
Kelly: Greetings and welcome to today's webinar on intrauterine devices, also known as IUDs. We will begin covering both hormonal and non-hormonal IUDs. My name is Kelly McDonald, and I am the Knowledge Management Coordinator for the Advancing Partners and Communities Project. Before we begin today's presentation, I'd like to quickly review the Adobe Connect environment and set a few norms for today's webinar.

Today's webinar has three presentations followed by a discussion period, during which our speakers will address your questions. Within the webinar environment, please make use of the Q&A box on the bottom right side of your screen to share your thoughts, note your questions, or ask for help with sound during the presentation. Questions you ask are only visible to you, our presenters, and technical support. If you are experiencing technical difficulties, our technical support will respond to your question privately. We will collect your questions for our speakers and will save them for the discussion period.

It is great that we were able to connect people from so many places today, but your experience may vary based on your internet connection and computer equipment. I will briefly go over a few troubleshooting steps if you have any technology challenges today.

Here are some tips: If you do lose connectivity or cannot hear, please close the webinar. Reenter the meeting in a browser other than Google Chrome by clicking on the webinar link provided. You can also use the Q&A box to ask APC tech for assistance. If these steps are still not successful, please rest assured the webinar is being recorded and you will receive an email with a link to the recording following today's events.

Questions that don't get answered during the Q&A session will be compiled after the webinar, shared with our presenters, and responses from presenters will be shared with participants. To get us started, I will now turn it over to our moderator, Tabitha Sripipatana.

Tabitha: Thanks for that, Kelly. You did just fine on my last name. Greetings, everyone. I'd like to welcome and thank everyone for joining us today. My name is Tabitha Sripipatana. I'm the Deputy Division Chief of the Research Technology and Utilization Division within the Office of Population and Reproductive Health at USAID.

Today's webinar is organized by the Advancing Partners and

Communities Project in collaboration with Family Planning 2020, the Implementing Best Practices Initiative, and USAID's Office of Population and Reproductive Health. This webinar on intrauterine devices will cover both hormonal and non-hormonal IUDs and is the fourth in a series of webinars that will highlight several family planning assets.

So, the objectives of this – I think I went too far. Hold on just one second. Sorry about that. A bit of an overview of this series: So, APC and IBP and FP2020 have sponsored this webinar series, which is designed to highlight a range of family planning methods. Each webinar will provide details on a single method.

Target audiences for this webinar are ministries of health, policymakers, donors, and program managers. The series will provide information on family planning methods, including how to use them, their effectiveness, how they work, medical eligibility criteria for use, and hot topics specific to each method. It includes case studies for each family planning method service delivery channel.

The objectives include providing technical information and updates on a broad range of family planning methods, engaging the global audience to discuss emerging trends, highlighting programmatic successes and challenges, and of course, we're answering questions specific to each method.

And, though we're going over one category of methods, all of this is really embedded in volunteerism and informed choice. Of course, programs and in practice, we expect that clients have access to a broad range of methods.

Clients receive client-centered counseling on a range of contraceptive methods, discuss lifestyle, reproductive intentions and practices, and can ask questions. Clients freely choose the method without coercion. Clients receive detailed information on the chosen method, can discuss the method with the provider, and ask questions. Providers are able to offer and counsel clients on a range of methods, even those that they do not offer themselves, but might be available via other providers or resources. And, I'd like to now introduce our first speaker, which is Mark Hathaway of Jhpiego. Thank you.

Mark:

Good morning, everyone, or good afternoon, or good night. I presume some of you are entering into the nighttime. I'm really happy to be here to talk about one of my favorite topics,

intrauterine devices, and I will begin by going over some basics, and Kate will follow me and do a deeper dive into the hormonal IUDs, and Laura will then talk about some global experiences regarding IUDs.

So, just for starters or for basics, we're going to use several terms interchangeably: The intrauterine device, the intrauterine system, the intrauterine contraception. We're also going to use, on occasion, the acronym LARC, which refers to long-acting reversible contraceptives, which include the types of IUDs we're going to mention as well as the implant.

So, in general, IUDs are small, T-shaped devices that are placed in the uterus. They're small, and you can see by this picture, they're about the size – they fit in the palm of one's hand. They're simple to use, also known as low-maintenance, they're highly effective, and they're immediately effective, and they're very safe.

So, I often use three phrases together. I say these methods are incredibly safe, incredibly simple, and incredibly effective. Indeed, the effectiveness is almost immediate. Once placed in the uterus, they provide very quick and immediate protection from pregnancy. They also have a rapid return to fertility, or they're very quickly reversible once removed from the body. They're also – a woman returns to her previous fertility very rapidly. And, they provide long-term protection from pregnancy.

How do they work? I'm going to start with the one on the left, the non-hormonal IUD. It's a copper IUD. It basically incapacitates the sperm. It helps the sperm or makes the sperm immotile, or in other words, it doesn't swim very well. It stops swimming, and it never gets to the egg, indeed, by preventing fertilization so the egg and the sperm never meet. It has an impact also on the oocyte or the egg, but the main action is on incapacitating the sperm.

On the right, you'll see the hormonal IUDs, or the levonorgestrel IU intrauterine system. The "LNGIUS" refers to levonorgestrel intrauterine system, and that's a progestin-containing hormonal IUDs. All of the hormonal IUDs are progestin-only, and it mainly functions by thickening the cervical mucus.

The cervix is particularly susceptible to progestins, so progestins – when in the body – thicken the cervical mucus of the sperm. It never passes through, never gets to the egg. There's a secondary mechanism of action by preventing or inhibiting ovulation to some degree, but its main mechanism is by thickening cervical mucus.

So, again, fertilization is thwarted, or it prevents fertilization.

This is a job aid that we created about a year ago, and it points out all in one page how all of the contraceptive methods that we use function, how they work, or better known as their mechanisms of action. On the top left, you'll see the copper IUD incapacitates the sperm, and on the right, the green circle around the hormonal IUDs function mainly by thickening the cervical mucus. The other two categories prevent ovulation on the far left, and on the bottom right, the methods that block the sperm. All those four methods all function by preventing fertilization, and this also helps to explain to folks that none of these methods cause abortions.

This is the non-hormonal IUD depicted here with a small, little picture. It's the copper T IUD. The trade name is Paragard. It releases copper ions, and it's approved by the FDA – the Food and Drug Administration – for up to ten years of use. We now know that it's effective for up to 12 years of use, and probably even longer than that.

This is a picture of a couple of the types of hormonal IUDs – again, levonorgestrel intrauterine system. The one that we're primarily going to talk about today is the levonorgestrel 52-microgram releasing system, and once it's placed in the body, the release is about 20 micrograms per day, and that's enough to inhibit pregnancy or stop – prevent pregnancy.

The two trade names – or, the two methods that are primarily available globally as well as in the United States, are the Mirena, which is approved for up to five years, and the Liletta, which is now approved for up to four years. There are two other methods that are available. We're not going to talk about them much, but Kyleena down on the bottom, and Skyla, also on the bottom. They release slightly less hormones per day.

The advantages and disadvantages – there's many on both sides. These methods – I'm going to start with the column on the left. The advantage is very effective and cost-effective as well over time. They're easy. Some people refer to them as the “get it and forget it” methods. There's no partner cooperation needed. They're safe for breastfeeding. Both the hormonal and the copper IUD are safe for women who desire to breastfeed. They're reversible, with a quick return to fertility.

The hormonal IUD has a particular advantage in that it relieves heavy menses or cramps and may even have an impact on reducing

anemia. They can be inserted after vaginal delivery as well as during time of a C-section or during post-abortion care. Laura is going to speak more to that as well. They also are known to reduce some cancer risks, in particular endometrial and ovarian cancer. There are some studies recently that show that it probably has an impact on reducing cervical cancer risk.

Disadvantages: The device cost. Primarily, when I mention this, I'm referring to the hormonal IUDs. The copper IUD has been available for many years in many countries for pennies, but the hormonal IUD is fairly new to the global market, particularly the developing country global market. There's also the insertion cost, which needs to be taken into account. They require – for insertion, they require a provider that's skilled in insertion technique as well as for removals. There are several instruments and equipment needed. I'll touch on that in a second.

There's some pain or discomfort at the time of placement. Copper IUDs may cause increased cramping and bleeding with some women. A lot of women refer to that bleeding and cramping that lasts about three or four months, and then, most women say they don't notice much of a difference after several months of having a copper IUD in place. And, it's important to mention that neither of these or any of the IUDs provide protection from STIs or HIV.

Here's a quick picture of the instruments or the equipment needed: The speculum, which is a fancy name for a tool used to look at the cervix. That's the top part of that picture. Then, there's long scissors used to cut the strings of the IUD after insertion. There's a ring forceps in the middle there that's used to – basically, used with a cotton swab or gauze that's used with some Betadine or Hibiclens to clean off the cervix. And then, there's a single-toothed tenaculum, depicted at the bottom, to grasp the cervix to hold it while placing the IUD, and then there's a sound, used to measure the depth of the uterus.

When talking about different contraceptive methods, this is one of the charts that I like a lot. It's taken from James Trussell, and it's been adapted several times by the WHO. It depicts the effectiveness of different contraceptive methods, with the more effective methods at the top. Less than 1 pregnancy will occur in 100 women using these methods.

So, the top – on the far right of that group, it will be the two types of IUDs depicted, as well as the implants – or the LARCs – are in that category. They have the same effectiveness as vasectomies or

female sterilization. So, in places where obtaining and getting a female sterilization or vasectomy, IUDs can function very well for women who are wanting to limit or avoid pregnancy for a long time.

This is another – just a little tool that I like to show, just to show how one can use that previous chart – the tier effectiveness chart – and show all the methods in something a little more colorful, maybe a little more user-friendly or patient-friendly. This was put together by Bedsider folks as well as the UCSF Bixby Center. On the far right, you’ll see what is your chance of getting pregnant – less than 1 in 100 – and then, it goes down the different groups and different categories.

Sometimes, the word “more effective” or “most effective” works, but then, you can also use the term on the far left really well. It functions really well, or okay, or not as well. It’s just another tool. I’ve seen many ways that IUDs are shown and depicted for clients. One of my main, most important comments that I like to say is it’s really important to have the IUD in your hand and be able to show clients what it feels like and what it looks like when doing counseling. I say that for all the methods.

This is a chart that shows about continuation rates. This comes from a large study that was done in the U.S., the largest contraceptive study done in the U.S., at Washington University. It’s called the Choice Project, and they enrolled about 9,300 women, providing them any and all methods they want, good-quality counseling with discussing all the methods, and they found that a large portion of women chose copper IUDs or the hormonal IUDs.

And, after a year of following these women, they found that lots of women continued and stuck with them for up to the tune of about 80 percent, bracketed out in that red. They also followed these women out for longer, and at three years, they were still following about 4,000 or so women, and they found that again, continuation rates stayed at fairly high levels, at around 70 percent for both of the IUD types as compared to non-IUD types or non-LARCs at about 30 percent. That includes the pill, the patch, the ring, and the injectables.

So, again, continuation is very high for these methods. It’s not so easy to compare continuation rates, however, with methods that are easy to stop – for example, the pill or the injectable. If you decide you don’t want to continue with those methods, you just stop,

versus a LARC, where you have to come in and get it removed by a skilled provider. So, they knew about this notion or the difference, and they looked at satisfaction.

They followed these women and they asked them, “Would you recommend this method to another friend, or would you use it again for yourself?” To a high degree, there was high satisfaction in women who chose these methods, and indeed liked them continuously, and would recommend them to friends for all different age groups – high satisfaction with all of the LARCs.

So, I often get the question, “How do you discern between a copper IUD and a hormonal IUD for patients, or for clients, or for trainings?” And, I like to point out that it’s really important to make sure that you’re doing client-centered counseling, and making sure that you’re asking lots of questions, and listening to clients’ concerns, and then help them decide on what may be the best method for them. So, copper IUD – women may want to choose a copper IUD if they want to have regular periods, or if they don’t want anything to do with hormones – they want to avoid hormones completely.

The hormonal IUD, on the other hand – women who perhaps would like to have less bleeding or less menstrual flow – Women who use the hormonal IUD tend to have lighter periods, sometimes no periods at all. About 20 percent of women who use the hormonal IUD end up becoming amenorrhoeic, or no bleeding at all. Women who have dysmenorrhea, or painful menses and cramps – this would be perhaps a good choice for those women because it tends to relieve those cramps and periods – the painful periods.

There are lots of myths about IUDs or intrauterine contraception, so I’m going to go down the column on the left. IUDs are not abortifacients. They do not cause abortions. IUDs are not large in size. They do not cause ectopic pregnancies. They do not cause pelvic infections. They do not decrease the likelihood of future pregnancies. They do not need to be moved for pelvic inflammatory disease. A woman can be treated for pelvic inflammatory disease and leave the IUD in place.

They can be – I’m now jumping to the column on the right – they can be used by women who have had an ectopic pregnancy. They can be inserted the same day, provided you’re reasonably certain a woman isn’t pregnant. They can be started immediately postpartum or during post-abortion care. They can be used for

nulliparous women, or women who have never had a child. They have high continuation rates – 76 to 87 percent in one year.

I'm sure – I'm hoping most of you are aware or acknowledge a little bit about the medical eligibility criteria, the WHO's tool used to help figure out whether a woman – you can recommend a safe method for a woman. So, this is based on evidence-based information, and it aids with recommendations for safe methods for women with medical conditions or medically relevant characteristics. So, the four categories. Category 1: You can use the method in any circumstance. Category 2: You can generally use the method. Category 3: Use is usually not recommended. Category 4: Absolute contraindication, so the method should not be used.

So, this now comes in the form of an app, and a wheel, and a chart. It's an incredibly important and helpful tool for helping women – helping remove barriers for contraceptive methods that we've had for many years. It's very important and effective tool to be used. This is a chart that was developed by several colleagues – several organizations. This is just a quick snapshot of one part of the chart, and it just lists down the left-hand column different medical characteristics or conditions, and then you can see that boxed off in yellow, the copper IUD and the hormonal IUD conditions when they can be used.

I also need to point out or want to recommend or mention the Selective Practice Recommendations, or the SPR, which is a companion guide to the medical eligibility criteria. This is the latest version – and just a portion of it – regarding copper IUDs and hormonal IUDs. It basically points out the examinations or tests that need to be undertaken prior to insertion of an IUD. Class A refers to when an exam is mandatory, and so, pelvic exam and general exam is mandatory, as well as an STI risk assessment. That could be a medical history and a physical exam, looking at the cervix to try to discern whether there's an infection present.

Ideally, they have access to STI screening tests, or even hemoglobin tests, but again, an STI test is not mandatory or an exam mandatory for an IUD insertion. A good look at the cervix – in many cases, you can discern – when going over a medical history with a patient, you can discern whether an infection is present or whether you may want to avoid inserting an IUD. On that note, I'm going to hand the microphone back over to Tabitha. Thank you very much.

Tabitha: Thanks so much, Mark. That was great. For participants, please continue adding your questions for Mark in the Q&A box for our discussion session. With that, the next presentation is from Kate Rademacher of FHI 360.

Kate: Great. Thank you, Tabitha. Just to confirm, can you hear me?

Tabitha: Yes, we can hear you.

Kate: Okay. Thanks again, Tabitha, and thank you so much, Mark, for that wonderful overview. In my presentation, I'm going to do a deeper dive about the current status of the hormone-releasing IUD, which in many settings is not available or is underutilized. The method is also referred to – as Mark noted – as the LNGIUS or the IUS, and I will refer to it as the LNGIUS in my presentation today.

As Mark described, the LNGIUS is a highly effective contraceptive method that has been popular in countries where it's available. In addition, it has important non-contraceptive benefits, including reduction of menstrual cramps and blood loss, fewer side effects compared to some other hormonal methods, and possible alleviation of anemia in some populations. All of these attributes could potentially provide substantial benefits to women in FP2020 countries.

Several recent studies and small-scale assessments, which I'll be talking about more in my presentation in a few minutes, have shown that women and healthcare providers have favorable perceptions of the LNGIUS, and in settings where unmet need for family planning is high, increased availability of more affordable LNGIUS products could result in increased demand among women.

Importantly, in 2015, the World Health Organization added the LNGIUS to their essential medicine list. However, the reality is that access and use of this method remains very limited in FP2020 countries at this time. One of the main barriers to access has been the high price of existing commodities. As I'll discuss more in the next slide, in many developing countries, the LNGIUS is only offered on a very limited basis and at a high price in private for-profit clinics, or not at all. However, this global landscape may be changing as new, more affordable products are starting to become available.

So, you can see here on this slide some of the LNGIUS products that are currently available. On the left, as Mark noted, Bayer

Healthcare manufactures three LNGIUS products: Mirena, Kyleena, and Skyla. Over the past few years, FHI 360 has collaborated with partners and conducted market assessments for the LNGIUS in Kenya, Zambia, and Nigeria. Through that work, we've documented that Mirena is available on a very limited basis in some private clinics and urban settings, and priced anywhere between U.S. \$60.00 and \$400.00, including the cost of insertion.

In the middle column, you can see the ICA Foundation, which stands for the International Contraceptive Access Foundation. This foundation is a public/private partnership between Bayer Healthcare and Population Council. The ICA Foundation distributes free non-branded LNGIUS products. Programs can apply for these donations, and since 2005, over 100,000 units have been distributed for free in 35 countries.

Finally, in the third column, an important development in recent years has been that Medicines 360, which is a nonprofit pharmaceutical company based in the U.S., has had their LNGIUS product approved by the U.S. Food and Drug Administration. It is sold as Liletta in the U.S., and it's Avibela in FP2020 countries. As Laura will be talking in her presentation next, we're excited to share that Avibela has been approved in Madagascar and Zambia and is being registered in additional countries.

The public-sector price for Avibela that Medicines 360 is offering will vary by volume between U.S. \$12.00 and \$16.00 depending on volume. For an order of 100,000 units, the public-sector price will be approximately \$15.00 per unit. This price is substantially lower than other products on the market that are sold commercially, so it's an important development, as I noted. In addition, there are several Indian-based manufacturers that are making LNGIUS products. For example, Pregnant International makes Eloira LNGIUS, and they are pursuing registration in several FP2020 countries as well.

Several years ago, USAID convened a new interagency LNGIUS working group, which is convened of donors, implementing agencies, and manufacturers. This group has been a great platform and is a lab for coordination, developing a shared learning agenda, and aligning on research approaches and M&E questions. You can see in the circles on the slide some of the questions that are included in the global learning agenda that we've developed in collaboration.

It includes questions about potential demand, what effective

demand creation strategies for the LNGIUS might be, whether there are specific service delivery strategies that are more effective than others and how we can learn from the copper IUD experience, whether the LNGIUS is cost-effective compared to other methods, including other LARCs, and what the impact is of the non-contraceptive health benefits, including how they're perceived by women and providers.

There are several pilot introduction efforts that are underway with funding from USAID, including in the countries listed on this slide, and the partners who are involved are currently evaluating those introduction efforts and are sharing those findings with the global community.

So, now, I'm going to just briefly go over some of the recent research and assessments that have been underway, focused on the LNGIUS, to build the evidence base about the potential impact of this method. On this slide, you can see a summary of results by a study of a colleague of mine at FHI 360, David Hubacher and team, who led a study in Kenya several years ago under the USAID-funded Progress Project. That study offered a full variety of methods to postpartum women, and among the 671 clients offered the LNGIUS, 16 percent chose the method.

A cohort of women was followed over 12 months, and as Mark noted, as we see in other studies, the LNGIUS also had high continuation rates and high satisfaction rates, which were comparable to implants. Importantly to note, approximately one-third of users said if the LNGIUS had not been available on the day they went for family planning, they would have chosen a shorter-acting method. Specifically, only 21 percent said that they would have chosen the copper IUD instead, which suggests that the LNGIUS can fill a niche in the market that the copper IUD is not currently filling.

In addition to the study, FHI 360 – in partnership with the Family Health Society of Kenya – conducted a market assessment in Kenya, which included interviews with key opinion leaders and interviews with women who were early adopters of the Mirena in Nairobi. We conducted qualitative interviews with these women and their partners to determine why they chose the method and how they experienced it. The most common reason that women cited for choosing the Mirena was the perception that the method had fewer side effects than other family planning methods.

As Mark noted, the levonorgestrel in the LNGIUS has a mainly

local effect, which means that the method has minimized side effects compared to other methods, and what was important from the findings from this assessment was that women who chose the Mirena understood this message about lower side effects and selected the method because of it.

This is also an important finding because as we think about how to reduce unmet need for family planning, we can think about research from Guttmacher and others, who have documented that the No. 1 reason for unmet need is concern among women about side effects. So, again, this is an important finding about the LNGIUS specifically.

In Kenya, as part of the market assessment, we also did a cost comparison of the different methods per CYP. CYP stands for the couple-years of protection, and it's a conversion factor that allows us to compare the estimated protection provided by different methods over one year of time.

The costs that are included in this analysis include the commodity cost and the provider time and supplies for insertion, removal, or resupply over one year. In this calculation, we assumed that the Medicines 360 LNGIUS, which is currently under review for registration in Kenya, would be registered and available for approximately \$15.00 per unit. You can see here that the LNGIUS compares favorably to other methods on a cost-per-CYP basis.

In partnership with PSI, WCG, and Society for Family Health, FHI 360 also led a market assessment in Zambia in 2016. This market assessment included interviews with key opinion leaders, healthcare providers, and potential users, including women who are currently using other LARCs, short-acting methods, or no method at all, as well as postpartum women. All three of the groups that we interviewed identified important advantages of the method and expressed interest in its introduction.

We shared the findings of the market assessment, which are available online in the K4Health IUDs toolkit. We shared those findings with the Family Planning Technical Working Group, which subsequently endorsed public-sector introduction of the LNGIUS. Currently, PSI, SFH, WCG, and Jhpiego are leading pilot introductions efforts and ongoing research studies in collaboration with the Ministry of Health to further document the impact of these introduction efforts.

In Nigeria, several partners are also introducing the LNGIUS in

pilot settings. One of these pilots is led by Marie Stopes International, and in partnership with MSI and FHI 360, we've been documenting women's and providers' perception of the method, as well as, again, key opinion leaders. We don't have time to go into a lot of the findings, but those will also be available on K4Health.

One of the questions that we asked women who had chosen the method – the LNGIUS – we asked them, “Can you briefly tell me the reason you chose the method today instead of another method?” You can see here the reasons that women offered. Providers were not instructed to read the list aloud and women were able to mark all that apply.

The No. 1 reason that women noted for choosing the method was reduced menstrual bleeding. This is an important finding because in many settings, there's a persistent perception among some healthcare providers and some public health professionals that women are not supportive of reduced menstrual bleeding.

But, this and other research findings indicate that women may really welcome reduced menstrual bleeding, and we're starting to see across countries and projects a picture emerge that women are definitely open and enthusiastic about reduced bleeding. The picture becomes more murky and complicated when it comes to amenorrhea, or no bleeding, which some women like and some women don't like, and further investigation is needed on this topic specifically.

To further expand the evidence base and to better evaluate the potential demand and impact of the LNGIUS, a new project was launched in late 2017 which was funded by the Bill and Melinda Gates Foundation, called Learning About Expanded Access and Potential of the LNGIUS, or the LEAP LNGIUS Initiative. This project will be looking at several questions, including estimating potential demand of three countries, measuring continuation rates and assessing client satisfaction, looking at cost-effectiveness, as well as potential strategies to accelerate regulatory approval.

In addition, just before I close, I wanted to mention that several of the partners involved in LNGIUS pilots are working together to establish a subsection within the IUD toolkit on the K4H website, which is focused on the LNGIUS. Many of you may be familiar with the toolkits on K4H and the IUD toolkits specifically.

Right now, there are resources on the LNGIUS, but they're kind of

scattered throughout, so we're collating those, and they'll be available in a special subsection for those of you who are interested in LNGIUS provision. Thanks so much, and I'll hand it back now to Tabitha.

Tabitha: Thank you so much, Kate. Again, continue adding your questions in the Q&A box for our discussion section at the end. Next up is a presentation from Laura Glish of Population Services International.

Laura: Thanks, Tabitha. Can you hear me?

Tabitha: You're coming in loud and clear.

Laura: Excellent. Good afternoon from Tanzania, everyone. Thanks to Kate and Mark and Tabitha for the great lead-in. So, I'd like to finish up off with some global experiences with intrauterine contraception, which includes the copper T, which I'll refer to as the IUD, PP IUD, which is the postpartum IUD, and the IUS.

So, it might surprise some of you to learn that the IUD is actually the most commonly used reversible method in the world. This is second only to female sterilization among all methods. It has been fairly constant over the past 20 years. A large factor in this is high use in China, which obviously has a very large population, but it is also the most common method in several other countries in Asia, and also Egypt.

So, one study that Mark has already mentioned shows us how women who have access to the IUS and the IUD feel about choosing the method, about using the method, and about continuing the method is the Choice Project. During this study, women were given free access to the method of their choice after comprehensive counseling, and you can see here that over half of them chose an IUD or an IUS. Even among youths 20 years and below, the intrauterine contraception – both the IUS and the IUD were very popular choices. As Mark mentioned, these methods have high continuation rates and high satisfaction rates among users of all ages.

So, the question is could the Choice study apply outside of the United States to different contexts? One example that we had here in Tanzania is a DFID-funded project providing mobile outreach to facilities that do not normally have LARCs available, offering free services also, with highly dedicated providers who have very good skills and LARC insertion counseling, and are also there that day to specifically offer family planning methods, who are not pulled

in by the many other responsibilities that are usually present in the public sector.

The result from this, we can see, is that when IUDs are highly available and affordable, women do choose them also in other contexts besides just the U.S. So, here in Tanzania, we have about almost half of our clients coming in for these special days when LARCs are available choose the IUD.

So, it takes a couple of things to have a successful IUD program. As I mentioned, providers need to feel confident and they need to be competent. The IUD insertion process is the most clinically complicated among the different methods, and there is a potential for complications if the provider is not sufficiently skilled. The method also takes more time to physically insert than other methods, and sometimes can take a little bit more counseling on the part of the woman who have might have additional questions.

We also see that having all of the equipment and materials in place can be a challenge, so the health system needs to be well set up to support IUD provision, including the equipment and consumables that Mark mentioned, but also, ways to decontaminate and sterilize the equipment, a private space to be able to perform the insertion, and at least a table for the woman to be able to lie down to have the procedure. So, having a supportive health system that makes sure all of these items are in place is essential because without them, no woman – however much she might want the IUD – will be able to access it.

Satisfied users have also shown to be important in helping women understand what it's like to use an IUD in their day-to-day lives. The method itself can be intimidating for some women, so it is helpful to be able to sit and talk, explain well, to hold it in your hand – as you see in this picture – and to overcome those barriers about fear, mostly around the insertion process itself.

So, we found when doing intensive education, not only with providers to increase their confidence, competence, and motivation in offering IUDs, but also in showing women that it can be a very useful method for someone who's looking for something simple with few side effects that it's very quickly reversible, that we see younger women, women with fewer children, as well as less educated women who often have less access in the general population – all of these types of women also can choose IUDs when they are available.

So, you'll see here that during the interventions in these different countries, we saw higher rates of younger women who were choosing the method, as well as lower education levels.

So, as Mark mentioned, the IUD can be inserted immediately postpartum in the first 48 hours following delivery. This can be a great time to meet women, when they're already in the facility, they have a high motivation to not get pregnant in the near future, and the cervix is already open, so the insertion technique can be simpler than in an interval insertion. However, this does require special training on the part of the provider to be able to place the copper T, and it can need some different equipment than what is normally available in the delivery room.

So, one way that we have been able to overcome some barriers on the provider side is – this is a new dedicated PP IUD inserter. So, this product has the same copper T that we all know and love. You can see at the top, it's what a normal inserter looks like, and the bottom here is the dedicated PP IUD inserter. The extra-long sleeve means instead of the traditional way of removing the IUD from the package with forceps and placing it into the postpartum uterus, the IUD can be put directly into the uterus using a longer sleeve, all the way to the fundus. The longer strings allow the strings to still be visible as the uterus contracts back down in size.

And, we have already – in the past few years, over 60,000 units have been distributed in 13 different countries. In some countries, they have found that it does not require separate registration of the product, but can be amended – added onto existing copper T registrations, and the final product itself is the same. This is currently undergoing WHO prequalification, which will allow more agencies to be able to procure it and hopefully make it more widely available.

Last year, with funding from **CISPO 2**, PSI conducted a case study in Mali where providers had been trained back in 2011 on the traditional forceps insertion for PP IUD and have now been using the dedicated inserter for a few years. We conducted some interviews, as well as analyzed routine data, and found overwhelmingly that the providers preferred the dedicated inserter. It made their job easier and they felt more comfortable. As you can see here, the public-sector staffs know that if the providers are more comfortable doing the procedure, they will be more likely to counsel their clients and offer the method.

Here is some quick data from the time that the dedicated inserter

was introduced in 2016. We've seen a significant increase in the number of PP IUDs provided in both public and private sector. If you want to learn more, there is a case study about this on PSI's website.

And, I will finish up with the IUS – not just another IUD. So, as Kate so wonderfully described, the IUS has a lot of different attributes than the traditional copper T that most of us are used to, and now that we are introducing into more countries, we don't want people to see this as just another type of the same old method.

In fact, the copper T and the LNGIUS are very different in terms of user experience, and we can see that for example, when Mirena was introduced in the U.S. in the year 2000, the overall percentage of women in the U.S. using contraception has increased exponentially. This method has the potential as well in other countries to revitalize the IUD market, to make more people aware and to have more options for an easily reversible and easy-to-use, highly effective method.

When we are thinking about how do we differentiate between the IUD and the IUS, we have come up with potential user archetypes to help women understand which method would fit best for their life if they're interested in using contraception. Both of them are discrete, both of them are easy to use, both of them are very quickly reversible and have few side effects.

For the IUD user, we're positioning this product more for someone who's more of a traditionalist, who wants to feel connected to her body and her period, who wants a method that makes her feel the same as she does now, whereas the IUS user sees herself more as modern, sees her period as a hassle she would rather not deal with, and wants a method that not only protects from pregnancy, but also improves her lifestyle.

Currently, we have three ongoing pilots in three countries: In Zambia in the public sector, supported with USAID funds through **ECONSRI**, in Nigeria in private franchises nationwide, supported by CISPO 2, and in Zimbabwe in a mix of PSI and franchised clinics, also supported by CISPO 2. These have been going on since Q2 of 2017, and some initial data we have on what types of clients are choosing the IUS versus the IUD – you can see here that we're having a much greater uptake among women under 25 with the IUS than we are with the IUD.

We are also collecting the same data that Kate presented earlier

from Nigeria across all of our pilots along reasons they're choosing the method, what they would have chosen in place of it, and all of these are being collated among different partners so that we can see what are the different reasons driving method choice between different countries and programs.

Finally, as Kate mentioned, we are super excited to announce that Madagascar became the first country to launch Avibela. Their training of trainers was last week, so we've officially had Avibela available for women in Madagascar throughout our pilot sites. In Madagascar, we have positioned this as a method for women who want lighter periods.

French has a very nice –maybe it's nice, maybe it's not. "Rules" and "period" is the same word in French, so the tagline for Avibela is, "With fewer rules/fewer periods, life is beautiful." We are really trying to sell the less bleeding and cramping and potential amenorrhea as not a side effect, but a benefit, and the reason why women would want to choose this method.

We also understand – as Kate mentioned – that amenorrhea and changes to bleeding can be stressful for women if they don't understand what's happening. We find that actually, many of our male colleagues think that women really enjoy having their period every month because they get so many complaints when they don't have it every month, but a lot of this for many women is driven more by anxiety about what a lack of period might mean for her health, for her future fertility, or if, in fact, she is pregnant.

PSI and FHI 360 worked together to develop a job aid for providers to remember what are some key messages to cover when counseling women on methods that may change their periods so they understand that it's normal, it can be a positive opportunity, but their fertility and their periods will return to normal once they stop using the method.

Different methods have different changes in bleeding, so you can choose what you'd like based on what's most likely with each method. Absence of menses does not mean you're pregnant if you're using your method consistently and correctly, and if the changes are limiting your lifestyle, you can always cease treatment or change your method.

We've tested out this tool with providers in several countries, and it was also used last week in the TOT in Madagascar to counsel real clients. So far, positive results. This is available in French and

Spanish, and soon to be Portuguese. You can find it on FHI's website as well as the K4H toolkit.

Finally, lessons for scaling up. So, as I mentioned, before anything can get started, you have to have not only the commodity, but equipment and supplies in place. Matching supply and demand from the beginning is extremely important. From the training itself, having enough clients to get the providers to actually practice on real people under supervision to become certified and competent right off the bat goes a long way with ensuring they will continue offering this service. That still needs to be coupled with demand creation ongoing to make sure that they maintain their skills over time.

Finding IUD and IUS champions at all levels, from the client level to the provider level to the ministry of health level, is very important in ensuring that women have the opportunity to learn about IUDs and provide themselves the opportunity to provide them. And, with the IUS, as Kate mentioned, there are a couple of different product options. There are very few countries right now that the IUS is registered in, and there should be also taken into consideration the cost of the product and supply chain. Thank you very much, and I will pass it back over to Tabitha for the next phase.

Tabitha:

Thanks so much, Laura, and thanks to all three of our presenters for a great job. I think they were all very strong presentations. We have been getting questions from folks, so now, we're going to take time for discussion. So, there is a question box, and we're going to try to get to as many questions in the time we have remaining. So, I'm going to read the questions out loud, and then I'll identify who should start answering that, and hopefully, we'll get to as many as we can before our time is up. We have about 10 minutes.

Okay, the first question I'm going to ask for Mark Hathaway to answer is would LNGIUDs protect against upper reproductive tract infections or PID?

Mark:

Hi, Douglas. Thanks for joining today. Yes, that's a great question, and it's been theorized for several years, as I'm sure you're aware. There is an ongoing study that's being done looking at that exact point, and there is some good theoretical information and possibly some good evidence that by thickening the cervical mucus, sexually transmitted infections can't answer and can't cause upper tract infections, but I don't think that evidence is yet available, and

I think it's from that same crowd in Washington University.

There's another question that you asked as well. I may as well address it right now. That refers to retention rates with immediate post-abortion insertion as well as postpartum. As you probably are aware, there are several studies all over, and the range – and, I really love the fact that you used the word “retention rates” because retention rates are extremely high in those settings, to the tune of about even greater than 80 to 90 percent.

So, if you think of a woman that's having trouble choosing and picking a contraceptive method and gets to a hospital for a birth or a miscarriage management, and she's able to get an IUD at that time, it's a fantastic time to provide her one if she wants one. The retention rates are very high.

Probably, the best evidence comes from the folks who have been doing it for a long time in India and Bangladesh and some countries that Jhpiego has been working with for many years, and they have very low expulsion rates or very high retention rates, to the tune of about 95 percent in almost all of their settings. But, there's lots more we can talk about, but I'll leave it at that. Thanks.

Tabitha: Great, thanks, Mark. Our next question is for Laura. In many PRH countries are hormonal IUDs available?

Laura: Great question. So, right now, Mirena – as Kate mentioned – is available in some countries, although often at quite high prices, and it's not always registered. The ICA Foundation product is currently registered in Ghana, Nigeria, and Kenya, but it's actually available in a much wider range of countries. You can find the full list on their website. However, it's not able to be registered as of now. It needs to be brought in under a waiver.

For Avibela, we have it currently available in Madagascar, soon to be available in Zambia, it's undergoing registration in Nigeria and Kenya at the moment. Eloira is also currently registered and Nigeria, India, and I think a couple of other countries.

Tabitha: Great. Thanks for that. This next one is for you, too, Laura. We have a challenge in procurement of IUDs. Why are IUD and IUD kits procured differently?

Laura: So, I'm going to assume IUD kits here are referring to the full package of consumables plus IUDs. In some countries, we have seen packaging together the consumables with the IUD can help

eliminate some of the barriers of having the product, but not having the consumables in place.

It can be challenging because the products have different shelf lives, so the expiration date of a packaged kit is often different than each individual component, and they have been sourcing some aspects – such as the Betadine – can be in a one single-dose package, can be expensive and difficult. However, some countries have found that this is a good way to make sure that if a woman wants an IUD, she has not only the product, but the accompanying consumables to be able to provide it.

Tabitha: Great. Thanks for that. This one is for Kate. Kate, if you want to expand on this comment around cost-effectiveness –should be seen in totality for the LNGIUS, which offers other benefits which are significant. If you wanted to add to that.

Kate: That's a really great point. Thanks, Tabitha, and thanks for the comment. Yes, as we think about the cost-effectiveness of the LNGIUS, we need to think about all aspects of service delivery. One side of that is the demand creation, and as Laura indicated in her presentation, some additional work likely is needed to both inform providers and clients about the LNGIUS and how it's different from the copper IUD and other methods.

So, one thing we need to consider as we think about costing and cost-effectiveness is to what degree this method is going to require a heavier lift for demand creation. On the other side, as the comment indicated, we really need to look at the whole picture in totality, and the non-contraceptive health benefits offer important health benefits to women and from a public health perspective. So, we're going to be diving into this question more deeply under the LEAP Project and under other USAID-funded activities. That's a great point. Thanks so much.

Tabitha: I'll keep you on, Kate, to see if you have any comments. There's another question about the challenge of male involvement and acceptance of male partners in the postpartum IUD. Was the male involvement piece involved with that?

Kate: That's also a great question, Tabitha. As for all family planning, male involvement is really key, and there's a lot of great work being done around male involvement, around friendly planning in general, and of course, as well, for the copper IUD and LNGIUS. I'll just speak briefly from a male involvement perspective. We're interested, of course, in male perspectives, and so, I mentioned

briefly that we did a market assessment in Kenya and interviewed early adopters of the Mirena LNGIUS.

We also interviewed a subset of their male partners and ask what they liked and disliked about the method. Like the women's responses, the most common response to what men liked about the method was that their partner did not experience any side effects. They also talked about the longevity of the method and the flexibility to be able to remove it at any time.

When we asked men what they disliked, several of them did not have anything negative to say. The most common response was changes in their partner's period, which I think speaks to – as Laura talked about – the importance of informing and educating women about changes to their periods, but also including men in that education as well, about how hormonal methods and the copper IUD can change menses, and that it's normal. Thanks, Tabitha.

Tabitha: Thanks so much, Kate. Next question is for Mark. What is the current wisdom –?

Mark: I can jump in. Nancy, thanks for this question. As you know, it's a tricky one. It's a combination of –

Tabitha: Wait, Mark. I'm sorry. The question keeps on coming off from me. Can you read off the question? It's the provider skill.

Mark: Sorry, yes. The question is what is the current wisdom on volume of insertions the provider should do, such as how many per month, to maintain his or her skills? I don't think we have any evidence on that – at least, some good scientific evidence on that notion. I think as many skills, we talk about if you don't feel comfortable and confident in providing the skill, you should refer to someone else in general. We often think about how many C-sections does it take before you feel like you're adequate, and you're good, and you're comfortable, and there are all kinds of ranges, so it varies tremendously from one clinician, one provider to another.

Many of us do IUD insertion trainings, and we feel that after about four or five, most clinicians are pretty darn comfortable and competent, but it varies tremendously, and if you do one this year, and then, you don't do one for another five years, obviously, your skills will be diminished, or your hand memory won't work as well. So, I think it's a big, broad question, so it really varies tremendously from setting to setting.

Tabitha: All right. And, I think we're actually coming close to time here. I apologize if we didn't get to your question. I think we're going to try to respond to the remaining ones in writing. But, before we wrap up, I want to give a big thank you to all the participants for giving their time and expertise today. In the next few days, you'll be receiving an email with the link to today's recording, but before we close the room, I want to encourage you to take a moment to fill out the poll question. Feedback really helps us for future webinars. So, I want to thank everybody again, and have a wonderful day wherever you are.

[End of Audio]

Duration: 60 minutes