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SUPPLEMENT ARTICLE

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FIGO postpartum intrauterine device initiative: Complication rates across six countries

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Abstract

Objective: To record and analyze complication rates following postpartum intrauterine device (PPIUD) insertion in 48 hospitals in six countries: Sri Lanka, India, Nepal, Bangladesh, Tanzania, and Kenya.

Methods: Healthcare providers were trained in counselling and insertion of PPIUD via a training-the-trainer model. Data were collected on methodology, timing, cadre of staff providing care, and number of insertions. Data on complications were collected at 6-week follow-up. Statistical analysis was performed to elucidate factors associated with increased expulsion and absence of threads.

Results: From May 2014 to September 2017, 36 766 PPIUDs were inserted: 53% vaginal and 47% at cesarean delivery; 74% were inserted by doctors. Follow-up was attended by 52%. Expulsion and removal rates were 2.5% and 3.6%, respectively. Threads were not visible in 29%. Expulsion was less likely after cesarean insertion (aOR 0.33; 95% CI, 0.26–0.41), following vaginal insertion at between 10 minutes and 48 hours (aOR 0.59; 95% CI, 0.42–0.83), and when insertion was performed by a nurse (aOR 0.33; 95% CI, 0.22–0.50).

Conclusion: PPIUD has low complication rates and can be safely inserted by a variety of trained health staff. Given the immediate benefit of the one-stop approach, governments should urgently consider adopting this model.

KEYWORDS
Absent thread; Complications; Expulsions; FIGO initiative; Outcomes; Postpartum intrauterine device; PPIUD; Removal

1 | INTRODUCTION

The postpartum period is recognized as a timeframe that has high unmet need for contraception, with limited choices available to women.[1] An increasing focus in recent years has been on the opportunity provided by facility births to meet this need and overcome the significant challenge of barriers to access.[2] Offering insertion of a postpartum intrauterine device (PPIUD) prior to discharge after a facility birth may be a particularly convenient option for eligible women, with the distinct advantages of long-term nature, reversibility, and less follow-up required.[3]

Existing research into how PPIUD programs are delivered, in particular the significance of provider cadre and insertion technique, remains limited. Data assessing the impact of provider status on

patient outcomes is of notable importance in an environment where task-sharing among doctors, midwives, and other healthcare professionals is increasingly used to expand and deliver family planning services.[4] Current available evidence is supportive of task-sharing in PPIUD provision. One case-control study analyzing secondary data from a PPIUD program in India found no association between provider cadre and adverse outcomes such as expulsion or infection.[5] This remains to be demonstrated across a variety of settings.

There is currently no consensus in the literature on methods of insertion of PPIUD. Common insertion techniques include manual insertion, Kelly forceps, ring forceps, and dedicated PPIUD inserters.[6–8] It has been posited that high fundal placement, which can be achieved either manually or with instruments such as Kelly forceps or a dedicated PPIUD inserter, may be desirable to minimize expulsion rates.[6,7] However, many existing studies on PPIUD do not describe the methods used, or simply characterize the insertion as instrumental versus manual. More research is imperative to guide and optimize delivery of PPIUD in family planning services.

Interpreting data on complication rates following PPIUD insertion is equally problematic for service providers. While rates of infection and perforation following insertion are consistently low,[9] the authors of a 2015 Cochrane review called for more research assessing expulsion rates.[10] Existing studies vary hugely in their rates of expulsion after PPIUD insertion, from under 2% to over 25%.[6,11] Comparisons are made even more challenging by inconsistencies in definition of expulsion (complete vs incomplete) and timing of follow-up. In addition, very few studies have included rates of lost threads with IUDs in situ after insertion. This complication has the potential to cause significant patient anxiety, particularly where access to follow-up services such as ultrasonography may be problematic.

Thus, the question at the core of current debate around PPIUD remains: to what extent does PPIUD represent a trade-off of convenience and usefulness versus potential complications?[10] More evidence is essential to enable healthcare professionals to counsel their patients and expand contraceptive choices for women in the postpartum period. The present article describes experiences gained from a FIGO initiative to provide PPIUD in 48 facilities across six low- and middle-income countries. Data are included on insertion timing and technique, provider cadre, and subsequent rates of complications at the 6-week postnatal check including infection, expulsion, and lost threads. To the authors' knowledge, this is one of the largest studies in the literature on this subject to date.

2 | MATERIALS AND METHODS

The FIGO PPIUD initiative started in Sri Lanka in July 2013 where six facilities were chosen to take part in a pilot project. Following successful implementation, the initiative expanded in 2015 to a further 12 hospitals in Sri Lanka and six facilities in each of five additional countries: Tanzania, Kenya, Nepal, Bangladesh, and India. The countries were chosen based on contraceptive prevalence, unmet need for contraception, presence of an obstetrics and gynecology national society willing to work with FIGO, and governments that were accepting of PPIUD.

The facilities selected in each country were referral hospitals with over 5000 deliveries per year. Meetings were held with senior clinicians and hospital managers to explain the health benefits of birth spacing and the advantages of PPIUD. Following this, a training-of-trainers model was used to train providers in family planning counselling and PPIUD insertion techniques following vaginal and cesarean deliveries. This involved teaching a core of 12–18 master trainers, who would then go on to repeat the training sessions in their own facilities.

All six countries were given the same training materials, which included a standard set of slides, training videos, and outlines for practical sessions including role plays for counselling and Mama-U models (Laerdal, Stavanger, Norway),[12] with accompanying clinical equipment for insertion of PPIUD. A FIGO minimal training standards document was shared and adhered to by all countries to ensure standardization.

Following correct practice insertions on the Mama-U model, each provider had to perform supervised insertions on a live patient followed by unsupervised successful insertions before being signed off as competent. The thresholds set varied from country to country as skill level and cadres of health staff were different. A unique identifier number allowed their progress to be tracked over the course of the initiative. Facility mentors could then follow up their trainees' achievements over time.

A total of 4904 providers were trained in counselling and insertion over the period studied. Not all of these providers went on to be productive as many were clinical managers not directly providing services. It was nevertheless important to include them to gain support for the initiative. All providers were trained in providing balanced counselling where all available methods of family planning, including PPIUD were discussed. In India, Nepal, and Bangladesh, additional family planning counsellors were employed by the initiative as clinical staff were overloaded and could not spend sufficient time counselling women. These counsellors were employed from the start in India, but midway through the project in Nepal and Bangladesh. Women were counselled prenatally (preferably at multiple clinic encounters), in early labor (if it was felt appropriate), and also immediately postpartum (within 48 hours of birth). Consent for insertion was taken at any of these encounters.

For vaginal deliveries, the insertion technique taught used the 33 cm long, curved Kelly hemostatic forceps (Sklar Surgical Instruments, West Chester, PA, USA) that ensure high fundal insertion. This technique has been well described in the literature.[6,9,10,13–15] Timing of insertion after vaginal delivery was categorized as either postplacental (within 10 minutes of delivery of the placenta) or immediate postpartum (within 48 hours) (Table 1). Insertion after 48 hours was not recommended owing to the known higher risk of complications.[3] Cadre of health staff trained in insertion varied from country to country (Table 2).

Women were asked to return for follow-up at 6 weeks postpartum so that information on adverse effects and complications could be obtained. The majority of women attended at around the 6-week mark as this was the recommended time to return. No cases were excluded from the analysis if they returned before or after 6 weeks. As a result of low face-to-face follow-up rates, telephone follow-ups were also

TABLE 1 Categorization of timing of PPIUD insertion after delivery.

Delivery type	Timing of insertion		
Vaginal	Postplacental	Within 10 min of placental delivery	Insertion conducted using 33 cm long curved Kelly forceps to ensure high fundal placement
	Immediately postpartum	Between 10 min and 48 h after placental delivery	Insertion conducted using 33 cm long curved Kelly forceps to ensure high fundal placement
	After 48 h	48 h after placental delivery	Not recommended owing to increased risks of complications
Cesarean	Intraoperative	Following delivery of placenta	Insertion is under direct vision through the uterine incision. Can be performed manually or using instruments

conducted in all six countries. Those who were followed up by telephone could not have a speculum examination, nor could the same level of detail be ascertained with regard to complaints. However, this was preferable to having no information on outcomes. Missing data are acknowledged in the results tables.

Women delivering in those facilities taking part in the initiative were asked for their consent to take part in a short 15-minute face-to-face structured interview. In those cases where consent was obtained, in-country data collection officers (DCOs) conducted the interview prior to their discharge from hospital following birth.

Healthcare providers seeing women at the 6-week follow-up were asked to fill in a follow-up questionnaire. Data were entered using tablets and stored in a CommCare database (Dimagi, Cambridge, MA, USA). Univariate and multivariate analyses were performed using Stata version 15.0 software (StataCorp LLC, College Station TX, USA). When looking at expulsion rates and missing threads, factors adjusted for were country, cadre of health staff, and method of insertion. It was not possible to adjust by experience of provider; however, as PPIUD services were new in all facilities, if provider experience had affected expulsion rates then this should have been the same across all sites.

An external evaluation of the initiative was conducted by the Harvard School of Public Health over a 1-year period in three of the six countries (Nepal, Tanzania, and six facilities in Sri Lanka). These data are also included in the overall analysis. The questionnaires used were slightly different, as were follow-up rates in the two sets of data. The Harvard questionnaire was longer with more detailed questions about the service provided and included longer follow-up. This analysis only reports outcomes at 6 weeks across both data sets where the questions asked were the same, making it possible to amalgamate and interpret the data. The FIGO PPIUD initiative did not follow up women who had a PPIUD inserted after the 6-week postnatal check.

Data were anonymized and appropriate ethics committee approvals were obtained from the respective country's institutions, as well as from the London School of Hygiene and Tropical Medicine for analysis and publication.

3 | RESULTS

From May 2014 to September 2017, a total of 725 647 deliveries occurred in the 48 facilities participating in the initiative. Following counselling and consent, a total of 36 766 PPIUD insertions were undertaken: 53% performed following vaginal and 47% following cesarean delivery, although this varied from country to country (Fig. 1). A total of 27 395 insertions were performed by doctors, 5695 by nurses, and 2969 by midwives (Fig. 2). In Sri Lanka, all insertions were performed by doctors, whereas in other countries vaginal insertions were also performed by midwives, nurses, and other professionals. In Kenya and Tanzania, the majority of vaginal insertions were performed by midwives. In one facility in India, nurses performed 4326 vaginal insertions, totaling 26% of all insertions done in the country, whereas in the remaining five facilities insertions were conducted by doctors only. In Nepal, skilled birth attendants (classified as "Other") contributed to 19% of insertions. In Bangladesh, although

TABLE 2 Cadres of health staff trained in PPIUD insertion.

Cadre of health staff	Description
Doctor	Includes both junior and senior doctors working on maternity wards. Senior doctors are obstetrics and gynecology specialists and junior doctors are those who have not completed specialist training
Nurse	Includes all staff with a nursing degree working on maternity wards. In this study the vast majority were from India with either a General Nursing and Midwifery course (3 y) or Bachelor in Science Nursing (4 y). There were no Auxiliary Nurse Midwives (1–2 y course)
Midwife	Includes all midwives and nurse-midwives with degrees or diplomas. In this study these were from Tanzania and Kenya. In Kenya, all nurses receive comprehensive midwifery training and were therefore classified as midwives
Clinical Officer	Practicing in Kenya and Tanzania. These are nonphysician healthcare professionals with 3–4 y diplomas who function like doctors and occasionally work on maternity wards. Tanzanian assistant medical officers were also included in this category. These have 2 y additional clinical training to achieve an advanced diploma

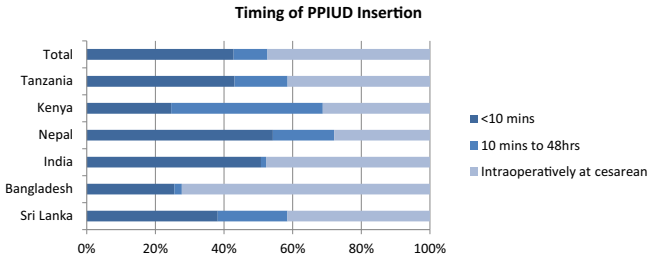

FIGURE 1 Timing of PPIUD insertion across the six countries participating in the initiative. [Colour figure can be viewed at wileyonlinelibrary.com]

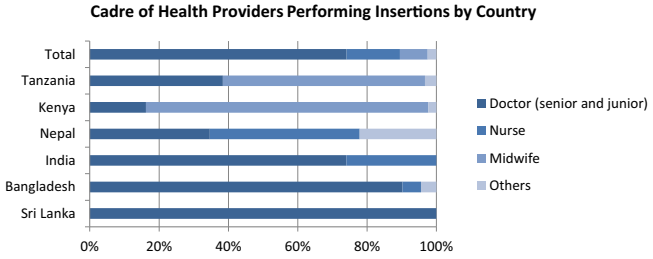

FIGURE 2 Cadre of health provider performing PPIUD insertion by country. [Colour figure can be viewed at wileyonlinelibrary.com]

midwives contributed in some facilities, the vast majority of insertions were performed by doctors. Only 46 insertions were performed by clinical officers, which were also classified as "Other".

Across all six countries, PPIUD was successfully inserted in 98% of cases. When inserted successfully, 97% of these insertions occurred after one single attempt. At vaginal insertion, Kelly forceps were used in 15 499 cases (87%) with 924 insertions occurring manually (5%). Complications during insertion were reported in 134 cases out of a total of 36 697 insertions with data available (Table 3). The most common complication was heavy bleeding at the time of insertion (0.14%). No perforations were recorded.

Women attended follow-up in 52% of cases. Among completed interviews, approximately 49% were followed up by face-to-face interview and 51% were followed up by telephone. Table 4 demonstrates the distribution by type of insertion of women who attended for follow-up compared with those who did not.

Overall outcomes are presented in Table 5. Expulsion rates varied from 1.2% in Tanzania to 4.3% in Kenya. Removal rates also varied from 2.6% in India and Kenya to 8.3% in Tanzania. Overall expulsion and removal rates were 2.6% and 3.7%. The most common complaint was persistent vaginal discharge in 6.9% of cases and the second most common was abdominal pain (4.4%), as outlined in Table 6. Strings were visible in 71% of cases.

Table 7 presents the results of univariate and multivariate analysis of expulsions stratifying by type of insertion (vaginal or cesarean delivery), cadre of inserter, and timing of insertion following vaginal delivery. Following cesarean delivery, after adjusting for country, women were 67% less likely to have an expulsion than following insertion after vaginal delivery (aOR 0.33; 95% CI 0.263–0.406). Looking at the timing of insertion following vaginal delivery, after adjusting for country and method of insertion, expulsion was 41% less likely if it occurred between 10 minutes and 48 hours after placental vaginal delivery as opposed to within 10 minutes of vaginal delivery of the placenta (aOR 0.59; 95% CI 0.002–0.417). Vaginal insertions conducted by nurses were 67% less likely to result in an expulsion when compared with senior doctors after adjusting for country and method of insertion (aOR 0.33; 95% CI 0.216–0.495). There was no difference detected across other cadres.

After adjusting for country and cadre, IUD threads were significantly less likely to be seen following insertion intraoperatively at cesarean delivery (aOR 2.88; 95% CI 2.496–3.316) than following vaginal delivery.

TABLE 3 Information on insertions (n=37 383) across all six countries.

	No.	%
PPIUD successfully inserted		
Yes	36 766	98
No	615	2
(Missing data 2)		
Number of attempts		
Single	35 484	97
Multiple	1194	3
(Missing data 705)		
Method used at vaginal insertion (n=19 786)		
Kelly forceps	15 499	87
Ring forceps	189	1
Manually	924	5
Other	1202	7
Total	17 814	
(Missing data 1972)		
Complications at insertion (multiple responses allowed n=36 697)		
Heavy bleeding	50	0.14
Severe pain	29	0.08
Perforation	0	0.00
Other	11	0.03
No explanation given	49	0.13
Total complications occurring	134	0.37
(Missing data 686)		

TABLE 4 Type of insertion among women who did and did not attend follow-up 6 weeks after PPIUD insertion.

	Attendance at follow-up, %		
Type of insertion	No	Yes	Total
Vaginal			
<10 min	48.9	36.4	42.6
10 min and 48 h	8.3	11.2	9.8
>48 h	0.6	0.6	0.6
Cesarean	42.2	51.8	47.1
No.	18 423	18 960	37 383

TABLE 5 Details of outcomes following PPIUD insertion for each country participating in the initiative.

	Sri Lanka	Bangladesh	India	Nepal	Kenya	Tanzania	All countries
Period of time monitored	1 May 2014 to 30 Sep 2017	7 Nov 2015 to 30 Sep 2017	1 Dec 2015 to 30 Sep 2017	1 Dec 2015 to 30 Sep 2017	24 Sep 2015 to 30 Sep 2017	11 Mar 2016 to 30 Sep 2017	
No. facilities	18	6	6	6	6	6	48
No. deliveries	291 861	87 951	72 195	119 844	72 340	81 456	725 647
No. providers trained	932	1014	914	210	1007	827	4904
No. insertions	8055	5255	16 643	2503	1651	2659	36 766
No. followed up	3375	2829	8786	2091	716	1163	18 960
Follow-up rate, %	42	54	53	84	43	44	52
No. expulsions[a]	66	84	198	80	27	14	469
Expulsion rate, %	2.3	3.3	2.3	3.9	4.3	1.2	2.6
No. removals[b]	121	71	229	150	16	95	682
Removal rate, %	3.7	2.8	2.6	7.4	2.6	8.3	3.7

[a]Missing data in 850 from 18 960 reports collected on expulsion (rates calculated excluding missing data).
[b]Missing data in 526 from 18 960 reports collected on removals (rates calculated excluding missing data).

4 | DISCUSSION

The data collected over the course of this initiative is vast, which strengthens its scientific value. Nevertheless, it is important to recognize some limitations. First, all the facilities involved in the initiative are large referral units of over 5000 births per annum. One must therefore exert caution in generalizing the findings to smaller peripheral hospitals. However, it is interesting to note that from an implementation perspective, the initiative seemed to work best in the smaller referral institutions where initial buy in, as well as training and monitoring were much easier to achieve. One could postulate that it may be easier to roll out in smaller units and achieve more impressive results. A second limitation was that not all women were followed up, and these rates varied from country to country. Analysis of the characteristics of the two groups showed some differences with a slightly higher proportion of women who had a cesarean delivery in the follow-up group (52% vs 42%; $P<0.001$). This is to be expected, as these women would be more likely to attend for postnatal follow-up given their postoperative state. Outcomes at 6 weeks could therefore be skewed toward those expected following insertion after cesarean. Multivariate analysis did demonstrate a lower expulsion rate after insertion at cesarean delivery compared with following vaginal delivery, and this should be taken into account. One could also postulate that women would be more likely to attend for follow-up if they had encountered problems or wanted the IUD removing, which would make complication rates higher in the follow-up than in the lost-to-follow-up group. However, this is the opinion of the authors and cannot be accurately ascertained.

TABLE 6 Follow-up across all six countries (n=18 960).

	No.	%
Adverse effects reported		
Yes	3711	22
No	13 302	78
(no data 1947)		
Adverse effects		
Vaginal discharge	1177	6.9
Abdominal pain	742	4.4
Irregular bleeding	403	2.4
Threads not palpable	437	2.6
Threads coming out of vagina	147	0.9
Pelvic inflammatory disease	12	0.1
Other	292	1.7
Speculum examination (face-to-face only: n=11 326)		
Strings visible	5940	71
Strings not visible	2405	29
(Missing data 2981)		

Despite these limitations, analysis of the data was possible and it is interesting to interpret the results. The data demonstrate that PPIUD is a safe and acceptable form of contraception. Success rates of insertion were 98%, and only 3% required more than one attempt at insertion. There were few recorded complications during insertion, with heavy bleeding at insertion being the main complaint (0.14%). No perforations were recorded. This is to be expected as the immediate postpartum uterus differs greatly from the nonpregnant uterus—which is at known risk of perforation during interval insertion. The large, thick walls of the immediate postpartum uterus make perforation highly unlikely.

The follow-up data suggest that adverse effects were also uncommon. Vaginal discharge and abdominal pain were the most common complaints (6.9% and 4.4%, respectively). Pelvic inflammatory disease (PID) requiring hospital admission and intravenous antibiotics was rare, with only 12 recorded cases (0.1% of total insertions). One out of the six countries had a policy of giving a short course of antibiotics to

TABLE 7 Statistical analysis of PPIUD expulsion and missing thread data.

	Univariate analysis			Multivariate analysis		
	Crude OR	*P*>*z*	95% CI	aOR	*P*>*z*	95% CI
Type of delivery[a]						
Vaginal	1.00			1.00		
Cesarean	0.43	<0.001	0.354–0.525	0.33	<0.001	0.263–0.406
No.	18 110			18 110		
After vaginal delivery[b]						
Timing of insertion						
<10 min	1.00			1.00		
10 min to 48 h	0.67	0.009	0.492–0.903	0.59	0.002	0.417–0.825
Cadre of staff						
Senior doctor	1.00			1.00		
Junior doctor	1.27	0.089	0.964–1.685	0.93	0.654	0.659–1.299
Nurse	0.62	0.007	0.440–0.876	0.33	<0.001	0.216–0.495
Midwife	0.78	0.239	0.516–1.179	0.41	0.164	0.117–1.441
Others	1.52	0.061	0.981–2.365	0.52	0.028	0.295–0.932
No.	8664			8664		
Missing threads[c]						
Type of delivery						
Vaginal	1.00			1.00		
Cesarean	1.30	<0.001	1.181–1.429	2.88	<0.001	2.496–3.316
No.	8345			8345		

[a]Multivariate analysis adjusting for country.
[b]Multivariate analysis adjusting for country and method of insertion.
[c]Multivariate analysis adjusting for cadre and country.

all women who had an IUD inserted, which may also have contributed to the low rates of PID. However, the questionnaire was not well set up for recording mild infections. Complaints of vaginal discharge and abdominal pain could indicate a mild infection and this would not have been picked up in this study.

Interestingly, 147 cases (0.9%) of follow-ups mentioned threads coming out of the vagina as a complaint. Threads were not trimmed at insertion and it was always a concern that this could occur. Women were advised of the potential risk, and were asked to return for the threads to be trimmed if this happened, but it appears also to be a rare complaint. Absence of strings was more common, and was recorded in 29% of cases that were followed up with a speculum examination.

Further statistical analysis demonstrated that missing threads were 2.88 times more common following insertion after cesarean delivery. During cesarean, the provider must make an extra attempt to straighten the threads once insertion has occurred; following vaginal insertion the threads should naturally sit at the cervical os. Although laying threads is the standard protocol at cesarean delivery, it is an extra step, and one that providers might forget. This could explain the difference. All healthcare providers trained in insertion were also provided with information on the benefits of using a thread retriever and the need for ultrasound in cases where it was not possible to confirm the location of the PPIUD. However, in reality, thread retrievers and ultrasound machines were not readily available in many of the facilities involved in the initiative and this needs to be taken into account during future implementation. There may have been a slightly higher rate of invasive procedures such as hysteroscopy to retrieve IUDs with lost threads. However, the data were not set up to analyze this further.

The data also demonstrate that insertion can be safely achieved by a variety of health staff and need not be limited to doctors. Task-sharing to nurses and midwives was safely and effectively performed in all participating countries other than in Sri Lanka. In Sub-Saharan Africa, midwives and nurse-midwives have taken on a variety of additional roles, increasing access to health care that would otherwise have been limited to those fortunate enough to have care provided by doctors.

With low doctor:patient ratios in several countries, task-sharing is an essential strategy ratified by the WHO.[16] In Kenya and Tanzania, midwives performed 94% of all vaginal insertions. Statistical analysis demonstrated that there is no difference in expulsions rates between insertions of PPIUD by senior doctors and midwives and, therefore, this skill can be safely added to their list of competencies. In India, one out of the six facilities was able to expand training to nurses working on maternity wards. The impact in this one institution was dramatic, with a sudden increase in insertion rates as the service became more available to women with normal vaginal deliveries who are often in and out of the facility too rapidly for doctors to intervene.

Analysis also demonstrated that insertions by nurses were less likely to result in expulsion compared with insertions performed by senior doctors. Perhaps their skills with normal vaginal insertions surpass those of the senior doctor. In all countries where other health cadres perform insertions, insertions occur more frequently following vaginal delivery than following cesarean. Doctors are not always available immediately following vaginal deliveries as they are during cesarean, where they tend to be the main providers. Therefore, PPIUD became more accessible to all women.

Expulsion rates and removal rates varied from country to country and our experience monitoring this initiative suggests that removal rates depended on the quality of counselling. Women were less likely to ask to have the IUD removed at follow-up if inclusive and comprehensive counselling had been undertaken prior to insertion. In Nepal this has been a problem throughout the initiative, with removal rates always slightly higher than in the other countries. High volume of patient to staff ratios and reliance on group counselling may explain this. Compared with the other five countries, Nepal trained fewer providers (only 210) owing to restrictions by the government on who could be trained. Another postulated reason is that Nepal has a large migrant population where husbands often work abroad, leaving their wives alone during pregnancy and only returning briefly for the birth of the child. Consequently, they were not present during counselling sessions and often objected to the method once they returned home, particularly given their perception that once they had left their wife to return to work, there was no more need for contraception.

Tanzania also had a high removal rate, but interestingly, a very low expulsion rate. Some removals were reported to have been undertaken due to partial expulsion. Unfortunately, the questionnaire was not robust enough to pick up these subtleties, but it may be that a proportion of the removals were in fact partial expulsions. There was also concern that visualization of the stem of the IUD in the cervical canal may have been erroneously construed as a partial expulsion, resulting in an unnecessary removal.

Overall expulsion rates were much lower than those recorded in the literature. However, expulsion and removal rates are very similar to those published by Pfitzer et al.[2] who also conducted an implementation study across six countries[3] using the same methodology for insertions. There is a general perception that high expulsion rates are a consequence of the inability of the inserter to place the PPIUD high at the uterine fundus. Insertion during cesarean delivery is straightforward given that the inserter has the uterus open and is therefore able to place the PPIUD under direct vision.

During training it was evident that for vaginal insertions, using the Kelly forceps takes skill in ensuring that the PPIUD is correctly positioned. Consequently, during monitoring and evaluation throughout the life of the initiative it was observed that all the countries showed a learning curve when teaching the technique to new trainees. As experience and expertise increased, expulsion rates dropped. When staff moved on and a new batch was trained, expulsion rates would rise again. It is not surprising then that the data demonstrated that expulsion is 67% less likely following insertion during cesarean than following vaginal insertion. Overall, expulsion rates after vaginal delivery were 3.6%, which is similar to the rate of approximately 5% reported following interval insertion.[17] PPIUD should therefore not be limited to women undergoing a cesarean.

Timing of insertion after vaginal delivery also appears to have an impact on expulsion rates. Expulsions were slightly less likely if PPIUD was inserted between 10 minutes of placental delivery and 48 hours rather than within 10 minutes of placental delivery. It may well be that the uterus has had more time for involution at between 10 minutes and 48 hours and have progressively less frequent uterine contractions and blood flow, which may have contributed to a lower chance of expulsion. It may also be easier to correctly place the IUD at the fundus with a more involuted uterus. However, expulsion rates when insertion occurred within 10 minutes of placental delivery are not high enough to warrant that this practice should be replaced by later insertion. A "one-stop" procedure following delivery is more efficient and is likely to be more attractive to women who may be reluctant to return for a second procedure within 48 hours of delivery.

5 | CONCLUSION

The vast data from this initiative of over 36 000 recorded insertions collected across six different countries have demonstrated that PPIUD is a safe and effective method of contraception that can be delivered by a variety of cadres of health staff. Although expulsion rates are lower when inserted intraoperatively at cesarean delivery, they are still low and comparable to interval IUD insertion when inserted within 48 hours of vaginal delivery. Given the immediate benefit of a one-stop approach for women who struggle to return to health facilities after giving birth, governments should consider adopting PPIUD into the mix of contraceptive methods currently offered as a matter of urgency. Given that the copper IUD is cost-effective and readily available, the only extra issue with implementation is training healthcare providers in counselling and insertion, which this initiative has demonstrated to be highly feasible.

AUTHOR CONTRIBUTIONS

AM wrote the manuscript with assistance from NT. Data cleaning, analysis, and presentation were performed by MS and KM. SA planned the initiative and directed implementation together with AM. PM, EO, HD, FP, KT, and GP coordinated activities in their respective countries. All authors reviewed the manuscript before submission. MS worked on the project while employed by FIGO.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

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