DECEMBER 2023

Assessing acceptability and feasibility of introducing **LNG releasing IUS (Hormonal IUD)** in the national family planning program of Bangladesh

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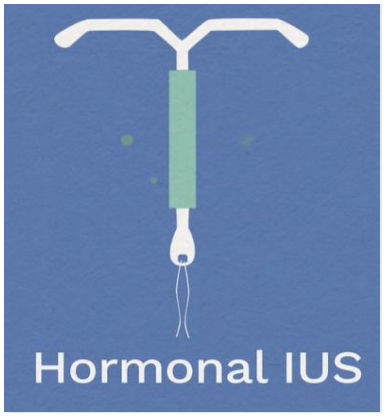

USAID'S ACCELERATING UNIVERSAL ACCESS TO FAMILY PLANNING (AUAFP) / SHUKHI JIBON PROJECT

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LIST OF ACRONYMS

BMRC Bangladesh Medical Research Council
C-section Cesarean section
CI Confidence Interval
COVID-19 Coronavirus Disease of 2019
CCSDP Clinical Contraception Services Delivery Program
DGDA Directorate General of Drug Administration
DGFP Directorate General of Family Planning
DGHS Directorate General of Health Services
DHS Demographic Health Survey
DUB Dysfunctional Uterine Bleeding
FP Family Planning
FWV Family Welfare Visitor
FWA Family Welfare Assistant
FWC Family Welfare Centre
GOB Government of Bangladesh
HIUD Hormonal IUD
ICA Foundation International Contraceptive Access Foundation
IUD Intra Uterine Device
IEC Information Education Communication
IDI In-depth Interview
LARC Long-Acting Reversible Contraception
LNG-IUS Levonorgestrel-Releasing Intrauterine System
LMIC Low- or Middle-Income Country
MFSTC Mohammadpur Fertility Services and Training Centre
MCHTI Maternal and Child Health Training Institute
MCWC Maternal and Child Welfare Centre
MCH Maternal and Child Health
MO Medical Officer
MO-MCH Medical Officer-Maternal and Child Health
MO-Clinics Medical Officer-Clinics
NTC National Technical Committee
OGSB Obstetrical and Gynecological Society of Bangladesh
OR Odds Ratio
OCP Oral Contraceptive Pill
PMs Permanent Methods
PPFP Postpartum Family Planning
PPH Postpartum Hemorrhage
SRH Sexual and Reproductive Health
TRP Training Resource Package
UHC Upazila Health Complex
USAID The United States Agency for International Development
UNFPA United Nations Population Fund
WHO World Health Organization

EXECUTIVE SUMMARY

The hormonal Intra Uterine Device (HIUD) is a highly effective intrauterine contraceptive device that gives pregnancy protection for five years. The national family planning (FP) program has been using the copper Intra Uterine Device (IUD) for decades, but has not been successful in increasing its use rate. The National Technical Committee (NTC) and the Directorate General of Family Planning (DGFP) advised conducting a pilot study to assess acceptability and feasibility of introducing the HIUD in public sector facilities in 2020, which was approved by the Bangladesh Medical Research Council (BMRC). from January 2022 to October 2023, the Clinical Contraception Services Delivery Program (CCSDP) and DGFP implemented a 24-month prospective cohort study with support from the USAID Shukhi Jibon project, Pathfinder, and the Population Council in seven high-volume facilities under DGFP, Directorate General of Health Services (DGHS), and the private sector. The objectives were to assess the feasibility of introducing the HIUD in the public sector's facilities, the acceptability of this method (from the perspective of both providers and clients), and the level of clients' satisfaction with the HIUD. This report contains the salient findings from the study.

Most (67.5%) of the women who participated in the study and gave the socioeconomic information were in their 30s or under. Most of them had two children, low parity, and primary to secondary levels of education. It reflects the acceptability of HIUD among young and comparatively educated women. Among the new contraception users, 61% accepted the HIUD from the study facilities. Of these new HIUD acceptors, 30% were using a short-acting method and 8% were using copper IUD as their last method before the HIUD. Of the new HIUD acceptors, 78% chose the HIUD for its long-acting properties, while 22% chose it for both contraceptive purposes and treatment for heavy bleeding. A smaller proportion of acceptors, about 7%, cited insertion due to treatment of the heavy bleeding or painful period.

Of the new HIUD acceptors, 61% were not previously using contraception. Among those who were using contraception, 77% used short-acting methods, 3% used an Implant, and 7% used copper IUD. Throughout the study, continuation rates of HIUD were 81% at six months and 78% at 12 months. Satisfaction with the method and with the bleeding pattern was higher overall for the HIUD than for the Copper IUD. 93% of clients were satisfied with HIUD, and continued for 12 months. 96% of HIUD continuers did not report any side effects. Only 4% reported experiencing changes in menstrual bleeding patterns. Of clients who chose to discontinue using the HIUD, 38% cited continuous bleeding as the major cause.

Acceptance of HIUD is better than the copper IUD. However, utilization was slow due to the limited number of trained service providers at the study facilities and limited HIUD supply. Comparatively, younger women and new family planning method users preferred the HIUD. The satisfaction level was high among clients who continued using the HIUD 12 months after insertion, and women reported finding the HIUD a better option since it is the only long-acting contraception that gives 5 years of protection. Doctors showed a promising cadre for providing HIUD, especially during the postpartum period. However, the Government needs to strategize the role of supporting family welfare visitors (FWVs) to improve the quality of services for HIUD. Training packages for doctors need to be different from packages to FWVs in terms of duration. Counseling services also need to be strengthened to improve the retention of the method and to decrease the discontinuation.

INTRODUCTION

The national FP program of Bangladesh has been trying to increase uptake of long-acting reversible contraception (LARC) and permanent methods (PM) through various program strategies, including program-driven counseling and FP service provision for postpartum women. The LARCs currently included in Bangladesh's Essential Drug List and Over the Counter List (and therefore available to clients) are the hormonal implant and the copper IUD.[1] The DGFP's five-year sector plan (January 2017—June 2022) included a plan to increase the proportion of LARCs and PMs from their current 9% of the modern contraceptive method mix to 20%, and to reduce the discontinuation rate for these methods from 37% to 20% by 2022[2]. However, the program faces many challenges, particularly training public sector FP service providers on IUD insertion and removal to increase the number of providers with sufficient knowledge and competence to provide IUD services and contribute to increased IUD uptake. In the most recent Bangladesh Demographic Health Survey (DHS), only 0.4% of married women aged 15—49 reported using an IUD.[2] A combination of factors, including clients' lack of information, misconceptions and myths about IUDs, providers' attitudes, providers' lack of knowledge base, side effects associated with IUD use, and cultural and religious reasons are responsible for this low uptake of IUDs.[3] For example, in Bangladesh and other Muslim-majority countries, studies have found that clients feel that heavy or unpredictable bleeding associated with IUDs use interfere with women's religious and social activities.[4] Lack of community awareness about the benefits of LARCs for spacing and limiting pregnancy further amplifies the problem.[5]

Discontinuation rates of contraceptive methods are extremely high in Bangladesh, and much higher for short-acting methods like condoms (45%), pills (42%), and injectables (34%) than for long-acting methods like implants (11%). An analysis of 49 DHS studies from 2009 to 2022 found that over 70% of women who discontinued their contraceptive method due to reasons related to the method (i.e., not related to a desire to become pregnant) resumed contraception within three months.[6]

The 2017—2018 DHS could not calculate a discontinuation rate for IUDs, because the numbers were too low in the sample, and data on discontinuation from the 2022 DHS is not yet available. A 2019 study that analyzed 2,306 IUD discontinuation cases between 2004 and 2014 found that the 12-month IUD discontinuation rate hovered around 40% in the years between 2004 and 2010 and rose to up to almost 70% between 2010 and 2014. Moreover, the team found that almost half of the women (42%) who discontinued using an IUD did not choose a new method after discarding their

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6 Gemmill A, Sarnak D, Bradley SEK, Brecker E, Patierno K. Reproductive outcomes following contraceptive discontinuation for method-related reasons: An analysis of 49 Demographic and Health Surveys. PLOS Glob Public Health. 2023 Nov 8;3(11): e0002143. doi: 10.1371/journal.pgph.0002143. PMID: 37939155; PMCID: PMC10631694.

IUD, and less than 2% switched to an implant (another LARC).[7] There are various reasons why women discontinued IUD use in Bangladesh. The most common reasons cited were side effects, particularly excessive bleeding and pain.[8] A 2007 study suggests that while many women identified abnormal discharge, weakness, and fever as the most common side effects of their IUD, these were not the key reasons for IUD removal. The study found that painful sex, vaginal discharge, and general weakness were tolerated by women longer than bleeding problems and/or abdominal pain before they made the decision to remove their IUD. The study also noted that most of the discontinuers who had bleeding problems did not tolerate it for more than a month before removing the IUD, despite the fact that irregular bleeding after IUD insertion typically resolves after 6 months. One month post-insertion could be a critical time for follow-up, side-effect management, couple counseling, and reassurance for clients.

The HIUD is a highly effective intrauterine contraceptive device that gives pregnancy protection for five years.[9] Since its introduction into the United States market in 2001, more than 18 million women have selected Mirena® HIUD as their method of choice. While Mirena® HIUD has been registered in 120 countries, it has not yet been registered in any FP2030 countries, including Bangladesh.[10] In 2019, the 71st NTC meeting of DGFP approved the piloting of HIUD service provision in public sector facilities considering its added advantage of treatment of idiopathic menstrual bleeding in addition to contraception. The purpose of piloting the HIUD was to assess the acceptability and feasibility of introducing the HIUD in public sector facilities. The DGFP sought technical assistance from Pathfinder to conduct the pilot study.

The same national guidelines for IUD insertion, removal, counseling, infection prevention, side-effect/complication management, and follow-up strategies were followed in the study. The DGFP central supply system was used to supply the donation of HIUD from the ICA Foundation in the seven selected facilities for distribution. The Clinical Contraception Services Delivery Program (CCSDP) of DGFP led the study Shukhi Jibon provided the implementation support, and the Population Council was involved in the technical support for the study.

[7] Bhadra, S., Haider, M. M., & Rahman, M. (2019). Discontinuation of contraceptive intrauterine devices and implants in Bangladesh. Dhaka, Bangladesh and Chapel Hill, NC, USA: icddr,b and MEASURE Evaluation, University of North Carolina.

[8] Jain A, Reichenbach L, Ehsan I, Rob U. "Side effects affected my daily activities a lot": a qualitative exploration of the impact of contraceptive side effects in Bangladesh. Open Access J Contracept. 2017 Jul 10; 8:45-52. doi: 10.2147/OAJC.S140214. PMID: 29386952; PMCID: PMC5774554.

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METHODOLOGY

This 24-month prospective cohort study sampled 540 women of reproductive age (15—49) with at least one living child, who chose the HIUD as their method of contraception. While the study period was extended in attempt to reach the target sample of 600 enrollees, the study ultimately fell short of the full target sample size. The study ran from January 2022 to October 2023 and spanned seven selected public health facilities across the country. FWVs, midwives, and Medical Officers screened the eligible women who came to the selected facilities seeking long-acting contraception and checked for appropriateness of this method. Follow-up with adopters were conducted at specific intervals after the HIUD insertion—at 1 month, 6 months, and 12 months.

During the recruitment of the study participants, both the copper IUD and the HIUD were offered to women interested in an intrauterine device. In their counseling on methods, providers mentioned the added advantage of treatment for heavy menstrual bleeding offered by the HIUD. Emphasis was provided to women with idiopathic menorrhagia and wanted a LARC specifically. Under the pilot, the HIUD was offered as an interval contraceptive method as well as a postpartum contraceptive method, as one of the methods considered appropriate for postpartum family planning (PPFP). The pilot ensured that the same national guidelines for the copper IUD were followed for the HIUD, including guidelines related to insertion, removal, counseling, infection prevention, side-effect/complication management, and follow-up schedules. The DGFP central supply system was used to collect and supply HIUD commodities to the respective facilities for distribution.

Facilities affiliated with both the Directorate General of Health Services (DGHS) and the Directorate General of Family Planning (DGFP)[11] were selected to participate in the pilot at the district levels considering the increased number of copper IUD utilization in the last two years (in 2019—2020) and capacity to handle a large client load with an adequately large number of trained staff. The activities for the pilot were implemented in three stages: (1) Training of service providers, (2) provision of initial HIUD services to consenting clients who enrolled in the study, and (3) provision of follow-up counseling and/or services alongside data collection for HIUD adopters at specific intervals post-insertion.

Purpose and objectives

The purpose of the study was to assess the feasibility of introducing HIUD in the public sector's facilities, the acceptability of this method (from the perspective of both providers and clients), and the level of clients' satisfaction with the HIUD. The specific objectives of the pilot were to:

- Introduce service provision for the HIUD in seven high-volume health and FP facilities to understand acceptance, satisfaction, and feasibility of the method
- Document the opportunities and challenges in introducing HIUD in the selected facilities

Study population: Married women of reproductive age (ages 15—49) were the primary population of interest for the study. The pilot also sought to understand the experience and perspectives of

[11] Due to the bifurcated nature of the Bangladeshi health system, providers and facilities affiliated with the DGFP provide primarily family planning and some maternal, newborn, and child health services (MNCH), while DGHS facilities and staff offer curative, MNCH, and more general health services.

service providers (FWVs/midwives, Medical Officer-Maternal and Child Health (MO-MCH) Clinics, and facility managers).

Study setting: The study was designed to select a diverse range of facilities and settings in terms of geographic locations and management authorities. This selection process was undertaken with the aim of ensuring that the findings from this study are informed by different perspectives and experiences, which ultimately informed the future roll-out of HIUD at scale. One facility was under the management of the DGHS, one was a private Obstetrical and Gynecological Society of Bangladesh (OGSB) hospital), and the rest were under the management of the DGFP. Clients received HIUDs free of charge in all facilities. Under the management of DGFP, two facilities were specialized hospitals and selected for training support at the national scale up stage.

Table 1: Descriptions of study facilities

Sl#	Name of study facility	Type of facility
1	The Dhamrai Upazila Health Complex (UHC)	A health complex at the sub-district level under the management of DGHS
2	The Mohammadpur Fertility Services and Training Center (MFTC)	A specialized 200-bed hospital under the management of the DGFP that provides comprehensive sexual and reproductive health (SRH) training and SRH/FP services in Dhaka
3	Maternal and Child Health Training Institute (MCHTI), Azimpur	A specialized 100-bed DGFP-run hospital specialized in MCH services in Dhaka Urban, Dhaka
4	Mymensingh Maternal Child Welfare Center (MCWC)	A high-volume district-level FP service facility under the management of the DGFP serving the poorest population of Mymensingh
5	Narsingdi Maternal Child Welfare Center (MCWC)	A high-volume district-level FP service facility under the management of the DGFP serving the poorest population of Narsingdi
6	Lakshmipur Maternal Child Welfare Center (MCWC)	A high-volume district-level FP service facility under the management of the DGFP serving the poorest population of Lakshmipur
7	OGSB hospital, Mirpur Dhaka	A private hospital serving the Dhaka urban population that receives contraceptive commodity supplies from the DGFP and does not charge for contraceptive methods and services

Hypothesis: If HIUD is made available in the public system in addition to the copper-T 380A IUD, more women will use the HIUD than the Copper-T 380A IUD.

Study sample:

Sample size estimation: The sample size was estimated using the following formula:

Null hypothesis

H_0: $P = P_0$

Alternative hypothesis

H_0: $P \neq P_0$ (IUD used rate will be changed after offering HIUD)

Type of hypothesis test: Two-tailed, non-directional. Sample size calculation formula for two-tailed test is:

$$n=\left[\frac{Z\alpha_{/2}\sqrt{P_0(1-P_0)}}{E}\right]^2 \times deff$$

n= Estimated sample

$Z\alpha_{/2}$= Z statistic for a level of confidence (for significance level of 2.5%, Z=2.24)

P_0= Current IUD used rate, which is 0.6% (the P_0 value 0.006)

E= Margin of error (We assume margin of error 1%)

Deff= Design effect

$$n=\left[\frac{2.24\sqrt{0.006(1-0.006)}}{0.01}\right]^2 \times 2$$

n =599.25

n≅ 599

The total sample size was 600 with a 97.5% confidence interval (2.5% significance level) and with a 1% margin of error. The HIUD acceptors proportionate to the total copper-T 380A IUD acceptors were used in each of the seven study facilities.

Table 2: Data collection methods

	Learning/research questions	Method of data collection
1.	Do eligible women accept the HIUD as their preferred method of contraception?	Data on 600 HIUD adopters extracted from IUD client registers at participating facilities
		Data on contraceptive service delivery extracted from the health management information systems of the DGFP and DGHS for relevant facilities and reports from private participating facilities
		In-depth interviews with 30 study enrollees who adopted an HIUD.
2.	What are the profiles of the clients who choose to use the HIUD?	Data from study-specific questionnaire of 600 HIUD adopters
3.	If the HIUD wasn't available today, what method would the clients have chosen instead?	Data from study enrollment checklists of 600 HIUD adopters
4.	What are healthcare providers' perceptions about the HIUD, particularly as it compares to the copper-T IUD 380A?	In-depth interviews with 15 service providers who provide IUD services

	Learning/research questions	Method of data collection
5.	What demand generation and provider training approaches would be required to overcome potential barriers to uptake of the HIUD compared with other long-acting reversible contraceptive methods?	In-depth interviews with 15 service providers who provide IUD services, MoMCH, and facility managers
6.	Is the training provided to service providers enough to insert, remove, counsel, manage side effects, and follow up with HIUD?	Pre- and post-training tests of 30 service providers who completed the pilot study's training
7.	What are the opportunities and barriers to introducing the HIUD as a new contraceptive method in different types of health service facilities?	In-depth interviews with 20 health facility staff members, including service providers who provide IUD services, MoMCH/MO clinic/MO, and facility managers

Study definitions: We have defined LNG IUS as HIUD (Hormonal IUD) all through the report according to the WHO. The following terminology is used throughout the report to distinguish between categories of study participants:

HIUD acceptors/enrollees: Women who chose the HIUD from among all the family planning methods available at health facilities participating in the study and had it inserted for the first time.

HIUD adopters: Women who consented to take part in the study and chose to have a HIUD inserted at one of the study facilities and continued using the HIUD for 12 months after insertion without any interruptions.

HIUD discontinuers: Women gave informed consent to participate in the study and initially had a HIUD inserted at one of the study facilities who then chose to remove the HIUD by the service providers within 12 months after insertion and did not insert a new HIUD months in that period.

Figure 1: Study implementation timeline

Study period: The study was initially designed to last 24 months with the objective of following up with 600 clients who chose to have a HIUD as late as 6—12 months after insertion. The total period of the study was considered after receiving approval from the BMRC in April 2020. Due to national lockdowns associated with the COVID-19 pandemic in 2020, there was a delay in obtaining formal permission from the Directorate General for Drug Administration (DGDA) to import the HIUD from the ICA Foundation. Ultimately, following DGDA approval in March 2021, HIUD units reached the central warehouse of the DGFP in two batches.The first batch arrived in August 2021, and the second batch arrived in December 2022. There was a gap of four months to get the resupply from the ICA Foundation. These delays led the study team to extend the implementation period through

October 2023 to maximize the number of insertions of HIUD to reach the target sample of 600 clients. The timeline (Figure 1) shows the total study period.

Study instrument and follow-up measures: The study developed a questionnaire for enrollees in which service providers recorded sociodemographic information; obstetrical, gynecological, and contraceptive history; the reason for choosing the HIUD; menstrual history; medical history; and results of a physical examination during client screenings for the HIUD before they inserted the device. The study used government enrollment forms. After the insertion, service providers advised women to return for follow-up visits at the 1-, 6-, and 12-month mark post-insertion. While the intention was for all follow-up visits to occur in person at facilities, when clients failed to appear at facilities, the study team decided to contact them by phone and obtain informed consent for a verbal check-in to ensure they were not lacking for the care they needed and to complete the follow-up questionnaire.

Questionnaires developed by the study team to be used at these follow-up check-ins recorded status of use (continuation/discontinuation), menstrual patterns, side effects, complications, and satisfaction related to the HIUD. Acceptability of the HIUD was measured in terms of satisfaction level, experience compared to expectations, whether the client would recommend the HIUD to a friend or relative, and husband's perceptions. Questions about acceptability were asked after 12 months amongst those who continued using the HIUD, at the point of removal for those who chose to do so, or at the health facility visit following a reported expulsion.

Participating clients who attended their scheduled follow-up check-ins at the service facilities met with FWVs, who conducted an examination to check device status. Those participants who did not attend their scheduled 12-month follow-up for a month after the intended date received a discreet telephone call from the study coordinator to complete the final questionnaire orally, while maintaining confidentiality. If this was not possible, the interview was cancelled. For women with whom the study team followed up through phone calls or at home, the same questionnaire was administered, but no physical examination was conducted. Women who did not come to the health facility and could not contacted by telephone were considered lost to follow-up.

Ethical considerations: The protocol was reviewed by the BMRC and was approved on April 30, 2020, Registration Number: 277 16 02 2020.

Study Limitations: There are a number of limitations to consider with respect to this study. To reach the target sample size, the study considered only health facilities that had recently seen high volumes of copper IUD acceptance relative to other facilities. The selection of these facilities, however, does not necessarily allow the study team to assess the feasibility of HIUD service delivery.

Uptake of the HIUD at participating facilities proceeded at a slower pace than anticipated. While the study period was extended in attempt to reach the target sample of 600 enrollees, the study ultimately fell short of the full target sample size. Part of the reason that HIUD uptake was slower than anticipated—and slower relative to other contraceptive methods, including copper IUDs—was that HIUD unit were provided in limited numbers to participating facilities, so they sometimes ran out. There was also a period of several months between the delivery of the two lots from the ICA

Foundation during which HIUDs were not available in some facilities. In addition, only selected providers who had been trained by the study team could insert the HIUDs, and they were not always available to provide these services. The limited number of qualified staff declined further over the course of the study period due to retirements, transfers to other facilities, and maternity leave, which further limited uptake of the HIUD. All client-reported side effects were documented and have not been further verified. Service providers' and managers' perspectives might not be generalizable for all types/levels of service providers whose work include IUD service delivery or for facility managers across the country. Finally, the selected study facilities were predominantly in urban areas and had staff consisting of multiple service providers, which may not fully reflect the challenges that facilities in rural settings may face, particularly as these facilities (family welfare centers) typically have just one service provider for family planning services.

STUDY INTERVENTION PROCESS

Introduction of the HIUD

The introduction of the HIUD into the Bangladesh FP program started with a Pathfinder-hosted inception meeting that announced the roll-out of the acceptability trial by the Pathfinder-led USAID Shukhi Jibon project in collaboration with the Government of Bangladesh (GOB), the private Obstetrical and Gynecological Society of Bangladesh (OGSB) hospital, and Population Council.

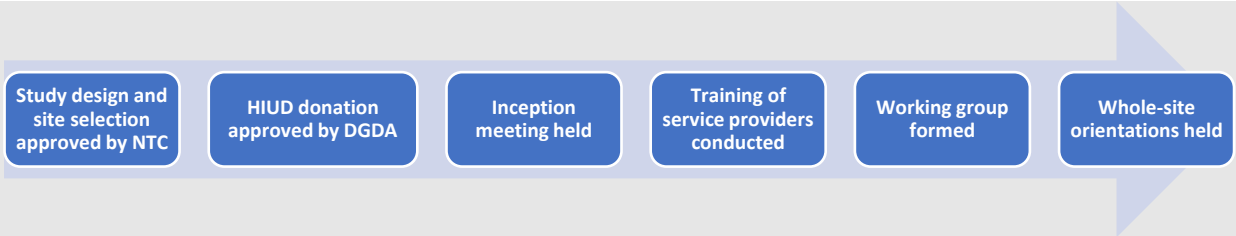

Figure 2: Study intervention process

The purpose of the inception meeting was to gain support and approval from GOB partners and the NTC, as well as share the design of the study. The Shukhi Jibon project team invited national- and district-level managers, as well as representatives from the selected study facilities, to attend this meeting to gain knowledge about the HIUD, a new long-acting family planning method. Through this meeting, participants were able to learn more about both the advantages and disadvantages of using HIUDs and how the study would be conducted. This gave them a better understanding of what was expected from them throughout the piloting process.

Approval from the Directorate General of Drug Administration (DGDA): Shukhi Jibon obtained approval from the DGDA to receive a donation of HIUD commodities from the ICA Foundation. This is an important milestone, as the HIUD is a newly developed family planning method that has yet not been added to the list of approved methods by DGDA. A total of 600 HIUD units were sent from the ICA Foundation in two lots: one in August 2021 and one in December 2022. The use of HIUD is not in conflict with government policy, because it is recommended by WHO and there are limited options for LARC at the public system.

Monitoring of the study activities: To strengthen the monitoring of study implementation, a working group consisting of representatives from different units of the DGFP, OGSB representatives, members of the Population Council's staff, and members of the Shukhi Jibon project affiliated with Pathfinder was formed. Ten members of the working group were chaired by the Line Director of the DGFP's Clinical Contraception Services Delivery Program (CCSDP), the principal investigator of the study. Members of the working group conducted monitoring visits to the facilities during the course of the study's implementation to ensure proper implementation of the study's protocol and observe any challenges that need attention.

Whole-site orientations: Given that the HIUD is a new contraceptive method in Bangladesh, all staff members at each study facility received an orientation on the HIUD. Additionally, and to ensure all were informed about the implementation of the study, The study team involved doctors, midwives, nurses, and support staff in these whole-day orientations and invited community health workers

from the catchment areas adjacent to the study facilities. These orientations were intended to secure staff members' support for the study's implementation and ensure appropriate referrals of potential HIUD clients would be made to the facilities. Facility staff was generally supportive of the orientations as they were not only introduced to the study but they also had the opportunity to learn more about the inclusion of the HIUD in the facilities' family planning services.

Training of service providers: From December 22, 2021 to January 10, 2022, after the whole-site orientations, the study team conducted training for participating service providers using the Training Resource Package (TRP), developed by WHO, USAID, and UNFPA with contributions from other expert agencies. The HIUD providers (doctors, family welfare assistants (FWAs), nurses, and midwives) were trained to be able to screen potential clients for the HIUD, incorporate the HIUD into their counseling on the full contraceptive method mix, insert the HIUD, provide follow-up care, and manage potential side effects. A team training approach[12] was followed. Doctors and nurse-midwives experienced in copper IUD insertion were trained on assessing the eligibility of clients' enrollment in the study, inserting the HIUD device, providing follow-up care, and ensuring proper documentation using the study's forms and following all required steps. While the TRP content was originally designed to be delivered over three days, the training duration was extended to 5 days. This expansion allowed the training to be consistent with the national training curriculum provided for copper IUD service provision.

Photo: TRP Website (https://www.fptraining.org/)

A total of 11 doctors, 9 FWVs, 2 nurses, and 2 midwives were trained. The training was conducted at the Mohammadpur Fertility Services and Training Center (MFSTC) in Dhaka, which provides comprehensive SRH training and services and has been selected as one of the study's health facilities for HIUD service provision. The study team managed the trainers, who consisted of senior gynecologists and staff members from OGSB who had been trained on HIUD service provision for the first time through Grameen Kalyan[13] in 2010, long before the HIUD's introduction in Bangladesh. There were 4 trainers involved in the training, and Shukhi Jibon technical staff led the technical sessions of the training.

Photo: (from left) Certificate distribution after training, Training at MFSTC, Demonstration session in January 2022

[12] https://www.indeed.com/career-advice/career-development/train-the-team
[13] https://ica-foundation.org/projects/past-projects/bangladesh/

The different trainee participants had varying roles when it came to providing services for the HIUD. The trained doctors were all gynecologists, and they expected to insert the device after C-sections or normal deliveries if requested by the client during postpartum. In addition, doctors would insert a HIUD for the treatment of heavy menstrual bleeding after an appropriate assessment and diagnosis of dysfunctional uterine bleeding (DUB). FWVs would typically be expected to insert the device for clients during an interval period (i.e., not in the immediate postpartum period), though in some cases they would also insert devices after a normal delivery. FWVs were trained to support doctors with HIUD insertion after C-section, and nurses and midwives were trained to complete all relevant documentation for the study.

Development of information, education, and communication (IEC) materials: Shukhi Jibon developed IEC materials and job aids in Bangla to aid providers in screening potential HIUD clients and improving the quality of counseling they provide to HIUD clients. Most of the materials were adapted from materials prepared by the ICA Foundation or as part of the TRP to align with the Bangladesh government's policies. Specifically, the study team adapted the ICA Foundation's job aid for service providers to better serve the Bangladeshi context and translated it into Bangla. The client screening/selection checklist was adapted from the WHO's TRP. The study team adapted the copper IUD insertion job aid developed by Engender Health under the Mayer Hashi project in Bangladesh (2013—2018) and to make it appropriate for HIUD insertion.

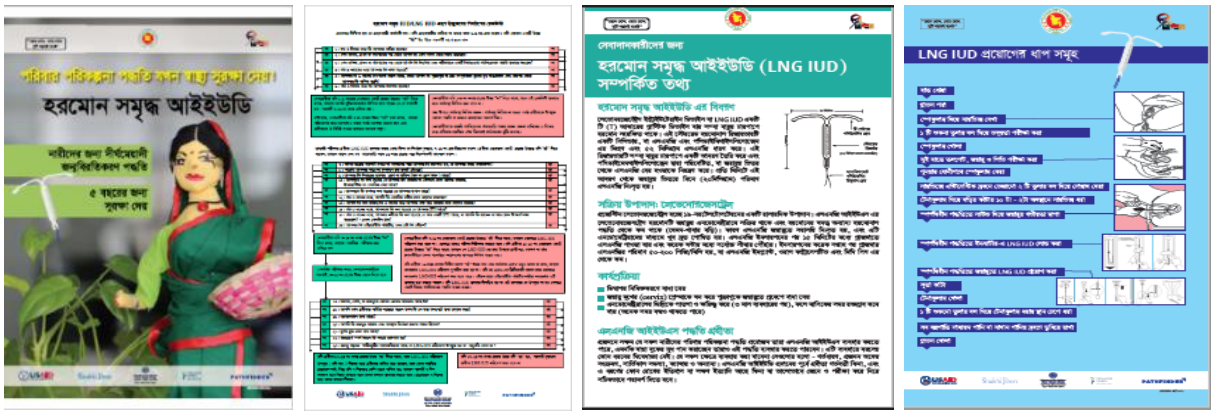

Photo: (from left) Poster for clients, Screening checklist, Job-aid for service providers, Job-aid for service providers

FINDINGS

While the protocol had called for recruiting 600 women for the study, a total of 539 women across all the participating study facilities had been recruited and had accepted a HIUD as of October 30, 2023. All participants had provided their informed consent to participate in the study, including answering the initial questionnaire and completing the follow-up check-ins post-insertion. 273 out of 300 eligible women completed their follow-up check-ins 12 months after insertion. The study team therefore analyzed the acceptability of the HIUD within the full sample of 539 women and further analyzed the adoptability within the sample of 273 women who completed the 12-month follow-up visit.

Figure 3 shows the status of insertion, removal/expulsion, and follow-up among study enrollees from **January 2022 to October 2023**. During to the practicum training, seven real clients received HIUD during demonstrations; these women were also included in the sample.

Out of the 600 HIUD units supplied by the ICA Foundation, 41 were not used and remained available at the facilities as of October 30, 2023. Five HIUDs were damaged during insertion, four were needed for reinsertion when the previous commodity had been expelled, and four HIUDs expired due to the low HIUD utilization rate in one of the study facilities in May—June 2022. At that time, the facility was busy with the national copper IUD training, and the HIUD insertion was stopped.

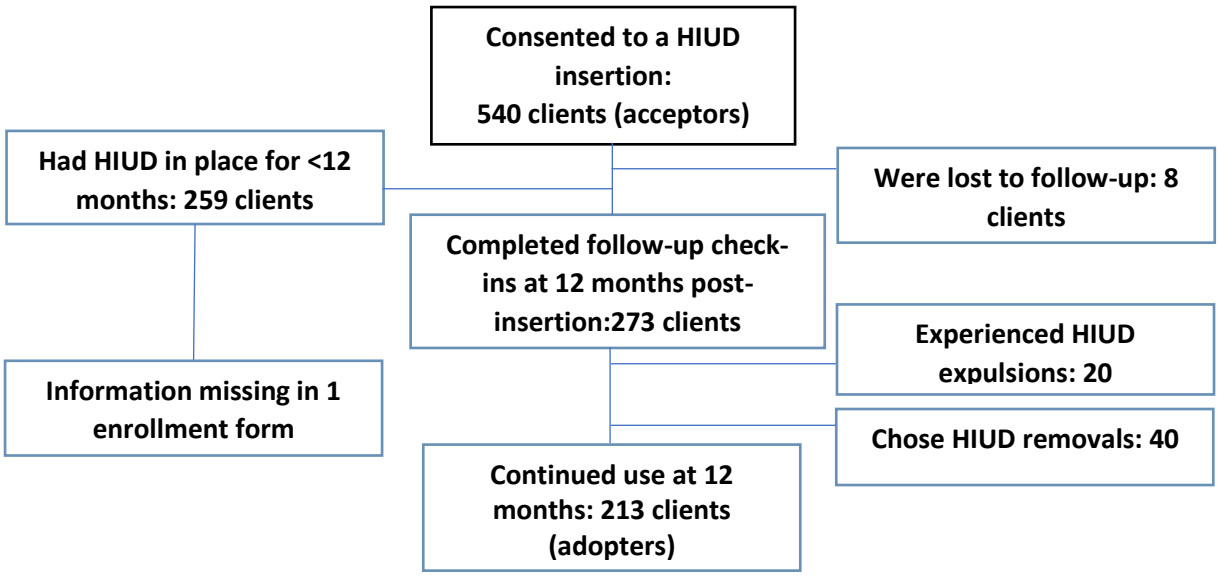

Figure 3: The study population for assessing the HIUD's acceptability

Section A: Client profiles of HIUD acceptor

More than half of the clients were less than or equal to 30 years of age (Table 3). Less than 10% of clients were over 40 years. Most clients had two children. Clients had a range of education levels, with nearly 40% having a secondary education more than 30% having higher secondary education or above, and almost 90% having no occupation outside of homemaking.

Table 3: Demographic characteristics of HIUD acceptors

Variables	n (%)
Client Age (n = 528)	
<=20	90 (17.1)
21-30	277 (52.5)
31-40	129 (24.4)
> 40	32 (6.1)
Number of living children *(n = 484)*	
1	146 (30.2)
2	208 (43.0)
≥ 3	130 (26.9)
Educational level *(n=513)*	
No education	31 (6.0)
Primary	122 (23.8)
Secondary	201 (39.2)
Higher Secondary and above	159 (31.0)
Client Occupation *(n = 515)*	
Housewife	458 (88.9)
Day laborer	12 (2.3)
Services	31 (6.0)
Business	6 (1.2)
Student	8 (1.6)

Figure 4 shows the proportion of copper IUD and HIUD insertions completed at participating facilities during the study period. The study team collected data on IUD insertions at each facility from March 2022 to September 2023 (Since October data was not ready at the service facilities) to understand the comparative clients' preferences for both types of IUDs in study facilities. In all, out of the total number of clients receiving some form of IUD from a participating facility over the course of the study period (3754), 16% chose the HIUD (Figure 5).

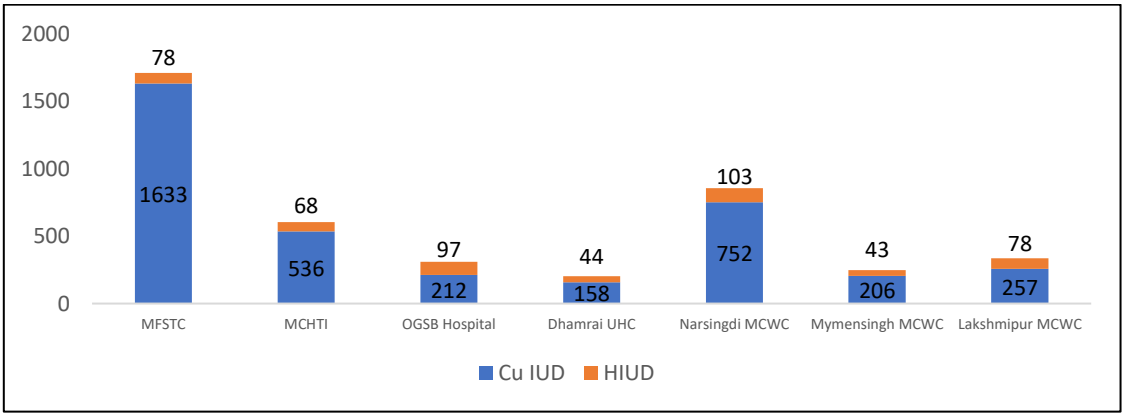

Figure 4: Number of Copper IUD and HIUD insertion in study facilities

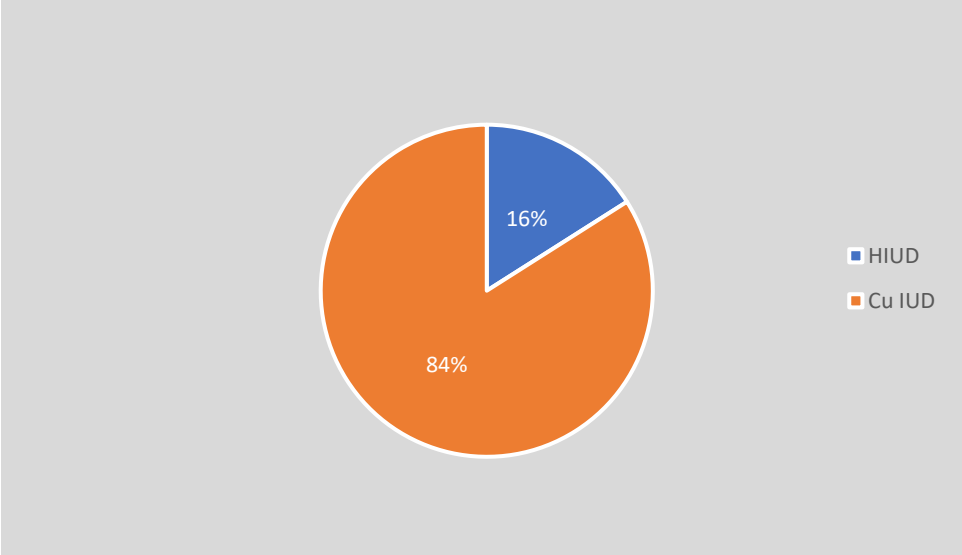

Figure 5: Acceptance of HIUD and copper IUD in study period in all sites

The study revealed that about 60% of women who chose to have an HIUD inserted within the study facilities were new users (Table 4). The remaining 40% switched to the HIUD from another contraceptive method, mainly the contraceptive pill (41% of this group), followed by condoms and the copper IUD (20% in both cases). In-depth interviews with the HIUD adopters revealed that some women who had come to the facility for a new contraceptive method following the expiration of their copper IUDs selected the HIUD over another copper IUD because it lasts for a shorter period (5 years) compared to the copper IUD (10 years) (Table 4). Moreover, the study shows that about 74% of the women who accepted an HIUD selected it as a contraceptive method while the remainder chose it for treatment of a bleeding issue as well as for contraceptive purposes. In-depth interviews with service providers revealed that service providers recommended HIUDs to women who complained of heavy menstrual bleeding, and, in some cases, they informed old clients about the availability of HIUDs at their service facility who came earlier for heavy menstruation bleeding.

Table 4: Past contraceptive method uses prior to HIUD insertion and reasons for selecting the HIUD

Variables	n (%)
Method used ever before HIUD use (n=500)	
Yes	198 (39.6)
No	302 (60.4)
Method used before HIUD use (n=198)	
Pill	82 (41.4)
Condom	39 (19.7)
Copper IUD	39 (19.7)
Injectable	31 (15.7)
Implant	6 (3.0)
Reasons for choosing HIUD (n=500)	
Only for long-term contraception	359 (71.8)
Only for heavy menstrual bleeding	32 (6.4)
Both for long-term contraception and heavy menstrual bleeding	109 (21.8)

Section B: Service provision for the hormonal IUD

The table below (table 5) shows that the highest number of HIUDs inserted among all service provider categories were nearly evenly split between MO (MCH-FP)/MOs and FWVs. A total of 63% of HIUDs were inserted by doctors (Consultants and MOs) (339) as opposed to other types of service providers as categorized by professional certification.

Table 5: Number of HIUD insertions completed in study facilities, by category of service provider

Service providers	Total n (%)
Consultant Doctors	141 (26.2)
MO (MCH-FP)/MOs	198 (36.7)
FWVs	197 (36.5)
Midwives	2 (0.4)
SACMO	1 (0.2)

Of the 539 total enrollees, 280 clients enrolled in the study early enough to have completed the 12 months before the study's end, and 273 completed the 12-month post-insertion follow-up period. 213 (78%) among 273 continued to use the HIUD up until that point. The remaining of the study's 266 enrollees did not yet have the HIUD completed for 12 months (266 clients).

Most of the follow-ups were done over the phone by the study coordinator from the Shukhi Jibon project. Data from the 12-month check-ins with clients shows that clients did not always come to the service facilities after the HIUD insertion if they did not experience any side effects/sickness related to the method. The qualitative data from interviews with clients who completed 12 months also supports this conclusion. They mentioned that they did not visit the service facility when they did not have a specific problem. In addition, the IDIs revealed that moving to a new area and living far away from the facility were also crucial reasons for not visiting the facilities among the clients who lived in Dhaka.

> *"I was not sure why I needed to visit the hospital when I was okay with my new family planning method. Yes, I will go there whenever I need to remove this"*
>
> - One of the clients from MFSTC (28), Dhaka

We were able to do 12-month follow-up check-ins with 273 out of 281 (97%) eligible women, including at the study facilities and over the telephone. Another 266 clients were followed up with for 6 months, but were ultimately not able to complete a 12-month follow-up due to the study's endpoint.

Table 6: Client's enrollments and follow-ups

Number of HIUD in different periods	n (%)		
	Number of clients who had a HIUD inserted (acceptors)	Number of clients who completed a follow-up visit/check-in 12 months after insertion	Number of clients who continued using the HIUD at 12 months (adopters)
	539 (100.0%)	273 (50.6%)	213 (78.0%)

Table 7 shows the different phases of HIUD insertion during the study period. Although most of the HIUDs (48%) were inserted during the interval period, insertions after C-sections made up nearly as large a proportion of the instances of HIUD insertions (40%). In fact, when insertions after C-sections and normal vaginal delivery (NVD) are considered together, more than half 52% of the study's HIUDs were inserted during the postpartum period.

Table 7: Clients' HIUD insertion phase across all study sites

Phase of insertion	Interval n (%)	After C-section n (%)	After NVD n (%)
Total (n= 539)	258 (47.9%)	218 (40.4%)	63 (11.7%)

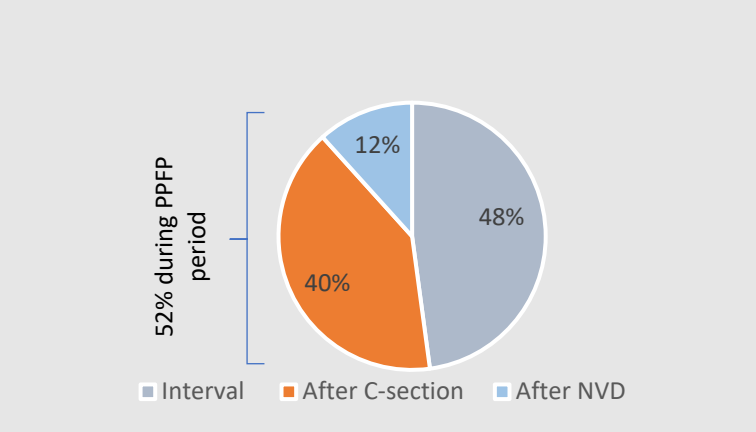

Figure 6: Phase of HIUD insertion

The consultant doctors did the insertions after the C-sections, which is not always the case for the other trained doctors. Currently, FWVs insert the copper IUD during the postpartum period and doctors rarely insert copper IUD after normal vaginal delivery.

Section C: Continuation of HIUD

As noted above, among the 273 women who completed a follow-up check-in 12 months after insertion, 213 (78%) continued HIUD use at 12 months.

Among the 213 women who continued using the HIUD for 12 months, 93% were satisfied with this method (Table 7). About 96% of women reported no side effects after continuing for 12 months. It is noted here that only 4% of women reported side effects that continued for 12 months. The most reported side effect was amenorrhea, followed by irregular bleeding.

Figure 7: Acceptability of HIUD amongst women who completed 12 months post-insertion

Variables	n (%)
Completed a follow-up visit/ check-in 12 months after insertion	273
Continued use of the HIUD at 6 months	221 (80.9)
Continued use of the HIUD at 12 months	213 (78.0)
User satisfaction over 12 months (n=217) Satisfied Dissatisfied	 201 (92.6) 16 (7.4)

Variables	n (%)
Will advise friends or relatives to use the HIUD method (n=220)	201 (91.4)
Side effects (n=213)	
No	170 (95.7)
Yes	27 (4.3)
Types of side effects reported (multiple responses) (n=27)	
Amenorrhea	12 (36.0)
Irregular bleeding	9 (27.0)
Discomfort due to thread	6 (18.0)
Other (white discharge, lower abdominal pain, vertigo)	6 (18.0)

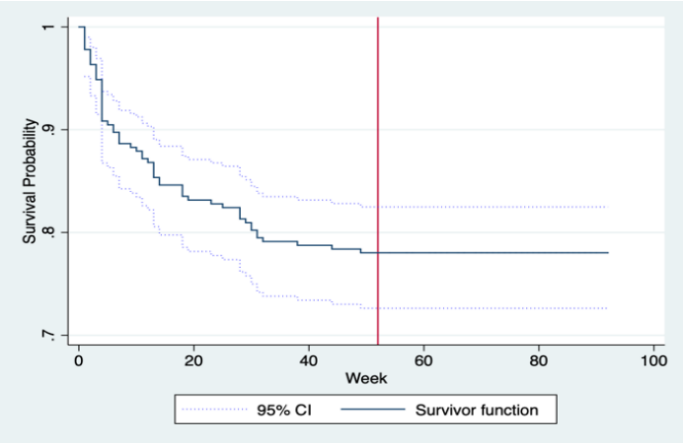

Figure 8: Among HIUD users who completed the follow-up visit/check-in 12 months after insertion, overall continuation rates (n=273)

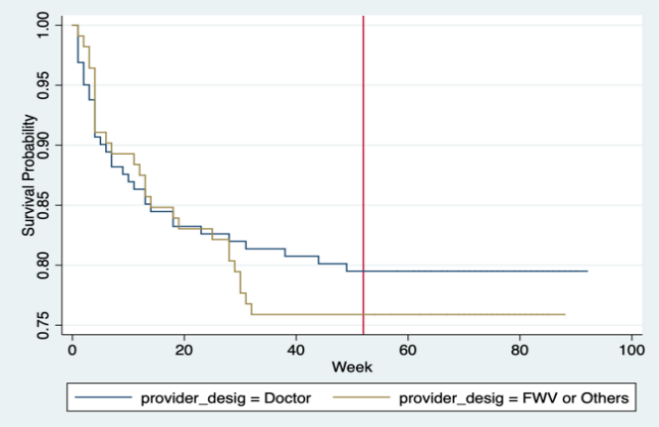

Figure 9: Among HIUD users who completed the follow-up visit/check-in 12 months after insertion, continuation rates by type of provider (n=273)

Figure 8 shows that there was approximately a 78% chance (survivor function, 0.7802 and 95% confidence interval (CI), 0.7263 - 0.8248) of continuing use of the HIUD after the 12th month (52 weeks) following the insertion.

As Figure 9 shows, after 12 months (52 weeks) post-HIUD insertion, there was an approximately 80% chance of continued use of the HIUD among clients who had had their HIUD inserted by a doctor (survivor function, 0.7950 and 95% CI, 0.7241 - 0.8496), a 76% chance of continued use of the HIUD among clients who had had their HIUD inserted by a FWVs (survivor function, 0.7589 and 95% confidence interval, 0.6685 - 0.8278). Further analysis through the Log-rank test showed no significant difference across types of providers in terms of clients' continued use of the HIUD after 12 months (p< 0.5427).

Table 8: Multivariate analysis for continued HIUD use at 12 months by selected variables (n=213)

Variables	Odds ratio (OR) for continued use of the HIUD at 12 months (95% CI)
Age	0.990 (0.932 - 1.051)
HIUD insertion phase	
Interval (ref.)	
After C-section	3.242 (1.227 - 8.566) **
After NVD	0.807 (0.321 - 2.028)
Number of living children	
1 (ref.)	
2	1.975 (0.899 - 4.339)
3	3.017 (1.041 - 8.743) *
4 & above	7.303 (0.772 - 69.093)
Educational level	
No education (ref.)	
Primary	2.167 (0.548 - 8.574)
Secondary	1.387 (0.389 - 4.946)
Higher Secondary and above	2.062 (0.560 - 7.592)
Service provider	
Doctor (ref.)	
FWV and others	1.710 (0.817 - 3.582)

*Significant at * p<0.05, ** p<0.01, *** p<0.001, ref. indicates reference category*

However, multivariate analysis revealed that clients who had their HIUD inserted following a C-section (odds ratio (OR), 3.242 and 95% CI, 1.227 - 8.566) and those who had 3 children (OR, 3.017 and 95% CI, 1.041 - 8.743) were statistically significantly more likely to continue the use of the HIUD ($p<0.018$ and $p<0.042$, respectively) (Table 8).

Section D: Discontinuation of the HIUD

Out of the 273 clients who completed the follow-up check-in 12 months after insertion, 40 women (15%) opted to remove the HIUD and 20 (7%) reported experiencing spontaneous expulsion. Table 9 shows that across the study facilities, the highest number of removals occurred within six months. Most clients who had the HIUD removed did so between the first and sixth month after insertion (23 out of 40, or 58%). A similar number removed the HIUD within the first month (9) as did so between 6 and 12 months (8).

The highest number of expulsions occurred within 1 month of insertion (12 out of 20 clients, or 60% of cases), with the remaining 8 cases occurring between 1 and 6 months. No expulsions were reported after 6 months post-insertion. The highest discontinuation rates (combining removals and spontaneous expulsions) were seen among clients who had the HIUD inserted at specialized hospitals. MFSTC and MCHTI, with rates of 7% and 6%, respectively. This was in comparison to the discontinuation of about 7% among clients who received their HIUD in one of the remaining study facilities. A total of When looking only at the voluntary removal rates, these were higher among

clients who had received their HIUD at specialized hospitals (i.e., MFSTC and MCHTI), at about 15%, compared to about 9% among clients who had had their HIUD inserted in any of the other study facilities.

Table 9: Period in which clients discontinued use of the HIUD through removal or spontaneous expulsion, calculated in months post-HIUD insertion n=60

Discontinuation at different periods	Within 1 month		Between 1 and 6 months		Between 6 and 12 months		Total discontinuation	
	Removal	Expulsion	Removal	Expulsion	Removal	Expulsion	Removal	Expulsion
n (%)	9 (3.3)	12 (4.4)	23 (8.4)	8 (2.9)	8 (2.9)	0 (0)	40 (14.7)	20 (7.3)

In-depth interviews with women who chose to have their HIUD removed revealed that in some cases, the clients felt the service providers at the specialized hospital did not mention much about the new method to them. Some clients also said they also could not visit the service facilities for follow-up check-ins due to the distance of the facility from their house. About half of the 40 clients who had their HIUD removed reported that they had been using other methods prior to their HIUD insertion (pills, condoms, injectables, and copper IUDs), while the rest were not using any method before the HIUD. Among the clients who chose to discontinue use of their HIUD, changes in menstruation were cited as the primary reason for the discontinuation. These changes ranged from amenorrhea to increases in bleeding compared to before the HIUD's use. In two cases, women were diagnosed with uterine fibroids, which caused increases in menstrual bleeding after HIUD insertion. These two clients ultimately underwent a hysterectomy.

Table 10 shows that the clients who chose to have their HIUDs removed most frequently reported heavy/continuous bleeding (45% of removal clients), irregular bleeding (32%), and abdominal pain (20%) among the reasons for removing the method.

Table 10: Reasons for choosing to discontinue use of the HIUD among study clients (n=40)

Variables	n (%)
Had device removed within 12 months (n=273)	40 (14.6)
Reasons for removal within 12 months (Multiple responses) (N=40)	Response
Heavy or continuous bleeding/ spotting	18 (38.3)
Irregular bleeding	13 (27.7)
Abdominal pain	8 (17.0)
Change in reproductive intention (resistance from husband and others; religious reasons; husband went abroad)	4 (8.5)
Displacement	2 (4.3)
Diabetes	1 (2.1)
Discomfort	1 (2.1)

Table 11 shows that the number of HIUD removals were highest among clients aged 21—30 years of age, which was also the age group that most often chose to have an HIUD inserted. More women who had an interval HIUD inserted (i.e., not in the postpartum period) chose to remove the method than did those who received an HIUD postpartum, and more women who had two children chose to have the HIUD removed than did those with one or three or more children. The average time of expulsion was 26 days, and the average days of removal was 113 days.

Table 11: Characteristics and reasons for removal among clients who chose to have their HIUD removed

Variables	n (%)
Age	
<=20	8 (20.0)
21-30	19 (47.5)
31-40	11 (27.5)
>40	2 (5.0)
HIUD insertion phase	
Interval	27 (67.5)
After C-section	8 (20.0)
After NVD	5 (12.5)
Number of living children (n=37)	
1	13 (35.1)
2	18 (48.7)
3	6 (16.2)
4 & above	0
Educational level (n=39)	
No education	4 (10.3)
Primary	9 (23.1)
Secondary	13 (33.3)
Higher Secondary and above	13 (33.3)
Category of providers who had inserted the HIUD and removed later (n=40)	
Doctors	19 (47.5)
FWV and others	21 (52.5)
Time of discontinuation (mean±SD)	
Time of removal in days (n=40)	112.8±88.0
Time of expulsion in days (n=20)	25.9±18.4

Section E: Experience with HIUD service delivery at study facilities

The study team interviewed clients to understand their experience with the HIUD and the services they received from the study facilities. Clients interviewed included those who continued use of the HIUD at 12 months (25) and clients who had discontinued HIUD use within the 12-month post-insertion period (15).

Experiences among clients who continued using the HIUD at 12 months. Most of the women interviewed reported satisfaction with the services they received during the insertion of the HIUD. Almost all women said that they were satisfied so far with their current family planning method and almost all would recommend others to go to the same service facility to take the services. Many of them mentioned that service providers gave enough information to choose them during insertion. However, a few women mentioned that service providers misbehaved during follow-up check-ins when they reported the side effects and denied removal. Most of the women expressed how happy they were with the services they received after getting a HIUD inserted. Nearly all the women expressed satisfaction with their current family planning method thus far, and nearly all of them would advise others to use the same facility for these services. Many of them stated that during insertion, service providers provided them with adequate information. A few women did, however, indicate that when they disclosed the side symptoms during follow-up appointments, they misbehaved.

Since they generally had few complaints related to the HIUD, most of the IDI participants who had continued their HIUD only occasionally visited facilities for follow-up care. The distance to the service facility was the main factor limiting their visits. The majority of them did, however, note that service providers reminded them to visit the facility for examinations. Just two women stated that they went to the service center three times to have the device's positioning checked.

When asked why they had chosen HIUD, most of the women said that they had converted to this new contraceptive method because of the adverse effects of the prior one. Numerous individuals claimed to use it as a long-term form of contraception protection.

Experiences among clients who chose to remove their HIUD within 12 months post-insertion. Fifteen women who had their HIUD removed before the full 12-month period participated in in-depth interviews. Most of these women said the insertion process was well-executed. A few of the participants did, however, mention that the HIUD was not discussed much by the service providers.

Some of the HIUD removal clients mentioned that service providers did not specifically mention the follow-up schedules during insertion. They also added service providers were very positive about the new method and in some instances pursued the clients to continue with managing the client reported side-effects. However, in some cases, they removed as and when clients persistently reported and requested removal.

> *"Yes, the hospital informed me that this is an effective method of family planning. However, I wasn't sure whether the side effects were less than the copper T."*
>
> - A woman removed the copper T for a HIUD, which they later took out (28) MCHTI, Dhaka

Some of them mentioned that the distance of the service facility from their home was one of the reasons for irregular follow-up check-ins. A few dropout clients went for unscheduled follow-up check-ins due to experiencing side effects like menstrual problems. Most of the clients who removed HIUD did not go for any other methods after removal, as mentioned during the interviews.

Most of the clients who chose to remove HIUD at the same study facility where they had had the device inserted and mentioned that there were no problems during the removal of the HIUD.

Section F: Service providers' and managers' perceptions of the HIUD

As part of the study, 15 service providers trained on the HIUD and five managers from some of the study facilities were interviewed to understand their perceptions of the HIUD. Most of the managers and service providers reported that the HIUD is a useful addition to the FP method mix, as there had previously been no long-term method in the FP program that could offer contraceptive protection for 5 years. Before the introduction of the HIUD, there was no long-term method that provided five years of pregnancy prevention. The copper IUD is a longer-term option (10 years), making the HIUD ideal for those seeking shorter-term contraception (5 years). FWVs mentioned that sometimes women do not prefer Copper IUDs, since it has a longer expiration date after insertion. Doctors' perceptions of HIUD are much better than the perception of FWVs, since doctors can realize more about the advantages of the method for the women health. Study doctors who are working at the specialized hospitals and the OGSB hospital knew about the advantages of HIUD and some of them also had experience with the insertion.

> *"I used the HIUD for some of my patients after the C-section at my private practice. Those are single handed, and the insertion process is easier to handle compared to the HIUD provided in the study"*
>
> - One of the trained doctors from MFSTC

Some of the doctors and FWVs stated that the tread of the HIUD is thicker and longer than that of the copper IUD, which is difficult to manage. However, some of them reported that the length and thickness of the tread are not a problem, they also added it is all about the technique of insertion.

Most of the doctors mentioned HIUD as a very good FP method. Some of them recommended that DGFP should be careful during the scale-up all over the country due its five-year expiration date. Most of the managers recommended that the HIUD should be available at the higher-level service facilities and the clients could be referred from FWCs after proper screening. This would reduce the risk of poor removal due to inadequate services or improper screening process. However, some managers recommended supplying experienced FWVs for copper IUDs at FWCs and providing a demand-based supply of HIUDS from Upazila stock/warehouses to avoid oversupply leading to expired products. Lastly, they proposed testing feasibility at union levels before scaling up this product.

Managers have suggested that service providers need to be sufficiently trained in counseling to reduce the number of removals. This is because it is an expensive method and better training can help prevent clients from changing their minds due to unwanted side effects, such as irregular bleeding or expulsion of HIUD. Comprehensive counseling should include informing clients about these potential side effects so they are aware before making a decision.

Section G: Service providers' training and appropriate demand generation strategy

Training scores of the different service providers improved for all the cadres (Table 12). Average score increases ranged from 9 percentage points among midwives to 24 percentage points for the one nurse who took part in the training.

Table 12: Pre-test and post-test scores

Service provider	Average scores		
	Pre-test	Post-test	N
Doctor	69.4	83.0	8
Nurse	54.0	78.0	1
Midwife	67.0	76.0	3
FWV	62.0	78.8	10

The minimum score requirement for the training was 80. Therefore, the post-test scores indicated that the training package was sufficient for the doctors, while it was insufficient for the other cadres of providers. This suggests that the training would need to be modified and additional mentoring and supervision would need to be provided to FWVs, nurses, and midwives to be fully equipped to provide quality HIUD services at service delivery points. In our study setup,trained doctors mentored the FWVs at the study facilities during HIUD insertions.

The study team interviewed 10 FWVs and 5 doctors about their experience and impressions of the training they underwent. In-depth interviews revealed that all were satisfied with the training. However, most of the FWVs mentioned that they needed more practicums to practice HIUD insertions, as the HIUD was a new contraceptive method. Many FWVs also mentioned that they needed refresher training. Some of them mentioned that FWVs might need mentoring on HIUD insertion after the training if it is not possible to provide sufficient real clients to do practicums during the training period. Many of the FWVs mentioned that while the training content was very rich, it should provide more information about the effects of the HIUD's hormone (Levonorgestrel) on women's health, which would help the providers share this information during counseling. Some of the FWVs mentioned that IEC materials on HIUD helped them to talk about the new method with the clients. Some of the FWVs mentioned that all training content, especially the presentation slides, should be in Bangla to make the content easier to understand.

On the other hand, in-depth interviews with the doctors disclosed that the 5-day duration of the training is unnecessary. Most of the doctors mentioned that since they have the copper IUD training and things are not very different compared to the copper IUD, 3 days of training might be enough for them. However, some of the doctors mentioned that the 5-day training duration is good to have enough scope and time of practicum.

Most of the service providers agreed that copper IUDs are not popular in Bangladesh. However, they thought that appropriate demand-generation activities would help improve HIUD utilization. Some of the service providers highlighted that appropriate IEC materials would be helpful for the clients to know about the functions and advantages of the hormone in the HIUD. They pointed out that the

existing copper IUD is the only long-acting FP method without hormones, and they always highlight this advantage to the clients. They also mentioned that the HIUD needs to be introduced very carefully into the public health system, emphasizing the additional benefits of the hormone (in terms of regulating menstrual bleeding) to potential clients. Service providers experienced that HIUD acceptance was good among young and educated women, since they understand the health advantages of the method. Therefore, these clients could be the advocates for others to improve the use of this new family planning method.

Many of the service providers and managers suggested including the service providers from the health department since these providers are responsible for the predominant number of deliveries at the service facility. Managers emphasized the challenges due to vacancies in the DGFP at the field level.

> *"PPFP services are not only dependent on us. If doctors and nurses from the health complex and district hospitals are trained on HIUD, they can insert more than us"*
>
> - One of the MO-MCHs

DISCUSSION

The study shows that a large number of clients who were enrolled in the study and accepted the HIUD (52%) were under 30 years of age, which stands in contrast to Bangladesh's record with the copper IUD, which has generally been accepted at higher rates among women 30 years or older in Bangladesh.[3] Most of the clients had two children, and many had a primary to secondary level of education, all of which reflect the acceptability the HIUD among young and comparatively educated women. This finding is similar to the copper IUD acceptance (49%) assessed in 2018.[2] The majority (70%) of women who accepted the HIUD already had two or more children, and the rest of the 30% accepted the new method from the study facilities after giving birth to their first child, which is similar to what was found during an acceptability trial that was conducted in India from 2015 to 2019.[14] Analysis of the Bangladesh 2017-2018 DHS data shows that women with >3 children prefer LARC more compared to those women with fewer children.[15]. The present study shows HIUD acceptance among younger women in the Bangladeshi study sites was higher than in Madagascar, and Zambia.[16]

About 78% of acceptors chose to use the HIUD specifically for contraceptive purposes, whereas 22% of the clients who opted for its insertion did so for the dual reasons of contraception and treatment of heavy or irregular menstrual bleeding. The study team anticipated that women with heavy menstrual bleeding would be more likely to select the HIUD than women without these health issues. However, the study showed only 6% (out of 539) of women took it for heavy menstrual bleeding treatment purposes. It might suggest that service providers need to be more specific about the therapeutic use of HIUD to treat bleeding disorders alongside an effective long-acting reversible contraceptive method during counseling of the clients. Because heavy menstrual bleeding is highly prevalent and adversely impacts the quality of life in women across LMIC settings. It needs further attention to understand determinants and identify and implement solutions to the problem.[17] Assessment from Nigeria found that common reasons for women choosing the HIUD included reduced menstrual bleeding (61%) and long duration of action (52%).[18] However, this is not the case in Bangladesh. It might suggest improving the service providers' capacity to identify women with dysfunctional uterine bleeding to take them under treatment as well as contraceptive services. Non-contraceptive benefits of the HIUD, including reduced bleeding and the potential for fewer side effects, might make it a particularly attractive option for some women and should be emphasized in efforts to generate demand.

Our study suggests that it is feasible to deliver the HIUD device as a long-acting reversible contraceptive option in an urban care setting and that women accept it well, with 16% of women accepting the new method among all IUD acceptors in all sites during the study. However, different studies assessed the acceptability of HIUD within service facilities in different ways. We assessed the

[14] Sharad Iyengar (2022). Observational study of feasibility and acceptability of the levonorgestrel-releasing intrauterine device as a long-acting reversible contraceptive in a primary care setting in India. Contraception: X

[15] Sharif AB, Hasan MT, Naziat MH, et al. Permanent, long-acting and short-acting reversible contraceptive methods use among women in Bangladesh: an analysis of Bangladesh Demographic and Health Survey 2017–2018 data. BMJ Open 2023;13:e073469. doi:10.1136/ bmjopen-2023-073469

[16] Danna, K., Jaworski, G., Rahaivondrafahitra, B. et al. Introducing the hormonal Intrauterine Device in Madagascar, Nigeria, and Zambia: results from a pilot study. Reprod Health 19, 4 (2022). https://doi.org/10.1186/s12978-021-01300-x

[17] Sheela S Sinharoy (2023). Prevalence of heavy menstrual bleeding and associations with physical health and wellbeing in low-income and middle-income countries: a multinational cross-sectional study. Lancet Glob Health 2023; 11: e1775–84.

[18] Regulatory Assessment — Learning about Expanded Access and Potential of the Levonorgestrel Intrauterine System (LEAP LNG-IUS). (2018). LEAP LNG-IUS initiative. FHI360

acceptance of HIUD among total women eligible for both copper IUD and HIUD in proportion to the number of women who accepted the method during the study period. It gives an approximate idea about the acceptance of this new family planning method during the very first introduction in the public system.

Of women who switched from other FP methods to the HIUD, about 20% were copper IUD users and only 3% were implant users. The majority of the women used short-acting family planning methods, where the use of pills was the highest at 41%. Both quantitative and qualitative data showed that most of the women switched to having long-term protection. Switched from another long-acting method was found higher in our study compared to African countries about 12-19%.[19]

The study shows that about 61% of women didn't use any contraceptive method before accepting the HIUD during the study period, compared to 42% of women in the feasibility study conducted in India.[14] The HIUD shows promise for improving the LARC contribution in the method mix. Service providers mentioned that the new users were attracted by the HIUD, especially after the delivery, as it can be used for spacing of birth for 5 years. Unlike the copper IUD and the implant, the HIUD can be placed at the middle in terms of birth spacing. We found that about 52% of women accepted HIUD during the postpartum period. It shows an additional benefit when doctors were the service provider for 63% of insertions. 40% of the insertions took place after the C-section. In our study, this is the first time doctors were included in the HIUD training to provide the service. We found them very instrumental throughout the study period. Multivariate analysis showed that insertion during C-section and women who had 3 children correlated with the continuation. In a study from India, doctors and nurse-midwives were trained to assess eligibility, insert the device, and follow up in addition to existing contraceptives. Nurse-midwives under the medical supervision of gynecologists inserted the device. In addition to this, they also hired counselors to improve the utilization. It might have some effects on improved utilization as well as low discontinuation compared to our study.

Throughout the study, 40 HIUD users reported that they stopped using their methods before completion of 12 months. Continuation rates for the HIUD were 81% at 6 months and 78% at 12 months. We selected all high-performing FP service facilities for the study, where the service providers were very busy ensuring the appropriate counseling to the clients to share sufficient information about the new method at their facility. Using effective contraceptive counseling,[20] uptake, continuation, and satisfaction may all be positively affected.[21]

> *"I am really satisfied with this IUD. I have not found anything wrong with the method. One of the best things is that I was suffering from heavy and continuous bleeding and after inserting this method it was cured. That's why my experience is quite good"*
>
> - a satisfied client (aged 25 years) at OGSB Hospital, Dhaka

[19] Kendal Danna (2022). Introducing the hormonal Intrauterine Device in Madagascar, Nigeria, and Zambia: results from a pilot study. Reproductive Health (2022) 19:4. https://doi.org/10.1186/s12978-021-01300-x

[20] Malia Johnson (2019). Increasing Rates of LARC Uptake and Continuation Through Contraceptive Counseling: An Effective Approach for Women with Underutilization.

[21] Malia Johnson (2019). Increasing Rates of LARC Uptake and Continuation Through Contraceptive Counseling: An Effective Approach for Women with Underutilization.

Satisfaction among the users who continued after 12 months was about 93%, a similar satisfaction level with the Indian women. It might be related to the lack of side effects experienced by about 96% of women after HIUD insertion. It indicates that if the women got accustomed to the HIUD for about 6 months, they continued for 12 months. We found there was no expulsion of the method after 6 months.

Only 36% of HIUD users said they had experienced reduced bleeding. Women reported that reduced bleeding had a positive impact on their lives overall, and the acceptability of changes in bleeding patterns was very high. In-depth interviews with women showed menstrual bleeding changes were very common, but women who were continuing to use the method at 12 months did not feel anxious about these changes due to the information they had received from the service providers during insertion. It shows that side effects could be successfully managed with appropriate and timely communication with the clients. However, our study showed that HIUD users who discontinued this method did so for reasons that included experiencing heavy to continuous bleeding changes (66%) and cramping/abdominal pain (17%), while another study reported that the most common reason for copper IUD users to stop their method was bleeding changes (35%) and cramping (17%).[22]

CONCLUSION

Acceptance of HIUD is better than the copper IUD. However, the utilization was slow due to the limited number of trained service providers at the study facilities and limited supply of HIUD. Comparatively younger women and new FP method users preferred HIUD as a long-acting option of contraception. The satisfaction level was high who continued 12 months after the insertion. Doctors showed a promising cadre for providing HIUD, especially during the postpartum period. However, the Government needs to strategize around supporting FWVs to improve the quality of services for HIUD. In the study area, women found HIUD as a better option since it is the only long-acting contraception that gives 5 years of protection. Training packages to doctors need to be different from packages to FWVs s in terms of duration. Counseling services also need to be strengthened to improve the retention of the method and to decrease the discontinuation.

[22] Diedrich JT (2015). Three-year continuation of reversible contraception. Am J Obstet Gynecol. 2015 Nov;213(5):662.e1-8. doi: 10.1016/j.ajog.2015.08.001. Epub 2015 Aug 7. PMID: 26259905; PMCID: PMC5292132.

ANNEXURE

Annex A: Study Facility wise Performance and detailed tables

Table 13: Number of HIUDs inserted by different types of service providers in the study sites

Type of service providers	Name of study facilities							
	MFSTC	Narshingdi MCWC	Mymensingh MCWC	Lakhmipur MCWC	OGSB Hospital	MCHTI	Dhamrai UHC	Total
Consultant	38	0	0	0	102	1	0	141
MO (MCH-FP)/MOs	28	81	37	32	0	20	0	198
FWVs	30	21	7	48	0	48	43	197
Midwives	1	0	0	0	0	0	1	2
SACMO	1	0	0	0	0	0	0	1
Total	**98**	**102**	**44**	**80**	**102**	**69**	**44**	**539**

Table 14: HIUD client's enrollments and follow-ups by study site

Name of study facilities	n (%)			
	Number of H IUD inserted (acceptors)	Completed 12 months period after insertion	Continued 12 months (adaptors)	Completed 3 follow-ups
MFSTC	98 (18.2)	70 (25.6)	55 (25.8)	48 (25.3)
Narshingdi UHC	102 (18.9)	39 (14.3)	35 (16.4)	34 (17.9)
Mymensingh MCWC	44 (8.2)	29 (10.6)	25 (11.7)	21 (11.1)
Lakhimpur MCWC	80 (40.8)	30 (11.0)	25 (11.7)	23 (12.1)
OGSB Hospital	102 (18.9)	30 (11.0)	22 (10.3)	22 (11.6)
MCHTI	69 (12.8)	45 (16.5)	25 (11.7)	21 (11.1)
Dhamrai UHC	44 (8.2)	30 (11.0)	26 (12.2)	21 (11.1)
Total	**539 (100)**	**273 (100)**	**213 (100)**	**190 (100)**

Table 15: HIUD insertion phase by study site

Timing of insertion	Interval	After C-section	After NVD	N
MFSTC	58	28	12	98
Narsingdi UHC	16	81	5	102
Mymensingh MCWC	2	36	6	44
Lakhimpur MCWC	39	18	23	80
OGSB Hospital	67	35	0	102
MCHTI	33	20	16	69
Dhamrai UHC	42	0	1	44
Total	**258**	**218**	**63**	**539**

Table 16: Continuation of HIUD at 6 and 12 months by facility

Continuation status	Completed 12 months after insertion	At 6 months (%)	At 12 months (%)
MFSTC	70 (25.6)	59 (21.6)	55 (20.1)
Narshingdi MCWC	39 (14.3)	39 (14.3)	37 (13.6)
Mymensingh MCWC	29 (10.6)	25 (9.2)	25 (9.2)
Lakshmipur MCWC	30 (11.0)	23 (8.4)	23 (8.4)
OGSB Hospital (Mirpur)	30 (11.0)	23 (8.4)	22 (8.1)
MCHTI	45 (16.5)	27 (9.9)	26 (9.5)
Dhamrai UHC	30 (11.0)	25 (9.2)	25 (9.2)
N = 273	**273 (100)**	**221 (81.0)**	**213 (78.0)**

Table 17: Time of dropout of HIUD clients

Name of study facilities	Time of removal in days (mean±SD) (n=40)	Time of expulsion in days (mean±SD) (n=20)	N
MFSTC	105.4±103.5	42.8±30.73	15
Narsingdi MCWC	215± 7.1	0	2
Mymensingh MCWC	141.0± 28.3	28.0±31.1	4
Lakhimpur MCWC	117.7± 48.0	18.0±7.7	7
OGSB Hospital	145.8± 140.8	18.8±12.5	8
MCHTI	93.7± 80.9	27.4±2.4	19
Dhamrai UHC	98.3±62.3	7.00±0	5
Total	**112.8±88.0**	**25.9±18.4**	**60**

Table 18: Discontinuation of HIUD by facility and timing

Name of study facilities (n=273)	within 1 month		within 6 months		within 12 months		Total n (%)	
	Removal	Expulsion	Removal	Expulsion	Removal	Expulsion	Removal	Expulsion
MFSTC	4	2	3	2	4	0	11 (4.0)	4 (1.5)
Narshingdi MCWC	0	0	0	0	2	0	2 (1.0)	0 (0)
Mymensingh MCWC	0	1	2	1	0	0	2 (1.0)	2 (1.0)
Lakhimpur MCWC	0	4	3	0	0	0	3 (1.0)	4 (1.5)
OGSB Hospital	1	4	2	0	1	0	4 (1.5)	4 (1.5)
MCHTI	4	0	9	5	1	0	14 (5.1)	5 (1.8)
Dhamrai UHC	0	1	4	0	0	0	4 (1.5)	1 (0.4)
Total n (%)	9 (3.3)	12 (4.4)	23 (8.4)	8 (2.9)	8 (2.9)	0 (0)	40 (14.7)	20 (7.3)

Annex B: Study Tools

Adolescent Inform Consent Form (Married Emancipated Minor 15+)

Good morning/afternoon. My name is _____. I work for DGFP, Ministry of Health and Family Welfare/or an international non-profit organization, the Pathfinder International/Shukhi Jibon. We are conducting a research to assess acceptability and feasibility of introducing contraceptive LNG-IUS in the public sector facilities. Although the legal age to provide consent for research is 18 years and above, in Bangladesh, you are considered as an emancipated minor by virtue of your marital and pregnancy status and can provide informed consent to participate in a study. I would like you to take part in this research study. Before you make a decision to participate, you should understand why the research is being done and what your participation will involve. Please take the time to read [or to listen as I read] the following information. Please ask me if there is anything that is not clear, or if you would like more information. Of course, you may talk to others about the study if you wish. When all of your questions have been answered and you feel that you understand this study, I will ask if you would like to participate in the study, and if you agree, I will ask you to sign this form to show that you have agreed.

Purpose of the Study and Study Requirements

Purpose of the study: The purpose of the study is to assess the acceptability and feasibility of introducing contraceptive LNG-IUS in the public sector facilities. This study is implemented by the Pathfinder International/Shukhi Jibon, in cooperation with the Ministry of Health and Family Welfare. The United States Agency for International Development (USAID) funds the study.

Why have I been invited to take part? You have been invited to participate in this study because you live in this area, married and sought family planning service from this facility, which we selected for the study purpose. Additionally, although the legal age to provide consent for research is 18 years and above, in Bangladesh, you are considered as an emancipated minor by virtue of your marital and pregnancy status and can provide informed consent to participate in a study. If you are interested, we will fully explain the study, and then ask you if you wish to participate.

What will happen if I take part? If you agree to take part in the study, we will ask you to sign this form indicating your informed consent. We will then enroll you in the study for one and half years and collect information on address, telephone number, age, education, number of child, pregnancy status, medical and surgical history, drug history to will assess your health conditions. In a private interview at the end of one year, we will ask questions regarding your perceptions, attitudes, and experiences using the method. According to national protocol, you will be asked to come back at the facility around one-month, 6th month and 12th months for follow-ups. If you agree to take part in the study, we will ask you to sign this form.

Your responsibilities are to: Read the consent form completely and ask any questions you may have. You should understand what will happen to you if you agree to participate in the study. Fulfill the responsibilities of participation as described on the consent form unless you are discontinued participation.

Show up for any regular follow-up visit. Continue as a participant up to 12 months.
Do not share or disclose the content of this study with any other service providers or clients.

How long will the intervention last? The intervention will last 18 months. You are enrolled as participant of the study for 12 months. At the beginning the enrolment assessment will take 20-25 minutes to complete in addition to the LNG-IUS insertion. During the follow-ups and at the end of 12th month, follow-up assessment and the interview will take 15-25 minutes to complete.

We will contact you again: As part of the sponsor's monitoring program, you need to acknowledge the possibility that an interview may be requested by a representative of the sponsor of the trial or by the Pathfinder International/Shukhi Jibon staff to determine whether informed consent was given. If an interview is requested, then you will have the option of accepting/declining the interview. In addition, national and international regulatory agencies may request access to medical or other confidential records, but your identity will remain confidential. The research team will collect your personal identifying information including telephone number to follow you up.

Discomforts and Risks

What are the risks of the study? There are some risks associated with the insertion procedures/participation of an IUD such as perforation, infection and expulsion in addition to chances of contraceptive failure. Most women will not have any problems using an LNG-IUS (like IUD). LNG IUS is 99.9 percent effective. However, as the service providers will be thoroughly trained on the subjects and improving skills, we hope the provider will efficiently insert the LNG-IUS. Post-insertion side-effects and complication management is available in all public facilities. In the event of any side effects/complications, you will be provided treatment and/or transferred to the referral facility for proper care.

We are going to ask you to talk about your experiences in the interview. Although these questions are not intended to be offensive, please remember, you do not have to respond to any question that makes you uncomfortable. It is completely fine if you decide not to answer any question or choose not to participate in the interview entirely. Just tell me if you prefer not to answer and we'll move on to the next question. If you are not at all interested in participating in the study, you are free to decline, and this will not affect what any benefit you are entitled from the facility.

As a participant in this study, you may find the time and effort required for this interview to be a minor inconvenience. Another risk is the possibility of a breach of confidentiality information. This means the possibility that something that you say might be accidentally shared with others. However, let me assure you that we will make every effort to ensure that there will be no breach of confidentiality, but this possibility cannot be ruled out.

Benefits

What are the benefits of participating? Participating in the interview may not gain any benefit to you. However, you may have certain benefits from accepting the LNG-IUS as a contraceptive method. By using the device, you will be able to prevent pregnancy for five years, at the same time some women will be benefited by having treatment for heavy and prolonged menstrual bleeding. In addition, the findings from this study will generate additional knowledge on the clinical performance

and acceptability of LNG-IUS and benefit potential users of this method in the future. Additionally, through our follow ups with you, you will receive immediate attention or referral services for any side effects/complications.

In addition, your participation, experiences, and opinions will be useful in developing strategies for service providers to provide LNG-IUS services in the country. You may find an indirect benefit in knowing that you have participated in an important study that could help others in the future. Data gathered from the study will be used to provide programmatic recommendations to the DGFP for better programing in future for women who need LNG-IUS. Thus, your participation will benefit your community.

Confidentiality

Will my participation in the study be kept confidential? The information that is collected during the enrolment and interview will be kept private. No one will be told that you have participated in the study. The study team will make every effort to protect your privacy and maintain the confidentiality of all the information you provide. Your name or other identifiers will not be included in reports from this study. Data will be stored in a password-protected computer in the Pathfinder International/Shukhi Jibon, Dhaka office. Only researchers dedicated to this study can access the data.

Voluntariness

What are my rights as a research participant/subject? Your participation in this study is completely voluntary. If you decide not to participate, you will not lose any existing benefits from this facility or others to which you are entitled. If you agree to participate in this study, you may end your participation at any time without penalty or loss of existing benefits to which you are entitled. If you decide to take part, you are free to skip any questions. You are free to withdraw at any time without affecting your relationship with the service providers or study team.

May I change my mind? Yes. A researcher will tell you of any information learned during the study that might cause you to change your mind about taking part in the study.

The research team has the right to end your participation in the study at any time, with or without your consent, for any of the following reasons:
If you have an adverse reaction or side effect to LNG-IUS.
If you need a treatment not allowed in this study.
If you do not keep appointments.
If you do not continue LNG-IUS; or
If the study is canceled.

The participants will be read the following statement:
“I also understand that the Principal Investigator may require me to withdraw from the study if, in his/her medical judgment, it is in the best interest of my health or if it becomes impossible for me to follow the experimental procedure of this study. If this is necessary, I will not receive compensation for all aspects of the study in which I have participated."

Additional Information

Are there alternatives? Yes, there known alternative such as copper IUD but do not work for heavy menstrual bleeding. Please discuss your health problems or concerns with your health care provider.

What will I receive for participating? You will not receive any money for your participation in this study, except the cost for transportation for follow-up visit(s) and referral. The following statement will be read out to the participants:

"I understand that I will be paid exclusively for travel for follow-up visit(s) or referral with my participation in this study. I will receive taka 200/visit for transportation."

What will happen to the results of the research study? The results of the study will be discussed and publicly shared in a variety of settings, including local and international meetings, conferences, and publications. However, none of the results shared with internal or external audiences will include any information that could identify individual participants.

Who has reviewed the study for ethical issues? This study has been reviewed Bangladesh Medical Research Council (BMRC).

What if I need more information? If you have any other questions, please contact the researchers who will do their best to answer your questions. Please contact the Pathfinder International/Shukhi Jibon's investigator Mr. Liaquat Ali tel no: 01711354106. If s/he cannot be reached you may contact Dr. Marufa tel no:01710830770.

What if there is a problem? Any complaint about the way you have been treated during the study or any possible harm you might suffer will be addressed. Please contact Bangladesh Medical Research Council (BMRC) at 8811395/8828396.

What do I do if I experience any side effects or injuries? If you require medical treatment as a result of physical injury arising from your participation in this study, immediate, essential and short-term medical care and treatment as determined by the providers in this study will be made available without any cost to you. You will receive no monetary compensation for any other care, but medical consultation and appropriate referral services as government policies. The following statement will be read out to the participants: "I understand that if a medical emergency arises in association with the use of this drug or if I feel a medical emergency will affect my ability to participate in the study, I may contact with the facility provider for remedy."

If you experience any unusual or unexpected symptoms during the course of this study, you should immediately contact the Medical Officer at the first referral facility.

Medical Officer-MCH-FP: Name of the Medical Officer at Upazila Health Complex. Daytime telephone number: <telephone #> Will be add later for each sub-district as there are 12 sub-districts 24-hour contact number: <telephone #> Will be add later for each sub-district as there are 12 sub-districts

Do you have any questions? Yes/No If yes, note the questions

Participant's Statement:
"I have read, or it was read aloud to me, the Informed Consent for this study. I have received an explanation of the planned research, procedures, risks and benefits, and privacy of my personal information. I have had the chance to ask questions, and my questions have been answered.

"I understand that my participation in this study is voluntary. I understand that I do not have to participate and that I may end my participation at any time without penalty or loss of benefits to which I am entitled"

"I agree to take part in this study and to follow the instructions provided to me. I will contact the study doctor immediately if I experience any unexpected or unusual symptoms. During the study, I will notify the study doctor of any other medical treatments that are necessary for me. I further understand that my records will be kept confidential and that I may withdraw from this study at any time."

"I understand that my withdrawal from this study or my refusal to participate will in no way affect my medical care from the hospital or clinic."

" I agree to allow my health information to be used by the Population Council and by government authorities for this research study."

Your name: _____

_____ _____

Date Signature of Participant/thump impression

Investigator or person who conducted Informed Consent discussion: "I, the undersigned, confirm that I have personally explained to the participants in a language he/she understands, the nature and extent of the planned research, study procedures, potential risks and benefits, and confidentiality of personal information."
Name of person obtaining consent: _____
Signature of person obtaining consent: _____Date:_____

Name of witness: Signature:

Annex C: LNG-IUS adopter's/enrollment checklists

(Instruction: Please tick mark or write)

Participant ID: ☐☐☐☐☐

Are you enrolled as participant in any other clinical trial? (If yes, stop enrolling as participant for this study)	1. Yes	2. No
Offer made for both Copper-T IUD and LNG-IUS contraception?	1. Yes	2. No
Informed consent given to be a participant for LNG-IUS study?	1. Yes	2. No
Enrolled as participant:	1. Yes	2. No
Reasons for non-enrolment: 1. Participant not interested	2. Refer	3. Not eligible

Serial No:	Registration No:	Insertion Date: ☐☐ ☐☐
Facility name:	Insertion provider name:	
Provider Designation: 1. FWV 2. Midwives 3. MO	Signature:	Date: ☐☐ ☐☐ ☐☐

A. PARTICIPANT'S SOCIO-DEMOGRAPHIC PROFILE:								
SL	**QUESTIONS**	**CODING CATEGORIES/RESPONSES**						**CODE**
1	Participant's name				Mobile number: _____			☐☐☐
2	Participant's age	_____ Years						☐☐
3	Husband's name				Mobile number: _____			☐☐☐
4	Husband's age	_____ Years						☐☐
5	Participant's education	1. Illiterate	2. Primary (1-5 grade)	3. Secondary (6-10 grade)	4. Higher secondary (11-12 grade)	5. Graduation & above (above 12 grade)		☐
6	Participant's occupation	1. Housewife	2. Day labourer	3. Service	4. Business	5. Student	7. Others (Specify) _____	☐
7	Current address	Village/Mohalla: ☐ Unit: ☐ Union: ☐ Upazila/thana: ☐ District: ☐			Alternate/additional mobile number: _____			
8	Currently using any contraceptive method?	1.Yes ☐			2.No		7. Others (Specify)_____	☐

9	If yes, which method?		1. Pill 2. Condom 3.Injectable 4.Copper-T IUD	5.Implant 6.Safe period 7. Withdrawal 8.Others (specify)	☐ ☐
10	Reasons for choosing the LNG-IIUS method?	1. Only for long-term contraception 2. Heavy menstrual bleeding	3. Both long-term contraception and heavy bleeding menstrual	7. Others (specify)	☐

B. PATICIPANT'S OBSTETRICAL, GYNECOLOGICAL AND CONTRACEPTION HISTORY:

11	Date of last menstrual period (LMP)? (It may be approximate)		Date: ☐☐ ☐☐ ☐☐	In months: ☐	
12	a. Duration	b. Cycle	c. Amount of blood	d. Pain during menses	
	_____days	1.Regular 2.Irregular ☐	1.Normal 2.Not normal ☐	1. Yes 2. No ☐	
13	Does participant have regular menses when not pregnant and not breastfeeding?		1.Yes	2.No	☐
14	Is participant currently breastfeeding?		1.Yes	2.No	☐
15	Number of living children (Should have atleast 1 living child)	1. Son ☐	2. Daughter ☐	Total: ☐	
16	History of MR/abortion? (should be after 4 weeks)?	a. 1.Yes ☐ 2. No	b. If yes, number of times? ☐	c. Date of last MR/abortion?	☐
17	Date of last delivery (should be after 4 weeks)?	a. Date: ☐☐ ☐☐ ☐☐		b. In months: ☐☐	
18	Mode of last delivery	1. Normal	2. Assisted delivery	3. Caesarean section	7. Others (Specify) ☐

C. PARTICIPANT'S MEDICAL HISTORY

19	Has pain during intercourse?	1.Yes 2. No	If yes, need treatment	☐
20	Has bleeding during intercourse?	1.Yes 2. No	If yes, need treatment	☐

21	Has any history of following diseases?	01. Congenital or acquired uterine anomaly 02. fibroids 03. Pelvic Inflammatory diseases 04. Postpartum endometritis	05. Infected MR/ abortion in the last 3 months 06. Known or suspected uterine or cervical neoplasia	07. Known or suspected breast cancer 08. Uterine bleeding of unknown etiology 09. Untreated acute cervicitis or vaginitis	**10.** Acute liver disease or liver tumor 11. Hypersensitivity to any component of this product	77. Others (Specify)	☐☐ ☐☐ ☐☐ ☐☐

D. PHYSICAL EXAMINATION

	General examination						
22	Weight:	23.Temperature: .		24.Pulse		25.Blood pressure /	
26	Anaemia: (Can't insert if haemoglobin 7gm/dl or <45%)	1. Mild (+)	2. Moderate (++)	3. Severe (+++)	4. None		
	PV examination by speculum and both hands						
	27. PV examination by speculum				28. PV examination by both hands		
	a. Cervical os	1.Normal	2.Not normal		a.Uterine shape	1.Normal	2.Not normal
	b. Discharge	1.Present	2.Not present		b.Uterine size	1.Normal	2.Not normal
	c. Vaginal wall	1.Healthy	2.Infected		c.Uterine position	1.Anteverted	2.Retroverted
	d. Pus/ulcer in cervical os	1.Yes	2.No		d.Uterine mobility	1.Can move	2.Can't move
	e. Cervical erosion	1.Present	2.Not present		e.Pain during Uterine/cervical movement	1.Yes	2.No
	f. Cervical polyp	1.Present	2.Not present		f. Fornix vaginae/uterine fornix	1.Free	2.Not free
	g. Bleeding on touch on cervix	1.Yes	2.No		g.Currently pregnant	1.Yes	2.No
					If pregnant, how many weeks? (Note: If depth of the uterus less than 6cm, IUD can't be inserted)		
29	Result of breast exam	1.Normal	2.Abnormal (refer)	7. Others (Specify)			
30	Result of liver exam	1.Normal	2.Abnormal (refer)	7. Others (Specify)			
31	Date of next follow up at facility	At one month	At 6th month	At 12th month			
32	Prefer for follow up through telephone or in person?	1. Telephone; No: 2. In-person					
33	Refer to physician/referral facility if any pre-existing diseases: Reasons for referral?	Write: _____					
34	Any complications during insertion of LNG-IUS?	1.Yes	2.No				
35	If yes, specify complications:						
36	Will discomfort during insertion prevent you from getting another LNG-IUS in the future?	1.Yes	2.No/				

Annex D: HIUD Adopter's Follow-Up Checklists

Participant ID: ☐☐☐☐

F. FOLLOW-UP

1	**Facility name:**	☐	4	**Registration No:**	
2	**Adopter name:**	☐	5	**Age:** _____years	☐
3	**Husband name:**	☐	6	**Age:** _____years	☐
7	**Current address** Village/Mohalla: Unit: Union: Upazila/thana: District:	☐ ☐ ☐		Alternate/alternate mobile number: _____	☐☐
8	**LNG-IUS insertion date:** ☐☐ ☐☐ ☐☐		9	**LNG-IUS removal date:** ☐☐ ☐☐	☐☐
10	**Name of service provider:**	☐	11	**Designation:** 1. FWV 2. Midwives 3. MO	☐
12	**Signature:**	☐	13	**Date:** ☐☐ ☐☐ ☐☐	

14	**Follow-up information**					
	Standard schedule	Scheduled date	Followed-up date	Problems	Advise/treatment	Signature
	Regular: 1st month ± 7 days					
	Regular: 6-month ± 7 days					
	Regular: 12-month ± 7 days					
	Irregular					
	LNG-IUS removal	Scheduled date	Removal date	Reasons for removal	Accepted method	Signature

15	Are you satisfied with the LNG-IUS?	1.Yes	2.No	☐
16	Has your menstrual bleeding decreased to tolerable level?	1.Yes	2.No	☐
17	Would you refer your relative or friend to this provider / facility for LNG-IUS services?	1.Yes	2.No	☐

18	If you do not want to refer, why?	1.Service is not up to the mark	2.Provider does not take care	3.Not all service available	4.Expensive	5. method is not good	7.Others(specify)	☐ ☐

Annex E: Consent form for in-depth interview with service provider/facility manager

Good morning/afternoon. My name is _____. I work for DGFP, Ministry of Health and Family Welfare/or an international non-profit organization, the Pathfinder International/Shukhi Jibon. We are conducting a research to assess the acceptability and feasibility of introducing LNG-IUS in the public sector facilities. I would like you to take part in this research study. Before you make a decision to participate, you should understand why the research is being conducted and what your participation will involve. Please take the time to read [or to listen as I read] the following information. Please ask me if there is anything that is not clear, or if you would like more information. Of course, you may talk to others about the study if you wish. When all of your questions have been answered and you feel that you understand this study, I will ask if you would like to participate in the study, and if you agree, I will ask you to sign this form to show that you have agreed.

Purpose of the Study and Study Requirements

Purpose of the study: The purpose of the study is to assess acceptability and feasibility of introducing LNG-IUS in the public sector facilities.

This study is implemented by the Pathfinder International/Shukhi Jibon, in cooperation with the Ministry of Health and Family Welfare. The United States Agency for International Development (USAID) funds the study.

Why have I been invited to take part? You have been invited to participate in this interview because you have worked in one of the facilities targeted by this study and have provided the relevant services. If you are interested, we will fully explain the study, and then ask you if you wish to participate in the interview.

What will happen if I take part? If you agree to take part in the study, we will ask you to sign this form indicating consent to take part in the interviews. We will then conduct a private interview, in which you will be asked questions on your experience with IUD insertion and removal. These questions will help the research team to identify barriers to service provision and potential improvements.

Your responsibilities are: Read the consent form completely and ask any questions you may have. You should understand what will happen to you if you agree to participate in the interview. You can ask questions about the study, if you have. Fulfill the responsibilities of participation as described on the consent form unless you decide to discontinue your participation. Not share or disclose the content of this interview, either with any other service providers or with clients.

How long will intervention and interview last? The intervention will last for 18 months. We hope you remain a participant until the end of the intervention, but you are free to discontinue participation at any time. The in-depth interview at the post-intervention periods will take approximately 20-25 minutes to complete.

We will contact you again: As part of the sponsor's monitoring program, you must acknowledge the possibility that an interview may be requested by a representative of the sponsor of the trial or by Pathfinder International/Shukhi Jibon staff to determine whether informed consent was given. If an interview is requested, then you will have the option of accepting/declining the interview. In addition, national and international regulatory agencies may request access to the confidential records of your participation, but your identity will remain confidential.

Discomforts and Risks

What are the risks of the study? We are going to ask you to talk about your work experiences. Although these questions are not intended to be offensive, please remember, you do not have to respond to any question that makes you uncomfortable. It is completely fine if you decide not to answer any question or choose not to participate in the interview entirely. Just tell me if you prefer not to answer and we'll move on to the next question. If you are not at all interested in participating in the study, we will not push for any departmental action, nor will it affect your annual performance report.

As a participant in this study, you may find the time and effort required for this interview to be a minor inconvenience. Another risk is the possibility of a breach of confidentiality information. This means the possibility that something that you say might be accidentally shared with others. However, let me assure you that we will make every effort to ensure that there will be no breach of confidentiality, but this possibility cannot be ruled out.

Benefits

What are the benefits of participating? There are no direct benefits to you for your participation in the interview. Your participation, experiences and opinions will be useful in developing strategies for introducing LNG IUS in the public facilities. In addition, data gathered from the study will be used to provide programmatic recommendations to help service providers and the DGFP, Ministry of Health and Family Welfare for better programming in the future. Thus, your participation will benefit your community. By participating in the study, you will benefit from the training, which will improve your knowledge and skills/practices about LNG IUS. You will be able to apply this knowledge and skill in your professional field.

Confidentiality

Will my participation in the study be kept confidential? Your participation in the study will be kept confidential. The information collected during the interviews will be kept private. No one will be told that you have participated in the study. We will not share any of the information you provide with any other participants or anyone in the community. The study team will make every effort to protect your privacy and maintain the confidentiality of all the information you provide or record keeping. Your name or other identifiers will not be included in the study reports. Data will not contain your personal name or any other identifying information. Consent forms will be kept in a locked cabin. All data collected will be stored in a locked location at the Pathfinder international/Shukhi Jibon office dedicated to this study that only the study team can access.

Voluntariness

What are my rights as a research participant/subject? Your participation in this study is completely voluntary. If you decide not to participate, you will not lose any existing benefits from this facility or

others to which you are entitled. If you agree to participate in this study, you may end your participation at any time without penalty. If you decide to take part, you are free to skip any questions. You are free to withdraw at any time without affecting your relationship with the study team or your supervisor.

May I change my mind? Yes. A researcher will tell you of any information learned during the course of the study that might cause you to change your mind about participating. The research team has the right to end your participation in the study at any time, with or without your consent, for any of the following reasons:

If you have not performed the assigned job as planned; or If the study is canceled.

What will I receive for participating? You will not receive any money for your participation in this study.

What will happen to the results of the research study? The results of the study will be discussed and publicly shared in a variety of settings, including local and international meetings, conferences, and publications. However, none of the results shared with internal or external audiences will include any information that could identify individual participants or localities.

Who has reviewed the study for ethical issues? This study has been reviewed by the Bangladesh Medical Research Council (BMRC).

What if I need more information? If you have any other questions, please contact the researchers who will do their best to answer your questions. Please contact the Pathfinder International/Shukhi Jibon's investigator Mr. Liaquat Ali tel no: 01711354106. If s/he cannot be reached you may contact Dr. Marufa tel no: 01710830770

What if there is a problem? Any complaint about the way you have been treated during the study or any possible harm you might suffer will be addressed. Please contact the Bangladesh Medical Research Council (BMRC) at 8811395/8828396.

Do you have any questions? Yes/No If yes, note questions.

Participant's Statement:

"I have read or it has been read aloud to me the above considerations regarding my participation. I have been given an opportunity to ask any questions I may have, and all such questions or inquiries have been answered to my satisfaction. I further understand that my records will be kept confidential and that I may withdraw from this study at any time. I understand that my participation in this study is voluntary. My withdrawal from this study or my refusal to participate will in no way affect my job. I have been informed orally and in writing of whom to contact in case of any query. I agree to participate in this study as a volunteer subject."

Your name: _____

_____ _____

Date Signature of Participant/thump impression

Investigator's statement: "I, the undersigned, have explained to the participants in a language he/she understands the nature and extent of the planned research, procedures to be followed in the study, the potential risks and benefits involved, and confidentiality of personal information."

Name of person obtaining consent: _____

_____ _____

Date Signature of Investigator

Annex F: In-depth interview guidelines for service providers

General instructions for data collector

1) An in-depth interview often describes as "conversation with purpose". Typically, in-depth interviews are much more like conversation than formal structured interviews.
2) When you do an **in-depth interview**; focus is on that person, his/her opinions and behaviors. Here we ask, "**what did YOU DO/THINK**----------". We are asking informants to relate information about specific behaviors, actions and beliefs concerning their own personal lives.
3) In in-depth interview, participant's perspectives are counted NOT the researcher views. Question like "What do you think are the causes of discontinuation of OCP? What is true FOR YOU?"
4) Make sure that before asking any question, the informants know meaning of your **key word**. For example, if "PPH" is being discussed, informants should have **clear understanding what is** PPH. Special care should be taken to **check** the informants' understanding of your questions.
5) Do not use double barrel questions (two separate questions in a question which have two separate answers). For example, are you married and have children?
6) Never contradict with participant's responses and say, "**it is wrong**". Do not indicate any judgment about what is acceptable and what is not. Interviewers should be careful and avoid influencing responses.
7) To get detailed and complete answers, PROBING and asking the same questions in different ways, two or three times are useful, and **encouraged**.
8) Questions should be asked precisely as they are written. Rewording and explanations should be provided only when absolutely necessary.
9) As far as possible expand you notes on the **same day**, soon after completion of the interview.

Informant's details		
1	**Name**	
2	**Designation**	
3	**Health facility name**	
4	**Have training on copper IUD insertion and removal?**	

1. How do you describe your services in this facility?

Probe: How long she is providing services in this facility? What services you provide, which day, how long she is providing IUD services and which day, how many IUD insertion and removal per week/month, what is her experiences while providing IUD services, etc.?

2. Why do you think women discontinue IUD so frequently?

Probe: whom with discontinuation is more evident, young, older women? What roles husband play here? What are her experiences with IUD removal process?

3.You have received IUD training. How do you describe the IUD training you have received?

Probe: How long was the training? Was it sufficient enough for providing IUD services? What about practices on actual clients? Has got enough clients to practice on? What are some good and bad points of IUD training, please explain it?

4. You have also received LNG-IUS training. How do you describe the LNG-IUS training you received?

Probe: How long it was? Was it sufficient enough for providing LNG-IUS services, in regard to duration, methods of training, training materials used, uterine model used in training, client counseling, client screening, logistics, training place, etc.? Were there enough clients for practices? What are some good and bad points of LNG-IUS training, please explain it??

5. We have prepared and supplied an LNG-IUS IEC material for clients. How do you describe the IEC materials used in the piloting program on LNG-IUS?

Probe: Can she describe the client perception about the IEC materials? What clients said? Does she think women understand the IEC material? Is there any need of improvement, could have been better, what is your suggestions? or Need a new one?

6. How many clients you have inserted and removed LNG-IUS? (may be 100 clients). Could you describe your experiences in providing LNG-IUS services?

Probe: Who mostly choose LNG-IUS, younger, older women? Why they choose? Who mostly remove LNG-IUS? Why? Do husband play any role here? What are her opinions about the insertion and removal of LNG-IUS? What problem/difficulties did service providers faced during inserting or removing LNG-IUS?

7.You have given LNG-IUS services over one year. How do you rate LNG-IUS as a contraceptive method? Why do you think so? Are you satisfied with the LNG-IUS as a contraceptive method? Why and why not?

Probe: Has she you experienced any problems in providing LNG-IUS, if yes, please describe. What are some good and bad points of LNG-IUS? Are the clients satisfied using the method? Why and why not? Do client complaint while using LNG-IUS? What are those? Are service providers satisfy with the LNG-IUS, please explain?

8. In your opinion, how is the demand for LNG-IUS?

Probe: Whom do service providers think the demand is more, young, older women? Why? Would she encourage or recommend women to use LNG-IUS? What are the women's reactions? How demand for LNG-IUS can be increased?

9. What opportunities prevails in the country to introduce and scale up LNG-IUS in the public system?

Probe: available large cadre of IUD trained providers, copper-T IUD available in the system, DGFP wants more options particularly long-acting, there are demand for suitable long-acting method, logistics available, etc.?

10. What are some challenges/barriers prevails in the country to introduce and scale up LNG-IUS in the public system?

Probe: many providers are not trained in IUD, there are lack of demand of IUD, husband is a barrier of IUD use, women do not want it for side-effects, discontinuation is more, time consuming service provision for service providers, lack of logistics, etc.?

11. You know, we are piloting LNG-IUS in only 5 facilities. Do you think LNG-IUS services should be made available in the other parts of the country? If not, why do you think so?

Probe: How we can improve the LNG-IUS service provision. How we can encourage providers to improve LNG-IUS services? How we can expand it to the other parts of the country, what is your suggestions. What would be the training modalities, training and IEC materials, etc.?

Annex G: Guidelines for exist interviews/home interviews

General instructions for data collector

1) An in-depth interview often describes as "conversation with purpose". Typically, in-depth interviews are much more like conversation than formal structured interviews.
2) When you do an **in-depth interview**; focus is on that person, his/her opinions and behaviors. Here we ask, "**what did YOU DO/THINK**----------". We are asking informants to relate information about specific behaviors, actions and beliefs concerning their own personal lives.
3) In in-depth interview, participant's perspectives are counted NOT the researcher views. Question like "What do you think are the causes of discontinuation of OCP? What is true FOR YOU?"
4) Make sure that before asking any question, the informants know meaning of your **key word**. For example, if "PPH" is being discussed, informants should have **clear understanding what is** PPH. Special care should be taken to **check** the informants' understanding of your questions.
5) Do not use double barrel questions (two separate questions in a question which have two separate answers). For example, are you married and have children?
6) Never contradict with participant's responses and say, "**it is wrong**". Do not indicate any judgment about what is acceptable and what is not. Interviewers should be careful and avoid influencing responses.
7) To get detailed and complete answers, PROBING and asking the same questions in different ways, two or three times are useful, and **encouraged**.
8) Questions should be asked precisely as they are written. Rewording and explanations should be provided only when absolutely necessary.
9) As far as possible expand you notes on the **same day**, soon after completion of the interview.

Participant's details:			
1	**Participant ID:**		
2	**Participant name:**		**Age:**
3	**Husband name:**		**Age:**
4	**Address:** Village/Mohalla:		Unit:
	Union:	Upazila/thana:	District:
5	**Insertion facility name:**		

6	**Date of insertion:**	**Date of interview:**
7	**Location of interview:**	
8	**Name of service provider:**	

Greetings

1. **Let's talk about your children. How many living children do you have? When the last child was born? How it borne?**

   Probe: ask about how many died, no. of MR/abortion done, when was the last time? Last delivery was normal, assisted delivery, caesarian section?

2. **You have inserted LNG-IUS contraceptive about one year before, how are you feeling still now? Please describe your experiences at the FACILITY/PROVIDER during insertion. Please explain if you had experienced any problems during insertion of LNG-IUS or removal, if removed?**

   Probe: How is her satisfaction level using LNG-IUS? Any husband concerns? Satisfaction level about menstruation, bleeding, cycle, duration, volume, etc.?

   Probe: pain, infection, failed to insert, etc.? needed any medical attention for any of these problems? If yes, where she gone for that treatment? Was it easy to get medical attention? If not, why? How far she traveled for removal or get medical assistance?

3. **Have you visited the assigned facility/service providers 3 times for follow-up over the last one year? If not, why?**

   Probe: At what times she has gone for follow-ups, 1-mont, 6th month and 12th month? What experiences she had at 1-mont, 6th month and 12th month? Who provided services during follow-ups visits? Can she describe any issues during follow-ups she had?

4. **Have you conducted any unscheduled visit to the facility/providers? Why and for what reasons? Please describe your experiences during unscheduled visits.**

   Probe: Any other facility/providers? What impelled her to go for unscheduled visit? Do she needed any treatment? What treatment, counseling/advise the providers had given?

5. **Did you use any contraceptive method before inserting LNG-IUS? Which method? Why you have chosen to insert LNG-IUS?**

   Probe: for short-acting/long-acting, why she left it, side-effects, excessive menstrual bleeding, etc.

6. **How was your menstruation before using LNG-IUS (while you were not pregnant or breastfeeding)? Was it normal in regard to duration, cycle, and amount of blood loss? If no, what was the problems? What about after the insertion of LNG-IUS?**

   Probe: after LNG-IUS insertion, decreased heavy bleeding, reduced pain, feeling better, any other issues, etc.?

7. **Have you experienced any other serious* health problems/complications since last visit (after 12th month)? If yes, please describe.**

Probe: lost string, lost LNG-IUS, perforation, ectopic pregnancy, intrauterine pregnancy, life threatening condition, hospital overnight admission, disability or incapacity?

8. **What has your overall experience with the LNG-IUS been so far? Please describe. Why are you continuing with this method? Can you explain what do you like most about the method and what do you like least? Will you use another LNG-IUS? What about husband, does he like it?**

   Probe: no access to removal, afraid of pain during removal, etc.?

   Probe: last for 5 years, low risk of pregnancy, reduce heavy bleeding, etc. and not like because of menstrual changes, insertion procedure, husband concerns, etc.

9. **What has your menstrual cycle been like since the insertion of LNG-IUS? Please describe.**

   Probe: regular bleeding, irregular bleeding, frequent bleeding, spotting, reduced volume, decrease duration, no bleeding, irregular cycle, etc. Whether she likes it or not the problem (s) experienced and why?

10. **Have you noticed any other changes in your physical or mental health that may be related to the LNG-IUS use? Please describe the changes.**

    Probe: headaches, acne, mood changes (depression, anxiety), etc.

11. **If she removed the LNG-IUS, where did you remove it? Why did you remove it? What is your experiences in removing LNG-IUS?**

    Probe: NGO clinic, government clinic, private doctor/clinic, it came out by itself, etc. duration of removal, discomfort, how far she travelled to remove it? How easy or difficult was it to find a doctor to remove the LNG-IUS? Did she pay for the removal? Any complications during removal? If yes, what? Has she started another method of contraception after removal? Which method? If not, why?

13. **How satisfied or dissatisfied were you with the SERVICES provided to you at insertion and at any later visits? Please explain.**

    Probe: procedure, waiting time, service times, friendliness of service providers and other staff, privacy maintained, quality of advice and information, experiences during insertion, removal and follow-up, etc.?

14. **Were you given clear instructions regarding what to do or where to go if you had any problems or side effects from the procedures done? What has been told?**

    Probe: GO/NGO/Private facility; what to do if she has pain, expulsion, excessive bleeding, loss of string, etc.?

15. **Were you given enough information about where to go if you decide to remove your LNG-IUS?**

    Probe: this clinic, doctor, specialist, GO/NGO/Private facility, other facility, etc?

16. **Were your referred somewhere? Please describe, where and where?**

Probe: If yes, reasons for referral? String lost/became small, Severe lower abdominal pain, Amenorrhoea, Irregular menses, Heavy bleeding, Prolonged bleeding, Suspected pregnancy, PID, Sepsis, Investigations, etc.?

17. **Would you return to this provider or facility for health care services**? Why/why not?
    Probe: Service is not up to the mark, Provider does not take care, Not all service available, Expensive, etc?

18. **Would you recommend the LNG-IUS method to your friends/relatives who needed contraception? If yes or not. Why?**
    Probe: need long-acting method, good method, work for 5 years, reduce menstrual bleeding, etc.

19. **Would you refer your relatives/friends to this provider/facility for LNG-IUS services? LNG-IUS Why and why not?**
    Probe: Service is not up to the mark, Provider does not take care, Not all service available, Expensive, method is not good, etc?

Annex H: In-depth interview guidelines for facility managers

General instructions for data collector

1) An in-depth interview often describes as "conversation with purpose". Typically, in-depth interviews are much more like conversation than formal structured interviews.
2) When you do an **in-depth interview**; focus is on that person, his/her opinions and behaviors. Here we ask, "**what did YOU DO/THINK**-----". We are asking informants to relate information about specific behaviors, actions and beliefs concerning their own personal lives.
3) In in-depth interview, participant's perspectives are counted NOT the researcher views. Question like "What do you think are the causes of discontinuation of OCP? What is true FOR YOU?"
4) Make sure that before asking any question, the informants know meaning of your **key word**. For example, if "PPH" is being discussed, informants should have **clear understanding what is** PPH. Special care should be taken to **check** the informants' understanding of your questions.
5) Do not use double barrel questions (two separate questions in a question which have two separate answers). For example, are you married and have children?
6) Never contradict with participant's responses and say, "**it is wrong**". Do not indicate any judgment about what is acceptable and what is not. Interviewers should be careful and avoid influencing responses.
7) To get detailed and complete answers, PROBING and asking the same questions in different ways, two or three times are useful, and **encouraged**.
8) Questions should be asked precisely as they are written. Rewording and explanations should be provided only when absolutely necessary.
9) As far as possible expand you notes on the **same day**, soon after completion of the interview.

Informant's details		
1	**Name**	
2	**Designation**	
3	**Facility name**	

1. How do you describe your services in this facility?

Probe: How long are you managing this facility? What activities do you do, which day, how many providers are you supervising? How do you describe your experiences with the service providers (FWV, midwives, MO) in providing health and FP services? How do you describe their motivation and commitment for providing FP services?

2. Copper IUD services are being provided from your facilities. Why do you think IUD utilization is low in the country? How do you describe copper IUD services from your facilities?

Probe: How do you describe IUD services provided by your staff? What problems you see in providing IUD services? Why do you think women discontinue IUD so frequently? Whom with discontinuation is more evident, young, older women? What roles husband play here? What are her experiences with IUD removal process?

3. Have you ever received IUD training? If yes, how do you describe the IUD training you received?

Probe: What do you think about the IUD training for the services providers? Duration, contents, practical class, training materials, supervision, place of training, etc.? What are some good and bad points of IUD training?

4. Have you attended LNG-IUS training with the service providers. How do you describe the LNG-IUS training conducted for the service providers?

Probe: Was it sufficient enough for providing LNG-IUS services, in regard to duration, methods of training, training materials used, uterine model used in training, client counseling, client screening, logistics, place of training, etc.? Were there enough clients for practices? What are some good and bad points of LNG-IUS training?

5. We have prepared and supplied an IEC material for clients. Have you seen it? How do you describe the IEC materials used in the piloting program on LNG-IUS?

Probe: Can she describe the client perception about the IEC materials? Does she think women understand the IEC material, even the service providers? Is there any need of improvement, could have been better, what is your suggestions? or Need a new one?

6. How many LNG-IUS inserted and removed in your facility? (may be 100 clients). How do you describe your experiences in providing LNG-IUS services in your facility?

Probe: Who mostly choose LNG-IUS, younger, older women? Why do they choose? Who mostly remove LNG-IUS? Why? Do husbands play any role in removal? What are her opinions about the insertion and removal of LNG-IUS? What problem/difficulties did she sees during inserting or removing LNG-IUS?

7.Your facility has given LNG-IUS services over one year. How do you rate LNG-IUS as a contraceptive method? Why do you think so? Are you satisfied with the LNG-IUS as a contraceptive method? Why and why not?

Probe: Have you or your service providers experienced any problems in providing LNG-IUS, if yes, please describe. What are some good and bad points of LNG-IUS? Are the clients satisfied using the method? Why and why not? Do client complaint while using LNG-IUS? What are those? Are you satisfy with the LNG-IUS, please explain?

8. In your opinion, how is the demand for LNG-IUS?

Probe: Whom do you think the demand is more, young, older women? Why? Will you encourage/suggest women to use LNG-IUS? What are the reactions of women? How demand for LNG-IUS can be increased?

9. What opportunities prevails in the country to introduce and scale up LNG-IUS in the public system?

Probe: available large cadre of IUD trained providers, copper-T IUD available in the system, DGFP wants more options particularly long-acting, there are demand for suitable long-acting method, logistics available, etc.?

10. What are some challenges/barriers prevails in the country to introduce and scale up LNG-IUS in the public system?

Probe: many providers are not trained in IUD, there are lack of demand of IUD, husband is a barrier of IUD use, women do not want it for side-effects, discontinuation is more, time consuming service provision for service providers, lack of logistics, etc.?

11. You know, we are piloting LNG-IUS in only 5 facilities. Do you think LNG-IUS services should be made available in the other parts of the country? If not, why do you think so?

Probe: How we can improve the LNG-IUS service provision. How we can encourage providers to improve LNG-IUS services? How we can expand it to the other parts of the country, what is your suggestions. What would be the training modalities, training and IEC materials, etc.?

"I am really satisfied with this IUD. I have not found anything wrong with the method. One of the best things is that I was suffering from heavy and continuous bleeding and after inserting this method it was cured. That's why my experience is quite good"

- a satisfied client
(aged 25 years)

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