LARC and PM Community of Practice

Streamlining Service Delivery to Expand Access:
Innovations in IUD Insertion Technology

MEETING HIGHLIGHTS

Washington, D.C.
July 13, 2016
Background
USAID, the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, DFID, and KOICA joined together to launch Saving Lives at Birth: A Grand Challenge for Development, to find the tools and approaches to help the mothers and newborns during their most vulnerable hours. The partnership supports innovative ideas that can leapfrog conventional approaches in three main domains:

1. technology;
2. service delivery; and
3. “demand side” innovation that empowers pregnant women and their families to practice healthy behaviors and be aware of and access health care during pregnancy, childbirth and the early postnatal period, especially the first two days after birth.

Voluntary family planning, including postpartum family planning (PPFP), enables the healthy timing and spacing for pregnancies. Yet more than 220 million women and girls in developing countries have an unmet need for contraception. Experts estimate that if all couples in developing countries spaced their pregnancies by 24 months or more, maternal deaths around the world would decline by 32% and childhood deaths by nearly 10%.  

As a highly effective method of long-acting reversible contraception (LARC), intrauterine devices (IUDs) are an important option to include among the range of methods available immediately postpartum and outside of the postpartum period (interval insertions). Saving Lives at Birth invested in the development of new IUD insertion technologies to simplify IUD insertion and expand the number providers with the ability and confidence to offer clients this important option.

Meeting objective
In this meeting, members of the LARC and permanent methods Community of Practice came together for presentations of two innovations in IUD insertion technology. Through USAID’s Support for International Family Planning Organizations 2 (SIFPO2) project, Population Services International (PSI) serves as the current Secretariat of the Community of Practice and hosted this meeting.

The objective of the meeting was to share information about two new IUD insertion technologies supported by Saving Lives at Birth:

- A reusable IUD inserter designed by Bioceptive to make interval IUD insertions simpler, safer, and more intuitive.
- A postpartum IUD (PPIUD) inserter designed by PSI, Pregna International Ltd., and the Stanford Program for International Reproductive Education (SPIRES) to allow for a standardized, easy-to-learn insertion technique in the immediate postpartum period.

The 29 meeting participants represented USAID, the Bill & Melinda Gates Foundation, the Ministry of Health of Nigeria, two academic institutions, a private company (Bioceptive), and five cooperating agencies involved in strengthening family planning service delivery: EngenderHealth, FHI 360, Jhpiego, Pathfinder, and PSI including PASMO, PSI’s network member in Guatemala. This report highlights key messages delivered by the speakers. Links to the presentations and resource documents are included at the end of the report.

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Opening remarks
Monique Burckhart, SIFPO2 Deputy Director at PSI, welcomed participants and underscored the importance of work to expand family planning options and access by improving the process of IUD insertion.

Emily Hillman, a Public Health Specialist in USAID’s Maternal and Child Health Division, provided opening remarks with Patricia McDonald, a Senior Technical Advisor in USAID’s Office of Population and Reproductive Health.

Ms. Hillman spoke about how Saving Lives at Birth helps foster groundbreaking, scalable ways to reduce infant, maternal and child health, through investments in innovations like those presented at the meeting. She highlighted the need to expand access to family planning as a key part of global efforts to reduce maternal mortality. Ms. Hillman framed the meeting as an exploration of two technological advances designed to make the IUD insertion process easier, safer, more intuitive, and affordable for women who desire IUDs.

Ms. Hillman said, “By studying the safety and accessibility, feasibility and efficacy of these interventions, these technologies could be game-changers and revolutionize the standard of practice.”

Ms. McDonald began by emphasizing that family planning saves lives. She asserted the need to overcome barriers related to the provision of underutilized, provider-dependent methods like IUDs. Addressing challenges related to provider skills and confidence can increase the availability of more methods as well as the quality of service delivery, ultimately expanding choice for women. She introduced the two technologies and welcomed participants to generate thoughtful discussion and challenging questions during the meeting.

“These technologies can break through barriers, making it easier for providers and lower-level cadres to safely provide these methods,” said Ms. McDonald.

Introducing the reusable IUD inserter
Bioceptive, represented by Shuchi “SK” Khurana (COO) and Ben Cappiello (CEO and President), introduced their work to create a reusable IUD inserter.

Mr. Khurana provided an overview of IUD usage rates (8% in the US, 5% worldwide), saying there is still significant room for growth in the overall IUD market if barriers can be overcome. Studies show a 2 to 12% expulsion rate and 17.8% insertion failure rate among advanced practice clinicians in the US. He noted that a tenaculum (the surgical clamp traditionally used to insert IUDs) can cause pain and discomfort for the client.

Bioceptive’s new technology aims to make the IUD insertion process easier for providers, less painful for clients, and less likely to result in perforations or expulsions. Mr. Khurana called it “incredibly simple to insert,” and explained that it does not use a tenaculum. The device uses gentle suction to engage the cervix which also creates a portal into the uterus and dilates the initial segment of the cervical canal. Early trials suggest that this suction-based retractor may eliminate bleeding and lower pain. (Studies were not powered to detect a statistically significant difference). No uterine sounding is needed as this new inserter automatically detects the fundus and also automatically deploys the IUD. The force-limiting mechanism is expected to eliminate perforations and the inserter’s fundal detector ensures consistent placement of the IUD at the top of the uterine cavity. Clinical trials will begin in the US and Bangladesh in August 2016.

Ultimately, Mr. Cappiello said that the goal for this technology is for any qualified health care worker, anywhere in the world, to be able to insert an IUD safely and reliably. “This isn’t a tool for people who are already experts,” he noted, “it is for providers who might not be gynecologists or primary care doctors. We are aiming to democratize
IUD insertions. Our goal is for a provider inserting an IUD for the first time to achieve the same outcome as one who has done thousands of insertions.”

Introducing the PPIUD inserter
Dr. Anne Burke, the Director of the Family Planning Division of John Hopkins Medicine, and Dr. Leo Han, a Fellow in Family Planning at Oregon Health and Science University, presented the next innovation: the dedicated PPIUD inserter. Dr. Burke and Dr. Han have collaborated with PSI and SPIRES, the developers of the inserter, to advance access to PPIUD services.

Dr. Anne Burke began by describing a problem. The postpartum period is a time when women are particularly likely to desire birth spacing or limiting, but unlikely to be using modern contraception: across 27 countries, 65% of postpartum women have a prospective unmet need for family planning. Barriers preventing women from returning to a health facility often impede PPFP use, especially for women living in rural areas.

PPIUD insertion is a safe, effective, and reversible contraceptive option within the 48 hours following delivery, while the woman is still in the hospital. Dr. Burke described PPIUD services has providing “one-stop shopping convenience for women.” She noted that women offered contraception immediately postpartum are more likely to be using a method six months later.
However, PPIUD insertion comes with certain challenges due to the shape and size of the uterus postpartum:

- Conventional IUD inserters are neither long nor firm enough to reach the postpartum uterine fundus. As a workaround, providers have used forceps, which requires them to remove the IUD from the inserter sleeve, place it at the tip of the forceps, and then insert it into the uterus.
- The string in conventional copper IUDs is too short to be visible after PPIUD insertion. Visibility of the string ensures that an IUD is in place.

PSI partnered with SPIRES and Pregna to create a low-cost inserter designed specifically for PPIUD insertion. The dedicated PPIUD inserter addresses the particular insertion challenges during the immediate postpartum period. The new inserter eliminates the need to use forceps for insertion, making the PPIUD insertion technique easier and more similar to interval insertion. Its firm consistency still allows it to bend to accommodate the shape of the postpartum uterus and its longer string is visible after PPIUD insertion. The pricing structure for the PPIUD inserter is between 75 cents and $1.50 USD depending on volumes purchased and negotiated agreements. Dr. Burke presented the results of studies in India showing the safety and acceptability of the PPIUD inserter and noted that demonstration projects are underway in seven countries. USAID’s Office of Population and Reproductive Health supported the development of provider materials for the PPIUD inserter as well as introduction efforts that are underway in Mali.

Dr. Leo Han, a Fellow in Family Planning at Oregon Health and Science University, continued the presentation with an overview of his experiences in Guatemala and Nicaragua, where he trained master trainers from PSI/PASMO in the use of the PPIUD inserter. Dr. Han described the training materials and said use of the inserter is easy to teach, as it significantly simplifies the process of PPIUD insertion. “While the idea is perhaps novel to some providers, the skill set is the same as that for managing a post-gravid uterus,” he observed. Dr. Han noted a challenge for training in either PPIUD insertion technique: it can be difficult to find sufficient opportunities for supervised clinical practice by trainees because demand for the service depends upon the timing of deliveries.

Dr. Han also noted his appreciation for the Mama-U, a portable device that acts as an anatomical uterus model and was also sponsored by Saving Lives at Birth. Mama-U supports PPIUD training for health providers using either the dedicated inserter or the forceps approach.
Participant practice stations
Demonstration stations with an anatomical uterus models allowed participants to observe and practice using the reusable IUD inserter and the dedicated PPIUD inserter. Family planning experts (both clinical and non-clinical) took the opportunity to engage with the products, ask questions, and provide feedback.

Closing remarks
In closing, Elaine Menotti, Technical Advisor in USAID’s Office of Population and Reproductive Health, reminded participants of the importance of expanding access to family planning services, and underscored the need for innovative products to streamline service delivery. Ms. Menotti encouraged the family planning community to share feedback and product details with other partners.

Resources
Saving Lives at Birth: A Grand Challenge for Development
- Website

Presentation on Bioceptive’s reusable IUD inserter

Presentation on the dedicated PPIUD inserter

Global Health: Science & Practice articles on the PPIUD inserter:
- Dedicated inserter facilitates immediate postpartum IUD insertion
- A Dedicated Postpartum Intrauterine Device Inserter: Pilot Experience and Proof of Concept

PSI publication: Enabling the Healthy Spacing and Limiting of Pregnancies: Programmatic Approaches to Expand Postpartum IUD Access (in English and French)

For more information
Please contact Ashley Jackson (ajackson@psi.org), Technical Advisor at PSI.