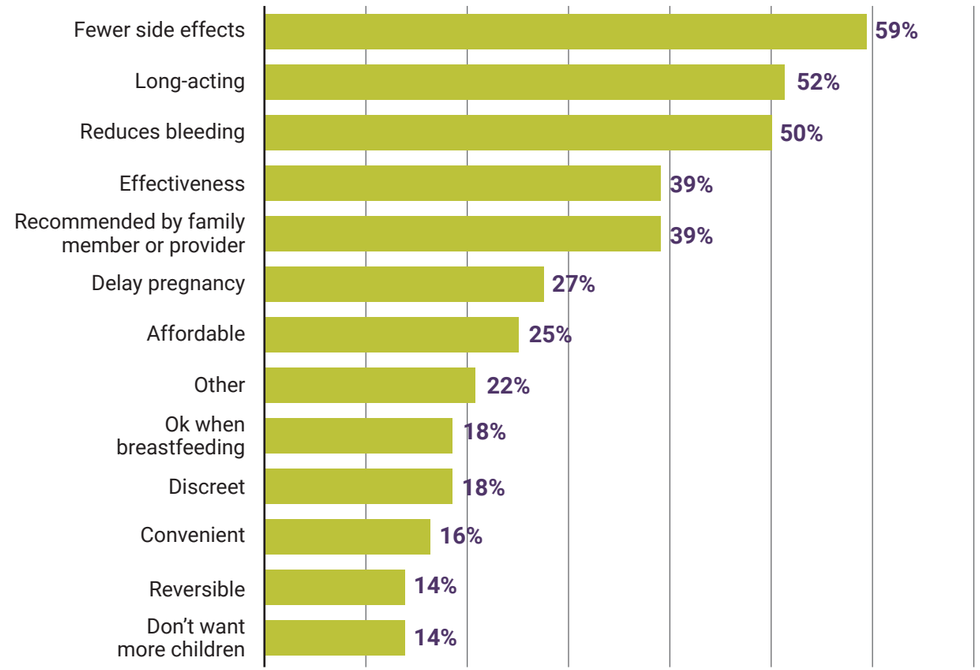
[13] Data in figures 10, 11, 12 and 14 is preliminary data. Full study findings will be published when the studies are complete.

Figure 12. **WOMEN'S RESPONSES TO WHICH METHOD THEY WOULD HAVE CHOSEN, IF THE LNG-IUS HAD NOT BEEN AVAILABLE IN MADAGASCAR**



74% in Madagascar (n=44) report that if the LNG-IUS had not been available on the day of their service, they would have chosen a short-term method, or left with no method at all.

Figure 13. **REASONS WOMEN IN MADAGASCAR REPORT CHOOSING THE LNG-IUS**



Key Insights & Next Steps

EECO project LNG-IUS activities are ongoing. Though the findings to-date are preliminary, the EECO team has identified some key insights.

REGULATORY INSIGHTS

- **An in-country regulatory landscape assessment ensured a smoother registration process.** The assessment creates an opportunity to advocate for the product with local stakeholders, find key contacts and method champions, and understand how best to navigate an often-complex registration pathway.

PROCUREMENT INSIGHTS

- **Higher order volumes are needed.** Delivery of product was delayed 2-3 months due to the real or perceived need to obtain the unique country-specific packaging and labeling components needed for production of these limited size product sub-lots, along with the manufacturer's commitments to larger commercial orders outside of the EECO order. Due to low order quantities, it can be challenging for suppliers to adhere to product delivery timelines. In the future, pooled procurement across multiple countries may be a way to both drive down costs and secure higher prioritization from the manufacturer.

SERVICE DELIVERY INSIGHTS

- **Selection of sites that already offered copper IUDs as part of their method mix enabled EECO to establish high quality LNG-IUS services more quickly.** The project made a strategic choice to add LNG-IUS services to sites that already offered copper IUDs. These providers already had many of the skills and motivation needed to counsel clients on FP and provide intrauterine contraception for those clients who wished to use the method, so that the rollout was relatively easy.
- **Securing a commitment from the MoH not to shift providers** away from program sites once they are trained would have prevented loss of institutional knowledge in the public sector. With reduced numbers of trained providers in project clinics, insertion rates fell, and training of new providers was required.
- **When messages about the non-contraceptive benefits and unique characteristics of the LNG-IUS were clear, new users and clients who were not previously interested in LARC methods chose the IUS as their method.** Good messaging on method attributes showed that many clients considered these individual characteristics an important factor in their decision to try the method.
  - In the public sector in Zambia, initial MIS data on LNG-IUS users showed that most women selected the method because it was "long-acting," even though other long-acting methods were also available (namely, implants and copper IUDs). Fifty-eight percent of women in Zambia stated that the side effect and bleeding profile were among the reasons they chose it over other methods.
  - In Madagascar, providers have explained to clients that the charge of $20 for the LNG-IUS (in contrast with only $1.50-4.00 for other LARC methods) was justified in part because of the non-contraceptive benefits of the LNG-IUS. As a result, they found that 50% of clients who chose the LNG-IUS reported the bleeding profile as one of the reasons behind their decision. However, EECO plans to experiment with a price reduction or sliding scale for the LNG-IUS in Madagascar to expand access to more women.
- **Out-of-pocket payments and donor subsidies are not the only sources of potential funding for the AVIBELA LNG-IUS.** Some of the private providers working with EECO in Madagascar accept employment-based health insurance that covers AVIBELA. Insurers likely save money by providing this coverage since the health costs associated with pregnancy, childbirth, and infant care vastly outweigh the costs associated with contraception. Thus, insurance coverage for the AVIBELA LNG-IUS and other contraceptive

options benefits not just the client, but the provider and the insurer as well.

RESEARCH INSIGHTS

- **Some clients are willing to pay the higher cost for the LNG-IUS, offsetting costs to other payers.** AVIBELA is the most affordable of several quality-assured LNG-IUS products. With a procurement price of around $15/unit, AVIBELA is economical in the long-run—with a cost per CYP that is comparable to many OC pills and implants.[xxx] Yet relative to other methods of contraception, AVIBELA has a higher upfront cost to clients, donors, and/or other payers such as health insurance companies. In Madagascar, EECO learned that some clients are willing to pay prices that allow for significant cost recovery. We will continue to evaluate this question as the project reaches more clients to understand if these initial findings hold true on a larger scale.

NEXT STEPS: MOVING FROM PILOT TO SCALE

EECO's collaborative approach to product introduction incorporates the entire life cycle of the product –from registration to end use -- thus creating a roadmap for the integration of the LNG-IUS into the range of contraceptive method options in the market. Though evaluation of the introduction is ongoing, preliminary findings suggest that women in Madagascar and Zambia are responding positively to messaging on the method's unique non-contraceptive benefits. Findings also show that most women who are choosing the IUS would have otherwise chosen a less effective method, or no method at all. This suggests that the LNG-IUS may be filling an important gap in the market and meeting a need for women who would not otherwise be drawn to long-acting contraception. Forthcoming research will shed more light on these questions. The introduction of the method is not without its challenges. Both service delivery and cost barriers must be considered, but through this 5-stage process the EECO team believes that these challenges can be addressed and that a more sustainable market for the LNG-IUS is achievable.

EECO's next steps include working with the Ministries of Health to scale-up and institutionalize access to the LNG-IUS for more women. In Zambia, local stakeholders have already begun to meet with the MoH to discuss a potential roadmap for a phased scale up at more public facilities and development of new educational materials. In Madagascar, PSI will work with the MoH to integrate the LNG-IUS into national training curricula to build awareness of the method and capacity for service delivery outside of EECO. Through the continuation of these pilots, the EECO team will better understand the requirements and criteria for successful introduction on a larger scale. By taking advantage of ongoing research by both the EECO team, and other implementing partners in this space, such as the Gates-funded LEAP LNG-IUS Initiative, and similar USAID pilots in Zimbabwe and Nigeria, EECO will continue to refine the approach to LNG-IUS introduction in different institutional, geographic and sociocultural settings so that stakeholders and future programs have a clear path to a successful LNG-IUS introduction.

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