

## Questions & Answers From June 2020 “Hormonal IUS Updates: New Insights and Steps Toward Scale” Technical Consultation

In June 2020, the Hormonal IUS Access Group collaborated with the Method Choice Community of Practice, led by the Evidence to Action (E2A) Project, to host the “Hormonal IUS Updates: New Insights and Steps Toward Scale” technical consultation. The [recordings](#) of the two-day online event are now available for viewing. In addition, responses to questions that were received from participants during the online meeting are posted below.

### General

#### **Q: Is the hormonal IUS already available in the private sector in these countries?**

- **Response:** The hormonal IUS is available on a limited basis in some low- and middle-income countries (LMICs) in the private/commercial sector. The product(s) that are registered and distributed varies by country.

#### **Q: How have professional provider associations (particularly those with nurse/midwifery constituencies) been engaged in regard to generating demand in the early stage countries?**

- **Response:** In late 2019, several in-country stakeholder meetings were held (e.g., in Nigeria and Zambia) to plan for phased, intentional roll-out of the hormonal IUS on a national scale. Professional associations including groups representing nurse/midwives participated in these meetings. Moving forward, these types of groups will be important to continue to engage in planning and implementation of hormonal IUS introduction and scale-up.

#### **Q: The greatest challenge, when introducing a new method, is gaining new clients, i.e., making the "pie" bigger. But what usually happens is that the "pie" remains the same, but with a different share of the market going to new methods. Any suggestions?**

- **Response:** For the hormonal IUS, a strong demand generation strategy will be a critical component of the overall introduction strategy and roll-out plan. If the potential benefits of the hormonal IUS are messaged and marketed as part of a comprehensive contraceptive method mix with the goal of expanding choice, data suggest that the method could potentially attract new users (e.g., see results from pilot introduction efforts presented [here](#)).

#### **Q: Can the method be used in immediate postpartum period?**

- **Response:** Manufacturers' labels for hormonal IUS products do not currently include an indication for immediate postpartum insertions. However, the World Health Organization's Medical Eligibility Criteria for Contraceptive Use categorizes immediate postpartum insertion [<48 hours] of the hormonal IUS as a category 1 [no restrictions] in non-breastfeeding women and as a category 2 [benefits outweigh the risks] in breastfeeding women.

#### **Q: What do you see as the potential for "self-removal of the hormonal IUS?"**

- **Response:** There are some early data on feasibility and acceptability of IUD/IUS self-removal from the United States, with results suggesting that women may be [open to the concept](#) and potentially more willing to recommend an IUD/IUS because of the control over discontinuation, while [less likely to consider discontinuation](#) themselves. [Further research is needed](#) on feasibility and impact of self-removal, particularly in LMICs.

**Q: How will the Access Program ensure that activities and priorities are aligned with the needs of countries introducing (or planning to introduce) the product? Is there a mechanism or channel by which those needs will be better understood, collected, reflected upon, etc.?**

- **Response:** Governments are invited to engage directly with the Hormonal IUS Access Group via the Partners Group (see [here](#) for more information). As countries develop and implement strategies for broader introduction including costed rollout plans, the Hormonal IUS Access Group will serve as a mechanism where they can access resources and share their progress, challenges and needs. For more information, please [contact](#) the Hormonal IUS Access Group.

**Q: Is there documented feedback from users in low to middle income countries where this method is at scale?**

- **Response:** Our understanding is that the hormonal IUS is not yet available at scale in any developing country context. Results from initial pilot introduction efforts can be found on the new Hormonal IUS Access Portal website [here](#).

**Q: How has COVID affected the progress, particularly from the supply by manufacturers?**

- **Response:** During the [first day](#) of the webinar, the suppliers on the panel (Bayer Healthcare, Medicines360, ICA Foundation, and Pregna) were asked by the panel facilitator if COVID-19 has disrupted manufacturing, and all four reported that manufacturing capacity for their respective hormonal IUS products is currently at normal levels. More broadly, on [day two](#) of the webinar, Dr. Abdulmumin Saad from USAID and Dr. Gathari Ndirangu from Jhpiego discussed how COVID-19 is impacting provision of long-acting and reversible contraception (LARCs).

### **Research Results:**

**Q: For the studies that were described, how were providers trained to counsel and educate clients?**

- **Response:** The approach to provider training varied by country and context. For example, under the USAID-funded EECO and SIFPO-2 projects, providers were trained through classroom style didactic sessions followed by clinical training under supervision of a master trainer. Providers were trained to discuss with clients the attributes and potential benefits of the hormonal IUS in the context of informed choice and were encouraged to discuss side effects and bleeding changes of all methods with clients. Counseling of clients covered the range of available FP methods, not just the hormonal IUS. Providers used the [NORMAL tool](#) to support discussions around potential menstrual bleeding changes for all methods but otherwise they used the existing counseling approach in each country (for example, the Balanced Counseling strategy in Nigeria) to counsel clients. Under EECO and SIFPO-2, all providers trained already had experience providing other FP and LARC methods, including the copper IUDs, so hormonal IUS trainings were positioned as part of a continuing education.
- Through another project, the USAID-funded Maternal Child Survival Program (MCSP), providers in Kenya and Zambia were trained using the [LARC Learning Resource Package](#) (LRP), a modular set of training materials that focuses on hands-on practice for developing clinical LARC skills. These materials aligned with MOH plans for expanding LARC access in these countries. The MCSP project first trained providers selected to be

mentors. After training and becoming certified to provide hormonal IUS, mentors were then expected to do initial training and provide ongoing support to additional providers (mentees) in facilities where they worked or in nearby facilities, as well as continue to conduct insertions. In Kenya, mentors had been previously trained by MCSP in other LARCs (implants and copper IUD), but were inexperienced in hormonal IUS. So MCSP provided supplemental training on hormonal IUS and postpartum IUD insertion, using the appropriate modules from the LRP. Later, additional mentors in Kenya were trained on all LARCs under the USAID-funded Afyi Halisi project using the full LRP. In Zambia, MCSP leveraged the USAID-funded Safe Motherhood 360+ project to train maternity care providers in all LARCs using the full LRP. These providers were often inexperienced with offering LARCs and after training were expected to start integrating LARC counseling and provision into maternity services.

**Q: I wonder how much the perceived positive attributes reflected what was emphasized by the community health worker (CHW)/provider?**

- **Response:** Please refer to data that were [presented during Day 1](#) of the meeting. We can assume that the provider and the CHWs played important role in client education and demand generation, especially as this was a new method that most women were hearing about for the first time. In Madagascar, for example, where demand generation was more robust and community educators had a strategy of reaching out to potential clients who may desire the lifestyle benefits offered by the hormonal IUS, programs saw that the desirable side effect and bleeding profile ranked high among the reasons that clients chose the method. Providers/CHWs were trained to provide information about all contraceptive methods and to put women's unique needs at the center of all conversations with clients.

**Q: Can you explain a bit more on the bleeding changes? One slide shows women removing due to more bleeding and then another that women had less bleeding? How do you reconcile both in terms of the impact of bleeding changes on use?**

- **Response:** With the hormonal IUS, the number of spotting and bleeding days may initially increase but then typically decrease. However, specific experiences will vary across women. See [results presented during Day 1](#) for additional details.

**Q: Very reassuring data on desire and success in securing removal. Did this differ much between private vs public sectors?**

- **Response:** The [data](#) on desire and success in securing removals come from one study in Zambia and one study in Nigeria under the Gates-funded LEAP initiative. In Zambia, participants were women who received their method in the public sector, whereas in Nigeria, they were social franchise clients. However, we do not have data from public and private sector within the same country.

**Q: Please provide more detail on the segments. How are women put into the segments? Are there other ways to segment that might be more useful, based on the data you collected? Can more detail be provided on the "segments" used for demand creation and product interest/use analyses?**

- **Response:** The approach to segmentation under the LEAP Initiative, the Life Stages Approach, is a way to recognize that age and traditional demographic factors are not necessarily the most important factor in determining where a client is at in her family planning journey. Clients are segmented based on a combination of their parity, marital status, and fertility intention into groups that may apply to women across ages, wealth quintiles, etc. For example, the Life Stages show that a client may be “Discovering” family planning client even as she is older. The market research conducted under the LEAP Initiative did not show major differences in potential demand between these groups; rather, results indicated that there is potential for high uptake of the method across segments. In addition to the slides presented during the meeting, see [here](#) for more information on the market research and [here](#) for client profiles.

**Q: Do you have data on how effective targeting message/approaches to these different user segments was? More effective than a general message?**

- **Response:** As a community, we have not yet rigorously evaluated different messages/approaches to demand creation for the hormonal IUS. Our findings suggest that clients perceived positive attributes of the IUS may be influenced by the value proposition they are presented. For example, in [Madagascar](#) where Avibela materials put the bleeding and side effect profile at the forefront, clients often cited this as their reason for choosing the method. Additional research and M&E in this area would be valuable.

**Q: I'm curious about the menstrual bleeding volume between implant vs. hormonal IUS. Both features less including amenorrhea. Can the presenter provide additional insight into the Nigeria findings on use of amt of menstrual products?**

**Response:** [Findings presented](#) during the meeting do not support direct quantitative comparisons about menstrual bleeding volume between implant and hormonal IUS acceptors. The data that were presented are based on self-reports of how the quantity of menstrual products used at the time of the survey compared to the quantity of menstrual products used prior to receiving the method. This question was asked six months after receiving the method, and again twelve months after receiving the methods (the findings that were shown pertained to the six-month follow up). The results indicate that the proportion of hormonal IUS acceptors who reported using fewer products compared to before they received their method was greater than the proportion of implant acceptors reporting a reduction in menstrual products used. Because participants were not randomized into receiving a particular method, it is possible that these findings may be influenced by differences in bleeding patterns prior to receiving each method. Nonetheless, overall study findings in both Nigeria and Zambia are consistent in more commonly emphasizing reduction in bleeding as a feature of the hormonal IUS relative to implants. In both countries, more hormonal IUS acceptors reported reduced bleeding as a positive attribute of the method compared to implant acceptors; more hormonal IUS acceptors reported experiencing a lighter or shorter period compared to implant acceptors (although more implant acceptors reported experiencing amenorrhea); and more hormonal IUS acceptors reported a reduction in menstrual products used compared to implant acceptors.

**Q: For the study presented by Dr. Catherine Todd, what accounts for the differences in expulsions? What are potential reasons for this?**

- **Response:** The expulsion rate, which included both complete and partial expulsions detected at exam, differed significantly between the copper IUD (C-IUD) (5.6/100 person-years) and hormonal IUS (0.6/100 person-years). We attribute some expulsions to intrauterine contraception (IUC) malposition, which may have been clinically unrecognizable until the IUC was visible at the cervical os. Bahamondes and colleagues ([2015](#)) noted similar rates among C-IUD users, which they attributed to issues related to variability in inserter design. We believe that expulsions, particularly partial expulsions for the C-IUD, arose from two possible causes related to the generic device available in the public sector during the bulk of the enrollment period. First, the narrow insertion tube of the device was difficult to fold the C-IUD arms into prior to insertion and may have ejected early in the fundus with resultant malposition. Next, the narrow, somewhat pointed shape of the inserter tube may have resulted in clinicians hesitating to move the inserter all the way to the fundus and then back by 1 cm before advancing the C-IUD into the endometrial cavity due to perforation concerns. Our findings add to a mixed picture in the current literature, as one case series noted higher expulsion rates among C-IUD as compared to hormonal IUS users ([Merki-Feld, Inthurm & Keller, 2008](#)), but others found similar ([Madden et al. 2014](#)) or higher expulsion rates for the hormonal IUS ([Sanders et al. 2017](#); [Simonatto et al. 2016](#)).

**Q: Are there any drug interaction with the hormonal IUS and ARTs? e.g., reduced efficacy?**

- **Response:** We have not seen elevated pregnancy rates with the hormonal IUS among women using ART as compared to studies among general female populations where HIV status was not reported. That said, [the study](#) Dr. Todd discussed during the meeting had 199 participants. In our cohort, two pregnancies were among C-IUD users (both ectopic) and two among hormonal IUS users (one was intrauterine and one we believe was after an unrecognized expulsion as the patient presented with an incomplete abortion and no IUD was recovered at that visit or the subsequent curettage). [Kakaire et al. \(2015\)](#) had a cohort of 354 women randomized to hormonal IUS and 349 women randomized to C-IUD and there were 2 pregnancies with C-IUD in place and 1 with hormonal IUS in place within a cohort where 88% of women were using ART. Regarding ART efficacy, Todd et al., did not find any significant difference in proportion of women with suppressed viral load between C-IUD and hormonal IUS users across the cohort period, so do not have evidence to suggest reduced ART efficacy.

PowerPoint slides from the event are available for download. You can find slides from Day 1 [here](#) and slides from Day 2 [here](#).