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Maternal and Child Survival Program

Long-Acting and Permanent Methods Community of Practice

Technical Meeting:

What's Next with the LNG-IUS?

Meeting Report

Maternal and Child Survival Program Office
1776 Massachusetts Avenue NW, Suite 301, Washington, DC
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mcsprogram.org

The Maternal and Child Survival Program (MCSP) is a global, $560 million, 5-year cooperative agreement funded by the United States Agency for International Development (USAID) to introduce and support scale-up of high-impact health interventions among USAID's 25 maternal and child health priority countries,* as well as other countries. The Program is focused on ensuring that all women, newborns and children most in need have equitable access to quality health care services to save lives. MCSP supports programming in maternal, newborn and child health, immunization, family planning and reproductive health, nutrition, health systems strengthening, water/sanitation/hygiene, malaria, prevention of mother-to-child transmission of HIV, and pediatric HIV care and treatment.

* USAID's 25 high-priority countries are Afghanistan, Bangladesh, Burma, Democratic Republic of Congo, Ethiopia, Ghana, Haiti, India, Indonesia, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Nigeria, Pakistan, Rwanda, Senegal, South Sudan, Tanzania, Uganda, Yemen and Zambia.

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April 2019

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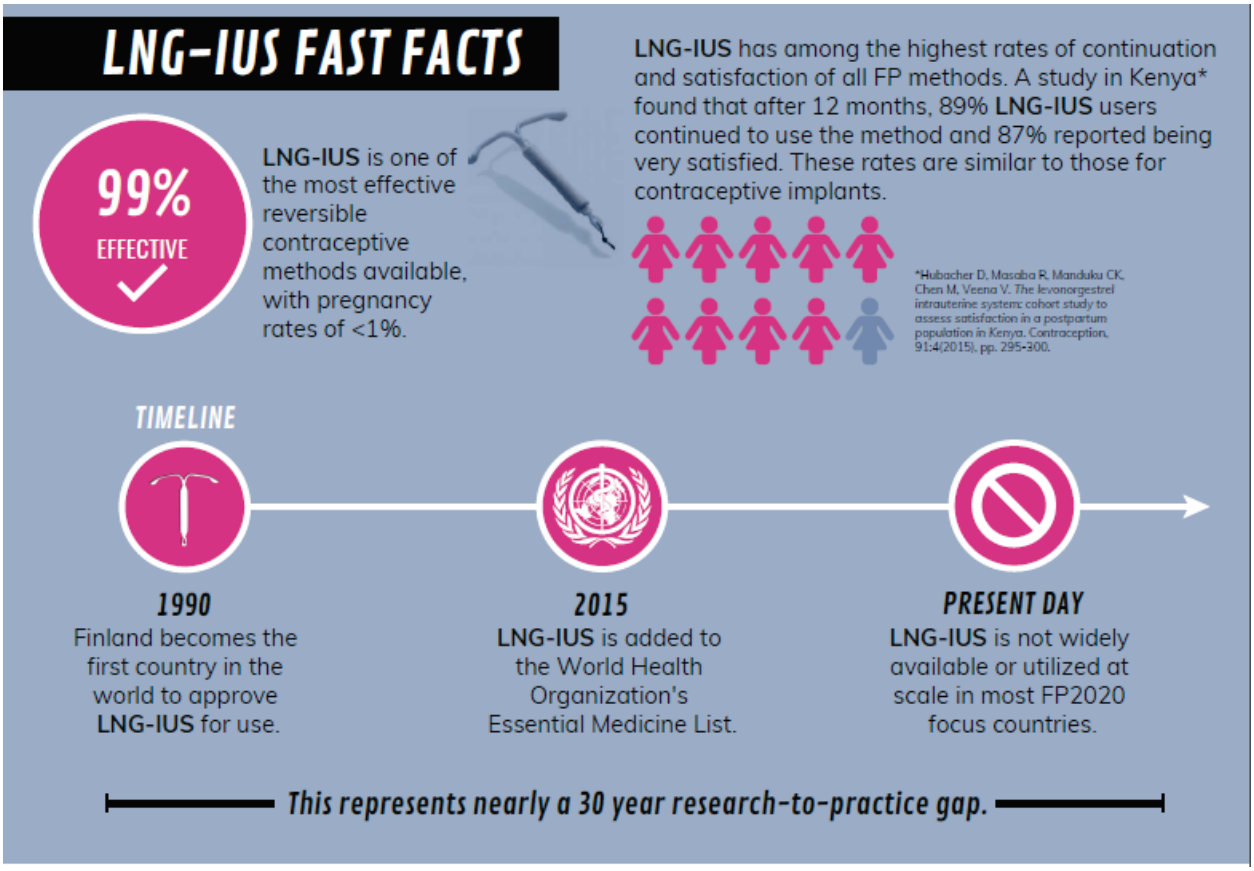
Abbreviations

COP	Community of Practice
EECO	Expanding Effective Contraceptive Options
FP	family planning
FP2020	Family Planning 2020
ICA Foundation	International Contraceptive Access Foundation
IUD	intrauterine contraceptive device
LARC	long-acting and reversible contraceptives
LAPM COP	Long-Acting and Permanent Methods Community of Practice
LEAP LNGIUS	Learning about Expanded Access and Potential of the LNG-IUS
LMIC	low- and middle-income countries
LNG-IUS	levonorgestrel intrauterine system
MCSP	Maternal and Child Survival Program
SRA	stringent regulatory authority
USAID	United States Agency for International Development

Overview

The levonorgestrel intrauterine system (LNG-IUS) is one of the most effective forms of reversible contraception with efficacy rates similar to subdermal implants and copper intrauterine devices (IUDs).[1] Although the LNG-IUS has proved to be a popular choice with women in developed countries where the method is available, and it has helped revitalize the IUD market in some settings,[2] the method is not currently available at scale outside of the commercial sector in any of the Family Planning 2020 (FP2020) focus countries,[3] and thus access to the larger population for this method is limited in these settings.



In light of this, on December 4, 2018, the Long-Acting and Permanent Methods Community of Practice (LAPM COP) convened a technical meeting to provide an overview of the current global efforts to increase access to LNG-IUS in
low- and middle-income countries (LMICs), review the evidence and explore approaches to expanding access to family planning (FP), and share learning from pilot introduction activities in Kenya, Madagascar, Nigeria, Zambia, and Zimbabwe.

Meeting Objectives

The meeting objectives were for participants to:

- Review the key features of the LNG-IUS and current product availability for low-resource countries,
- Gain a deeper understanding of the current state of global LNG-IUS evidence and use in LMICs,

[1] Trussell J, Aiken ARA, Micks E, Guthrie KA. 2018. Efficacy, safety, and personal considerations. In: Hatcher RA, Nelson AL, Trussell J, eds. *Contraceptive Technology*. 21st edition. New York, NY: Ayer Company Publishers, Inc.; 95–128.
[2] Hubacher D. 2015. The levonorgestrel intrauterine system: reasons to expand access to the public sector of Africa. *Glob Health Sci Pract.* 3(4):532–537.
[3] Family Planning 2020 (FP2020) website. http://www.familyplanning2020.org/entities. Accessed December 3, 2018.

- Discuss challenges to increasing accessibility and affordability of the LNG-IUS in LMICs,
- Learn about key national policy and measurement considerations,
- Hear from selected introductory projects about user profiles and potential demand, and
- Learn about providers' experience with the method and understand how provider-side barriers impact method provision.

Participants

The 50 in-person meeting participants represented the following projects and organizations (Annex A has a complete list of participants):

- Abt Associates
- Bill & Melinda Gates Foundation
- Clinton Health Access Initiative
- FHI 360
- Global Health Supply Chain Program-Procurement and Supply Management
- Jhpiego
- Johns Hopkins Bloomberg School of Public Health
- John Snow, Inc.
- Maternal and Child Survival Program (MCSP)
- Medicines360
- Pathfinder International
- PCI
- Population Council
- Population Services International (PSI)
- Reproductive Health Supplies Coalition (RHSC)
- Save the Children
- Sustaining Health Outcomes through the Private Sector Plus (SHOPS Plus)
- The Bizzell Group
- United States Agency for International Development (USAID)
- WCG Cares
- What Works Association
- World Vision

Introductory Remarks

Tabitha Sripipatana, Deputy Division Chief for the Research, Technology and Utilization Division in the Office of Population and Reproductive Health at USAID, opened the meeting by welcoming participants and reviewing the meeting goals and objectives. Sripipatana also reminded the audience that has been a long road for LNG-IUS scale-up, with research and development beginning in the 1970s, yet still very little use of LNG-IUS is taking place at scale in LMICs. However, she remained optimistic about the future of this product to provide more choices for women. (The full presentation is available on the Long-Acting and Permanent Methods Community of Practice (LAPM COP) website).

Presentations and Plenary Discussions

Plenary 1: Overview of the LNG-IUS and Global Learning Agenda

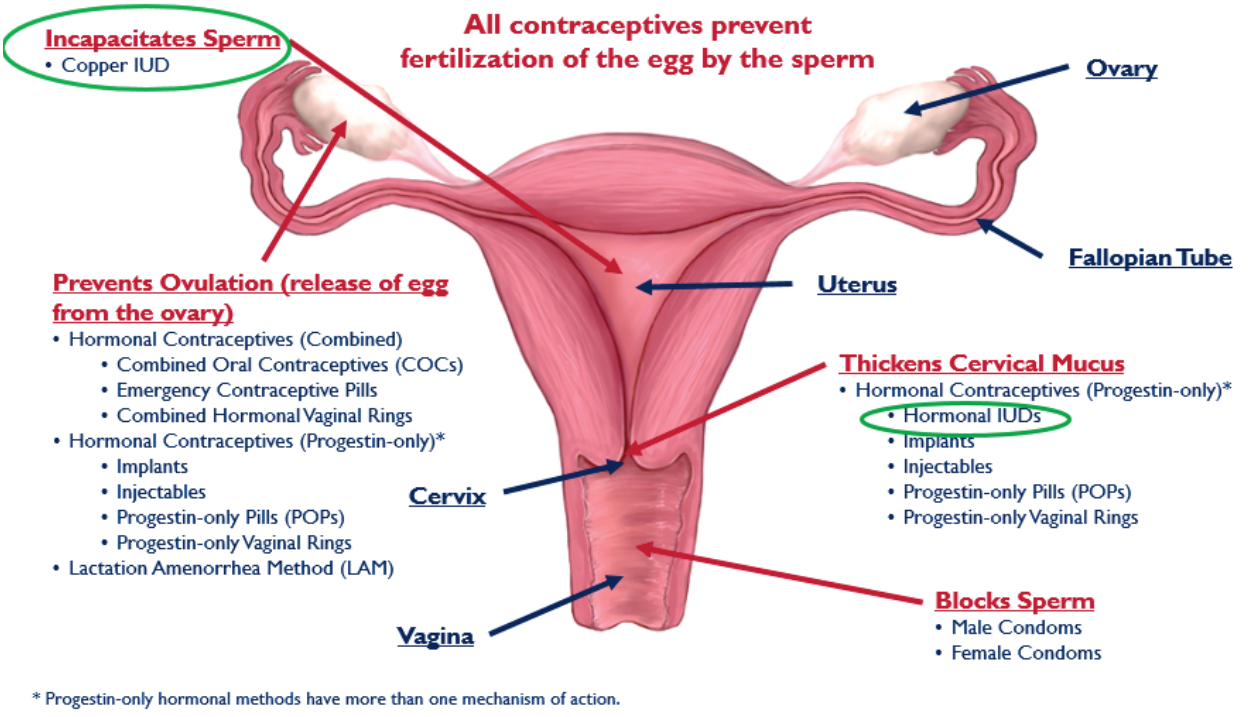
Tabitha Sripipatana, Deputy Division Chief for Research, Technology and Utilization at USAID, introduced and moderated the first panel of speakers. The three speakers in this panel focused on providing an overview of the products available, the recent evidence and the global learning agenda.

LNG-IUS 101

by Mark Hathaway, Senior Technical Advisor, MCSP

Mark Hathaway shared what an excellent opportunity this is to rejuvenate existing products that are great for women around the world and provided a general overview of the different IUDs and defined common terms, including IUS and IUD. Hathaway explained that the LNG-IUS contains the hormone progestin, and explained its simplicity, safety and how it works compared to other common FP methods (Figure 1).

Figure 1. Mechanisms of action of contraceptive methods



Evidence shows that the LNG-IUS is effective for up to 7 years. Currently, the Federal Drug Administration has approved Mirena® and Liletta® in the US for only up to 5 years, but Liletta is being studied for 10 years in an ongoing trial. Some of the advantages and disadvantages of the method are listed below.

Advantages	Disadvantages
• Very effective and cost effective (over time) • Easy: "get it, forget it" • Partner cooperation not needed • Safe for breastfeeding • Reversible with quick return to fertility • Hormonal IUD relieves heavy menses/cramps (anemia) • Can be inserted after vaginal delivery, cesarean section or during postabortion care • Reduces risks of endometrial and ovarian cancers	• Device and insertion costs • Requires skilled provider for insertion and removal • Instruments/equipment needed • Discomfort at time of placement • No protection from sexually transmitted infections or HIV

Hathaway showed that when comparing typical effectiveness of contraceptive methods, hormonal and copper IUDs are at the top and have very high continuation rates (one study showed 1-year satisfaction rates for LNG-IUS at 80%[4] while additional studies showed continuation rates of 70% at 3 years for LNG-IUS users[5]). Counseling is probably the most important component of any FP method, and Hathaway stressed the importance of tailoring counseling to a women's needs and encouraged use of the World Health Organization

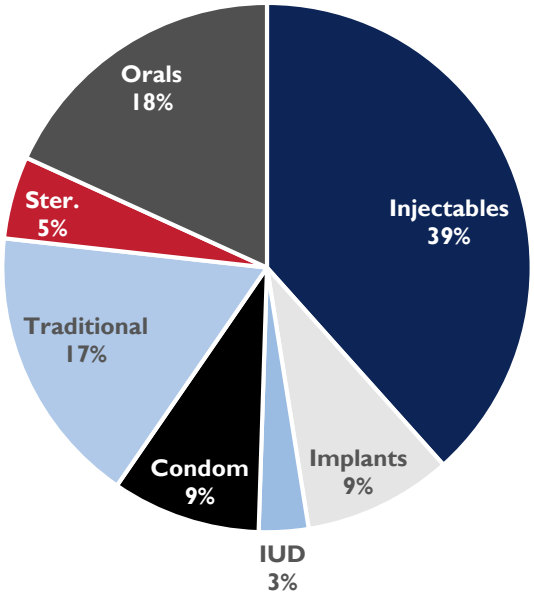
[4] Trussell J. in Hatcher R et al. *Contraceptive Technology.* 2011.
[5] The Contraceptive Choice Project. 2013. Rosenstock JR et al. 2012. *Obstet Gynecol.*; Peipert JF et al. 2011. *Obstet Gynecol.*; Diedrich JT. *Am J Obstet Gynecol.* 2015.

(WHO) Medical Eligibility Criteria (available in an app, wheel and chart). He also presented information on the equipment needed for IUD insertion.
Full presentation available on the Long-Acting and Permanent Method Community of Practice website.

Landscape of LNG-IUS: Overview of Manufactures, Products and Recent Evidence from Kenya

by David Hubacher, Senior Epidemiologist, FHI 360
Hubacher highlighted how the distribution of contraceptive method mix globally does not really reflect the will of the people. If one looks to the example of sub-Saharan Africa (Figure 2), the prevalence of sterilization is very low, but we know a large proportion of women say they do not want more children. IUD use is low as well, and we think with better access to service that would go up. Although increased access to subdermal implants has resulted in higher prevalence, there is still a very large proportion of injectable users (and injectables use is often associated with high discontinuation rates).

Figure 2. Contraceptive method mix in sub-Saharan Africa, 2016



Although the LNG-IUS was first approved for use in 1990, it was not until 2015 that WHO put LNG-IUS on the essential medicines list (which was an important signal to countries that this product offers great benefit), however, even after this milestone, the LNG-IUS is still not available at scale in any FP2020 country. In 1995, IUD prevalence in the US was about 1%. Mirena® was introduced in the US in 2000. And who was using it? Rates of use among female physicians (and particularly obstetricians/gynecologists) was much higher than the general population because they had the knowledge about safety, effectiveness, access and wanted a trouble-free method.[6] Now, about 12% of women in the US who are using FP are using an IUD—**highlighting how this product has served as a catalyst for intrauterine contraception**.

A USAID-funded study in **Kenya** of postpartum LNG-IUS users showed high uptake and acceptability.[7,8]

[6] Hubacher D, Kavanaugh M. 2018. Historical record-setting trends in IUD use in the United States. *Contraception* 98(6):467-70.
[7] Hubacher D, et al. 2013. Uptake of the levonorgestrel intrauterine system among recent postpartum women in Kenya: factors associated with decision-making. *Contraception* 88(1): 97-102.
[8] Hubacher D, et al. 2015. The levonorgestrel intrauterine system: cohort study to assess satisfaction in a postpartum population in Kenya. *Contraception*. 91(4):295-300.

- Among 671 clients, **16% chose LNG-IUS.**
- Approximately **one-third of users** said if LNG-IUS had not been available, they would have chosen a shorter-acting method.
- At 12 months, **continuation rate was 89%** for LNG-IUS; compared to 91% for implants.
- Women using the LNG-IUS reported slightly higher levels of acceptable bleeding patterns compared to women using implants.
- LNG-IUS users also reported lower blood loss.

Overview of LNG-IUS products

Table 1. Products with and without stringent regulatory approval

Products with Stringent Regulatory Authority (SRA) Approval
• Bayer-Mirena®: Provided commercially through private health care clinics in some developing countries on a very limited basis. Pricing between ~US$60-$400 documented in recent market assessments.*, †,‡ • International Contraceptive Access Foundation-LNG-IUS: Public-private partnership between Bayer and Population Council. Provides free LNG-IUS product; donated over 125K units since 2005. • Medicines360 – Avibela™: Approved by the US Food and Drug Administration 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.*

Products without SRA Approval
• Pregna International Ltd.– 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 Life Sciences – Fiona™: Meril, based in India, manufactures the Erinna™ and Fiona LNG-IUS products (with different inserters). Currently only registered in India. • HLL Lifecare Limited – 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.

*Rademacher KH, et al. 2016. Expanding access to a new, more affordable levonorgestrel intrauterine system in Kenya: A comparison of service delivery costs and perspectives from Key Opinion Leaders. *Glob Health Sci Pract*.4 Suppl 2:S83-S93.

†FHI 360, Society for Family Health, PSI, WCG. 2016. Market Assessment for Potential Introduction of a New Hormonal IUCD in Zambia. Report.

‡FHI 360 and Marie Stopes International. Forthcoming. Introduction of the LNG-IUS in Nigeria: Market Assessment & Service Delivery Research. Report.

Hubacher concluded by reminding us that a troubling research-to-practice gap for LNG-IUS still exists in most countries and that it is exciting to gather to talk about what's next, including our desire to generate further evidence & identify effective strategies for taking this product to scale.

The full presentation is available on the Long-Acting and Permanent Method Community of Practice website.

Global Learning Agenda and Potential Pathways to Increasing Affordability and Access

by Kate Rademacher, Technical Advisor, FHI 360

Rademacher began the presentation with a reminder that this product still has not been taken to scale in FP2020 countries, so we still don't know what demand would be if the method more widely available. In

addition, we need more evidence about how to best generate demand and awareness, and how to get providers comfortable providing high-quality LNG-IUS services.

Rademacher proposed several ways to increase access to the LNG-IUS, including:

- Generating evidence to further understand the value proposition of the LNG-IUS in FP2020 countries and identify effective strategies for introduction and scale-up,
- Supporting introduction of existing products in public and private sectors, and
- Reducing prices of LNG-IUS commodities further for public sector procurement.

Recommended Reading:

Rademacher KH, et al. 2018. *A Global Learning Agenda for the Levonorgestrel Intrauterine System (LNG-IUS): Addressing Challenges and Opportunities to Increase Access*. Global Health: Science and Practice 6(4): 635-43.

Please also see Annex C for a comprehensive LNG-IUS bibliography.

An **Interagency LNG-IUS Working Group** was convened by USAID in 2015 and is comprised of donors, implementing agencies and suppliers and allows for coordinating, developing a shared learning agenda and aligning research approaches and monitoring and evaluation questions (see Figure 3).

Figure 3. Global Learning Agenda for LNG-IUS

Global Learning Agenda for the Levonorgestrel Intrauterine System (LNG-IUS)

LEARNING AGENDA QUESTIONS
A. CLIENT DEMAND
1. What are the profile(s) of the clients who will use this product? 1a. Is there or would there be demand for this product among sub-populations with high unmet need for family planning (e.g., women in lower wealth quintiles, postpartum women, adolescents, post-abortion clients) 1b. Will introduction of the LNG-IUS help reach new family planning users (i.e., current non-users)? 1c. To what degree will introduction of the LNG-IUS result in "switching" and from what other methods (e.g., from short-acting methods)?
2. Does the LNG-IUS have the potential to 'revitalize' the IUD market in FP2020 countries? 2a. Will demand for the LNG-IUS be higher than demand for the copper IUD has been?
3. Would introduction of the LNG-IUS increase family planning use overall/increase contraceptive prevalence rate(s)? 3a. Can scale-up of this product help meet FP2020 goals?
4. How do continuation rates of the LNG-IUS compare to continuation rates of other LARCS in multiple contexts?
5. Does immediate postpartum access to the LNG-IUS increase use of postpartum family planning overall?
B. MARKETING
6. What are effective demand creation strategies with different populations and in different sectors?
7. How can promotion of family planning including the LNG-IUS be integrated into other health sectors such as nutrition programs or menstrual hygiene management programs?
C. SERVICE DELIVERY
8. How can we overcome barriers that have impacted provision of the copper IUD at the service delivery level when introducing the LNG-IUS?
9. What are health care providers' perceptions of this product?
10. What are effective service delivery models for LNG-IUS provision? How does it differ by context, channel, and/or user group? 10a. What are effective provider training strategies for the LNG-IUS?
D. NON-CONTRACEPTIVE ATTRIBUTES
11. How does knowledge of non-contraceptive attributes of the LNG-IUS affect uptake and use? 11a. What non-contraceptive attributes are most attractive to women in different contexts? 11b. What non-contraceptive attributes are seen as most beneficial by providers in different contexts?
12. What are perceptions of amenorrhea among providers and various clients segments?
13. Can scale-up of the LNG-IUS help reduce rates of anemia?
E. COST-EFFECTIVENESS AND PRICING
14. To what extent is the LNG-IUS cost-effective compared to other family planning methods including other long-acting reversible methods?
15. What is the willingness-to-pay for the LNG-IUS among different populations of clients and different stakeholder groups?

December 2018

The learning agenda questions were developed with USAID resources, and then prioritized by donors and implementing agencies and used to inform investment and programming decisions. The learning agenda also informed donor decisions for new research projects and maximized opportunities to leverage support among more funders. For example, the Learning about Expanded Access and Potential of LNG-IUS Initiative

(LEAP LNG-IUS Initiative) was launched in late 2018 with funding from the Bill & Melinda Gates Foundation.

In addition, the following three questions were prioritized by implementing partners to be administered across countries/programs, for those clients choosing LNG-IUS among a range of contraceptive method options:

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

Initial results from the harmonized learning questions show that across almost all countries, the majority of LNG-IUS users report that they would have used another LARC (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. The LNG-IUS may provide an option for women who desire a highly effective, long-acting method and who do not find the attributes of the other long-acting methods acceptable. In addition, across most countries, women's top reasons for choosing the LNG-IUS included its effectiveness, long-acting duration, reduced bleeding and fewer side effects. These results were compiled into an LNG-IUS Dashboard, which is a living document housed on K4Health that will be updated routinely.

Rademacher also shared **results from qualitative interviews** with early adopters in Nairobi, Kenya, that showed that the most common reason women opted for Mirena was the perception that the method had fewer side effects than other FP methods. Specific side effects women wanted to avoid included weight gain and "hormonal imbalances."[9]

Partners also came together to develop needed **counseling and training resources**, including MCSP's Long-Acting Reversible Contraceptives Learning Resource Package, which includes a comprehensive chapter on LNG-IUS, and a new job aid co-developed by FHI 360 and PSI called the NORMAL Counseling Tool for providers to counsel clients about menstrual bleeding changes.

Donors and implementing partners have also supported **early introduction efforts** of existing products in public and private sectors in multiple countries. Implementing partners with current or past USAID-funded pilots and/or evaluation activities include FHI 360, MCSP/Jhpiego, Marie Stopes International, PSI/Society for Family Health and WCG Cares.

Avibela, which is distributed by Medicines360, was recently registered in Madagascar and Zambia and is currently under review in Kenya and Nigeria. Avibela is currently available at a public sector procurement price of approximately US $15/unit (the price depends on volume)[10] and is substantially more affordable than other commercially available LNG-IUS products for sale in FP2020 countries. However, key opinion leaders at the global- and country-level indicate that affordability is still a barrier, especially when contraceptive implants can be procured for $6.90-$8.50/unit. Working group members are also looking at how to support further **price reductions** of LNG-IUS commodities for public sector procurement, including exploring results from a price reduction analysis to map pathways to further reduce commodity prices.

Rademacher concluded her presentation with a call to continue sharing knowledge from the field to expand learning and identify additional knowledge sharing opportunities. The full presentation available on the Long-Acting and Permanent Method Community of Practice website.

[9] Nanda G, et al. 2018. Experiences with the Levonorgestrel Intrauterine System (LNG-IUS) in Kenya: Qualitative Interviews with Mirena Users and their Partners. *Eur J Contracept Reprod Health Care.* 10:1-6.
[10] Rademacher KH, et al. 2016. Expanding access to a new, more affordable levonorgestrel intrauterine system in Kenya: A comparison of service delivery costs and perspectives from Key Opinion Leaders. *Glob Health Sci Pract.* 4 Suppl 2: S83-S93.

Key Points from Question and Answer Session

Are there any reports of potential abuse or not taking out LARCs upon request? There also seems to be so little data on adolescents, why isn't there more focus on adolescents given recent focus globally?

- Currently just starting with pilots, regimented and highly managed projects, and have not heard any reports of abuse, but are watching closely for it as part of broader efforts to ensure informed choice.
- Under the LEAP project, they are doing focus group interviews with adolescents and are in the middle of doing qualitative data analysis now, so there will be informative findings to share on this topic at the next meeting.
- Several PSI service delivery projects focus a lot on reaching adolescents (Adolescents360, Support for International Family Planning Projects [SIFPO-2]), and they are seeing many adolescents voluntarily choosing LARCs.

Is reduced menstrual bleeding an advantage? Since some women cite that as a barrier.

- Not all women want reduced menstrual bleeding or amenorrhea, but it is attractive to a lot of women. There are also misperceptions about amenorrhea so that should be part of counseling too. A new job aid –the NORMAL counseling tool – was co-developed by FHI 360 and PSI for providers to discuss menstrual bleeding changes.
- Part of the LEAP learning agenda is to better understand reactions to bleeding changes. An abbreviated bibliography in Annex C includes a review by Chelsea Polis about bleeding changes called "There Might be Blood."[11]

Regarding the Demographic and Health Surveys, when might be the right time to get LNG-IUS added as different method to track use? And Performance Monitoring and Accountability as well.

- Consensus was it is still a bit premature for those levels, given the limited scale with which the LNG-IUS product has been implemented, but working with MOHs in countries to begin tracking it at national level.
- Generally, for Demographic and Health Surveys (and likely PMA 2020) surveys, country stakeholders can choose what contraceptive methods to include in their questionnaire to tailor the available methods to the context.

The costing analysis doesn't seem to take in unintended pregnancies and related costs.

- In Year 2 of LEAP, a cost-effectiveness analysis will be done that will include that.

Regarding issue of expulsions, there are vastly different expulsion rates across studies, why?

- There are two groups of clients that those studies look at, and postpartum expulsion varies tremendously. Global expulsion rates are low compared to US (suspect it's about technique); interval IUD expulsion rates are very low across the board.

Plenary 2: Country Experiences for Increasing Access to the LNG-IUS

Trish MacDonald, Senior Technical Advisor, USAID, set the stage for and moderated the second plenary, highlighting that we would be hearing from three of the five countries that are introducing LNG-IUS, looking specifically at service delivery considerations.

[11] Polis CB, Hussain R, Berry A. 2018. There might be blood: a scoping review on women's responses to contraceptive-induced menstrual bleeding changes. *Reprod Health.* 15(1):114.

Kenya: LNG-IUS Introduction through the Public Sector

by Brenda Onguti, Technical Advisor, Jhpiego Kenya

Project Intervention: In partnership with the Kenyan MOH, MCSP is supporting LNG-IUS introduction via public health facilities in Kisumu and Migori counties in Kenya. MCSP, in partnership with The Kenya MOH, Department of Family Health, through the Reproductive and Maternal Health Services Unit, sourced a donation of generic LNG-IUS from the International Contraceptive Access Foundation. MCSP worked closely with the national MOH to jointly plan all LNG-IUS introduction activities, including adapting the LNG-IUS module from the global MCSP LARC Learning Resource Package to the Kenya context and developing joint monitoring tools (the current health management information system does not differentiate between the two types of IUDs).

Implementation took place via already trained MOH LARC mentors who were then trained in LNG-IUS, with an emphasis on informed choice, quality of care, the WHO medical eligibility criteria and infection prevention. Once the LARC mentors were fully trained and certified in LNG-IUS, they, in turn, step down the training through an on-the-job approach (a 5-day structured mentorship approach to train providers at the facility in both hormonal and copper IUD insertion).

As of November 2018, LNG-IUS was introduced in 42 public sector facilities in Kisumu (18) and Migori (24) counties where MCSP was already working to strengthen FP/LARC services. In total:

- MCSP trained 48 qualified LNG-IUS mentors
- Mentors trained 190 service providers (nurses, midwives and clinical officers) to date
  - Kisumu County: 126
  - Migori County: 64
- MCSP conducted 30 total trainings

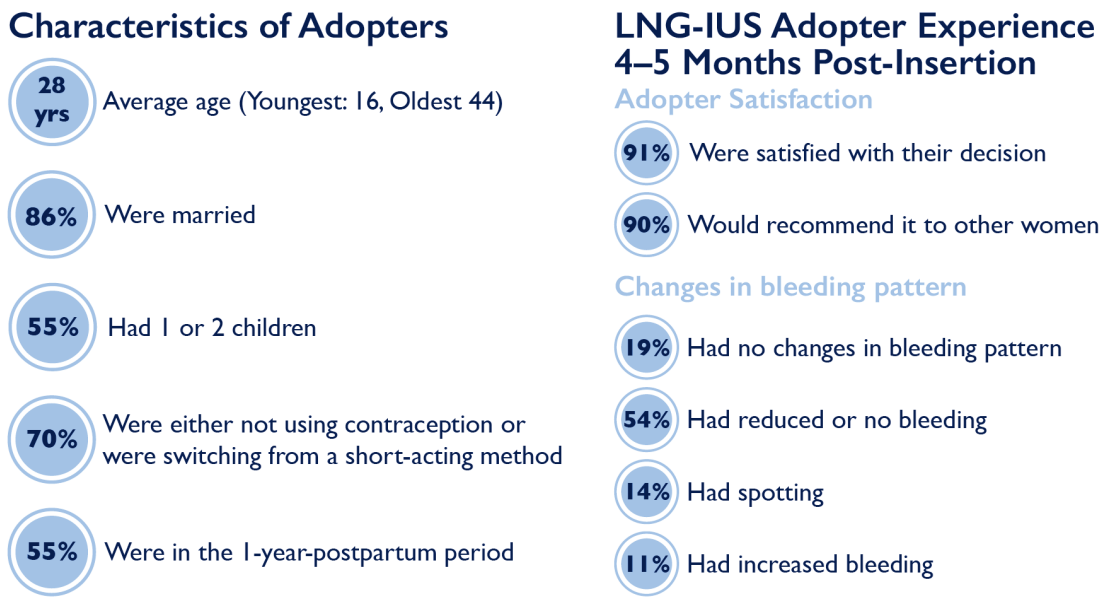
In 2019, under the USAID Afya Halisi bilateral in Kenya, MCSP is planning to scale up to 10 additional sites in Kisumu and Migori Counties as well as introduce LNG-IUS in Kakamega County.

Implementation Research:

- **Aim:** To investigate the effects of adding a hormonal IUD as an FP method option within a broader strategy to strengthen voluntary LARC services at governmental public health facilities in Kenya.
- **Methodology:**
  - FP clients receive voluntary FP counseling and services they desire, per client-centered care and quality standards.
  - Eligible women are informed and given the opportunity to participate in the study.
  - Interested, eligible clients consent to participate in the study immediately after LNG-IUS insertion
  - Provider administers survey
  - Follow-up phone calls conducted 4+ months after insertion
  - Data to be extracted from facility records in early 2019

From April 2017, providers administered short interviews to consenting women immediately after LNG-IUS insertion to document both the reason for choosing the method as well as their demographic information. Follow-up phone calls were conducted to assess early continuation rates as well as user experience and satisfaction. As of November 2018, 213 LNG-IUS adopters enrolled in the study. Initial results from the study are illustrated in Figure 4.

Figure 4. Initial results from MCSP Kenya IUD study



In addition, 77% of women experiencing absence of bleeding and 95% of women experiencing reduced bleeding viewed the change as having positive or neutral impact on their lives. "Major" problems were reported by 14% of adopters (most commonly cramping or pain during sex, too much bleeding, or abnormal discharge); only 2% of those still experienced the problem at the time of the follow-up interview. Two LNG-IUS adopters had expulsions, and five had the LNG-IUS removed.

Key project findings:

- Positive political/policy environment that has favored FP was helpful, allowing for critical MOH ownership and leadership, which in turn created an enabling environment at national and county levels.
- A holistic approach to strengthening health systems (from community to leadership levels) is needed. LNG-IUS was included in community-level strategies in two counties which is very promising.
- USAID support for LNG-IUS introduction made the work possible.
- Development/revision of necessary tools & documents (modular training learning resource package and reporting tools) to support rollout.
- Mentorship approach was used to increase knowledge and skill transfer.
- LNG-IUS inclusion in public facilities is feasible, but need to continue to think about sustainable strategies for commodities, and sustainable paths to scale it up.

The full presentation is available on the Long-Acting and Permanent Method Community of Practice website.

Kenya Q&A

Any best practices/challenges for ancillary equipment for insertion?

- In the two initial introduction areas, MCSP was able to support the equipment needs of the sites, and in 2019, the new project sites will be supported via the Afya Halisi bilateral. But moving forward, the government will likely need to include this in their costing to ensure that it's provided.

Regarding changing provider behaviors and attitudes for a changing method mix, what lessons can you share on messaging to providers to accept new methods?

- MCSP used the Balanced Counseling Strategy Plus tools which helps take out some of the provider biases. But it is really the use of mentors that helped with provider behavior change. Both Copper T and LNG-IUS were included in the training to ensure providers had skills for both methods.

Madagascar: Avibela Introduction through the Private Sector

by Francia Rasoanirina, Manager of Family Planning Programs, PSI/Madagascar & Ashley Jackson, Deputy Project Director for Expanding Effective Contraceptive Options (EECO), PSI

Product Introduction: To introduce new contraceptive methods, the EECO project progresses through five stages—from product registration to monitoring and learning.

Registration of Avibela: In March 2018, with support from the EECO project, Madagascar became the first country in Africa to approve registration of Medicines360's LNG-IUS. Zambia was second, also through EECO. (See notes from Panel 3 for more information on the process of registering Avibela in Madagascar).

Highlights from Market Research: Market research was conducted before introducing Avibela.

- Learned that one LNG-IUS product, Mirena, is available to some in Madagascar, but it is only known by wealthy women and a few providers due to the price of up to $250.
- Heard from women and providers that dissatisfaction with side effects of other methods drives discontinuation, and serves as a major reason for non-use of contraception in Madagascar.
- Learned that negative perceptions of IUDs and hormones are very common. Because of this, EECO sought to position Avibela differently – not just another IUD, not just another hormonal method. PSI chose to call Avibela by its brand name and highlight its side effect profile and effect on menstrual bleeding as features that distinguish the method from other options.

Figure 5. Avibela poster from Madagascar

Product Positioning: See Figure 5 for an example of a poster from EECO in Madagascar. The message, "With reduced periods, life is beautiful,"—highlighted the effect on menstrual bleeding as a characteristic that some women find desirable.

Procurement of Avibela: EECO secured a waiver to procure Avibela directly since it is not yet part of the catalog for USAID procurement by missions.

Madagascar Introduction Model:

- Private clinics in PSI's *Top Reseau* social franchise network
  - Trained 23 providers
  - PSI tracks service statistics
- Private clinics outside of franchise network
  - Trained nine providers
  - PSI does **not** track service statistics

Avibela is offered in the context of informed choice in facilities that provide a wide range of method options. The non-network providers are very interested in the product and have purchased larger quantities at a time. This is a partial cost recovery model – with PSI selling Avibela for nearly as much as they pay for it. The program-generated income through these sales will go back into the program, such as for additional demand generation or quality assurance activities or FP commodities and supplies.

Communication Strategy: Clients learn about the method through FP educators, FP counseling, posters in clinics, brochures and a forthcoming magazine placement.

Sales and Distribution: The number of clients so far is relatively low because this work is just beginning. As of the end of October, 101 clients had received Avibela from franchise providers.
Preliminary Findings from Client Study: Preliminary data shows that one-third of Avibela adopters said that if the LNG-IUS wasn't available, they would have used no modern method (see Figures 6 and 7). (This percentage was higher in Madagascar than in any other country represented in the LNG-IUS dashboard. This may be a result of the marketing approach, which focuses on the non-contraceptive benefits of the method).

Figure 6. Madagascar client study responses

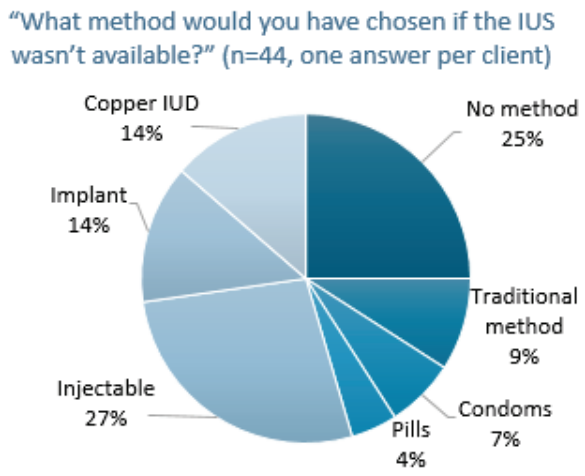
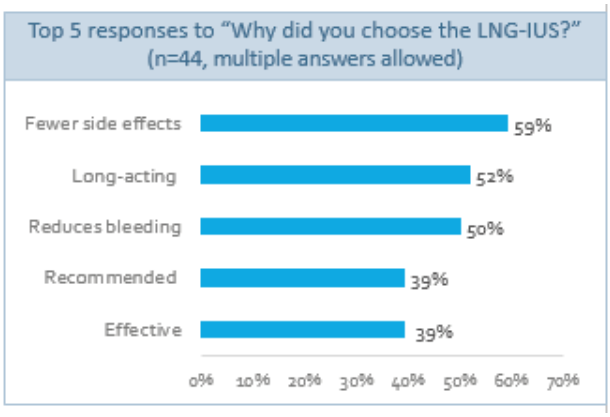


Figure 7. Top five reasons clients chose LNG-IUS



Key Considerations: Tensions around equity and sustainability exist.

- Although some women are willing to pay much more for this device than other methods, the majority of clients are in the lowest three wealth quintiles in urban Madagascar. However, the price is a barrier for many clients.
- This particular introduction is different because EECO is seeking a high level of cost recovery to test whether out-of-pocket payments or health insurance can bring down cost per couple-year of protection that is borne by donors.
- To increase equity, the EECO team is considering adjustments to the pricing model such as special service days for youth or free services on national FP day.

The full presentation available on the Long-Acting and Permanent Method Community of Practice website.

Madagascar Q&A

Counseling support is very important, especially with regards to side effects and the success of a method depends on this. What type of system exists for addressing this?

- Providers explained advantages and side effects of Avibela, and used the NORMAL job aid to discuss side effects. The FP educators also did close follow-up support for users over the first 4 months after adopting the method.

It is interesting that women were from lower wealth and education levels and saved up/planned ahead for this device. What type of program or anecdotal info do we have about them?

- Some women were interested by what they heard from FP educators, and so they start saving little by little for the method. FP educators visited often to check in with them, even to see how saving for the method was going.

Nigeria: LNG-IUS Services through Nongovernmental Organization (NGO)-supported Facilities

by Aurélie Brunie, Social Scientist, FHI 360 and Kendal Danna, Technical Advisor, SIFPO2

Findings on providers' perspectives and experiences through the Learning about Expanded Access and Potential of the LNG-IUS (LEAP LNG-IUS) Initiative: Aurélie Brunie introduced the overall learning agenda for the Gates-funded LEAP LNG-IUS initiative and explained that this presentation focused on the component seeking understanding of providers' perspectives and experiences offering LNG-IUS.

LEAP LNG-IUS Learning Agenda

1. Describe LNG-IUS acceptors and rejecters
2. Estimate potential demand in three countries
3. Measure continuation rates at 6 and 12 months and assess client satisfaction
4. Evaluate cost-effectiveness compared to other LARCs
5. Describe providers' experiences with method
6. Identify potential strategies to accelerate national regulatory approvals

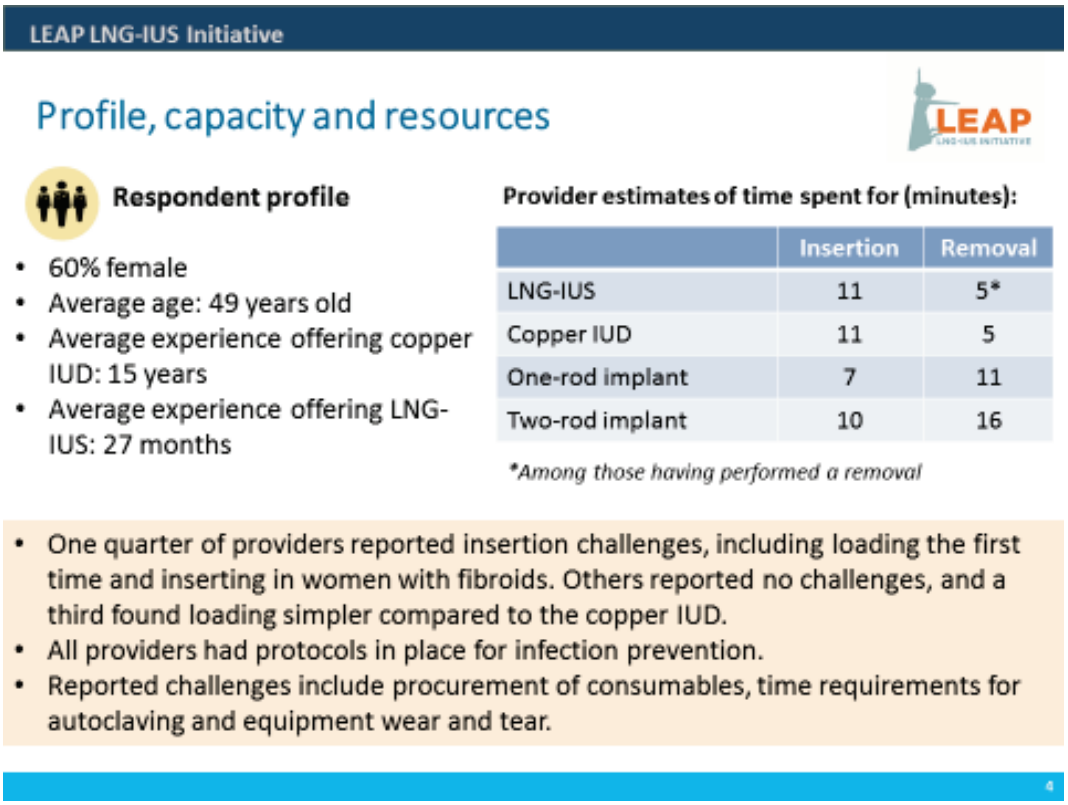
Brunie described an activity in Nigeria that is underway under LEAP to better understand providers' perspectives and experiences offering the LNG-IUS across five introduction programs. The assessment included in-depth interviews conducted in July 2018 with 20 providers across four states.

LNG-IUS products in programs:

- Four introduction programs using donated products from the ICA Foundation:
  - Society for Family Health, Marie Stopes International, Rotary and the University College Hospital Ibadan
- DKT introducing Eloira, Pregna's LNG-IUS, which was recently registered
- Medicines360 registering Avibela with support from WCG Cares
- Mirena™ available in private, for-profit clinics on a very limited basis

Key Findings: illustrated in Figure 8

Figure 8. Key findings from provider interviews in Nigeria



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

Advantages (Bold when cited by over half of providers)**:**

- No heavy bleeding compared to copper IUD
- Treatment of menorrhagia
- Other therapeutic benefits (For fibroids, endometriosis, and/or anemia)
- Reduced bleeding or amenorrhea
- Less or minimal side effects
- Reduced cramping

Disadvantages:

- No disadvantages reported by most providers
- Initial spotting
- Not suitable when active infections
- Extensive counseling required
- Providers reported dislikes or fears among clients related to: Uterine placement, hormones and amenorrhea

Key findings:

- Reasons for wanting to continue offering the LNG-IUS included non-contraceptive benefits, client satisfaction and expanding the method mix.
- Providers felt that cost remained a barrier because few service delivery points offered affordable LNG-IUS products and even subsidized prices could be prohibitive for some women.
- In programs using ICA Foundation donated products, reported prices to the client ranged from free to 3,000 Naira (USD 8). Prices for Eloira™ were higher, but providers noted it was less than Mirena™.

PSI's SIFPO2 Project and LNG-IUS work in Nigeria was presented by Kendall Danna who explained that PSI is supporting the same study in four countries, under EECO in Zambia and Madagascar and SIFPO2 in Nigeria and Zimbabwe.

- In all of these programs, the LNG-IUS is offered in the context of informed choice in facilities that provide a wide range of method options.
- SIFPO2 activities in these countries serve two purposes, the introduction of the method through different delivery models and extensive research with LNG-IUS users and providers to understand perspectives of the IUS, satisfaction rates and user profiles.
- Nigeria is one of the longest running LNG-IUS programs and is the furthest along in their research, having recently completed their 12-month follow-up surveys with users.

Implementation as of October 2018:

- Trained 8 trainers
- Trained 50 Private Providers
- Supported 40 pilot sites
- Performed 1228 voluntary LNG-IUS insertions
- Reported 18 (1.5%) IUS removals

"Supersites"

- Interpersonal communication agents provide 10 SIFPO2 sites with additional support for service delivery, equipment and materials, and demand generation
- Since this support began, SFH has seen increased service delivery and insertions from these sites

Demand Generation:

- At regular facilities, demand creation relies on provider motivation and the women being reached might already be in a facility for reproductive health (RH) needs.
- At supersites, interpersonal communication agents support facilities through community outreach activities-possibly reaching different users.

Insights into User Preferences: In Nigeria, 28% of women report that they would not have used a modern method at all if the IUS weren't available.

- LEAP and SIFPO2 are exploring whether this proportion grows with the introduction of the supersite model.
- They hypothesize that this may indicate that when women are engaged at this level by a health educator who is trained to talk to them about the unique benefits of the method (highlighting the difference in the non-contraceptive benefits as well) that women who may not otherwise show an interest in a LARC, or even a modern method at all, see the IUS as a method that can meet their needs.
- The plan is to disaggregate this data by facility to see what can be learned

Next Steps:

- The Society for Family Health (SFH) team is interested in expanding their product basket with a commercial LNG-IUS next year.
- SFH is the Market Authorization Holder for Avibela in Nigeria.

- With Avibela, which should soon be registered in Nigeria, SFH will work toward building a more sustainable, cost recoverable model for LNG-IUS service provision through the Healthy Families Network

The full presentation is available on the Long-Acting and Permanent Method Community of Practice website.

Nigeria Q&A

Regarding method mix of LNG-IUS vs. Copper T, IUD is low in general in Nigeria so how can we look more at this?

- PSI is trying to better understand how to put such a system in place to help understand the method mix, offer additional contraceptive method choice, and how the introduction of a new method might alter it.

Do either of the projects highlighted plan to expand/pilot in the northeast?

- SFH hopes to expand to more facilities from the current ones in 18 states, including in the NE.

Full Panel Q&A

We've heard about potential motivators, but have we looked at reasons for non-users, sources of dissatisfaction, etc. for non-users/rejecters?

- Looking at this under LEAP to develop profiles of users/non-users. LEAP is also doing two prospective studies in Nigeria and Zambia, including LNG-IUS, Copper T and injectable users. Will be looking at new users, reasons for method choice (including if knew about LNG-IUS), pain etc. Just completed baseline.
- In Madagascar, main reason for non-use of Avibela is price to client. There were only two removals so far, and both women had it removed due to side effects.

Who are these clients who say they would take a traditional or no method whatsoever if not LNG-IUS?

- In the case of Madagascar it is often women around age 30, with high level of education and wealth who have high fears of hormonal contraception.

Regarding dashboards, can the data on what else a client would choose be disaggregated? Will this product increase the number of new users?

- The dashboard reflects monitoring and evaluation of data of ongoing pilot programs. Data on previous use among LNG-IUS users is being gathered and will be reported under current research studies including the LEAP LNG-IUS Initiative.

Plenary 3: Panel Discussion on Products and Programming Opportunities

To close out the meeting, **Elaine Menotti, Technical Advisor, USAID** led a panel discussion with key experts focused on sharing lessons learned around LNG-IUS introduction to date and moving into a deeper discussion on where the community is going next.

Panelists:

- John Townsend, Director of Country Strategy, Population Council, and Chair, ICA Foundation
- Sally Stephens, Chief Business Officer, Medicines360
- Wilberto Robles, Sr. Director of Global Regulatory Affairs, WCG Cares

***Question for all three panelists**: Please introduce yourself and explain your role and interest in introducing this product:*

- Sally Stephens/Medicines360:
  - Medicines360 is a nonprofit pharmaceutical company focused on women's health. Mission is to expand access to high-quality women's health products to all women. Founded in 2009 and headquartered in San Francisco.
  - Currently have one product, the 52 mg hormonal IUD.
  - Started work with funding by a large anonymous donor to do a clinical trial in the US to offer an alternative to the high-priced Mirena™ product. They received first Food and Drug Administration approval for their product in 2015 for 3 years of contraception, and just recently got approval for 5 years. (The product is called Liletta® in the US).
  - While the initial focus of the work was the US, in 2015 started looking to expand work on this product into other countries. (The product is called Avibela® in LMICs).
- Wilberto Robles/WCG Cares:
  - WCG Cares is an international NGO based in San Diego that is committed to empowering, educating and enabling women and girls to make informed choices and increase access to critical RH products and services.
  - They have been patterning on introduction of LNG-IUS, especially around product registration.
  - WCG Cares is the prime of the USAID ECCO project, that also includes PSI, and the main goal is introduction of new technologies in LMICs.
  - Also collaborated with FHI 360 in development of the LEAP report (funded by the Bill & Melinda Gates Foundation) which will soon be available. The main goal of that work is to assess different aspects and challenges around registration activities for LNG-IUS in FP2020 countries, and/or in other countries that have been identified as high-priority for increasing access to the method.
- John Townsend/ICA Foundation:
  - Townsend serves as Chairman of the Board for the ICA Foundation, which was registered in Finland in 2005. (See http://www.ica-foundation.org for more information on the foundation, the product and projects.)
  - This is a public-private collaboration between Bayer (which is the licensee for the product) and Population Council to essentially distribute free of cost the Bayer LNG-IUS, as a non-commercial product, through public sector and NGOs in developing countries.
  - The product is manufactured by Bayer in Finland, and that is why the foundation is registered there.
  - They have donated over 125,000 LNG-IUS to date with over 20,000 donated each year of late.
  - The LNG-IUS is the same device as the Mirena but has the more traditional two-handed inserter. The product is defined as the device plus the inserter.
  - Donated to organizations working in 37 countries so far and has the capacity to donate 27,000 units per year from a single manufacturing batch.
    - For special larger programs they have the capability to add 54,000 units, but have not yet done so in a specific country.
  - When look at the value of product donated, using the market price of $40 USD for Mirena, it is equal to a donation of about $5M USD.
  - They are governed by a board, which includes members from PSI, Marie Stopes International, Pathfinder, IPPF, Jhpiego, Rotary Club and medical experts from FIGO.
  - They just signed another 5-year agreement between the Population Council and Bayer to ensure future supply.

Question for Medicines360: *Partnership is a key dimension to the Medicines360 business model and how it looks to expand access and choice. How do you identify good partners/make a good partnership to result in positive outcomes?*

- Medicines360 is only 35 people total, so partnerships are critical to making impact and meeting their mission. Their approach is they do NOT reinvent the wheel; if another organization has the expertise to help them meet the mission, they partner with them.
- In LMICs, that means that implementation partners like Marie Stopes International and PSI are heavily engaged. They have large in-country infrastructures to deliver services (e.g., education and counseling, insertion and removal training.)
- Medicines360 expertise lies more in the clinical trials and regulatory dossiers, with close familiarity of the clinical data.
- However, there was a gap: Neither Medicines360 nor its distribution partners had core competency in understanding regulatory authority requirements in developing countries, which is why they partnered with WCG Cares.
- One of the challenges is that Medicines360 is not the manufacturer, they partner with the manufacturer and are confined by the terms of the agreement with them. This makes Medicines360 the liaison between implementers and the manufacturer, which can be challenging.
- Another challenge is that they are a small nonprofit, the way they stay in business is royalties on US sales that they use to subsidize a low-cost product to the US public sector as well as subsidize the work in LMICs.
    - So, they're very cautious is protecting the US market so they can remain in business and are in turn cautious of how they approach LMICs (which can be hard for partners).
- As a non-profit they use a total market approach in the US – private sector sales subsidize a lower price in public sector (private sector price in US is determined by Medicines360's commercial partner). In their global work they seek partners who approach LMIC markets with similar philosophies.

Question for WCG Cares: *Around cracking the "nut" of regulatory requirements in countries – what types of relationships and skill sets are needed to register and introduce new products like LNG-IUS?*

- A thorough regulatory landscape assessment is an important first step, including going to the country and meeting with key stakeholders and authorities so they can really understand the landscape and the requirements, and what the options are to help register the product as soon as possible.
    - Meeting in person has been part of the recipe for success because sometimes the information found in the regulations differ from the current practice. This is also important to build relationships with key stakeholders and authorities that can support during the registration lifecycle.
- Need to understand not just requirements in-country, but also to ensure your dossier addresses special considerations that are specific to that country.
    - This is different than SRA such as in the US and European Union where the processes are very well outlined and checklists already exist etc.
- All of this helps understand whether or not the product is ready for regulatory approval (does it have the appropriate data to make the registration?
    - For example, understanding whether or not foreign entities are allowed to be the marketing authorization holder or if the dossier have the required stability data required for this country.

Question for ICA Foundation/Population Council: *What can we learn from other contraceptive markets like implants or a newer product, like the progesterone-only vaginal ring, to inform planning for LNG-IUS introduction and scale-up?*

- The Population Council sees development of new technologies as part of their goal to respond to unmet need of clients and providers. They are not a pharmaceutical company; rather they are a nonprofit organization that works on the development of contraceptive technologies, seeking to serve the largest number of people around the world with the best that science can offer.
- When looking at implants, the following were important:
  - Understanding the different products on the market
    - Developing guidelines so people could understand the different products and their relationship in the market.
    - Implants have been bio-similar, if not bio-equivalent, and the LNG-IUS is like that as well, so they are really similar products across the manufactures, with slight differences like different inserters.
    - Over time, people began to know implants better and identify the product and the more similar they are, made it easier to understand how to provide them from the perspective of providers and clients.
  - Reliable supply was also key at a volume that's important.
    - There are lots of people with unmet need. From implants, we learned you need multiple suppliers to ensure there's a reliable market. Dropping one product out of a narrow/shallow market is dangerous, and you need multiple manufactures to ensure competition and a reliable supply.
    - The implants volume guarantee helped diversify the market in developing countries, enhance predictability for manufacturers and lowered the price of procurement. In the first year, there was a 62% increase in implant use and growth continues.
    - So thinking about how predictability and price work together and the role of donors and partners in that is important.
- Because these are LARCs and are highly effective and have high levels of client continuation, essentially you are lowering the burden on the supply chain with LARCs as you don't need as much product volume to address the need for contraceptive protection.

Key Points from Question and Answer with the Audience

Beyond the initial countries discussed today, what other countries could we be adding LNG-IUS too?

- Medicines360 has commercial rights in 88 countries outside the US, around the world. They're trying to be thoughtful about where to go next as they can only manage a few registrations per year using their own resources and want to be impactful.
- ICA makes donations around the world, applicants generally can make requests from anywhere as long as the focus is the public sector and they seek to target vulnerable populations.
  - But there will come a time when 27,000 units a year won't make a difference. So the board is reviewing the strategy. They know LNG-IUS introduction is quicker in places with a history of IUD use.
  - Plus, they don't want to "replace" copper IUD use, they want to maintain service quality and make sure that the LNG-IUS is for those who want to use it.
  - ICA wants to make sure countries are using them well and needs are being met.

- There has been some discussion between Medicines360 and ICA about using the ICA stock as a proof of concept then transitioning to the MEDICINES360 product. This would help leverage the needs of both groups and better understand demand before purchasing larger quantities.

What are lessons learned from the LNG-IUS experience that can apply to other products? Specifically across three dimensions: (1) a new product category, (2) different manufacturers, (3) is the product SRA approved? When adding all these together, the pathway differs to get the product into the country. While we all agree on the principles of informed choice, each pathway is different. How do you prepare for that and what are the lessons that you have learned thus far from LNG-IUS and other products?

- At the time Medicines360 was looking at LMICs, the product was approved in Europe and the US for 3 years duration of use. They were hoping to base the LMIC dossiers on the United Kingdom dossier, but it was too complicated and Medicines360 realized they needed to create a completely new dossier in Common Technical Document format before embarking on the approvals in LMICs.
  - A lesson they'd like to learn but haven't yet: they're still struggling with the value of WHO pre-qualification and whether or not it makes sense for them.
- WCG Cares: Having SRA approval is the "how" to get there. SRA can be a helpful tool for building trust, especially in countries that rely on WHO or other decision-makers. Also, countries consider where the product was manufactured, so SRA can change the process and eliminate some hurdles.

Are countries becoming stricter on introducing products with import permits? And is ICA Foundation no longer registering the products?

- The foundation has decided not to register LNG-IUS in any more countries (currently registered in three). The reason has to do with the future of marketing of LNG-IUS so it can attract new producers. There are always delays in import approvals for products, but we have not seen increases in most LMICs. There have been some delays in Pakistan and Bangladesh.
  - Hope Medicines360 and others will champion registering, but do not think the import permits will be the real barrier as yet.
- Important to understand the regulatory space is complex. It is as complex as the market space.

Are there lessons learned, or questions we should be asking, based on learning from the places where ICA products have been donated?

- ICA does reviews and case studies, including one by David Hubacher in Kenya.
  - Shouldn't only think of procurement costs but how we develop markets.
  - Should not just look at cost but also the distribution of benefits (who benefits?)
  - The failure to focus on quality of service is a real mistake for any group entering the market.
  - Issues of supply chain are challenging when the product doesn't come through MOH or USAID.
  - Don't try to replace Copper T with an LNG-IUS from any manufacturer. The goal is to try and expand the market and choice, not compete for market share.

For Medicines360, you have the Food and Drug Administration registration of the product now for 5 years, are you thinking of going beyond that? And how does this affect in-country approvals?

- US clinical trial was extended to 10 years. They have women entering the 10th year this month.
- This means they will have to keep updating the approvals in all the countries as the product effectiveness is extended. They will do this in a thoughtful manner, for example they did not submit dossiers with 4-

year data, but instead are going straight from 3 to 5 years, and may just jump to 8 years next, pending clinical trial results.

- Medicines360 is also running a heavy menstrual bleeding trial in the US so they can get that indication covered in the US. (Avibela already has a heavy menstrual bleeding indication based on European approvals).

For WCG Cares: Is the collaborative process for multi-country registration being explored?

- There is interest in collaborative approvals, and this is one way to expedite the process. But the approvals are applicable mainly only to specific regions and unfortunately there is currently no mutual recognition. Meaning that if it a product is approved in one country, it does not mean it is approved automatically in all the other countries in the collaborative, you still have to register the product individually in each country.
- If you have a full pre-qualification from WHO it can help expedite the process in some places.

Menotti closed the panel by thanking the panelists and reflecting that the work of making contraceptive choice a reality is tough work that takes upstream investments to develop new contraceptive technologies, to mid-stream investments to register them, then scaling them up in the context of an FP market is a long-term commitment for this community.

Closing and Next Steps

Anne Pfitzer, FP Team Lead at MCSP, thanked everyone for their participation in today's technical meeting. This was a rich and information-filled meeting. It also highlighted the really collaborative nature of the LNG-IUS group.

Pfitzer also reminded the audience that at the Implants Technical Meeting in October 2018 there was agreement to transition the LAPM COP to a broader Method Choice COP in 2019. MCSP, who currently chairs the COP, will reach out in 2019 to hold a deeper dive discussion on how to operationalize this change. If you want to be engaged in that discussion, please e-mail LA_PM_CoP@my.ibpinitiative.org.

Annex A: List of In-Person Attendees

1. Adrienne Allison, Independent Consultant
2. Alexandra Angel, PSI
3. Alexandra Morel, GHSC-PSM
4. Andree Sosler, Medicines360
5. Anita Deshpande, GHSC-PSM
6. Anne Pfitzer, Jhpiego
7. Ashley Jackson, PSI
8. Aurélie Brunie, FHI 360
9. Avery Waite, USAID
10. Bethany Arnold. Jhpiego
11. Brandon Hugueley, PCI
12. Chelsea Cooper, MCSP / Jhpiego
13. Christine Bixiones, PSI
14. Danielle Harris, WCG Cares
15. David Hubacher, FHI 360
16. Deborah Sitrin, MCSP/Jhpiego
17. Elaine Menotti, USAID/Washington
18. Eleni Han, CHAI
19. Emma Golub, SHOPS Plus, Abt Associates
20. Francia Rasoanirina, PSI
21. Halida Akhter, Johns Hopkins Bloomberg School of Public Health
22. Jill Gay, What Works Association
23. Julie Boccanera, USAID
24. Kate Rademacher, FHI 360
25. Katie Morris, Save the Children
26. Katie Meyer, Save the Children/US
27. Katy Mimno, Pathfinder International
28. Kendal Danna, Population Services International
29. Kristen Rancourt, USAID
30. Lauren VanEnk, World Vision
31. Leah Elliott, MCSP
32. Lindsay Georgestone, JSI
33. Lois Schaefer, USAID
34. Madeline Schneider, USAID
35. Mark Hathaway, MCSP

36. Megan Christofield, Jhpiego
37. Melissa Freeman, USAID
38. Morgan Simon, GHSC-PSM
39. Nicholas Hale, USAID
40. Noxolo Magubane, WCG Cares
41. Rose Amolo, The Bizzell Group
42. Safia Ahsan, RHSC
43. Sally Stephens, Medicines360
44. Sandra Laney, Bill & Melinda Gates Foundation
45. Saumya RamaRao, Population Council
46. Shannon Bledsoe, WCG Cares
47. Susan Mitchell, SHOPS Plus/Abt Associates
48. Tabitha Sripipatana, USAID
49. Trish MacDonald, USAID
50. Wilberto Robles, WCG Cares

Annex B: Speaker Biographies

Aurélie Brunie, PhD, is a Social Scientist in the Health Services Research division of FHI 360. She is currently the Research Lead of the multi-country Learning about Expanded Access and Potential of the LNG-IUS (LEAP LNG-IUS) Initiative, which is funded by the Bill & Melinda Gates Foundation, and a principal investigator on a study on access to removal services for long-acting contraceptives.

Kendal Danna, MPH, has served as a Technical Advisor for PSI for almost 3 years, first for the Lao PDR country platform, and now in Washington. Ms. Danna currently serves as the technical lead for PSI's LNG-IUS work, supporting the introduction of the LNG-IUS in Madagascar, Zambia, Zimbabwe and Nigeria across three projects: SIFPO-2, LEAP LNG-IUS Initiative, and EECO. In addition to the LNG-IUS portfolio, she supports both the EECO project's introduction of the DOT fertility awareness mobile app and SIFPO-2's research on PSI's Counseling for Choice model for improved FP counseling.

Mark Hathaway, MD, MPH, is a board-certified ob/gyn currently serving as a Family Planning and Reproductive Health Senior Technical Advisor for Jhpiego. Dr. Hathaway has served on several national-level work groups and committees, including the Institute of Medicine Standing Committee on Family Planning and the National Contraceptive Metrics Workgroup, and holds appointments at Johns Hopkins University Ob/Gyn Department and George Washington University. He also served on the board of directors of the National Family Planning & Reproductive Health Association, the Association of Reproductive Health Professionals, and Peace Corps Sexual Abuse Advisory Committee. He received his undergraduate degree in biology from the College of St. Thomas in St. Paul, MN; his MD from the University of Kentucky; and MPH from Johns Hopkins University.

David Hubacher, PhD, MPH, is a Senior Epidemiologist at FHI 360 in Durham, NC. For over 25 years, he has specialized in research on LARC (subdermal implants and intrauterine products) and has been principal investigator for large multi-year studies, including two National Institutes of Health research grants. For his work on IUDs, he has won numerous awards: Best Scientific Paper (1999), Outstanding Research Award (2005), Top 4 Oral Abstract Award (2017), and Outstanding Articles Award (2018). Dr. Hubacher serves on the Board of Directors for the Society of Family Planning and is on the Editorial Board for the journal *Contraception*.

Ashley Jackson, MSPH, is the Deputy Project Director for EECO, a global project funded by USAID and led by WCG Cares in partnership with PSI. Ms. Jackson also serves as PSI's co-lead for injectable contraceptives, including DMPA-SC. Previously, she managed programs at EngenderHealth to advance access to contraception and HIV services in East and West Africa. She has also worked for Management Sciences for Health and lived in Benin as a Fulbright Fellow.

Trish MacDonald is a registered nurse and public health specialist in FP and RH. Over the last three decades, she has lived and worked in several countries in Africa and Asia to train clinical providers, strengthen quality of care and health systems, design and conduct programmatic research, and manage maternal and projects. As a Senior Technical Advisor in the Office of Population and Reproductive Health in USAID's Bureau for Global Health, she provides leadership in areas of contraceptive method choice, LARCs/PMs, FP integration with maternal and child health, service communication, and scaling up evidence-based high-impact practices. She has an MPH in health behavior and health education from the University of Michigan.

Elaine Menotti is a Technical Advisor at USAID's Office of Population and Reproductive Health where she works on the Private Sector team, manages FP/RH and other health service delivery programming, and engages in strategic efforts to expand method choice and access globally. Previously, she worked in USAID's Nutrition division on community-based maternal and child health programming. Before USAID, Ms. Menotti worked at Futures Group (now Palladium) to strengthen FP and policies and programs in multiple countries. She worked in Central America with local and international NGOs, as well as domestically, to design,

implement and monitor community based MCH, FP and nutrition programs. She has an MPH in Health Behavior and Health Education and a Certificate in Reproductive and Women's Health from the University of Michigan and a bachelor of arts in anthropology from Duke University.

Brenda Onguti has a background in Public Health and Pharmacy. She worked as Technical Advisor with the USAIDs MCSP Program in Kenya where she was part of the team expanding the method mix through the introduction of the LNG-IUS. She is currently the Program Lead in the study that is generating evidence for Group Antenatal Care in Kenya.

Anne Pfitzer is the Family Planning Technical Team Leader for MCSP. Before this, she was Deputy Director for Save the Children's Saving Newborn Lives program, funded by the Bill & Melinda Gates Foundation. She has also served as Country Director in Ethiopia for Jhpiego, and Performance Improvement Advisor for a FP USAID bilateral program, called STARH in Indonesia.

Kate Rademacher, MHA, has 17 years of experience in FP program design, management, evaluation, and strategic communications. She currently works in the Contraceptive Technology Innovation department at FHI 360 where she supports the development and introduction of new, long-acting contraceptives for low-resource settings. Ms. Rademacher currently serves as the Project Director for the Learning about Expanded Access and Potential of the LNG-IUS (LEAP LNG-IUS) Initiative which is funded by the Bill & Melinda Gates Foundation. She also manages a portfolio of activities related to the LNG-IUS under the USAID-funded Envision FP project.

Francia Rasoanirina, MD, is the Manager of Family Planning Programs for PSI/Madagascar. She has worked for PSI for nine years, including as a clinical supervisor of health services. Previously, she worked as a private health care provider in PSI/Madagascar's social franchise and conducted research with the University of North Carolina.

Wilberto Robles is the Senior Director of Global Regulatory Affairs at WCG Cares and has over 17 years of professional experience in the pharmaceutical, medical device and cosmetic industry with a special focus in products. He holds a Bachelor's of Science in Microbiology and a Master's in Manufacturing Competitiveness/Industrial Engineering. His previous experience includes different positions at Wyeth, Bristol-Myers Squibb, APP Pharmaceuticals and Blu Pharmaceuticals. In these, he focused his professional experience in Regulatory Affairs, where he held different leadership positions working with international, EU, LAC and US registrations; quality assurance, validations, and project management.

Tabitha Sripipatana is the Deputy Division Chief for the Research, Technology and Utilization Division in the Office of Population and Reproductive Health at USAID. Ms. Sripipatana serves as the lead for the introduction of new FP and technologies. She provides technical guidance and leadership for program development, review and coordination of FP and related HIV/sexually transmitted infection biomedical prevention research, service delivery, and research utilization as conducted through USAID supported cooperating agencies. Before joining USAID, Ms. Sripipatana spent 9 years with the Elizabeth Glaser Pediatric AIDS Foundation implementing research and service delivery scale-up on elimination of congenital syphilis efforts and elimination of pediatric AIDS programs. Ms. Sripipatana earned a bachelors in biology and psychology from the University of Oregon and a masters in public health from University of California Los Angeles.

Sally Stephens is the Chief Business Officer at Medicines360. She oversees Corporate Strategy, Business Development, Marketing/Sales, and the Developing Countries Program at Medicines360. Ms. Stephens joined Medicines360 in 2011 and was instrumental in forming a groundbreaking partnership with Actavis, Inc. (now Allergan, plc) to develop, manufacture, and commercialize Medicines360's hormonal IUD, Liletta. Since the product was brought to market in 2015, she has overseen all business activities related to the successful commercialization and management of Liletta. Ms. Stephens received her bachelor of science in chemical engineering from University of California, Berkeley and her master's in business administration in health care management and finance from the Wharton School at the University of Pennsylvania.

John Townsend, PhD, is Director of Country Strategy at the Population Council. In this role, he provides leadership and support across the Population Council's country offices with the aim to maximize the Council's positive impact and ensure the organization's knowledge is effectively influencing national policy and programs. He is responsible for the initiation, development, and monitoring of Council country strategies and provides technical and managerial guidance related to program priorities in; Poverty, Gender, and Youth; and HIV/AIDS as well as support for the introduction of new health technologies in countries with Council presence. Dr. Townsend is chair of the RHSC and serves as co-chair of the Board of Trustees of the International Contraceptive Access Foundation, a public–private cooperation with Bayer AG, which provides access to long-acting intrauterine methods in developing countries.

Annex C: Meeting Agenda

Long-Acting & Permanent Methods Community of Practice

Technical Meeting

What's Next with the LNG-IUS?

Date and Time:	Tuesday, December 4, 2018, 9:00am – 2:00pm
Venue:	MCSP Offices, 1776 Massachusetts Ave, Suite 301, Washington, DC

Goal

The LAPM COP will convene to provide an overview of the current global efforts to increase access to the levonorgestrel intrauterine system (LNG-IUS) in low- and middle-income countries (LMICs), review the evidence and explore approaches to expanding access to family planning, including sharing learning from pilot introduction activities in Kenya, Madagascar, Nigeria, Zambia and Zimbabwe.

Objectives

Participants will:

- Review the key features of the LNG-IUS and current product availability for low-resource countries
- Gain a deeper understanding of the current state of global LNG-IUS evidence and use in LMICs
- Discuss challenges to increasing accessibility and affordability of the LNG-IUS in LMICs
- Understand key national policy and measurement considerations
- Hear from selected introductory projects about user profiles and potential demand
- Learn about providers' experience with the method and understand how provider-side barriers impact method provision

Agenda

Time	Session	Presenter
Breakfast & Opening		
8:30-9:00	Breakfast & Meeting Logistics	Leah Elliott, MCSP
Plenary 1: Overview of the LNG-IUS & Global Learning Agenda		
9:00-9:05	Welcome & Panel Introduction	*Moderator:* Tabitha Sripipatana, USAID
9:05-9:25	LNG-IUS 101	Mark Hathaway, MCSP
9:25-9:40	Landscape of LNG-IUS: Overview of Products & Recent Evidence from Kenya	David Hubacher, FHI 360
9:40-9:55	Global learning agenda & potential pathways to increasing affordability and access	Kate Rademacher, FHI 360
9:55-10:20	Q&A and Discussion	*Moderator*
10:20-10:40 Break		
Plenary 2: Country Experiences for Increasing Access to the LNG-IUS		
10:40-10:45	Country Panel Introduction	*Moderator*: Trish MacDonald, USAID
10:45-11:00	Kenya: LNG-IUS Introduction through the public sector	Brenda Ongunti, Jhpiego Kenya
11:00-11:05	Kenya Q&A	*Moderator*
11:05- 11:30	Madagascar: Avibela introduction through the private sector	Francia Rasoanirina, PSI Madagascar & Ashley Jackson, PSI/WCG Cares
11:30-11:35	Madagascar Q&A	*Moderator*
11:35-11:50	Nigeria: LNG-IUS Services through NGO-supported facilities	Aurélie Brunie, FHI 360 & Kendal Danna, PSI
11:50-12:15	Nigeria Q&A and Broader Country Experience Discussion	*Moderator*
12:15-1:00 Lunch & Marketplace		
Plenary 3: Panel Discussion on Products and Programming Opportunities		
1:00-1:05	Panel Introduction	*Moderator*: Elaine Menotti, USAID
1:05-1:30	Panel Discussion: Products & programming opportunities	John Townsend, ICA Foundation
		Sally Stephens, Medicines 360
		Wilberto Robles, WCG Cares
1:30-1:50	Q&A and discussion	*Moderator*
Closing		
1:50-2:00	Closing & Next Steps	Anne Pfitzer, MCSP

Annex D: Bibliography

The Levonorgestrel Intrauterine System (LNG-IUS):

Resources with a Focus on Emerging Evidence from FP2020 Countries

General/Global

- Rademacher KH, Sripipatana T, Pfitzer A, et al. 2018. A Global Learning Agenda for the Levonorgestrel Intrauterine System: Addressing Challenges and Opportunities to Increase Access. *Glob Health Sci Pract.* 6(4):635-643. Available here.
- Hubacher D. 2015. The Levonorgestrel Intrauterine System: Reasons to Expand Access to the Public Sector of Africa. *Glob Health Sci Pract.* 3(4): 532-7. Available here.
- Jacobstein R, Shelton JD. 2015. The levonorgestrel intrauterine system: a pragmatic view of an excellent contraceptive. *Glob Health Sci Pract.* 3(4):538–543. Available here.
- Hubacher D, Kavanaugh M. 2018. Historical record-setting trends in IUD use in the United States. *Contraception.* 98(6):467-470. Available here.
- WHO Essential Medicines List addition of the LNG-IUS.
- K4Health IUD Toolkit with LNG-IUS resources.

Kenya

- Nanda G, Rademacher KH**,** Solomon M, Mercer S, Wawire J, Ngahu R. 2018. Experiences with the Levonorgestrel Intrauterine System (LNG-IUS) in Kenya: Qualitative Interviews with Mirena Users and their Partners. *Eur J Contracept Reprod Health Care.* 10:1-6. Available here.
- Ongunti B, et al. 2018. Introduction of the Levonorgestrel Intrauterine System (LNG-IUS) in the Public Sector in Kenya Shows Early Positive Uptake. ICFP 2018. Poster. Available here.
- Rademacher KH, Solomon M, Brett T, et al. Expanding access to a new, more affordable levonorgestrel intrauterine system in Kenya: A comparison of service delivery costs and perspectives from Key Opinion Leaders. *Glob Health Sci Pract.* 4 Suppl 2:S83-S93. Available here.
- Hubacher D, Masaba R, Manduku CK, Chen M, Veena V. 2015. The levonorgestrel intrauterine system: cohort study to assess satisfaction in a postpartum population in Kenya. *Contraception.* 91(4):295-300. Available here.
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- Hubacher D, Akora V, Masaba R, Chen M, Veena V. 2014. Introduction of the levonorgestrel intrauterine system in Kenya through mobile outreach: review of service statistics and provider perspectives. *Global Health: Science and Pract.* 2(1):47-54. Available here.

Ghana

- Nyarko P, Adohinzin C, Tapsoba P, et al. 2009. *Acceptability and promotion strategies for LNG-IUS in Ghana: a public health assessment.* Accra, Ghana: Population Council, Regional Office for Sub-Saharan Africa. Available here.

Nigeria

- Eva G, Nanda G, Rademacher KH, et al. 2018. Experiences with the Levonorgestrel Intrauterine System among Clients, Providers and Key Opinion Leaders: A Mixed-Methods Study in Nigeria. *Glob Health Sci Pract.* 6(4):680-692. Available here.

Zambia

- FHI 360, Society for Family Health, PSI, WCG. 2016. Market Assessment for Potential Introduction of a New Hormonal IUCD in Zambia. Report. Report available here.

Menstrual Bleeding Changes

- Sergison, JE, Maldonado, LY, Gao, X, Hubacher, D. 2018. Levonorgestrel Intrauterine System associated amenorrhea: a systematic review and meta-analysis. Amer Journal of Obstet and Gynecol. Available here.
- Polis CB, Hussain R, Berry A. 2018. There might be blood: a scoping review on women's responses to contraceptive-induced menstrual bleeding changes. *Reprod Health.* 15(1):114. Available here.
- Rademacher KH, Sergison S, Glish L, et al. 2018. Menstrual Bleeding Changes are NORMAL: Proposed Counseling Tool to Address Common Reasons for Non-Use and Discontinuation of Contraception. *Glob Health Sci Pract.* 6(3):603-610. Available here.
- Darney PD, Stuart GS, Thomas MA, Cwiak C, Olariu A, Creinin MD. 2018. Amenorrhea rates and predictors during 1 year of levonorgestrel 52 mg intrauterine system use. *Contraception.* 2018;97(3):210-214. Available here.
- Schreiber CA, Teal SB, Blumenthal PD, Keder LM, Olariu AI, Creinin MD. 2018. Bleeding patterns for the Liletta® levonorgestrel 52 mg intrauterine system. *Eur J Contracept Reprod Health Care.* 23(2):116-120. Available here.

Websites of Manufacturers with LNG-IUS product(s) approved by SRA

- ICA Foundation
- Medicines360
- Bayer Healthcare (Mirena)

This list of publications related to the LNG-IUS was compiled by FHI 360 as part of the LEAP LNG-IUS Initiative in December 2018. It is intended to focus on resources that are relevant for FP2020 markets and is not intended to be a comprehensive bibliography of all literature on the method. For more information about the LNG-IUS, visit the IUD Toolkit on the K4Health website: https://www.k4health.org/toolkits/iud