

Evaluation of Safety, Efficacy, and Expulsion of Post Placental Insertion of Intrauterine Contraceptive Devices (PPIUCD) In A Tertiary Care Center

Neelam Rajput¹, Pratima Kumari², Neelu Rajput³, Divya Sinha⁴

¹Professor, Department of Obstetrics and Gynaecology, Kamala Raja Hospital, Gajra Raja Medical College, Gwalior, M.P. India

²Senior resident, Department of Obstetrics and Gynaecology, Birsa Munda Medical College, Shahdol, M.P. India

³Assistant Professor, Department of Obstetrics and Gynaecology, Kamla Raja Hospital, Gajra Raja Medical College, Gwalior, M.P. India

⁴Assistant Professor, Department of Obstetrics and Gynaecology, Kamla Raja Hospital, Gajra Raja Medical College, Gwalior, M.P. India

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Corresponding Author: Dr. Divya Sinha

Conflict of interest: Nil

Abstract:

Introduction: According to USAID/ACCESS 2009 survey, couple protection rate in India is 50.7% and unmet need is 12.8%. According to WHO the optimum interval between pregnancies should be 36 to 60 months. Pregnancy before 24 months of birth increases maternal and perinatal morbidity and mortality. PPIUCD has emerged as most cost effective and ideal postpartum contraceptive. The aim of this study is to evaluate acceptability, safety, efficacy and complications of PPIUCD at tertiary care center.

Method: This was a prospective and longitudinal study conducted in the Department of Obstetrics and Gynaecology in Kamla Raja Hospital, Gwalior over a period of two years from November 2019 to July 2021. This study included 255 women who were admitted for delivery. PPIUCD was inserted within 10 minutes of placental expulsion in vaginal deliveries and during caesarean section. Follow up of these patients at 6 weeks and 6 months. Various parameters were analyzed.

Results: Acceptance rate of PPIUCD was 1.66%, highest acceptance of PPIUCD was seen in para 2 (36.9%) followed by para 3 (25.0%) and (37.2%) patients were accepted due to its reversible nature. The mean age was 26.25 years. Most common complication was vaginal bleeding (15.2% at 1st follow up; 12.2% at 2nd follow up) followed by abdominal pain (10.9% at 1st follow up; 10% at 2nd follow up). Removal of PPIUCD due to mal position (21.2% at 6 week; 20% at 6 months) and vaginal bleeding (42.1% at 6 week; 40% at 6 months) of PPIUCD at follow up

Conclusion: During present study authors found that PPIUCD is highly effective, acceptable safe and with fewer side effects. PPIUCD is beneficial in Indian population where accessibility for contraception is lower during interval period and women do not come for contraception during postpartum period.

Keywords: Post-Partum Intrauterine Contraceptive Device, Post-Placental, Intra-Caesarean, Efficacy, Complication, Expulsion.

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Introduction

India is the 2nd most populous country of the world with 1.21 billion people and 17.64% decadal growth. According to census 2011 India's population harbors 17.5% of world's population and 2.4% of land mass. It also houses almost 17.3% of the world's protected couples and 20% of world's eligible couples with unmet need¹. This large population not only impacts its own demographic, social and health issues but also affects global indicators¹. So India is in dire need to improve its family planning services. India was the first country in the world to have launched a national programme for family planning in 1952. Objectives of family welfare programme in India are that people

should adopt the small family norm to stabilize the country's population at the level of some 1,533 million by the year 2050 AD². In the 1970's slogan was "Do Ya Teen Bas". In 1980's it became the two-child norm. The current emphasis is on three things "son or daughter two will do"; "second child after three years"; "Universal immunization". Couple protection rate in India is 50.7% and unmet need is 12.8%. This unmet need is increased in first year of post-partum to 65% according to USAID/ACCESS 2009 survey in India¹ According to World Health Organization (WHO) and other international organizations, the optimum interval between

pregnancies should be 36 to 60 months³. Pregnancy before 24 months of birth increases maternal and perinatal morbidity and mortality⁴. It also increases rate of MTP and septic abortion which further impacts on maternal morbidity and mortality. Women 2-3 months after childbirth are very vulnerable to unwanted pregnancy as exclusive breast-feeding decreases, sexual activity increases and menstruation returns. Family planning can avert nearly one third of maternal death and 10% of child mortality when couple space their pregnancy more than 2 years apart⁵. Hence the ideal time of family planning is postpartum period. There are various methods of postpartum contraception like lactational amenorrhea, barrier method, progesterone only pill, sterilization and IUCD.

Government of India launched the Janani Suraksha Yojana (JSY); in 2005, a conditional cash transfer scheme to encourage institutional deliveries⁶. It gives opportunity for state to provide PPIUCD in a big way.⁽⁹⁾ The government is now offering Intrauterine Contraceptive Device services free of cost under Johns Hopkins program for international education in Gynaecology & Obstetrics (JHPIEGO), which was implemented in 2009, it still remains largely underutilized. Total 10, 34,894 PPIUCDs have been inserted all across the country since the initiation of the PPIUCD programme⁷. Approximately 5, 90,217 PPIUCD insertions have taken place in 2014-15 as against around 3, 24,487 in 2013-14. (Annual Report 2015-16- Family Planning)². PPIUCD has emerged as most cost effective and ideal postpartum contraceptive available as it is highly effective, one-time application, safe, long acting, rapidly reversible, simpler to administer, cost effective, independent of coitus, no effect on breast feeding, relatively fewer side effects, require little medical supervision and can serve as both limiting and spacing in some cases⁸. There have been many misconceptions over IUCD use. Recent research studies have proved the safety of IUCD and cleared the misconceptions. As against earlier belief incidence of PID in IUCD users has no significant relationship. Infection following IUCD use is common in initial four months in women with high risk of sexually transmitted infections. Also there is no increased incidence of infertility or ectopic pregnancy following IUCD use in women without sexually transmitted infections. IUCDs actually are protective against ectopic pregnancies. Copper containing IUCDs are most commonly used in PPIUCD. Ministry of health and family welfare under National Family Planning Programme have introduced IUCD as two types: 1). long term IUCD: CU T380A (10 YEARS) 2). Short term IUCD: CUT375 (5 YEARS). Training of state level trainers has already been completed and process is underway to train service providers up to sub center level². PPIUCD has emerged as promising alternative for spacing methods in India and there is lot of focus to improve PPIUCD insertion rate by government by implementing newer policies and training programmes². Follow up data with PPIUCD insertion were available from international

sources but given scale at which PPIUCD services are being introduced in India, It was imperative to generate country based evidence on post insertion outcomes after introduction of PPIUCD Programme. The aim of this study is to evaluate acceptability, safety, efficacy and complications of PPIUCD at tertiary care center.

Aims and Objectives

- To know the percentage of PPIUCD insertion in Kamla Raja Hospital.
- To assess the acceptability, safety, efficacy, continuation rate and rate of expulsion of PPIUCD insertion.
- To determine the complication rate of post-partum IUCD insertion among the acceptors at 6 weeks and 6 months.
- To describe the factors associated with acceptability of PPIUCD insertion in women according to their socio-demographic and obstetrics characteristics, and future pregnancy desires.

Material and Methods: This was prospective and longitudinal study conducted in the Department of Obstetrics and Gynaecology in Kamla Raja Hospital, Gwalior over a period of two years from November 2019 to July 2021. CuT380A is inserted within 10 minutes of placental expulsion in vaginal deliveries and during caesarean section. Follow up of these patients at 6 weeks and 6 months. This study included 255 women who were admitted and delivered vaginally or by LSCS and inserted PPIUCD (Cu-T 380 A). Women willing for Copper T insertion and its follow up and meeting all the WHO medical eligibility criteria for Post-partum IUCD Insertion were included in the study. Women having fever during intrapartum or postpartum period, Intrauterine fetal death, unresolved PPH, extensive genital trauma, any abnormality of uterus distorting its cavity, large fibroid, chorioamnionitis or puerperal sepsis, prolonged rupture of membranes of >18hours, malignant or benign Trophoblastic disease and Pelvic Inflammatory Disease were excluded from study. Those patients who fulfilled inclusion criteria were counseled and PPIUCD inserted after talking informed consent. IUCD was placed within 10 minutes of delivery of placenta using Kelly's forceps in case of vaginal delivery and ring forceps was used to place IUCD in case of caesarean section. At the time of discharge patient were advised to come for follow up after 6 weeks. Patient were counselled about side effects like foul smelling vaginal discharge, excessive vaginal bleeding, severe lower abdominal pain, fever and expulsion of device and they were advised to report earlier if any of the symptom appear. Follow up scheduled was at 6 weeks after insertion and at 6 months; any complaints were noted and treated accordingly. The observations were noted and analyzed. Various parameters analyzed were age, parity, type of application (whether post-placental or intra-caesarean), spontaneous expulsion, manual removal, reason for removal, side effects and complications and failed contraception. Statistical Analysis: Descriptive data was summarized as percentage or means

Observations and Results: Total no. deliveries in KRH from Nov. 2019 to up to July 2021 = 15383 Total

no. of deliveries (vaginal + cesarean) accepted PPIUCD = 255 Acceptance rate in KRH = 1.66% .

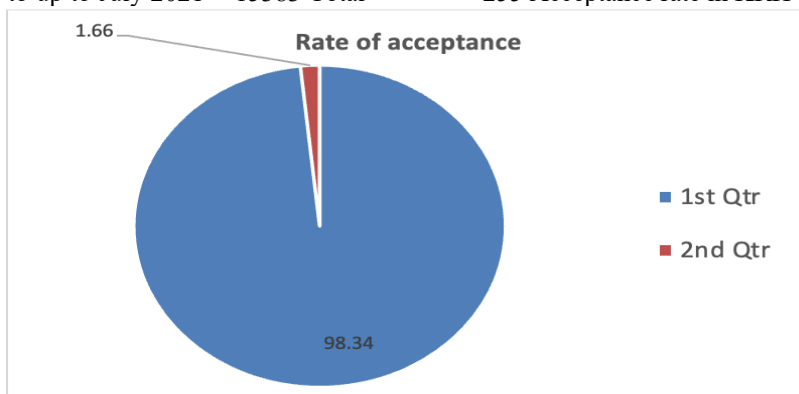


Figure 1: Acceptance rate

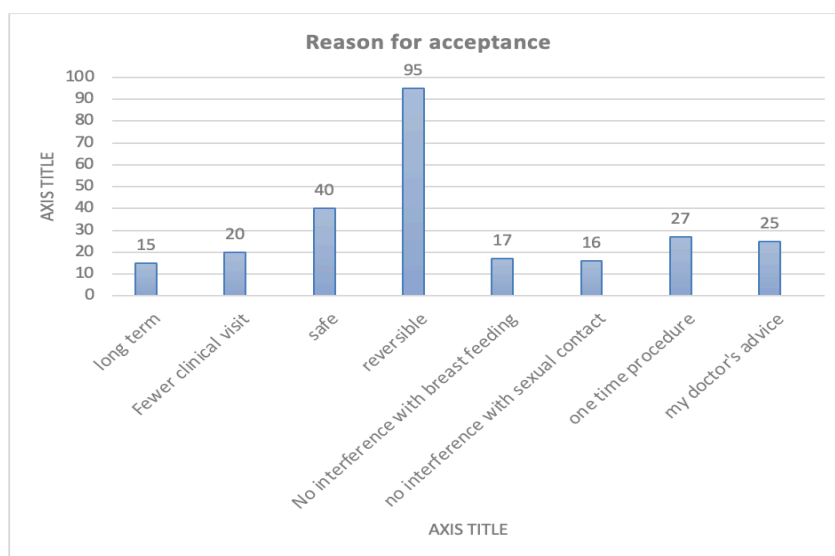


Figure 2: Reason for acceptance

Out of 255 patients, highest number 95 (37.2%) patients were accepted due to its reversible nature followed by 15.7% for safe and 10.6% as one time procedure compared to injectable or oral contraceptive pills.

Table 1: Age wise distribution of Study Participants

Age group	Frequency (N)	Percentage %
< 20 year	18	7.1
21- 25 Year	106	41.2
26-30 Year	82	32.2
31-35 Year	30	11.8
>35 Year	19	7.5
Total	255	100

The mean age was 26.25 years. Majority 106 (41.6%) patients belong to age group of 21-25 years.

Table 2: Education wise distribution of Study Participants

Education	Frequency (N)	Percentage (%)
Illiterate	90	35.3
Primary	61	23.9
Middle	32	12.5
Secondary	27	10.6
Undergraduate	30	11.8
Postgraduate	15	5.9
Total	255	100

Out of 255 patients, 90 (35.3%) patients were illiterate, 61 (23.9%) studied up to primary, 32 (12.5%) patients were up to middle standard, 27 (10.6%) patients were studied up to secondary, 30 (11.8%) patients were undergraduates, and 15 (5.9%) patients were postgraduates.

Table 3: Socioeconomic Status wise distribution of Study Participants

Socioeconomic status	Frequency (N)	Percentage (%)
Upper Class	15	5.9
Middle Class	80	31.4
Lower Class	160	62.7

The maximum acceptance of IUCD were seen among the women belonging to lower socio-economic group 160 (62.7%) and minimum acceptance 15 (5.9%) of IUCD belonging to upper class due to higher willingness of acceptance of permanent sterilization method among them.

Table 4: Parity wise distribution of Study Participants

Parity	Frequency (N)	Percentage (%)
Para 1	55	21.6
Para 2	94	36.9
Para 3	64	25.0
Para 4	41	16.1
Para 5	01	0.4

Out of 255 patients, highest acceptance of PPIUCD was seen in para 2 (36.9%) followed by para 3 (25.0%). This is because PPIUCD is used for spacing between two births or to delay pregnancy till they go for permanent method of sterilization after 2/3 children. Most of the couples undergo tubal ligation/NSVT, that's why its low after para 3.

Table 5: Distribution of cases according to mode of delivery

Mode of delivery	Frequency (N)	Percentage (%)
Vaginal delivery	169	66.3
LSCS	86	33.7
TOTAL	255	100

Out of 255 patients, 169 (66.3%) patients were delivered by vaginal and 86 (33.7%) patients were delivered by LSCS (cesarean section). The reason could be: Normal delivery is more than cesarean section (LSCS). The fear of complications due to PPIUCD insertion is more among the LSCS patients than the vaginally delivered patients. Large of patients undergoing LSCS were excluded from the study because of complications like PROM, chorio-amnionitis, placenta previa, couvelier uterus, obstructed labour etc.

Table 6: Follow up of cases

Follow up	1 st Follow up (at 6 week)		2 nd Follow up (at 6 month)	
	N	%	N	%
Follow up	230	90.1	180	85.71
Lost to follow up	25	9.8	30	14.28
Total	255		219	

Out of 255 patients, 230 (90.19%) came for 1st follow up, 25 (9.8%) patients lost follow up during 1st follow up at 6 weeks. Out of 230 patients 19 (8.26%) patients excluded from study due to removal of PPIUCD after 1st follow up at 6 weeks and 1 (0.4%) patient excluded from study after 1st follow-up due to expulsion of PPIUCD. During 2nd follow up at 6 months, out of 210 patients, 180 (86%) patients came for 2nd follow up at 6 months. 30 (14.3%) patients lost to follow up during 2nd follow up. Out of 180 patients, 15 (8.3%) patients excluded from study due to removal of PPIUCD after 2nd follow up and 1 (0.5%) excluded from study after 2nd follow up due to expulsion of PPIUCD.

Table 7: Total follow up, excluded, and lost to follow up cases

Follow up	Total lost to follow up	Total excluded cases due to removal	Total expulsion of PPIUCD	Cases followed at two times	Total
N	55	34	2	164	255
%	21.57%	13.33%	0.78%	64.31%	100%

Table 8: Distribution of removal of PPIUCD (unwilling to continue PPIUCD)

Cause of removal of PPIUCD	First follow up at 6 weeks		Second follow up at 6 months	
	N	%	N	%
Removal due to malposition	4	21.1 %	3	20 %
Removal due to bleeding	8	42.1%	6	40%
Removal due to pain	7	36.8%	5	33.3%
Removal due to pregnancy	0	0%	1	6.7%

At 1st follow up (at 6 weeks), 4(21.1%) patient removal PPIUCD due to malposition of PPIUCD, 8(42.1%) patients removed IUCD due to excessive vaginal bleeding, 7(36.8%) patients removed IUCD due to abdominal pain. At 2nd follow up (at 6 month), 3(20%) patients removed PPIUCD due to malposition of PPIUCD. 6(40%) patients removed PPIUCD due to excessive vaginal bleeding, 5 (33.3%) patients removed PPIUCD due to abdominal pain. 1(6.7%) patient removed PPIUCD due to continue her pregnancy.

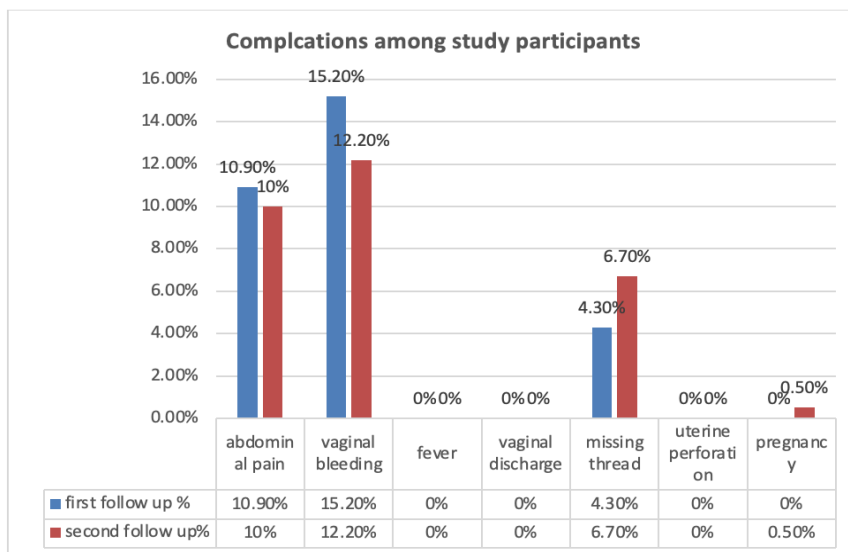


Figure 3: Complications among study Participants

25 (10.9%) patients had lower abdominal pain during the first follow up (at 6 week) and 18(10%) patients had lower abdominal pain during the second follow up (at 6 month). 35(15.2%) patients had bleeding per vaginum during the first follow up (at 6 week) and 22(12.2%) patients had bleeding per vaginum during the second follow up (at 6 month). 10(4.3%) patients had thread problem during the first follow up and 12(6.7%)

patients had thread problem during the second follow up. No patients had complication like perforation, foul smelling, vaginal discharge, fever during the follow up period. During 1st follow no patient came with pregnancy, vaginal discharge, perforation and fever. During 2nd follow up at 6 months 1(0.5%) patient had pregnancy

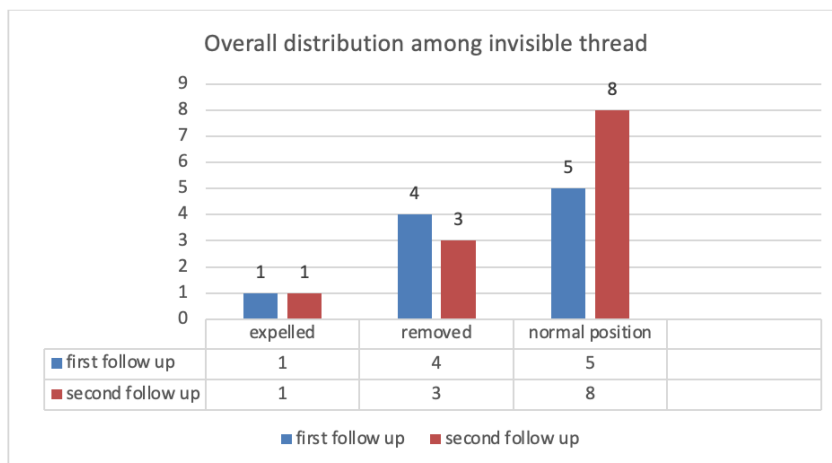


Figure 4: Overall distribution among the missing thread

Out of 22 patients who had thread problem, 1 patient had IUCD expulsion, 4 patients had IUCD removal due to malposition of IUCD and normal position confirmed in 5 patients at 1st follow up. 1 patient had IUCD expulsion, 3 patients had IUCD removal due to malposition of IUCD and normal position confirmed in 8 patients at 2nd follow up.

In present study acceptance rate for PPIUCD was 1.66% and majority of the women who accepted belonged to age group 21-25 yrs. (41.6%), the mean age was 26.25 ± 4.33 which was comparable to study done by Runjun Doley et al¹⁰ (2013- 2015) and Sahaja Kittur et al¹¹ (2010) and in the study done by Somesh Kumar (2014)¹², in which mean (SD) age of women accepting PPIUCD was 24 years.

Discussion

In present study 160(62.7%) belong to lower class, 60(31.4%) belonged to middleclass and 15(5.9%) belong to upper class. This is similar to Gunjan et al14 study were 62% of acceptors were from lower socioeconomic group which is comparable to studies. This high percentage of acceptance among lower socioeconomic group could be because these studies were carried out in government tertiary care hospitals which cater mainly to the needs of people belonging to lower socioeconomic groups and minimum acceptance of IUCD belonging to upper class due to higher willingness of acceptance of permanent sterilization method among them.

In the present study maximum number of acceptor were belonged to the para 2 group which accounted for 36.9% which was comparable to Srivastava and Bano13 were the maximum number of acceptors belonged to the para 2 group which accounted for 36.86%. This was because, this method is used either for spacing between two births or to delay pregnancy till they go for permanent method of sterilization. Most of the couples undergo tubal ligation/Non Scapel Vasectomy, thus its lower after para 3. This shows that women with higher parity prefer permanent mode of contraception.

In present study 62.7% belong to lower class, 31.4% belonged to middleclass and 5.9% belong to upper class. This is similar to Gunjan et al10 study, were 62% of acceptors were from lower socioeconomic group. This high percentage of acceptance among lower socioeconomic group could be because these studies were carried out in government tertiary care hospitals which caters mainly to the needs of people belonging to lower socioeconomic groups and minimum acceptance of IUCD belonging to upper class due to higher willingness of acceptance of permanent sterilization method among them.

In present study 16.8% developed lower abdominal pain, which was comparable to Sangeetha Jairaj et al17, were 17.14% had reported main complication as pain abdomen.

In present study 22.3% developed excessive bleeding per vaginum. In the study done by Sangeeta Jairaj et al, 14.28% developed excessive bleeding per vaginum.

In present study, no patient developed foul smelling vaginal discharge or perforation during the follow up period which was similar to Sudha TR et16 al and by Sahaja Kittur et al11 were infection and perforation were 0%, pregnancy reported were 0%. In the study done by Anjali Vivek Kanhere et al18 one patient reported with intrauterine pregnancy at 6 months with IUCD in phase. In present study 1 patient reported with intrauterine pregnancy at 2 months with IUCD in place.

In present study expulsion rate was 1% which was comparable to Runjuan Doley et al10 study, were expulsion rate was 1.6%. PPIUCD removal rate was very low 0.76% in Sudha TR et al16 and very high 7.6%, 7%, 6.2% in Mishra Sujnanendra et al9, Runjun

Doley et al10, Jisha Bai et al19 respectively. In present study removal rate was 17%. Main reason of removal was fear of bleeding. All women were counselled regarding their problem and reassurance was given. In study by Mishra Sujnanendra et al9 in which the reason of majority of women discontinuing Cooper T was bleeding. In present study continuation rate was 82% the study done by Runjun Doley et al10 and Jisha Bai et al19 continuation rate was respectively 90.84% and 91%.

Conclusion

Family planning services has emerged as one of the interventions to reduce not only total fertility rate but also maternal and infant mortalities and morbidities. It is well established that the states with high contraceptive prevalence rate have lower maternal and infant mortalities. The methods available currently in India are broadly divided into two categories, permanent methods, spacing methods and emergency contraception. Postpartum period is the best period to implement family planning services as women are highly motivated and receptive for it. Increase in Institutional deliveries all across the country created opportunities for providing quality family planning postpartum services. More emphasis on PPIUCD as spacing method by government. PPIUCD has distinct advantages as it is one-time application, provider has assurance that patient is not pregnant at the time of application and it can serve as both spacing and limiting in some cases. Main advantage of post placental IUCD is that no additional hospital visit is required for insertion of IUCD and no pain on insertion when used post-placental or intra caesarean. Also, initial cramping due to IUCD is shadowed with pain due to uterine contraction in puerperium.

Acceptance rate of PPIUCD is poor. It can be improved by motivating the couple during antenatal period. Repeated counseling of family members should be done regarding need of contraception, benefits and myths related with PPIUCD. Patient who comes to hospital only for delivery, counselling of patient and family members at time of admission might increase the acceptance.

Government of India is focusing on strengthen postpartum family planning services and post-partum intra-uterine Contraceptive Device (PPIUCD) is being focused to address high unmet need of spacing during postpartum period. Government of India has launched many schemes to strengthen PPIUCD services are as follows. Utilizing services of ASHAs with incentive for counselling couples to have spacing of 3 years after birth of first child. Incentive for beneficiary, service provider and ASHA for placement of PPIUCD.

“Alternative Training Methodology in IUCD” using anatomical, simulator pelvic models to train service providers in provision of quality IUCD services. placement of trained providers for PPIUCD insertion at district and sub district level. increasing provider base

for IUCD through AYUSH practitioners after short refresher course or training and allowed to perform IUCD insertion at public health facilities. onsite training of IUCD services as well as IUCD tracking software has been designed to track the progress of training, post training follow up and is operational now.

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