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# User Perspective of Misplaced PPIUCD and Factors Resulting in PPIUCD Removal: Qualitative Pilot Study

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## Abstract

**Objective**: The aim of the current study was to assess the impact of operative interventions for misplaced device among women who opted for PPIIUCD and the evaluation of reasons for PPIUCD removal within the follow up period of two years. **Design**: A descriptive exploratory study was conducted over three months among fourteen PPIUCD acceptors at a tertiary care health facility in Delhi, India. Face-to-face & telephonic in-depth interviews were conducted with a selected sample of PPIUCD acceptors who had later opted for its removal. **Results:** Participants (n = 14) aged 24 – 40 exhibited generally positive attitudes towards PPIUCDs indicating an indicate an understanding of the importance of PPIUCD in preventing unintended pregnancies. Menstrual disturbance and misplaced IUCD were major reasons for removal. despite their own experience necessitating the removal of IUCD, positive experience by other family members (mothers in law) in this study helped to keep the confidence on the contraceptive. Themes included (a) general experience of PPIUCD use (b) Health Facility accessed for removal of IUCD (c) Would she recommend it to others? (d) preferred contraceptive after removal of IUCD. **Conclusion:** Misplaced IUCD, missing thread, menstrual irregularities, and pain are all associated with PPIUCD and are important reasons for dissatisfaction. Appropriate, timely and supportive individualized care that address knowledge gaps, societal perceptions, and healthcare system challenges would certainly help in reducing dissatisfaction due to PPIUCD and thereby the removal rates.

**Keywords**

Postpartum Intrauterine Device, PPIUCD, LARC, Long Acting Reversible Contraception, Postpartum Family Planning, Contraception

## 1. Background & Purpose of the Work

Only a few women who give birth in a facility return for follow-up in low-resource settings. Postpartum intrauterine contraceptive device (PPIUCD) is known to be associated with less discomfort and fewer side effects like bleeding and perforation compared to interval insertion of IUCD [1]. Other advantages include its safety for use in HIV-positive women and lactating women [2]. In a study of PPIUCD experience from 6 countries (LMICS) the percentages of PPIUCD acceptors ranged from 2.3% of women counseled in Pakistan to 5.8% in the Philippines. Rates of complications among women returning for follow-up were low. Expulsion rates ranged from 3.7%-1.7%. Infection rates did not exceed 1.3% [3]. There has been a major shift towards PPIUCD which constitutes 70% - 80% of total IUCDs insertions in Delhi with public health facilities being the major sites for IUD/PPIUD insertion. (Data from Directorate of Family Welfare). It is notable that according to NFHS-5 (2019-21), the unmet need for contraception in India is 9% [4].

Based on a study conducted at VMMC & Safdarjung Hospital, out of 1200 women, 108 (9%) were knowledgeable about post-partum intrauterine contraceptive device (PPIUCD). Seventy-two (6%) women opted for PPIUCD prior to counseling. Eighty more women accepted PPIUCD as a method of contraception after counseling, bringing the total to 152 (12.6%) [5].

Specific **advantages** of an IUCD placed in the postpartum period include convenience, safety, a reliable birth spacing method, reduced perception of initial side effects (bleeding and cramping) due to the presence of normal puerperal changes, no effect on amount or quality of breast milk, the woman has an effective method for contraception before discharge from hospital [6]. The **limitation** of PPIUCD is a relatively higher risk of spontaneous expulsion, as compared to interval IUCD. Skilled clinicians with right technique of insertion are associated with lower expulsion rates.

**Timing of PPIUCD Insertion**

i. Post placental: Insertion within 10 minutes after expulsion of the placenta following vaginal delivery, on the same delivery table.
ii. Intra cesarean: Insertion during a cesarean delivery, after removal of the placenta and before closure of the uterine incision.
iii. Insertion within 48 hours of delivery.

Considering the recent inclusion of PPIUCD in the National Family Planning Programme, there is an urgent need to add objectivity to the various aspects of its use to aid in modifications in governmental policies for the long-term success of the Family Planning Programme.

## 2. Review of Literature

Discontinuation rates of 26% for IUD/PPIUD were noted by Kumar S et al though separate figures for interval and postpartum insertion were not stated [7]. Nearly 99.6% satisfaction among PPIUCD acceptors has been reported in a study from India [6].

A detailed literature search revealed that the problem of operative intervention for the removal of PPIUCD and its impact on the acceptor has not been studied adequately (Table 1).

**Table 1.** Studies addressing continuation and removal of PPIUCD.

| Author Name & Year of publication | Title of study | Sample size | Duration of follow-up (months) | Continuation rate (%) | Removal rate (%) | Reasons for removal |
|---|---|---|---|---|---|---|
| Swati A et al. 2022 [8] | Study of the client experience and continuation rate of postpartum intrauterine Copper-T device in semi-urban population in India | 880 | At least 1.5 post insertion | 73.3 | 7.5 | Abdominal pain, irregular menses |
| Nirmala Sharma 2021 [9] | Review of PPIUCD at tertiary care centre in Southern Rajasthan | 8611 | 6 | 92 | 6 | Irregular bleeding, abdominal pain |
| Somesh K et al. 2019 [10] | One-year continuation of postpartum intrauterine contraceptive device: findings from a retrospective cohort study in India | 844 | 12 | 62.8 | 19.3% | Bleeding, pain |
| Pulwasha M Iftikhar et al. 2019 [11] | Efficacy and Satisfaction Rate in Postpartum Intrauterine Contraceptive Device Insertion: A Prospective Study | 372 | 36 | 22.4- 61.5 | - | - |
| Shivani Barala 2017 [12] | Analysis of awareness, acceptance, safety and continuation rate of post-placental and intra-caesarean insertion of intrauterine contraceptive device | 100 | 6 | 92 | 6 | Menstrual disturbance, abdominal pain, pressure by family |
| Chandravadhana K et al. 2016 [13] | Evaluation of Safety, Efficacy and Continuation Rates of Postpartum Intrauterine Contraceptive Devices (PPIUCD) | 200 | 6 | 78.5 | 6 | Irregular menses, pain |

In the ongoing multisite ICMR Taskforce study (ICMR Registry of Levo-Ormiloxifene (Centchroman) & PPIUCD Contraceptive Users, 2019 - 2023), of the total 12921 PPIUCD users from 6 participating sites, there were 2039 removals (15.7%). At GTB hospital, there are at least 0 - 3 women posted for endoscopic procedures every month for removal of misplaced PPIUCD. Most of these women had visited a health facility to get their PPIUCD removed. These centers referred them to GTB Hospital because the IUCD thread was not visible. We observed that some of these women opted for a repeat IUCD insertion while

others chose other methods of contraception.

This qualitative study aims to understand the impact of operative intervention among PPIUCD users and determine the reasons for IUCD removal.

**Specific Objectives**

i. To assess the impact of operative interventions for misplaced device among women who opted for PPIIUCD.
ii. Evaluation of reasons for PPIUCD removal within the follow-up period of two years.

## 3. Methodology

**Study Design**

This descriptive exploratory study was conducted between November 2022 and January 2023 among fourteen PPIUCD acceptors at University College of Medical Sciences & Guru Teg Bahadur Hospital, Delhi, India. Face-to-face& telephonic in-depth interviews were conducted with a selected sample of PPIUCD acceptors who had later opted for its removal. The interviews were purposive aiming to understand the reasons for PPIUCD removal and the perspective of those who required operative intervention for removal of the IUCD. In addition, it was to ensure representation of PPIUCD acceptors who required operative intervention and those who did not. The interview was guided by a topic guide.

**Enrollment in the Study**

This study was conducted in the department of Obstetrics and Gynecology, UCMS & GTB Hospital, Delhi for three months. The participants were drawn from a sample of participants who were recruited for the ongoing ICMR Taskforce Registry of PPIUCD and Centchroman (2019 - 2023) from East Delhi which is location of the hospital. Briefly, the original study involved follow-up of clients who opted for either of the two contraceptives i.e. PPIUCD or Centchroman for 18 months, with the aim to evaluate satisfaction and continuation rates.

The interviews were conducted after obtaining informed consent (for recording also) in the consent form (annexure 1) for admitted women who required operative intervention and recorded for those interviewed telephonically. Transcription of the recordings was undertaken for writing the report.

We interviewed fourteen women, seven from each group, the first group of women requiring operative intervention, and the other PPIUCD users who had their devices removed.

**Study Instruments**

A detailed interview guide was developed in English to collect data from participants (online supplemental file 1). A semi-structured interview guide was used for the narrative approach for conducting interviews. The interview guide was pretested with five participants before formal data collection to ensure consistency. Interview questions explored participants' perceptions, beliefs, and experiences related to PPIUCD usage. The topics included reasons for removal of the IUCD, attitude regarding operative removal, choice of alternate contracep-

tion, whether the client would recommend PPIUCD or interval IUCD to other women known to her. Interviews were conducted in Hindi which was audiotaped, and then translated into English and transcribed. To ensure validity, clerical staff working in the department, proficient in Hindi verified a sample of the translations. As we explored participants' experiences within the overall narrative, we used probes to clarify and expand answers.

**Procedure**

The medical officer and medical social worker in the research team conducted interviews. Each interview lasted between 15 and 20 minutes, and consent was obtained from the participants for the audio recording. Research assistants and the lead researcher reviewed fieldwork experiences, discussed challenges, and provided feedback to examine the impact of the interviews, share lessons learned, and identify new issues.

**Analysis**

Based on Riessman's narrative thematic analysis, which emphasizes the content of the text rather than its manner, the transcribed interviews were analyzed. In order to capture the key points of the interviews, initial coding was done. As a team, we reviewed a subset of transcripts paying particular attention to emerging themes and patterns, the uniqueness of the complete stories and the study's objectives. Then we combined the ideas into the key story themes and created a codebook to record and arrange the final themes. We gave extra attention to any new themes or views that surfaced during this analytical phase. The team members reviewed and critically reflected on interpretations and findings to ensure that the conclusions were grounded in participants' experiences during the analysis. The themes and codes following narrations are listed in Table 2.

**Rigour**

The transcripts and data were independently read and analyzed by two researchers to ensure rigour and accuracy. As the themes emerged from the analysis, the original transcript text was constantly compared. A consensus was reached after reviewing and debating the themes. Transcripts of the interviews were used to record the words of the participants.

**Inclusion criteria**

i. PPIUCD acceptors who were admitted in the department of Obstetrics and Gynecology following an operative intervention for removal of the misplaced device.
ii. PPIUCDacceptors who opted for removal of the device.

**Exclusion Criteria**

All other PPIUCD acceptors who continue to use it or discontinued use due to spontaneous expulsion.

**Justification for Sample Size**

Qualitative studies addressing these themes are not presently available. For individual participant in depth interview, sample size of 5 - 50 is considered acceptable [14]. We have planned for a sample size of twelve PPIUCD acceptors as

is accepted by researchers for qualitative studies of this nature.

**Data Analysis**

The interviews were analyzed using a thematic approach that allows for themes to emerge through an iterative process of coding and discussion. A preliminary list of codes was created using the topic guide. Transcripts were independently reviewed by two members of the research team who assigned preliminary codes. To ensure reliability, all cases of conflicting results were discussed thoroughly in an open process until consensus was reached. This process included comprehensive data treatment and deviant case analysis, in which research team members actively sought out similarities and differences across accounts to ensure different perspectives were represented. The themes and codes following narrations are listed in Table 2.

Table 2. Socio demographic information of the participants.

| Variable | Total (N=14) |
|---|---|
| Age | Range 24-40 years |
| **IUCD Removal Procedure** | |
| Hysteroscopic removal | 7<br>(3 post LSCS, 1 after 2$^{ND}$ trimester MTP, 3 vaginal delivery) |
| Non operative removal | 7<br>(1 post LSCS, 6 Vaginal delivery) |
| **Religion** | |
| Hindus | 9 |
| Muslims | 5 |
| **Education** | |
| Uneducated | 2 |
| Primary | 3 |
| Secondary | 8 |
| College passed | 1 |

## 4. Results

The **sociodemographic information** of the participants is shown in Table 3. The results show that the age range of the participants was between 24 and 40 years. Seven participants in each group had hysteroscopic and vaginal removal of IUCD.

**Themes related to the study**

The study explored the narratives of PPIUCD users, shedding light on the complexities surrounding access to healthcare, side effects and reasons for removal of the contraceptive. The qualitative analysis reveals three interconnected themes that encapsulate the participants' experiences: (a) general experience of PPIUCD use (b) preferred contraceptive after removal of IUCD (c) perceptions of health service providers.

Table 3. Themes and Codes following narrations.

| | Codes | Definition/description | Quotes |
|---|---|---|---|
| **Experiences on PPIUCD use** | Duration of PPIUCD used | • Below 6 months<br>• 6-12 months<br>• 12-24 months<br>• 24-36 months<br>• Beyond 36 months (3 years) | |
| | Reasons for removal and difficulties faced due to PPIUCD | • Menstrual problem (irregular bleeding since the time of IUCD insertion)<br>• Pain during periods<br>• Pain and burning, epigastrium, lower abdomen pain,<br>• Pain while passing urine.<br>• Fever<br>• White discharge, genital itching<br>• Problem in cervix<br>• Thread string discomfort; Pricking sensation, partner discomfort at intercourse.<br>• Wants to conceive<br>• Misplaced PPIUCD | *"At USG, I was told that the CuT was shifted up, stuck to uterine wall"* (Patient underwent hysteroscopy _beyond 3 years of use) |
| **Health facility Accessed for removal** | Outpatient clinic (public or private) | • Local private health practitioner<br>• Traditional birth attendants (*Dai*) | *The doctor asked me the reason for wanting to get the CutT removed. I told her that the the thread was pricking me. She removed the Cu T without any other questions.* |
| | In-patient (public or private) | • Government health facility (GTB Hospital) | *"Very good care was given to me at the time of Cu T removal during surgery. I did not face any problem"* |
| **Would she recommend PPIUCD to others?** | Acceptability of PPIUCD | • Clients willingness to continue using IUCD<br>• Positive experiences of Cu-T use in family members<br>• Willingness to motivate others to use IUCD.<br>• Acceptance of 375CUT (multiload) over 380 CUT | *"It is up to them but I will certainly advice others to go for PPIUCD."* (Outpatient_3 years)<br>*"Yes, CuT is good and does not cause any problems."* (Inpatient_3 years)<br>*"My mother in law has multilord inserted and she has no complication."* (Outpatioent_3years)<br>*"Yes, no need to feel scared of Cu T. My mother is also using it"* (In-patient_3 years)<br>*"I will tell others about it.....it is a good method and one should definitely accept it."* (in-patieny_3years) |
| **Preferred contraceptive after IUCD removal** | Temporary | • Contraceptive tablets or injections<br>• Other family planning methods such as condom | *"Despite CuT my husband still uses condom."* (In-patient_3 years)<br>*"....My religion does not allow MTP also. I will use pills or an injection whatever is advised to me."* (In-patient_3 years)<br>*"I can't get ligation done—can't do namaz. I don't want CuT or ligation either. I will use injection or tablets."* (in-patient_3 years) |
| | Permanent | • Sterilization | *"No, I will undergo ligation as I have had LSCS."* (In-patient_3years) |
| | Traditional | • Physical distance with spouse | |
| | **Few patients reported that they have not thought or decided about contraception(after removal) | | |

**Theme 1: Experiences of Using PPIUCD**

**a) Duration of use**

The duration of PPIUCD use ranged from one month to nine years.

**b) Reasons for removal of PPIUCD**

Three of the 14 women got the PPIUCD removed as desired pregnancy. Problems faced by other women resulting for opting out included irregular bleeding, painful menses, abdominal pain and discomfort due to thread. Other discomforts included pain during urination, fever and white discharge. The following quotes illustrate these discomforts:

> Cu-T was stuck on the uterine wall, hurting and I had pricking sensation.
>
> I had heavy menstrual bleeding since insertion; Whenever I take treatment I am fine, but when I leave the treatment, again I get the same problem.
>
> "I had frequent and prolonged, heavy cycles, back pain and a long thread was coming out of my vagina.
>
> Q: Why did you not get thread shortened or get treatment for your problems?
>
> Ans: No, I just got it removed."

**Theme 2: Medical Health Facility Accessed for Removal of IUCD**

While women with visible IUCD threads preferred private practitioners or local untrained birth attendant, those with misplaced IUCD or missing thread opted for public hospital for its removal. Several factors contributed to this decision, including proximity to residence, familiarity with local practitioners, and distance to a public hospital. The experience of visiting the private practitioner was expressed through the quote below.

> "The doctor asked me the reason for wanting to get the CutT removed. I told her that the thread was pricking me. She removed the Cu T without any other questions."

For women with misplaced or missing IUCDs, the public hospital was preferred. The participants expressed satisfaction rather than negativity about their experience as can be seen from the following quotes:

> "it was done very smoothly but it was delayed I had to run from here to there for 2.5 months…nothing much".
>
> "I was well cared for and I am well satisfied".
>
> "I did not face any problem and now I am pregnant following my 2nd marriage".
>
> "Yes, I am comfortable. My only problem was that it got displaced and also I had completed tenure of copper t".

This participant (last quote) got a reinsertion of IUCD done in the same sitting.

**Theme 3: Would she recommend it to others?**

While exploring the circumstances surrounding the use of PPIUCD among

women, the participants' narratives reveal a notable theme of generally positive attitudes towards PPIUCD for continued usage, positive experiences in the other family members, better acceptance of CuT 375 (multiload) over Cu T 380. This positive sentiment is summarised in the following quotes:

"It depends upon the individual, but I would say there is no fear. Even have my mother has got cut inserted. So I will definitely advise".

"Yes, CuT is good and does not cause any problems."

"My mother-in-law has multiload inserted and she has no complication."

"I will tell others about it...it is a good method and one should definitely accept it."

I will tell them it is a good method, and one should definitely accept it.

It appears that PPIUCD is perceived as a safety net, offering reproductive health control to its users.

**Theme 4: Preferred contraceptive after IUCD removal**

The participants were interviewed to understand their preference for contraception after IUCD removal. All except one participant opted for ligation while others chose temporary methods. Another participant got an IUCD reinserted. Three women wanted conception. The other choices were condom, pills or injection or no contraceptive. The justifications for not opting for ligation included religious beliefs in the following narrations:

"Despite CuT my husband still uses condom."

"...My religion does not allow MTP also. I will use pills or an injection whatever is advised to me."

"I can't get ligation done—can't do namaz. I don't want CuT or ligation either. I will use injection or tablets."

## 5. Discussion

A total of 56619 eligible women were counselled in six study centres and out of the counselled eligible women 16262 women were accepted for the PPIUCD. The overall acceptance percentage was 28.7% [95% CI: 28.3 to 29.1%] while in East Delhi it was 24.6%. Overall acceptance of 10% - 39% have been reported from various parts of India [1]. The overall removals at 18 months were 19.5% (n = 3182). In a 12 month follow up study in India from retrospective cohort, removal rates were determined at 19.3%. The reasons were similar to those found in the present study [2]. Removal of PPIUCD have been reported in many other studies [3]-[5] [7]. However, this qualitative study aimed to understand the reasons and correctable factors to improve continuation rates.

It is noteworthy that there is generally a positive attitude among PPIUCD users. Responses indicate an understanding of the importance of PPIUCD in preventing unintended pregnancies. This positive attitude is indicative of responsible and proactive behavior, showcasing a willingness among the women to take charge of their reproductive health and adopt preventive measures in the face of

potential unplanned pregnancies. Additionally, this positive attitude could contribute to destigmatizing contraception within the community, challenging societal norms and fostering a more open and supportive reproductive health environment.

Postpartum involution of the uterus is mainly responsible for higher expulsions occasional dislocation of IUCD. Malposition of the IUCD is usually noted due to "missing strings" at the time of follow-up. In the study by Diallo et al, IUCD expulsion rates, menstrual problems and other outcomes were similar in both the cesarean and vaginal delivery group [15]. Successful and safe removal of misplaced IUCD has been well documented [16]. Our study highlights the importance of counselling in advance, easy availability of health services during follow-up period. In the usually very busy tertiary care centres, it may be challenging to provide personal care. Therefore, including all levels of public healthcare facilities and specially the private sector is important for the continuation of this contraceptive. It is important to emphasize that the postpartum uterine involution of the uterus is not affected by PPIUCD use.

Policies and trainings to dissuade easy removals by private practitioners and untrained healthcare workers are required at the earliest. The background for the request for removal needs to be addressed by way of treatment and counselling where applicable. It is important to delink IUCD removals with medical consultation fee as a first step to reduce the unwarranted removals in private clinics.

It is interesting to note that despite their own experience necessitating the removal of IUCD, positive experience by other family members (mothers in law) in this study helped to keep the confidence on the contraceptive.

The findings have implications not only for individual well-being, but also for public health, because delayed or avoided contraceptive use can result in unintended pregnancies and associated health challenges. The implementation of more inclusive and client-friendly reproductive health services should be the focus of efforts in providing confidential reproductive health services.

The study has notable strengths. Contrary to the expectation of dissatisfaction due to side-effects and operative intervention, we bring forth the clear prioritization of contraception by the women. Compassionate and effective management at the hospital ensured this positive feeling.

Participants requiring operative intervention and simple vaginal removal were included to ensure unbiased opinions. The women belonged to different religions and their education levels ranged from uneducated to college literate, thus enriching the findings.

There are, however, some limitations to the study. The findings may be specific to the setting of the study, so generalizations should be made with caution to other regions or populations. Second, participants may underreport sensitive information due to social desirability bias, affecting the accuracy of the findings. Lastly, the study focuses exclusively on women using PPIUCD, which excludes the perspectives of husbands and family members who play important roles in

decision making [6]. As a result, a comprehensive understanding of the dynamics surrounding the use of PPIUCD is hindered.

## 6. Conclusion

Expulsion and misplaced IUCD, missing thread, menstrual irregularities, and pain are all associated with PPIUCD. The positive attitudes towards the IUCD contrast with societal judgements and provider stigmatization. It is vital to develop tailored interventions that address knowledge gaps, societal perceptions, and healthcare system challenges to improve PPIUCD acceptability and utilisation among women who desire contraception. Appropriate counselling and efficient handling of operative procedures necessitated due to missing thread or misplaced IUCD ensure satisfaction and positive response from the users.

## Total Duration of the Study

3 months

Study end point Completion of interview of at least 12 patients, 6 in each group.

## Budget Required

There is no budget requirement.

## Conflict of Interest

This is to state that there is no conflict of interest to be declared.

## Funding

The author(s) received funding from Indian Council of Medical Research (ICMR), Grant number: RBMH/NTF/PPIUCD-Cent/2018.

## Data Availability Declaration

The datasets supporting the findings of this study are available from the corresponding author, AGR, upon reasonable request.

## Ethics Declaration and Consent to Participate

Participants were informed about the study's purpose and content before each survey interview and provided their informed consent. The study was ethically approved by the Indian Council of Medical Research and Guru Teg Bahadur Hospital (GTBH), Delhi, India.

## References

[1] Mohamed, S.A., Kamel, M.A., Shaaban, O.M. and Salem, H.T. (2003) Acceptability for the Use of Postpartum Intrauterine Contraceptive Devices: Assiut Experience. *Medical Principles and Practice*, **12**, 170-175. https://doi.org/10.1159/000070754

[2] Kapp, N. and Curtis, K.M. (2009) Intrauterine Device Insertion during the Post-

partum Period: A Systematic Review. *Contraception*, **80**, 327-336. https://doi.org/10.1016/j.contraception.2009.03.024

[3] Pfitzer, A., Mackenzie, D., Blanchard, H., Hyjazi, Y., Kumar, S., Lisanework Kassa, S., *et al.* (2015) A Facility Birth Can Be the Time to Start Family Planning: Postpartum Intrauterine Device Experiences from Six Countries. *International Journal of Gynecology & Obstetrics*, **130**, S54-S61. https://doi.org/10.1016/j.ijgo.2015.03.008

[4] Ministry of Health and Family Welfare GOI (2021) National Family Health Survey (NFHS-5) 2019-21. International Institute for Population Sciences (IIPS) and ICF. https://dhsprogram.com/pubs/pdf/FR375/FR375.pdf

[5] Gupta, N., Sinha, R. and Mangal, A. (2017) Knowledge, Attitude and Practice Study on Immediate Postpartum Intrauterine Contraceptive Device Method of Family Planning. *International Journal of Community Medicine and Public Health*, **4**, Article 2981. https://doi.org/10.18203/2394-6040.ijcmph20173357

[6] Family Planning Division MoHaFW and Government of India (2013) 2IUCD Reference Manual for Medical Officers and Nursing Personnel.

[7] Kumar, S., Sethi, R., Balasubramaniam, S., Charurat, E., Lalchandani, K., Semba, R., *et al.* (2014) Women's Experience with Postpartum Intrauterine Contraceptive Device Use in India. *Reproductive Health*, **11**, Article No. 32. https://doi.org/10.1186/1742-4755-11-32

[8] Chopra, K., Agrawal, S., Induja, R., Singh, A., Sood, S. and Puri, M. (2022) Study of the Client Experience and Continuation Rate of Postpartum Intrauterine Copper-T Device in Semi-Urban Population in India. *International Journal of Advanced Medical and Health Research*, **9**, 38-41. https://doi.org/10.4103/ijamr.ijamr_212_21

[9] Kumar, S., Srivastava, A., Sharma, S., Yadav, V., Mittal, A., Kim, Y., *et al.* (2019) One-Year Continuation of Postpartum Intrauterine Contraceptive Device: Findings from a Retrospective Cohort Study in India. *Contraception*, **99**, 212-216. https://doi.org/10.1016/j.contraception.2018.12.003

[10] Iftikhar, P.M., Shaheen, N. and Arora, E. (2019) Efficacy and Satisfaction Rate in Postpartum Intrauterine Contraceptive Device Insertion: A Prospective Study. *Cureus*, **11**, e5646. https://doi.org/10.7759/cureus.5646

[11] Deshpande, D.S.A. (2018) Evaluation of Safety, Efficacy and Continuation Rates of Postpartum Intrauterine Contraceptive Devices (PPIUCD) (cu-T 380 A). *Journal of Medical Science and Clinical Research*, **6**, 1047-1052. https://doi.org/10.18535/jmscr/v6i7.173

[12] Barala, S., Maheshwari, S. and Sharma, P. (2016) Analysis of Awareness, Acceptance, Safety and Continuation Rate of Post-Placental and Intra-Caesarean Insertion of Intrauterine Contraceptive Device. *International Journal of Reproduction, Contraception, Obstetrics and Gynecology*, **5**, 1974-1980. https://doi.org/10.18203/2320-1770.ijrcog20161701

[13] Sharma, N., Gupta, V. and Sharma, A. (2021) Review of PPIUCD at Tertiary Care Centre in Southern Rajasthan. *Asian Journal of Medical Sciences*, **12**, 91-95. https://doi.org/10.3126/ajms.v12i12.39110

[14] Boddy, C.R. (2016) Sample Size for Qualitative Research. *Qualitative Market Research: An International Journal*, **19**, 426-432. https://doi.org/10.1108/qmr-06-2016-0053

[15] Diallo, M., Daff, H.M.B., Diouf, A.A., Niass, A., Toure, Y., Fall, K., *et al.* (2019) Intrauterine Device in the Immediate Postpartum: Study Comparing Insertion after Cesarean Section and Vaginal Delivery. *Open Journal of Obstetrics and Gynecology*, **9**, 1510-1518. https://doi.org/10.4236/ojog.2019.911146

[16] Isidore, T., Rakya, I., Robert, T., Humphry, N., Georges, M., Charlotte, T., *et al.* (2024) Successful Laparoscopic Management of a Migrated Intrauterine Contraceptive Device in the Pelvic Cavity: A Case Report. *Open Journal of Obstetrics and Gynecology*, **14**, 36-43. https://doi.org/10.4236/ojog.2024.141005

## Informed Consent Form

**User Perspective of Misplaced PPIUCD and Factors resulting in PPIUCD Removal: Qualitative study**

This Informed Consent Form has two parts

1. Information Sheet (to share information about the research with you)
2. Certificate of Consent (for signatures if you agree to take part)

## PART I: Information Sheet

**Introduction**

Centchroman/Postpartum Intra-uterine Contraceptive Device (PPIUD) has been recently introduced in the National Family Planning Programme. This study addresses the use of this contraceptive. I am going to give you information and invite you to be part of this research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions you are welcome to clarify.

**Purpose of the research** (tick as applicable)

This study is aimed at

1. Identifying your experience and opinion of PPIUCD use, operative intervention necessitated due to missing thread
2. Identify the reasons for your decision to get Postpartum Intrauterine Device removed

**Intervention**

The registry involves one-time interview with regard your experience and opinion of PPIUCD use, operative intervention necessitated due to missing thread, understand the reasons for your decision to get Postpartum Intrauterine Device removed.

**Procedure to be followed during study**

We will have an open discussion (direct or telephonically) on all of the above-mentioned points

There are **no risks** involved in the study

**Monetary benefit** None

**Voluntary Participation**

Your participation in this registry is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating even if you agreed earlier.

**Confidentiality**

We will not be sharing the identity of those participating in the research. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is.

**Known side-effects**: None

**Sharing the Results**

The knowledge that we get from doing this research will be shared with you if needed before it is made widely available to the public. Confidential information will not be shared. After completion of the research, we will publish the results in order that other interested people may learn from our research.

**Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so. You may stop participating in the research at any time that you wish. It is your choice and all of your rights will still be respected. This will not affect your further treatment in the parent institute/hospital.

**Who to Contact** If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact-

Name:-

Number:-

Email:-

## PART II: Certificate of Consent

- I have read the information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.
- I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records in respect of the current study even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed if any information released to third parties or published.
- I consent voluntarily to participate in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the explained interview will be done.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the consent has been given freely and voluntarily.

Name
Signature
Date
Day/month/year