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Postpartum Contraception feasibility of providing postpartum family planning counselling and immediate Postpartum Intra Uterine Device (PPIUD) services in low and middle-income countries.

Anita Makins BMedSci, BMBS, MPH, FRCOG

Submitted in fulfilment of the requirement for the degree of Doctor of Philosophy by Published work

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Contents

List of illustrations and tables	4
Acknowledgements	5
Declaration	6
List of published works for consideration	7
Abbreviations	9
Abstract	11
Word Count	13
Background and rationale for this study	14
Theory of change	16
Detailed description of the overall initiative	17
Monitoring & Evaluation (M&E)	20
Description of nested studies	22
Other studies conducted within the initiative but not included in this thesis	23
Summary of Published work	24
Study 1	24
Study 2	25
Study 3	27
Study 4	29
Study 5	31
Study 6	33
Discussion	35
Emerging themes	35
Minimising expulsion rates is key	35
Task sharing as an invaluable resource in expanding access to services	36
The complexities of counselling	38
Cost-effectiveness and financing for sustainability	40
'South to North' learning	42
Limitations	43
Current and Future Research: Challenges and Perspectives	44
Conclusion	46
References	47
Appendices	53
Example of PPIUD data Collection Forms 1 &2	54

Example of Audit of Training on insertion in all 6 countries	
Example of Audit of Structure	73
Example Audit of Process	74
Data Safety Monitoring Boards	75
Bibliography of all published works by A Makins	76
Co-authors' statements of contribution	79
Publications	83

List of illustrations and tables

Figure 1 - Theory of change	Pg 16
Figure 2 – Map showing the countries involved	Pg 17
Figure 3 - Mama-U model	Pg 18
Figure 4 - Kelly's forceps compared to Rampley Sponge holding forceps	Pg 19
Figure 5 - Organogram of PPIUD Monitoring and Evaluation	Pg 21
Figure 6 – Theory of Planned Behaviour	Pg 26
Figure 6 – Distribution of providers performing insertions across six countries	Pg 34
Table 1 – Monitoring & Evaluation	Pg 20
Table 2 - Results of the costing analysis in Bangladesh and Tanzania	Pa 41

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Declaration

This thesis is submitted to the University of Warwick in support of my application for the degree of Doctor of Philosophy. It has been composed by myself and has not been submitted in any previous application for any degree.

List of published works for consideration

Study 1

Anita Makins, Neda Taghinejadi, Maya Sethi, Kazuyo Machiyama, Projestine Munganyizi, Elly Odongo, Hema Divakar, Parveen Fatima, Kusum Thapa, Gamini Perera, Sabaratnam Arulkumaran. FIGO postpartum intrauterine device initiative: complication rates across six countries. Int J Gynecol Obstet 2018; 143 (Suppl. 1): 20–27

Study 2

Anita Makins, Neda Taghinejadi, Maya Sethi, Kazuyo Machiyama, Kusum Thapa, Gamini Perera, Projestine S. Munganyizi, Ajey Bhardwaj, Sabaratnam Arulkumaran. Factors influencing the likelihood of acceptance of postpartum intrauterine devices across four countries: India, Nepal, Sri Lanka, and Tanzania. Int J Gynecol Obstet 2018; 143 (Suppl. 1): 13–19

Study 3

Kusum Thapa, Rolina Dhital, Sameena Rajbhandari, Shreedhar Acharya, Sangeeta Mishra, Sunil Mani Pokhrel, Saroja Pande, Emily-Ann Tunnacliffe, Anita Makins. Factors affecting the behaviour outcomes on post-partum intrauterine contraceptive device uptake and continuation in Nepal: a qualitative study. BMC Pregnancy and Childbirth 2019; 19: 148

Study 4

Kusum Thapa, Rolina Dhital, Sameena Rajbhandari, Sangeeta Mishra, Shanti Subedi, Bhogendra Raj Dotel, Sapana Vaidya, Saroja Pande, Emily-Anne Tunnacliffe, Anita Makins and Sabaratnam Arulkumaran. Improving post-partum family planning services provided by female community health volunteers in Nepal: a mixed methods study. BMC Pregnancy and Childbirth 2020; 20:123

Study 5

Rolina Dhital, Ram Chandra Siwal, Khem Narayan Pokhrel, Sabina Pokhrel, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins. Evaluating the impact of female community health volunteer involvement in a postpartum family planning intervention in Nepal: a mixed-methods study at one-year post-intervention. PLOS ONE. Published October 20, 2021. Available: https://doi.org/10.1371/journal.pone.0258834

Study 6

Anita Makins, Gillian Eva, Judy Gold, Suzanna Bright, Katherine Dean, Emily-Anne Tunnacliffe, Parveen Fatima, Afroja Yesmin, Projestine Muganyizi, Grasiana Kimario, Kim Dalziel. Economic evaluation of provision of PPIUD services in Bangladesh and Tanzania. Global Health: Science and Practice March 2021, 9(1):107-122; https://doi.org/10.9745/GHSP-D-20-00447

Abbreviations

AOR Adjusted Odds Ratio

BTL Bilateral Tubal Ligation

CHV Community Health Volunteers

COREQ Consolidated Criteria for Reporting Qualitative Studies

CYP Couple Years of Protection

DALYs Disability Adjusted Life Years

DCOs Data Collection Officers

FCHVs Female Community Health Volunteers

FGD Focus Group discussions

FIGO International Federation of Gynaecologists and Obstetricians

FSRH Faculty Sexual and Reproductive Health

HMIS Health Management Information Systems

IBM Integrated Behaviour Model

IDIs In-depth interviews

IEC Information, Education, Communication

IUD Intra-Uterine Device

KII Key informant interview

LARCs Long Acting Reversible Contraceptive Methods

LMICs Low and Middle Income Countries

M&E Monitoring and Evaluation

OBGYN Obstetrics & Gynaecology

OGSB Obstetrics & Gynaecology Society of Bangladesh

POP Progesterone only Pill

PPFP Post-Partum Family Planning

PPIUD Post-Partum Intrauterine Device

RCT Randomised Controlled Trial

RCOG Royal College of Obstetricians and Gynaecologists

SDGs Sustainable Development Goals

SLCOG Sri Lankan Society of Obstetrics & Gynaecology

TPB Theory of planned behaviour

TRA Theory of Reasoned Action

Abstract

High levels of unmet need for contraception in low- and middle-income countries (LMICs) are alarming and contribute significantly to maternal and child morbidity and mortality. This thesis describes the implementation of a six-country initiative aimed at setting up services providing postpartum family planning (PPFP) counselling and postpartum intrauterine device (PPIUD) insertion for those consenting across 48 referral hospitals. The countries involved included Nepal, Sri Lanka, India, Bangladesh, Kenya, and Tanzania.

Six published works are included. The first study analysed complications rates from PPIUD across all countries at the six-week postnatal follow up visit. Complications such as infection and perforation were minimal and expulsion rates were similar to when the intrauterine device (IUD) is inserted as an interval method in non-pregnant women (3%). Task shifting to nurses and midwives was safe, with no increase in complications reported. In the second study, analysis of four out of the six countries looked at which factors influenced women's decision to accept the method through quantitative analysis of exit interviews. Repeated counselling in the antenatal period was the only factor that increased uptake across all countries with each country having particular associated factors pertaining to their context.

Uptake of PPIUD was initially very low in Nepal. A third study was designed using qualitative methodology to understand how women made their decisions regarding consenting for PPIUD and which factors influence that choice. Subjective norms were found to have a strong influence. It was suggested that community agents known as Female Community Health Volunteers (FCHVs) could help modify this. Strategies were altered to allow for greater involvement of FCHVs. The fourth study used mixed methods to find that formal training increased FCHV's knowledge, their counselling of women and consequently PPIUD uptake. The fifth study looked at sustainability of this strategy. Using a mixed method approach the study found that after one year FCHVs were able to retain their knowledge and were active in counselling on PPFP/PPIUD albeit to a lesser extent than immediately post intervention.

Following implementation of the initiative through donor funds, the issue of sustainability of services through local governments became increasingly important. Information on cost-effectiveness of PPIUD in LMICs was lacking. The sixth study therefore looked at the cost-effectiveness of services in Bangladesh and Tanzania as well as cost savings to the health

system were these services to be expanded nationally. In both countries, services were highly cost-effective with national rollout saving more funds through aversion of associated morbidity and mortality related to unplanned pregnancies than it would cost to roll out.

In conclusion, the six studies form a cohesive group of research that expands the knowledge on PPFP/PPIUD in LMICs. They demonstrate that implementation of PPFP/PPIUD services was successful, cost-effective and highlighted the importance of: considering contextual realities when devising counselling strategies, using task shifting to increase access and the value of involving community agents. The sustainability of initiatives such as this one and the move to upscaling however remain a challenge.

Word Count

Total word count – 10 455

Background and rationale for this study

The World Health Organisation (WHO) defines the unmet need for family planning as 'those women who are fecund and sexually active but are not using any method of contraception, and report not wanting any more children or wanting to delay the next child.' (1, 2) It is estimated that there are more than 218 million women with an unmet need for contraception and that the vast majority are living in low and middle income countries (LMICs).(3)

In LMICs, access to health can be difficult and it is imperative that women are treated holistically and that the benefit of each health-seeking encounter is maximized through integrated services. Traditionally, contraception has only been offered to women when they attend for their six-week postnatal check, a universally implemented follow up, for women after birth. However, there is a high unmet need for contraception during this period (4) and short inter-pregnancy intervals exacerbate maternal morbidity and mortality as well as resulting in worse neonatal and childhood outcomes. Birth spacing of less than 24 months has been associated with increased rates of: miscarriage, planned abortion, maternal mortality, pre-term labour, small for gestational age babies and increases in malnutrition and mortality in children under the age of five (5, 6). Reducing the unmet need for contraception is one of the 17 Sustainable Development Goals (SDGs) - target 3.7, and advances would also impact targets 3.1 (maternal mortality) and 3.2 (reduce deaths of new-borns and under 5's) (7). Contraception alone is postulated to have the potential to reduce maternal mortality by 30% (8). Counselling on immediate postpartum family planning (PPFP), and subsequent access to long-acting reversible contraceptive methods (LARCs) such as the postpartum intrauterine device (PPIUD), offer women the opportunity to take a reliable break from childbearing. This allows them to look after their own health and that of their children, as well as consider further education and/or supporting the family financially if they choose to. This is turn helps to break the cycle of poverty.

This series of studies looks at the implementation of PPFP/PPIUD services in a variety of maternity settings in LMICs. The studies were conducted as prospective implementation research funded by FIGO's PPIUD Initiative. FIGO is the International Federation of Gynecology and Obstetrics, comprising the national Obstetrics and Gynaecology (OBGYN) societies of 132 countries. It has a vision that 'women of the world achieve the highest possible standards of physical, mental, reproductive and sexual health and wellbeing

throughout their lives' and achieves this through 'advocacy, programmatic activities, capacity strengthening of member societies, education and training' (9).

The author of this thesis was the director of the Initiative and principal investigator of the implementation research undertaken. Funding was generously provided by large anonymous donors. The project was centred on looking at the feasibility and acceptability of setting up postpartum family planning counselling services and postpartum Intra Uterine Device (IUD) insertion services in six different countries: Nepal, Bangladesh, India, Sri Lanka, Tanzania and Kenya. The initiative was set up with a view to contributing to the reduction of the unmet need for contraception in these countries, and hence contribute to the improvement of women's lives. Scientifically robust data collection systems were established from the start in order that results could be accurately documented with the intention of informing local governments and policy globally.

Theory of change

The ultimate aim of the initiative was to contribute to addressing the unmet need for contraception and hence reduce maternal and child morbidity and mortality in the six countries. The theory of change diagram below exemplifies how this would be achieved.

Figure 1 - Theory of change



Reduced maternal mortality Improved perinatal outcomes

Increased modern contraceptive rate better birth spacing

Decreased unintended pregnancies & unsafe abortions

Health system better equipped to provide PPFP/PPIUD services



Leadership and Governance

Capacity building national OBGYN societies to advocate for and provide PPFP services

National and global advocacy

Embedding PPFP in national guidelines and policy

Workforce

Training service providers in PPFP counselling and PPIUD insertion

Including PPFP and PPIUD in pre-service curriculum and training

Promoting task sharing to increase access

Service delivery

Supply - Establishment of balanced PPFP counselling and PPIUD services at facility level

Demand - Involving communities through training community health cadres and supporting production IEC materials

Data

Data feedback loops

Establishing data safety and monitoring boards and regular audit structure and process

 (\mathbf{i})

Inclusion of PPFP indicators in government HMIS systems

IEC - Information, education, communication; HMIS - Health management information systems

This theory of change was adopted across the project and was applicable in all 6 countries. The emphasis placed on each of the four pillars varied from country to country but in all cases implementing change in all 4 areas was essential to success. In Sri Lanka and Bangladesh, establishing SLCOG (Sri Lankan Society of O&G) and OGSB (Obstetrics and Gynaecology Society of Bangladesh) as technical advisors to the government on Women's Health was key to influencing policy, resulting in PPIUD being added to national guidelines on PPFP. In Tanzania and Kenya ensuring midwives were the prime counsellors and inserters of PPIUD allowed the method to become truly accessible at the point of care. In Nepal, involving FCHVs allowed for an increase in demand for PPFP and PPIUD whilst in Kenya influencing national HMIS to include indicators for PPFP/PPIUD paved the way to sustainability.

Detailed description of the overall initiative

The FIGO PPIUD initiative started in Sri Lanka in July 2013. Six facilities were chosen to take part in the pilot project. These were identified by senior Obstetricians & Gynaecologists in the country with the only stipulation being that they were referral hospitals with over 5000 deliveries (i.e., high volume). In 2015 following successful implementation in Sri Lanka, the initiative expanded to a further twelve hospitals in Sri Lanka and into five additional countries: Tanzania, Kenya, Nepal, Bangladesh, and India (see figure 2).

The countries were chosen based on four main parameters:

- relatively low contraceptive prevalence rates
- high unmet need for contraception
- presence of an obstetrics and gynaecology national society affiliated to FIGO
- a government that already provided interval IUD services free of charge



Figure 2 – map showing the countries involved

Senior O&G clinicians were identified as national leads and working together with them, six healthcare facilities providing maternity care were selected in each country. Meetings were

held with senior clinicians and hospital managers to discuss and explain the health benefits of birth spacing and the advantages of PPFP including PPIUD and to ascertain their enthusiasm for the project. Following this, a 'training-of-trainers' model was used to train providers in family planning counselling and PPIUD insertion techniques following vaginal and caesarean births. This involved teaching a core of 12 to 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, outlines for practical sessions including role plays for counselling, Mama-U models for hands on training (Laerdal, Stavanger, Norway), and any extra clinical equipment necessary – curved haemostatic Kelly's Forceps (Sklar Surgical Instruments, West Chester, PA, USA). A FIGO minimal training standards document was developed and shared with all countries. Following correct practice insertions on a Mama-U model (see figure 3), each provider had to perform supervised insertions on a live patient followed by unsupervised successful insertions before being signed off by the trainer as an independent practitioner. The thresholds set varied from country to country as skill level and cadres of health staff were different. Please see the document on 'Audit of training' in the Appendix for further details. A unique identifier number allowed the progress of trainees to be tracked over time. Facility mentors could then follow up their trainees' achievements. Six monthly audits were performed to ensure adherence to the protocols, standardisation and that quality service provision was maintained. The author of this thesis and her team at headquarters also performed regular monitoring and evaluation visits to the facilities in the countries.

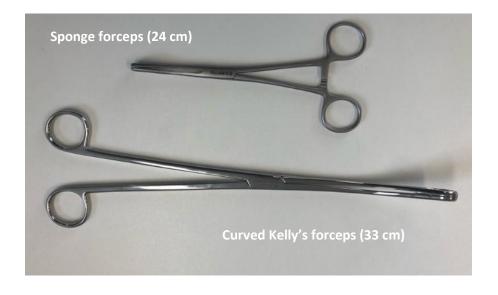
Figure 3 - Mama-U model



All providers were trained in providing comprehensive and balanced counselling where all available methods of family planning, including PPIUD were discussed. Availability of methods varied from country to country. PPIUD was however the only LARC available free of charge by government hospitals across the six countries at the start of the initiative. The implant became available halfway through implementation in a few isolated units in Kenya and Sri Lanka.

Women were counselled in the antenatal period, in early labour or within 48 hours of birth with consent for insertion being taken at any of these encounters. For vaginal deliveries, the insertion technique taught used the 33 cm long, curved Kelly haemostatic forceps (Sklar Surgical Instruments, West Chester, PA, USA). This technique has been well described in the literature (10-15) and ensures a high fundal placement when compared to using other instruments such as the Rampley sponge holding forceps which is much shorter (see figure 4). Insertion after 48 hours was not recommended owing to the known higher risk of complications (16).

Figure 4 - Kelly's forceps compared to Rampley Sponge holding forceps



Monitoring & Evaluation (M&E)

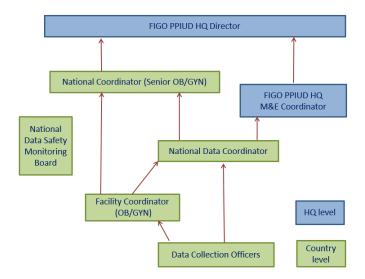
There were many different formats of M&E conducted as outlined in the table below.

Table 1 – PPIUD Initiative M&E activities

Activities	Conducted by	Source	Data collected	Frequency
Core Indicators	Collated by Facility Coordinators, reviewed by National Data Coord, sent to HQ	Hospital	N & type delivery	
			N trainings	
			N Counselled	Quarterly
			N Insertions	
			N Followed up	
Skype calls	HQ director & team	Meeting w country teams	Qualitative - notes on implementation	6 weekly
Quarterly narrative reports	National Coordinator, reviewed at HQ	Core indicators, narrative on implementation	Qualitative	Quarterly
Patient Interviews	DCOs, supervised by country data coordinator, reviewed at HQ	Patient exit interviews and 6 week follow up interviews	Quantitative See Forms 1 & 2 in Appendix	Daily
Audit Structure and Process	National Coordinators & HQ Director	Hospital visits and interviews with Country teams	See Appendix	6 monthly
Audit of training	National Coordinators & HQ Director	Interviewing Country teams & quarterly reports	See Appendix	Annual
Ensuring safety	Country Coordinator, reviewed by in country Data Safety Monitoring Board (DSMB)	Collated Questionnaires and Core indicators	See Appendix	6 monthly
6 country meeting	HQ director and team	All countries	Presentations and group discussion	Every 2 years

Details of the tools used for Patient Interviews, Audit of Strucure and Process, Audit of Training and Data Safety Monitoring Boards are outlined in the Appendix. The organogram overleaf explains the structure and relationship between those involved in the various aspects of M&E of the initiative. Although there were various components at facility, country and HQ level, the director of the initiative and author of this thesis was ultimately responsible. A successful M&E team was built through regular visits to all 6 countries in order that trusting relationships and a solid support system based on open communication was forged. There was also a constant feedback loop and on going communication so that any implementation issues could be addressed in a timely fashion.

Figure 5 - Organogram of PPIUD Monitoring and Evaluation



Papers 1 and 2 used data primarily from the patient interviews. The methodology used is described in more detail below.

Interviews

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. Data collection officers (DCOs) conducted the interview with those women who consented prior to their discharge from hospital following birth. Women were asked to return for follow-up at six weeks postpartum and healthcare providers seeing women at the six-week follow-up were asked to complete a follow-up questionnaire. Data were entered using tablets and stored in a CommCare database (Dimagi, Cambridge, MA, USA). The data were cleaned at country level but also at headquarters once received from the country. We sought support in the statistical analysis from the Department of Infectious Disease Epidemiology at the London School of Hygiene and Tropical Medicine (LSHTM), which was performed using STATA version 15.0 software (StataCorp LLC, College Station TX, USA).

Description of nested studies

As the initiative progressed in each country, it became clear that several new research questions were arising, leading to a need to incorporate further nested studies within the overall project framework.

In Nepal, uptake of the method was not as expected and removal rates were high. Funding was allocated from the overall project budget and in collaboration with the Nepali team, work was undertaken to explore the route cause for this (study 3). Qualitative assessment of 43 in-depth interviews (IDI) with postpartum mothers suggested that subjective norms played an important role in women's decision-making and that the formal involvement of agents of change such as the 'female community health volunteers' (FCHVs) would likely help women have a greater understanding of the benefits of PPFP/PPIUD. Based on this, implementation of the project in Nepal was revised in order to formally incorporate FCHVs. A training package was devised for a group of FCHVs in one province. A mixed methods study was organised to assess their post training knowledge on PPFP, the impact on counselling women and on outcomes in terms of any changes in the uptake of the method (study 4). We also wanted to understand the sustainability of the changes that had been implemented and so went on to look at outcomes one year post intervention (study 5).

There is very little published data on the cost-effectiveness of contraceptive methods in low and middle-income countries, particularly with regards to postpartum methods. This information is crucial for governments when decisions are made regarding resource allocation. It was assumed that PPIUD services would be cost-effective, given the fact that Copper coils are out of patent and widely available in LMICs free of charge, but it was not clear to what extent. An economic evaluation of the initiative was therefore designed in collaboration with the University of Melbourne's School of Population and Global Health. Bangladesh and Tanzania were the countries where the project remained the longest and where this information would influence the long-term sustainability of the services. The analysis was constructed to compare the intervention of PPFP counselling and insertion PPIUD with standard practice in those two countries.

Other studies conducted within the initiative but not included in this thesis

Together with colleagues in Tanzania, three further cohort studies were conducted within the overall PPIUD initiative. The first looked at the outcomes of PPIUD insertions conducted by midwives in the context of task sharing (17). The second was looking at the particular issue of reported prolonged lochia in PPIUD users (18) and the third a long term follow up study looking at outcomes at 1-year post insertion (19).

In Bangladesh, concerns were raised regarding the possible potentiating effect PPIUD may have on women at risk of or suffering with postpartum anaemia. To address concerns, a study was conducted which compared Haemoglobin levels of PPIUD users and non-users at several points over the period of one year postpartum. It showed no significant difference between the two groups (20).

The studies described above were not included in this PhD submission due to word count limitations but are nevertheless related to the subject and allowed for a greater understanding of implementing PPFP/PPIUD services in LMICs.

Summary of Published work

Study 1

Anita Makins, Neda Taghinejadi, Maya Sethi, Kazuyo Machiyama, Projestine Munganyizi, Elly Odongo, Hema Divakar, Parveen Fatima, Kusum Thapa, Gamini Perera, Sabaratnam Arulkumaran. FIGO postpartum intrauterine device initiative: complication rates across six countries. Int J Gynecol Obstet 2018; 143 (Suppl. 1): 20–27

The main objective of this study was to record and analyse complication rates following postpartum intrauterine device insertion in the 48 referral hospitals involved in the six country PPIUD initiative. This included twelve hospitals in Sri Lanka, and six hospitals in each of the other countries: India, Nepal, Bangladesh, Tanzania, and Kenya.

A total of 4904 providers were trained in counselling and insertion of PPIUD via a training-the-trainer model. Outcomes were recorded regarding complications including expulsion, perforation, infection, adverse effects and missing threads. Data were collected on number of PPIUD insertions, method used, cadre of staff involved and timing of insertion. The latter included information on whether the IUD was fitted intra-caesarean section or post vaginal delivery. If post vaginal delivery, further information was gathered on the exact timing: post placental (within 10 minutes of delivery of the placenta) or immediately postpartum (within 48 hours). Data on complications were collected at six-week follow-up and statistical analysis was performed to elucidate factors associated with increased expulsion and absence of threads.

From May 2014 to September 2017, 36,766 PPIUDs were inserted across the 48 hospitals; 53% were following vaginal delivery and 47% intra caesarean section. A total of 27,395 (75%) insertions were performed by doctors, 5695 (15%) by nurses, and 2969 (8%) by midwives and the remainder by others (clinical officers, medical officers). At vaginal insertion, Kelly forceps were used in 15,499 cases (87%) with 924(5%) insertions occurring manually and the remainder using other techniques (Rampley forceps). Success rates of insertion were 98%, with 97% occurring after one single attempt. There were few recorded complications during insertion, with heavy bleeding at insertion being the main complaint (0.14%). No perforations were recorded. Follow-up was attended by 52% of women. Adverse effects were relatively uncommon and reported by 22% of women, with vaginal discharge and abdominal pain 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). Overall, expulsion and removal rates were 2.5% and 3.6% respectively, although there was some variation by country. Threads were not visible in 29% of cases, which was to be expected given the fact that the threads are not cut, and the cervical canal is wide open at insertion.

Univariate and multivariate data analysis was performed. Following caesarean delivery, after adjusting for country, women were 67% less likely to have an expulsion than following insertion after vaginal delivery (adjusted odds ratio (AOR) 0.33; 95% confidence interval (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 (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 caesarean delivery (AOR 2.88; 95% CI 2.496–3.316) than following vaginal delivery.

This study concluded that PPIUD has low complication rates and can be safely inserted by a variety of trained health staff across different LMIC settings. Approximately one third of women had missing threads at six weeks. Recommendations were to use a thread retriever and a pelvic ultrasound if there was uncertainty about expulsion. Although expulsion rates were lower when inserted at caesarean delivery, they are still low and comparable to interval IUD insertion when inserted within 48 hours of vaginal delivery. Given the immediate benefit of the one-stop approach, it was suggested that governments should urgently consider adopting this model to reduce the unmet need for family planning (FP) in the postpartum period and its associated burden of disease.

Study 2

Anita Makins, Neda Taghinejadi, Maya Sethi, Kazuyo Machiyama, Kusum Thapa, Gamini Perera, Projestine S. Munganyizi, Ajey Bhardwaj, Sabaratnam Arulkumaran. Factors influencing the likelihood of acceptance of postpartum intrauterine devices across four countries: India, Nepal, Sri Lanka, and Tanzania. Int J Gynecol Obstet 2018; 143 (Suppl. 1): 13–19

The pilot intervention in Sri Lanka had demonstrated quite varied rates of uptake of PPIUD over time and across geographical regions and it was puzzling as to why that was the case. The objective of this second study was to examine factors that positively influenced the likelihood of accepting PPIUDs across all the countries.

Healthcare providers had been trained in all the facilities in counselling women on PPFP as described previously. In Sri Lanka and Tanzania, all counselling was provided by clinical staff (doctors, nurses, and midwives) working in the chosen facilities. In India and Nepal, counselling on family planning and PPIUD was conducted not only by medical and nursing staff already present, but also by designated counsellors employed by the initiative. These counsellors were not clinically qualified but received two days of training that included information on family planning methods, counselling techniques, and specific information on PPIUD. Women who gave birth in the 24 facilities were asked to take part in a 15-minute face-to-face structured interview conducted by in country data collection officers prior to discharge from hospital. When data were analysed, it was realised that it was not possible to include Bangladesh, Kenya and all 12 facilities in Sri Lanka because they had not achieved exit interview rates of >80%, raising concerns that the sample size would not be truly representative and could be biased. Data were therefore only included from the six facilities in each of four countries: Sri Lanka, Nepal, Tanzania, and India in this analysis. Univariate analysis was performed to investigate factors associated with acceptance of PPIUD. The factors investigated included: age, parity, survival of recent birth, number counselling episodes, and cadre of counsellor.

From January 2016 to November 2017, 6477 health providers were trained, 239,033 deliveries occurred, and 219,242 interviews were conducted, which equated to 92% of all women delivering across the 24 facilities. The median age of women interviewed was 25 years and median parity was two. Of those interviewed, 68% were counselled on family planning generally and 56% knew about PPIUD. Of those counselled, a total of 20% consented to PPIUD although this varied greatly between one country and another with rates ranging from 6% in Sri Lanka, 10% in Nepal, 11% in Tanzania and 34% in India. Sri Lanka was the only country where implants were also part of the method mix on offer to postpartum women and the ease of insertion was favoured by clinicians. Nepali institutions were overstretched and counselling on contraception was a new task to doctors and nurses who were already overburdened with other clinical duties. This was evident through monitoring visits to the hospitals when interviewing the staff on the ground. It seemed that both health care workers as well as the women viewed lay counsellors with suspicion. Further qualitative

studies were organised to better understand the factors at play in Nepal and these are discussed later in the thesis. In sub-Saharan African countries such as Tanzania, rural populations view contraception with suspicion, especially given the high neonatal and infant mortality rates. Adding to this trepidation was the outspoken pro-natalist rhetoric of the president of the time, John Magufuli (21, 22). This may have explained the relatively low counselling rates. India on the other hand benefitted from a government policy that incentivised both health care providers and the women to leave hospital with a form of contraception. India also benefitted from increased staffing levels of counsellors as well as a higher rate of multiple antenatal encounters where contraception was discussed. Multiple counselling sessions was the only factor resulting in higher consent rates (OR 1.30–1.39) across all four countries. Odds ratios for all other factors varied between countries and was greatly dependant on contextual factors.

The paper concluded that consent for contraception, specifically PPIUD, is such a culturally specific topic that generalization across countries is not possible. When planning contraceptive policy changes, including changing or expanding method mix, it is important to understand the sociocultural factors at play in each and every region in order to adapt successfully.

Study 3

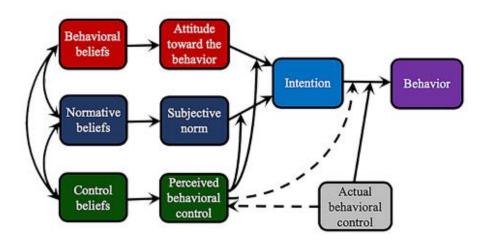
Kusum Thapa, Rolina Dhital, Sameena Rajbhandari, Shreedhar Acharya, Sangeeta Mishra, Sunil Mani Pokhrel, Saroja Pande, Emily-Ann Tunnacliffe, Anita Makins. Factors affecting the behaviour outcomes on post-partum intrauterine contraceptive device uptake and continuation in Nepal: a qualitative study. BMC Pregnancy and Childbirth 2019; 19: 148

Out of the six countries involved in the initiative, Nepal together with Sri Lanka was one of the countries with the lowest uptake of PPIUD, but alongside Tanzania, it also had one of the highest removal rates. It was not entirely clear why that was, but it was concerning as it implied that women were changing their mind about the method between birth and six weeks postnatally. To further investigate this, a research project was planned together with the Nepali team using a qualitative methodology, as the quantitative data collected previously had not clarified the situation. The aim of the research was to explore the factors affecting PPIUD uptake and continuation related behaviours among postpartum mothers within six weeks of childbirth.

Forty-three in-depth interviews (IDIs) were conducted among women who delivered in three selected hospitals in Nepal. Data were analysed through content analysis using the theory of planned behaviour (TPB) as the theoretical framework(23). TPB states that human behaviour is guided by three considerations: behavioural beliefs which create an attitude, normative beliefs creating subjective norms (for example as a result of social pressures) and control beliefs which depends on the women's ability to control her own desired actions(24). See Figure 5.

Figure 6 – Theory of Planned Behaviour

From Michael Bosnjak, Icek Ajzenb, Peter Schmidt. The Theory of Planned Behavior: Selected Recent Advances and Applications. Europe's Journal of Psychology 2020, Vol. 16(3), 352–356 https://doi.org/10.5964/ejop.v16i3.3107



Amongst the theories which attempt to explain health behaviour, TPB seemed to fit the analysis appropriately. The Theory of Reasoned Action (TRA) which precedes TPB lacks the important component of volitional control. When analysing behaviour regarding sexual and reproductive health, in particular regarding choice of contraception, perceived behavioural control plays an important role in shaping behaviour as many women in Nepal do not have reproductive autonomy. The concerns with high removal rates raised the possibility that husbands could be ultimately influencing decision-making and behaviour regarding uptake of PPIUD. The Integrated Behaviour Model (IBM), although more comprehensive, comprises additional components that had been collected separate to our qualitative data and were not part of this analysis (eg. knowledge, environmental constraints). Although breaking down perceived norms into injunctive and descriptive norms would be somewhat beneficial, there were other components such as habit that were not relevant given PPIUD was a new

method. IBM would over complicate interpretation and so TPB was selected as the most relevant theory for analysis of the data.

Many of the women in this study, irrespective of their behavioural outcome expressed a positive attitude towards PPIUD use. This attitude helped in shaping the intention but did not always lead to the behavioural outcome of PPIUD uptake and continuation. Subjective norms such as the family, peer and societal influences had a strong influence against PPIUD, negatively affecting the women's intention and behaviour related to PPIUD. Behaviour control belief also had an important role in the outcome with respect to PPIUD uptake and continuation. Women who had their own control over decisions tended to consent to and use PPIUD. However, for many women, external factors such as husband's views tended to negatively influence outcomes whilst health care providers tended to positively influence outcome.

The study concluded that multiple interlinked factors affected behaviour related to uptake and continuation of PPIUD. The results suggested that a multidimensional approach was necessary to change behaviour. It was also clear that subjective norms played a significant role and that the formal involvement of agents of change such as the 'female community health volunteers' (FCHVs) would likely help women and their husbands have a greater understanding of the benefits of PPFP/PPIUD. Based on this research, implementation of the project in Nepal was revised to incorporate formal training of FCHVs. This became the subject of future research which is further outlined in papers 4 and 5.

Study 4

Kusum Thapa, Rolina Dhital, Sameena Rajbhandari, Sangeeta Mishra, Shanti Subedi, Bhogendra Raj Dotel, Sapana Vaidya, Saroja Pande, Emily-Anne Tunnacliffe, Anita Makins and Sabaratnam Arulkumaran. Improving post-partum family planning services provided by female community health volunteers in Nepal: a mixed methods study. BMC Pregnancy and Childbirth 2020; 20:123

Following the findings from Study 3 demonstrating that subjective norms played an influential role in women's behaviour outcomes related to acceptance of PPIUD, funds were reallocated within the initiative to train FCHVs to counsel on PPFP. It was thought that FCHVs could play an important complementary role to formal health workers in improving the quality of PPFP counselling as well as in the coverage of services. The FCHV program in Nepal

began in 1988 and has been recognized as a pillar of the national health system, forming a vital link between communities and health care services(25). FCHVs are often the first point of contact for women in need of health services at the community level. They are not certified health providers but are women of different educational levels selected within each community to volunteer and promote health. There are over 52,000 FCHVs actively volunteering in Nepal, each reaching around 500 people (25). Although FCHVs do receive some basic training in family planning, Maternal New-born and Child Health (MNCH) and nutrition, it was not clear how much knowledge FCHVs already had regarding PPFP. This study's main aim was to assess the impact of training FCHVs on PPFP.

A mixed-methods study was conducted in Morang District in Nepal. The intervention involved training FCHVs on PPFP counselling and methods. Quantitative data were collected from three sources:

- 1. FCHVs knowledge assessment before and after the intervention;
- 2. FCHVs monthly reporting forms on counselling coverage of women at different stages of pregnancy in the community;
- 3. Interviewing women in their immediate post-partum period in the two selected hospitals to understand the degree of counselling by FCHVs.

To better understand their perception of PPFP and of the intervention, six focus group discussions (FGDs) were conducted with the FCHVs based on five a priori themes generated from the findings of the quantitative data. These included: knowledge on PPFP, perception of PPFP training, activities conducted on PPFP, challenges faced and suggestion for future trainings. The Consolidated Criteria for Reporting Qualitative research (COREQ) was adhered to in conducting, analysing and reporting the FGDs(26). Descriptive and multivariable analyses of the quantitative data and thematic analysis of the qualitative data were performed.

In total, 230 FCHVs participated in the intervention. The median age was 48 years (range 19–70 years), and the median years of working as an FCHV was 21 (range 2 months – 28 years). In total, 45.7% of the FCHVs (n = 105) had primary level education, 33.9% (n = 78) had secondary level education, and 19.1% (n = 44) had no formal education. The majority of the FCHVs (88.3%) had previously received a general orientation on different FP methods, however 73.9% had never received orientation specifically related to PPFP. The study found that their knowledge of PPFP improved significantly from 46.5% answering four or more questions correctly prior to the intervention to 95.2% post intervention. There was a 24-fold

increase in FCHVs ability to correctly answer 4 or more questions (AOR = 24.0, p < 0.001) and the intervention was the only factor significantly associated with their improved knowledge. FCHVs were able to counsel 83.3% of the 1872 mothers at different stages of their pregnancy in the communities. In the two hospitals, the proportion of women in the immediate postpartum period who reported they were counselled by FCHVs during their pregnancy increased from 7% before the intervention to 18.1% (P < 0.001) after the intervention. The qualitative findings from the FGDs suggested that the intervention improved their confidence in providing PPFP counselling.

The conclusion of this study was that the FCHV targeted training improved their knowledge of PPFP and their community-based counselling both in quantity and quality. It was nevertheless felt that follow-up studies were needed to assess the longer-term effect of the FCHV's role in improving community-based PPFP services as well as the sustainability of the intervention, hence the decision to embark on study 5.

Study 5

Rolina Dhital, Ram Chandra Siwal, Khem Narayan Pokhrel, Sabina Pokhrel, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins. Evaluating the impact of female community health volunteer involvement in a postpartum family planning intervention in Nepal: a mixed-methods study at one-year post-intervention. PLOS ONE. Published October 20, 2021. Available: https://doi.org/10.1371/journal.pone.0258834

This study was designed to provide a more long-term perspective by assessing the effect at one-year post-intervention (as described in study 4) where there had been no further support or funding from the original PPIUD initiative.

This was a mixed-methods study conducted in Morang district and included the two major referral hospitals namely, Koshi Zonal Hospital and Nobel Medical College Teaching Hospital and the catchment communities of the 23 peripheral health facilities covered by the FCHVs who received the PPFP orientation in December 2018. The study followed a sequential explanatory method where the qualitative approach intended to provide insights into the quantitative approach. The COREQ was used to collect, analyse, and report the qualitative findings(27). Qualitative data were collected through four FGDs with FCHVs involved in the intervention using the same format as before, and six new Key Informant Interviews (KII) with health care providers. A new checklist was developed for the KII, which was similar to

that used in the FGDs. The quantitative data collected were the same as used in study 4 to enable direct comparisons to be made. These included:

- 1. FCHVs knowledge assessment before and after the intervention;
- 2. FCHVs monthly reporting forms on counselling coverage of women at different stages of pregnancy in the community;
- 3. Interviewing mothers in their immediate post-partum period in the two selected hospitals to understand the degree of counselling by FCHVs.

We performed thematic analysis for qualitative data and descriptive and multivariate analyses for the quantitative data.

In total, 206 of the original 230 FCHVs trained, participated in the one-year post-intervention study. The proportion of FCHVs answering the questions correctly at one-year postintervention remained significantly higher than pre-intervention for all five questions. However, the percentage of FCHVs answering overall four or more questions correctly at one-year post-intervention had decreased from 95.6% to 90.3% (a drop of 5.5%) compared to immediately post-test. In the adjusted model, a 25-fold increase in FCHV knowledge had been observed at the immediate post-test (AOR = 25.4, CI 12.6-50.2, P<0.001) whilst at oneyear post intervention it remained 11-fold higher (AOR = 10.7, CI 6.3-18.1, P<0.001) as compared to pre-intervention. This implied some loss of knowledge over the year and the need for refresher courses to be undertaken. The FCHVs had counselled 71% of the pregnant women (n = 538) within their communities at one-year post-intervention compared to 83% in the previous study. The postpartum mothers interviewed had two times higher odds of being counselled by FCHVs during their pregnancy at one-year post-intervention (AOR = 1.8, P = 0.039) and three times higher in the previous study (AOR = 2.9, P < 0.001) than in preintervention phase. The qualitative findings suggested a positive impression regarding the FCHV's involvement in PPFP counselling in the communities, however, supervision and monitoring over a longer-term was identified as a key challenge.

It was concluded that overall, the intervention had been successful in training FCHVs to counsel women on PPFP/PPIUD and that there was a sustained effect over one year in terms of knowledge, engagement and coverage. However, there was some decline in its effect over time. The recommendation to the local government was to better engage district community health service managers in supporting FCHVs to do their work and to organise yearly refresher training to keep knowledge up to date and momentum, sustaining the excellent progress this far.

Study 6

Anita Makins, Gillian Eva, Judy Gold, Suzanna Bright, Katherine Dean, Emily-Anne Tunnacliffe, Parveen Fatima, Afroja Yesmin, Projestine Muganyizi, Grasiana Kmario, Kim Dalziel. Economic evaluation of provision of PPIUD services in Bangladesh and Tanzania. Global Health: Science and Practice March 2021, 9(1):107-122; https://doi.org/10.9745/GHSP-D-20-00447

Given the paucity of information in the literature regarding cost-effectiveness of PPFP/PPIUD services in LMICs and the concerns with sustainability of the initiative once donor funds ended, the decision was made to dedicate time and resources to this end. The aim of this sixth study was therefore to assess the cost-effectiveness of the PPFP/PPIUD services provided through the initiative compared with standard practice in two of the six countries, namely Bangladesh and Tanzania.

A decision analysis was constructed to compare the PPIUD program with standard practice, which was no PPFP counselling or service provision in the immediate postpartum period. The period was January 2015 to June 2018. In Bangladesh, 28 dedicated postpartum contraceptive counsellors received training on counselling and 1160 doctors were trained in PPIUD counselling and insertion. In Tanzania, 1515 nurse-midwives received counselling training and 1113 nurse-midwives and doctors received PPIUD insertion training. The analysis was based on the number of PPIUD insertions achieved across the six facilities in each country. These were then modelled using the Impact 2 tool to produce estimates of cost per couple years of protection (CYP) and cost per disability-adjusted life years (DALYs) averted. A micro-costing approach was used to estimate the costs of conducting the program, and the Impact 2 tool generated downstream cost savings. Results were presented first for the program as evaluated, and second based on a hypothetical national scale-up scenario. One-way sensitivity analyses were conducted.

Compared to standard practice, the PPIUD program resulted in an incremental cost-effectiveness ratio (ICER) of US\$14.60 per CYP and US\$91.13 per DALY averted in Bangladesh, and US\$54.57 per CYP and US\$67.67 per DALY averted in Tanzania. When incorporating estimated direct health care costs saved, the results for Bangladesh were dominant. This meant that PPIUD was cheaper and more effective when compared to standard practice. For Tanzania, the PPIUD initiative was highly cost-effective, with the ICER estimated at US\$15.20 per CYP and US\$18.90 per DALY averted when comparing to standard practice. For the

national scale-up model, the results were dominant in both countries. This meant that in both countries, were the initiative to be scaled up to a national level, both governments would save more money than they would spend. In Bangladesh, the main cost driver was staff at the facilities and the estimated cost of national scale up was US\$ 1,979,140 with estimated savings through averted morbidity and mortality of US\$ 2,648,284. In Tanzania, the main cost driver was training, with estimated costs of US\$ 6,910,494 and estimated savings through averted morbidity and mortality of US\$ 7,954,649.

In conclusion, the PPIUD initiative was highly cost-effective in Bangladesh and Tanzania, and national scale up of PPIUD could produce long-term savings in direct health care costs in both countries. These analyses provide a compelling case for national governments and international donors to invest in PPFP/PPIUD as part of their family planning strategies to reduce the unmet need for contraception.

Discussion

Emerging themes

Minimising expulsion rates is key

Although it is clear that providing PPFP counselling and PPIUD insertion services is advantageous in terms of effectivity, reversibility and convenience, there had been great variation in terms of quoted complications reported following insertion. While rates of infection and perforation following insertion had been reported as consistently low(11), the authors of the 2015 Cochrane review on 'Immediate postpartum insertion of intrauterine device for contraception,' called for more research assessing expulsion rates(10). In the literature, these had varied from under 2% (15) to over 25% (28, 29). This is likely to be the case because there is also little consensus concerning the best method of postpartum IUD insertion. The methodology of vaginal insertion is likely to impact on outcomes, as the IUD will be left in varying positions in the uterus. These can vary from using the Rampley Sponge Holding forceps (24 cm long), the Kelly's forceps (33cm long), dedicated postpartum inserters(30) or simply manually. We trained clinicians in a consistent method, which involved using the Kelly's forceps to ensure a high fundal placement. 87% of insertions were conducted this way. This study was the largest in the literature known to date and although we had a relatively low overall follow-up rate of 52%, we were still able to follow up 18,960 women, which demonstrated a 2.6% expulsion and 3.7% removal rate overall. Post vaginal insertion expulsion rates were 3.6%. This is close to the overall accepted expulsion rate for interval IUDs of 5%(31) and similar to those published by Pfitzer et al(32) who also conducted a study in low income countries using the Kelly's method.

Threads were absent in nearly one third of women (29%) at six weeks. This was not unexpected, as the threads are not trimmed at insertion, as would be the case with interval IUD insertion. It is said that once menstruation commences, the incidence of lost threads is reduced to 15% (personal communications: Sharon Cameron). The advice given to clinicians was to use a thread retriever or cytobrush to ensure the IUD was in situ and subsequently bring the threads down and/or offer an ultrasound. This may be problematic in LMICs given reduced availability and costs. Unfortunately, the data were not sufficient to reliably inform on the outcomes regarding lost threads at six weeks. This would be a subject for further research. Since the start of the initiative, a dedicated postpartum inserter has been

developed and commercialised for PPIUD insertion. A randomised controlled trial (RCT) comparing Kelly's insertion versus using the dedicated inserter showed little difference in outcomes between the two techniques.(33) High fundal placement was similar between the groups, and although the incidence of lost threads was less common in the dedicated inserter group (13.1% vs 22.4% p=0.04). A likely consequence of this was that more partial expulsions (10.8% vs 5.0%) and removals (1.7% vs 0) were seen. The considerable disadvantage with this technique is the need for earlier follow up to trim the long threads, negating the initial advantage of a one-stop procedure.

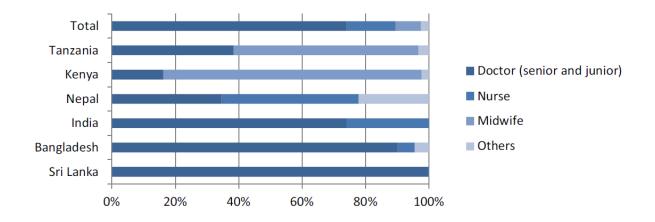
Study 1 demonstrated clearly that the Kelly's method is a feasible and acceptable methodology for postpartum insertion of the device and results in few complication rates. This is key in low resource settings where women face substantial barriers in returning for follow-up care and where access to a 'one stop' procedure resulting in long-term reliable reversible contraception is highly advantageous.

Task sharing as an invaluable resource in expanding access to services

Task sharing is defined as 'enabling additional cadres of health workers to provide health services through competency-based training' and has since been endorsed by the WHO as a strategy to improve access to family planning and contraception(34). It is an important and valuable policy and has been employed extensively in many LMICs in order to increase access to health (35, 36). Across the six countries in this study, the cadre of staff involved in both counselling and insertion of PPIUD varied greatly. Doctors, nurses, and midwives traditionally perform counselling tasks. Study 2 tried to capture quantitatively whether counselling was more effective when conducted by a particular cadre of health staff. This proved not to be the case but rather depended on the context in each country. To maximise access and improve the quality of PPFP counselling, other cadres of staff were employed in some of the countries in the initiative. In Kenya, it was important that women should be counselled together with their partners to allow both parties to reach consensus on decisions regarding contraception. Interviews on the ground had suggested that removal rates were high because partners who did not know about PPIUD were demanding it be removed at the six-week check. It was difficult to achieve couple counselling during antenatal consultations and so engaging community health volunteers in home based counselling was employed and proved to be a highly successful strategy(37). Similarly, in India and Bangladesh lay family planning counsellors were involved in counselling the women before they saw the doctors and midwives during antenatal consultations. These tended to be women who already had children and hence experience childbearing and so could empathise with the pregnant ladies regarding family planning. These counsellors already existed in India but the strategy was adopted very successfully for the first time in Bangladesh (38) as part of the south-to-south learning brought about by the initiative. Study 3 demonstrated the need for community involvement and studies 4 and 5 showed convincingly that FCHVs could fill this role, complementing the information that women were receiving at the hospital from the doctors and midwives.

Insertion of PPIUD was also a skill which could be task shared amongst different cadres of health. Traditionally this would be a task undertaken by doctors, but for many of the countries in the initiative it was also performed by nurses, midwives and clinical officers as demonstrated in the figure 6 below.

Figure 76 – Distribution of providers performing insertions across the six countries



Study 1 demonstrated that nurses and midwives were able to perform insertions successfully and that their complication rates were not significantly different from that of doctors. In fact, nurses were found to have significantly lower expulsion rates when compared to senior doctors (AOR 0.33 (CI 0.216–0.495)). The majority of nurses in the group came from Kalyani hospital in West Bengal, India – a busy district general hospital with over 7000 deliveries a year. When the decision was made to train the nurses to insert PPIUD, the method uptake increased dramatically as it became accessible to women having normal vaginal deliveries

who would otherwise never come into contact with a doctors trained in the technique (39). The nurses in turn became incredibly skilled at the procedure, hence resulting in very low expulsion rates. This was replicated in Kenya (40) and Tanzania (17), where midwives performed 94% of all vaginal insertions with few complications, with doctors doing few vaginal but many more caesarean insertions. Bangladesh was just training its first batch of midwives when the initiative was close to completion. We ceased the opportunity to train these midwives in counselling and insertion in order that they could provide these services once they started practicing.

Our studies demonstrated emphatically that task sharing of counselling in PPFP and insertion of PPIUD was a safe and highly successful strategy, which resulted in services being much more accessible to women attending the 48 hospitals included in the initiative.

The complexities of counselling

Paper 2 demonstrated quite convincingly that there is a need for deep local cultural understanding when it comes to setting policies for counselling on contraception. We explored various factors which we thought may influence a woman's choice regarding choosing PPIUD including: age, parity, number of children alive, cadre of staff doing the counselling and number of times counselling occurred. Only the latter consistently increased uptake of the method across the four countries analysed (OR 1.3 in India to 1.39 in Nepal and Tanzania). When multiple encounters for counselling are offered women are able to bring their husbands and close relatives to hear about the benefits of contraception, consequently the decision is accepted by all. This is crucial in cultures where women do not make their own reproductive health choices or where education or religion means that contraception is not well understood or accepted. In one of the Indian facilities, a radical decision was taken where prior to insertion of PPIUD, the health care providers requested written consent from the women, her partner and her mother-in-law to protect the health care workers from being physically attacked by disgruntled partners finding out postnatally that their wives had had PPIUD inserted without their knowledge.

With antenatal clinics under so much pressure in many LMICs, countries such as India and Bangladesh (38) benefitted greatly from the addition of lay family planning counsellors. It meant women had more time to discuss contraception with a woman who had experienced both childbirth and decisions regarding family planning, and who had more time available

than the doctors and nurses. Myths such as migration of the coil around the human body and the inability to be buried as a Muslim with an IUD in situ could be discussed at length. At the start of the initiative, Nepal also employed family planning counsellors in the hospitals but this strategy was not successful in this country and studies 3, 4 and 5 demonstrated that FCHVs, who were existing respected community members already knowledgeable about health, were crucial to women's decision making. Once incorporated into the initiative they played a vital role in increasing uptake. Kenya was also a country where involving community health volunteers (CHVs) proved to be vital. In Kenya they were often male CHVs and initiated 'couple' family planning counselling in the community, enabling partners to become involved in the decision making (37) which made uptake more likely and removal of the device at 6 weeks less likely.

Financial incentives also play a role. India had the highest uptake of PPIUD (34%), and it is likely that a government financial incentive for the woman, the community health worker and the health care provider will have influenced this (41). The Bangladeshi government also had incentives, but their administrative systems were so cumbersome that it rarely translated to the recipient receiving any significant funds in a timely fashion, negating its influence on behaviour.

Another likely influencer was the contraceptive method of choice available. PPIUD was often the only contraceptive method on offer other than tubal ligation at caesarean section, which is a permanent procedure. In Sri Lanka however hormonal implants became available free of charge at government facilities during the initiative, expanding method choice (42). The fact that implant insertion did not require an intimate examination, made it particularly popular with providers and women, lowering PPIUD insertion rates. In an ideal world, other methods would be provided on discharge from hospital free of charge, including the progesterone-only-pill (POP), Medroxyprogesterone Acetate (MPA), and even the implant and hormonal IUD, in order that women could select their preferred choice. The latter two are currently prohibitively expensive for widespread LMIC distribution.

Politics can also play a role in uptake. In Sri Lanka, the initiative became embroiled in the known ethnic tension issues in country where some believed that contraception was being used to limit the size of certain populations and was being used as a political tool. This impacted greatly on uptake of any form of contraception including PPIUD over a considerable period of time. Similarly, in Tanzania, even though the Ministry of Health (MoH) supported the initiative, the late president John Magufuli had a strong pro-natalist rhetoric, which

meant that health care workers became reluctant to discuss contraception with women in the event of being perceived as anti-government. In extremely poor rural areas in LMICs, having many children can mean relative wealth in the sense that there will be more help to plough the fields of those dependant on subsistence farming for survival. This attitude is compounded when infant and under five mortality rates are high as the relative proportion of surviving children will be lower.

In conclusion, counselling and acceptance of contraception is highly complex and multifaceted and requires thoughtful culturally appropriate interventions and policies.

Cost-effectiveness and financing for sustainability

In low- and middle-income countries health commodities such as contraceptives are scarce, particularly those provided centrally by the government which are free of charge. Universal Health Coverage has been a particular focus of the WHO recently and is the focus of SDG target 3.8(43). Recent global efforts have focused on expanding family planning access, including PPFP, through programs such as FP2020, now transitioning to FP2030(44). However, the funding landscape has been particularly volatile in the last decade with many High Income Country (HIC) governments cutting funding and/or shifting their attention to pressing issues such as the COVID-19 pandemic(45). With uncertainty in the continuity of donor funding, LMICs would be wise to move towards financially sustaining their own health services particularly in provision of contraception, an essential commodity on the road to women's empowerment and a cornerstone to promoting development. However, there is very little published data on the cost-effectiveness of contraceptive methods in LMICs, in particular regarding postpartum methods. Analyses in HIC have demonstrated that LARC methods are more cost-effective than short acting methods (46, 47) and that PPIUD insertion is cost-effective when compared to routine interval insertion (48). There is also one study which compares the costs of PPIUD and implants in Rwanda(49). This study demonstrated that PPIUD was more cost-effective than implants with costs per CYP quoted as \$6 per PPIUD compared to \$21 per postpartum implant. This is to be expected given the much higher cost of the commodity itself.

Large international initiatives are beneficial when they are in country but there is always a question surrounding sustainability and conducting an economic evaluation of the initiative was crucial to understanding feasibility regarding sustainability. Unfortunately, it was not

possible to do this in all six countries due to timing and logistics and so two countries were selected out of the six, namely Bangladesh and Tanzania. The project had run in these two countries for the longest and this information was considered pivotal to informing future resource allocation decisions and policy changes for governments and donors.

Study 6 provided compelling evidence that financing PPFP and PPIUD services would be an extremely beneficial policy and result in substantial savings in the long term if rolled out at a national level. To achieve this, both governments would need to make relatively large funds available upfront to reap future benefits going forward. For Bangladesh it was estimated that national expansion would cost USD 1,979,140 and for Tanzania USD 6,910,494.

Table 2 - Results of the costing analysis in Bangladesh and Tanzania (50)

	Bang	ladesh	Tanzania		
	PPIUD Initiative	National Scale-Up Model	PPIUD Initiative	National Scale-Up Model	
Program design					
Number of facilities ^a	6	36	6	28	
Setup period, months	4	4	4	4	
Implementation period, months	36	36	27	36	
Number of PPIUDs inserted	8,031	26,507	7,448	43,928	
Costing analysis					
Estimated total cost	US\$539,285	US\$1,979,140	US\$1,869,507	US\$6,910,494	
Estimated cost of direct PPIUD service provision ^b	US\$1.71	US\$1.71	US\$2.05	US\$2.05	
Cost per facility per year	US\$27,986	US\$17,373	US\$130,697	US\$79,223	
Main cost driver	Facility staff ^c (58% total cost)	Facility staff ^c (53% total cost)	Training (76% total cost)	Training (80% total cost)	
Estimated direct health care costs saved (Impact 2)	US\$802,368	US\$2,648,284	US\$1,348,744	US\$7,954,649	
Estimated total costs after including estimated health care costs saved (Impact 2)	-US\$263,083	-US\$669,144	US\$520,763	-US\$1,044,156	

With the relative defunding of several sexual and reproductive health programs in the recent past for reasons already discussed, funding unfortunately remains a problem. Yet the argument for reducing the unmet need for contraception is a compelling one given the overall improvement in development that it would likely result in. The recent concerns with Climate Change also link up directly with contraception. It is postulated that slower population growth could reduce carbon emissions globally by 40% or more in the long term (51). Investing in services which provide counselling on contraception and provision of methods is essential for addressing climate change and to promote development in LMICs (52). Perhaps this argument is more persuasive than that of fulfilling women's sexual and reproductive rights globally.

'South to North' learning

The term 'south to north' learning refers to what could also be described as 'reverse innovation,' where lessons learnt in LMICs predominantly in the southern hemisphere benefit populations in HICs generally in the northern hemisphere (53). The PPIUD initiative is an example of this. In a country such as the UK it is estimated that one third of pregnancies are unplanned,(54) with one study demonstrating that 1 in 13 women presenting for abortion or childbirth in a UK health board had conceived within 1 year of birth(55). It is likely that provision of PPFP would result in reduction in abortions and the known morbidities associated with unplanned pregnancies. During the PPIUD initiative, several NHS Trusts interested in offering PPFP/PPIUD made contact to learn from the trials and tribulations of our implementation. One UK Professor visited the initiative in Sri Lanka to understand how it was running and then replicated it in Lothian NHS Trust through a research grant. However, within the NHS, contraception is confined to sexual health departments and primary care trusts. Providing holistic, integrated maternity care, which includes contraception, is actually very difficult to achieve out of the research context within the NHS. Both the Royal College Of Obstetricians and Gynaecologists (RCOG) (56) and the Faculty Reproductive Health (FSRH) (57) released documents outlining the benefits of providing postpartum contraception but it was the COVID-19 pandemic which allowed for pivotal changes to occur(58). Access to contraception during lockdowns became limited and this meant that administrative processes and systems were put aside to make room for pragmatic solutions that could change practice in a short space of time. This was the case in Oxford University Hospitals NHS Trust, where within one month a reliable PPFP service was set up resulting in 40% of postpartum women leaving the unit with some form of contraception. Currently we are able to provide the POP, MPA subcutaneous and intramuscular, Implants and PPIUD (hormonal and copper) after both vaginal and caesarean section deliveries. Many of the implementation strategies used were a direct result of lessons learnt from the PPIUD initiative and its impact in LMICs.

Limitations

The original research work did not lend itself to a RCT methodology, which is considered the gold standard for evidence-based medicine due to the reduced chances of confounding factors influencing results. Instead, it was conducted as implementation research (59) using appropriate methodologies including quantitative observational, qualitative and mixed methods in order to best inform public health policy and practice. The use of multiple disciplines was necessary to enable cohesive partnerships to develop between communities, health care providers, policy makers, donors and governments. All countries had steering committees, which included members of all the mentioned groups to ensure agreement and iterative feedback loops in country. These were imperative for its success with a degree of flexibility necessary to complete the research, despite wars, changes in government, natural disasters and the recent global pandemic. This context needs to be considered when reviewing the papers and interpreting results.

Loss to follow up was high and impacted particularly on study 1. Most of the hospitals involved in the studies were large referral units where rural poor women would have travelled many hundreds of kilometres to reach health care provision. This means that follow-up once the woman had been discharged home could be quite challenging particularly when offering face-to-face appointments to a well woman with a new-born to care for. To ensure there was no statistical bias, comparisons were made between those who were followed up and those who were lost to follow-up to ensure there was no inherent bias in the group that could be accessed.

Study 1 was an observational study that analysed complication rates over time. The importance of task sharing and the differences in approach to task sharing by country were not obvious from the outset. With time it became clear that some ministries of health did not believe that task sharing of PPIUD insertion was a safe approach and neither that the technique would be sufficiently mastered to avoid an increase in complications such as expulsions. It became paramount to perform a secondary analysis of the data looking at expulsion rates by cadre of inserter (table 7). In hindsight, ideally a power calculation would have been performed in order to ensure the data we had collected had sufficient numbers for a correct interpretation of the results. Our finding that nurses had lower expulsion rates than senior doctors still holds as we achieved statistical significance and our confidence intervals are narrow. This is also makes sense from what we know from implementation

where the nurses in India were inserting high numbers, becoming experts at the technique. However, when interpreting the results for midwives it may be that the study was underpowered and the numbers were too small to detect a significant difference as the CI is wide - 0.117 to 1.441 resulting in a type II error. This is one of the limitations when adding in secondary analyses which were not there from the outset.

The context across the six countries were very different, each with their own particularities with regards to socio-cultural, economic, political, and religious realities. This mattered enormously when dealing with such a sensitive and complex issue such as contraception and so interpretation of results was made with this in mind, and generalisability was limited. Tacit knowledge was used but acknowledged, and a mixed method approach was a useful way of ensuring all aspects were appropriately assessed.

In hindsight, more detailed outcome data should have been collected on acceptance of other methods of contraception other than PPIUD in the postpartum period as well as more long-term follow-up. It became clear as the initiative progressed that the benefits of PPFP counselling were much more widespread than just the uptake of PPIUD at 6 weeks, which was our main outcome measure. Further studies not included in this thesis addressed longer-term outcomes (19), but it was not possible to assess impact on the uptake of other methods at different points in time.

Regarding study 5, estimating effectiveness of FCHV involvement on uptake and continuation of PPIUD would have been more accurately demonstrated with a cluster-randomised trial. A number of hospitals and their catchment areas could have been selected and randomly allocated to two groups — one group with FCHV involvement and one without. Both groups could have been followed up over the same time period in order to understand differences. This would have better ensured that there were no biases related to accompanying one group over two different time periods.

Current and Future Research: Challenges and Perspectives

This series of papers have demonstrated that implementation of a policy that facilitates context specific postpartum family counselling followed by accessible PPIUD services can be a highly successful and cost-effective strategy to reducing the unmet need for contraception in LMICs. Feasibility of implementation, evidence regarding low rates of complications

including expulsion, nuances regarding suitable counselling strategies and the safety of task shifting are invaluable contributions to the evidence base and existing literature.

However, some issues remain unanswered. One of the possible side effects described regarding use of the Copper IUD has been a prolongation of menstruation in the number of days but also in quantity of flow. Although a causational association with anaemia has not been found it is concerning when instituting a widespread policy of PPIUD counselling and insertion without prior confirmation of Haemoglobin levels. We therefore embarked on a study looking at anaemia in PPIUD users in Bangladesh and found there was no association with anaemia after 9 months to 1 year follow up(20). Given that fully breast-feeding women are amenorrhoeic for 6 months, their iron loss will only commence once they are menstruating after 6 months. Further research looking into longer periods such as 2 to 3 years postpartum is advisable.

The hormonal IUD is advantageous over the Copper IUD in the sense that it was devised to induce either amenorrhoea or a significant reduction in menstruation (60, 61). For women suffering with anaemia this could be the preferred option of PPIUD. However, the high cost of the device has been prohibitive with only a hand full of donor lead initiatives resulting in its use as an interval device in LMICs. Prices are dropping with the recent loss of patent. Future research should focus on its use as an immediate postpartum method in LMICs, particularly in countries with high rates of anaemia such as we found in Bangladesh.

Conclusion

This series of studies has demonstrated that PPFP counselling and PPIUD insertion is safe and cost-effective. Furthermore, they demonstrate that implementation is feasible and that strategies such as task shifting, contextual awareness and community involvement are essential to its success. Implementation and national scale up would likely result in enormous gains not only for individual women and children but also in terms of economic development for LMICs. Interestingly, the sharing of 'South to North' experiences has also demonstrated that the lessons learnt are not only applicable to LMICs but rather have a much broader global application including in high income countries.

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Appendices

FORM 1

National Coordinator: Deputy National Coordinator:	
Registration	
Record the following place and date information	
1. Facility Number (Enter '1' to '6' based on hospital codes below):	
01. Bangabandhu Sheikh Mujib Medical University	
02. Dhaka Medical College Hospital	
03. Shaheed Suhrawardy Medical College Hospital	
04. Chittagong Medical College Hospital	
05. Sylhet MAG Osmani Medical College Hospital	
06. Khulna Medical College Hospital	
2. DCO Identification Number (Enter 01-04):	
3. Date of interview (YYYY-MM-DD):	
4. Interview number – 2 digits describing the number of the interview that the	
enumerator is completing for that particular day. For example, if the respondent is	
fifth person being interviewed by that particular enumerator that day, the interview number is '05'.	V
	ام
The respondent ID number is a 13-digit number that is created by joining the 6 numeric responses recorded above in order, from response 1 to response 7. An example of a	dI
complete respondent ID number is given below.	
complete respondent is number is given selecti.	
Example: For the 13 th woman who is interviewed by DCO/Counsellor '02' at Shaheed	
Suhrawardy Medical College Hospital (hospital number '03') on 21st October (month '10) in
the year of 2017 (year '17'), the respondent ID number will be created as:	
3 0 2 2 0 1 7 1 0 2 1 1 3	
DESDONDENT ID NUMBED:	

Enter assigned number above proceeding to Introduction.

Hello. My name is	and I am from the Obstetrical and Gynecological
Society of Bangladesh . We are inte	erested in trying to understand the experience of women
who have recently given birth. We	would like to ask you some questions regarding your
experience with the services you ha	ave received in order to improve them. Please rest
assured that all information you pr	ovide will be kept confidential and will have no bearing
on the provision of healthcare that	you are entitled to.

DETERMINING ELIGIBILITY

No.	Question	Response	Skip Rules
1	Are you happy for us to ask you some	YES NO	IF NO, END VISIT
	questions about your experience? May I continue?		IF YES, GO TO 2
2	Have you recently given birth and do you live	YES NO	IF NO, END VISIT
	in Bangladesh?		IF YES, GO TO
			FORM 1 PART A
3	Full Name of Woman:		
	First Name		
	Family Name		
END	Thank you for your time. I have that you		END VISIT.
EIND	Thank you for your time. I hope that you have a good day.		EIND VISIT.

Form 1

IMMEDIATE POSTPARTUM IUD INSERTION

(To be completed for all mothers who deliver in the hospital)

Part A

Identification Details

To be filled by DCO when the woman is in the post-delivery recovery ward Use woman's pregnancy record to check answers if possible

Res	por	ident Identification Number:
1.	Fi	rst name of the woman: 2. Family name of the woman:
3.	Re	gistration Admission/Hospital Registration Number:
	(10	O digit code – numbers and letters. If unknown record '99'.)
4.		ntenatal Card Number:
	(10	O digit code – numbers and letters. If unknown record '99'.)
5.	Ag	e of mother in completed years:(years)
6.	De	livery Information: 7. Birth History
	a.	Date of delivery DD / MM / YYYYY a. Total number of pregnancies
	b.	Number of children born in this b. Number of living children birth:
	c. d.	Sex of child/ren: male: c. Number of children ever born, female: including those currently alive and those who died
	u.	are still alive? male: female: d. Number of all miscarriages, induced abortions, ectopic pregnancies or still births experienced
8.	W	oman's contact details:
	a.	Contact phone number of the woman:
	b.	Woman agreed to be contacted by phone?
	C.	Contact name and phone number of a close relative or friend: Name: Phone No.:
	d.	Agree that the close relative or friend mentioned in 12c can be contacted by phone: \square Yes \square No

Part B

Family Planning Counselling (To be completed by <u>DCO</u> for all women before discharge)

1.		Where did you attend A	NC?			
2.	□ □	Home This Hospital → go to Q3 which district did you atte	Commur Clinic/Up Health C Hospital end ANC?	pazilla entre	 □ District Hospital □ Other □ Did not attend ANC → go to Q3 	
3.	со	uring this pregnancy, were unselled about family pla acing? ☐Yes ☐No→	nning/birth	you cou	ner, how many times were nselled in total? Once fultiple times	
5.	re	which service delivery po ceive counselling for fami elect all that apply) Antenatal clinic During antenatal admiss Postpartum Other (please specify)	ly planning?	session	ital munity Clinic/Upazilla Health	
7.	w 	ho were you counselled b Doctor Midwife Nurse Community midwife Health education person		☐ Healt☐ Fema☐ Coun☐ Don'	th Assistant ale Health Care worker isellor t know r (please specify)	
8.		hat family planning metholease circle all that apply) Oral contraceptive pills Cap / Diaphragm Interval IUD Post-Partum IUD	Female Injectab Periodic	Condom le : nce/Rhythm	Male sterilization Emergency contraceptive pills	

	☐ Implants/Norplant ☐ Male Condom	☐ Withdr		zation		Lactational Amenorrhea Method
						Other (please specify)
9.	Did you discuss family plar with your significant other making your decision? Yes No	•	10.	Were you postpartuadmission Yes	ım IUD (n to the	PPIUD) before
11.	Before you were admitted for delivery, did you give ve or written consent (or a thu have a PPIUD inserted after birth? Yes No	erbal consent umb print) to	If re	<u>MM / YY</u>	<u> </u>	onsent given? <u>DD</u> / now the date, record
13.	Was a PPIUD sticker added booklet prior to admission hospital? ☐Yes ☐No	•	14.	after adm	nission to	lled about PPIUD the hospital?
15.	If you were counselled abowhen the counselling took		admis	sion to the	hospita	l, please indicate
	☐Before delivery ☐Afte	•		Both befor	e and af	ter delivery

16. VV	nen you were counselled about postpartum 100 (PP100) (at any time):
a.	Were you told about any benefits? ☐ Yes ☐ No→go to Q16c
b.	Can you mention at least one benefit (Circle all those she mentions without prompting)
	It can be inserted immediately after delivery and there is no need to return to a facility to have it inserted.
	It is one of the most effective reversible methods to space pregnancies.
	It works well as an alternative to sterilisation.
	It provides reliable contraception for a period of 10 years.
	It can be removed at any time if she wished to become pregnant or use another method.
	Less pain is experienced during the procedure when inserted immediately after delivery.
	Insertion can also be done at the time of caesarean section.
	The complication of perforation of the uterus resulting in IUD being sited outside the womb is less when done immediately or within 48 hrs of birth compared with interval IUD.
	It does not interfere with breastfeeding.
	None mentioned
	Other (please specify)
C.	Were you told of any disadvantages? ☐ Yes ☐ No→go to Q16Error! R eference source not found.
d.	Can you mention at least one disadvantage? (Circle all those she mentions without prompting)
	The IUD may get expelled in 5 % of cases.
	Women may experience heavy bleeding at insertion.
	Women may experience irregular bleeding.
	Women may experience pain.
	It provides no protection against sexually transmitted infections or HIV.
	Women may feel discomfort during intercourse.
	It may be expelled at time of periods
	None mentioned
	Other (please specify)
fo	/ere you told about the need for a 18. What other information were you provided about postpartum IUD?
	□No

19.		ere you given the postpartum IUD PIUD) information leaflet? \square Yes \square No	20.	ques	e you given an opportunity to ask tions about postpartum IUD JD)? Yes No Unsure
21.	ho ve a t	ter you were admitted to the spital for delivery, did you give rbal consent or written consent (or chumb print) to have a PPIUD serted after you gave birth? ☐ Yes ☐ No →go to Q27	22.	MM If res	t date was consent given? DD / / YYYY spondent does not know the date, rd '99/99/9999'
23.	wa co	consent for postpartum IUD (PPIUD) as given, do the notes or records ntain a green sticker or other entifier? Yes No	Hint: wom inser	post cons to Q Answe an prid ted du	you withdraw consent for partum IUD (PPIUD) after enting?
25.	res	yes, at what stage did you withdraw cospondent and circle one option) Antenatal On admission to elivery Other (please ecify)			
	wit	nat was the main reason for hdrawing consent? (Please circle one d skip to Q29)	27	wh	onsent for PPIUD was not given, at was the main reason (Please cle one and skip to Q29)
[Decided on another method			Did not know what a PPIUCD is
[Did not have time to discuss method			Decided on another method
	_	with husband/family			Did not have time to discuss
L		Not sure whether to have the IUD			method with husband/family
L		Heard a lot about side effects and is concerned			Not sure whether to have the IUD
[Concerned about failure rates		Ш	Heard a lot about side effects and is concerned
[Do not want to have a foreign body			Concerned about failure rates
		inside me			Do not want to have a foreign
[Husband/partner objection			body inside me
[Family members objection			Husband/partner objection
[Religious objection			Family members objection
[No need because husband/partner is			Religious objection
		away			
Г	\neg	Does not want to use family planning	_	Ш	No need because husband/partner is away

\square Was unsure which method to use	☐ Does not use family planning
Other (please specify)	☐ Wants to have another baby soon
	Has used an IUD in the past and had a bad experience
	☐ Was useure which method to use
	Does not know enough about family planning
	Other (please specify)
28. If you did not receive family planning cour circle one and go to Q31)	nselling, what was the main reason? (Please
□ Did not attend antenatal care visit□ I did not have time to wait and listen□ Staff were too busy	 □ I did not want advice because I know what family planning method I would use. □ Don't' know □ Other (please specify)
29. Overall, how satisfied were you with the family planning counselling and information provided to you? [PLEASE READ THE OPTIONS]	30. How satisfied were you with the postpartum IUD counselling and information provided to you? [PLEASE READ THE OPTIONS]
☐ Very Satisfied	☐ Very Satisfied
Satisfied	Satisfied
☐ Fairly Satisfied	☐ Fairly Satisfied
☐ Unsatisfied	☐ Unsatisfied
31. Was a PPIUD inserted? ☐ Yes ☐ No →go to Q34	32. Was there pain or discomfort when the PPIUD was inserted? ☐ Yes ☐ No → go to Q35
33. If there was pain, please indicate the degr ☐ Mild ☐ Medium ☐ Severe	ree of pain:
34. What was the reason why the PPIUD was	not inserted?
 Doctor recommended against the insertion because of medical reasons 	It was not provided (If answered, immediately refer to health
\square I changed my mind	provider and inform Facility Coordinator)
Due to problems at the time of insertion	Don't know

	Other [Specify]					
35. N	35. Name, designation and signature of the person collecting data:					
a.	Name					
b.	Designation					
c.	Date: DD / MM / YYYY					
	Signature					

End of Part B

Thank you very much for your time. This information will be very useful to improve services in the future.

Part C

PPIUD Insertion

(To be completed by the <u>Service Provider</u> responsible for inserting the PPIUD among <u>all</u> <u>women consenting to use PPIUD</u> whether or not PPIUD is inserted)

1.	Provider's 2. Name:	Provider's Reference Code:
3.	Designa Indoor medical officer Outdoor medical officer MO/EMO Honorary MO Assistant registrar Professor Asst. Professor Assoc. Professor	 Nurse Registrar Student Trainees Consultant Junior Consultant HMO Other
4.	First name of the woman: 5.	Family name of the woman:
6.	Registration Admission/Hospital Registration (10 digit code – numbers and letters. If unk	
7.	Antenatal Card Number: (10 digit code – numbers and letters. If unk	nown record '999999999'.)
8.	Date of delivery: DD / MM / YYYY .	
9. [Type of delivery: 10. At what time was P one option) delivery	ection
11.	How many insertion attempts were made:	
a.	What method was used to insert the PPIUD on the first attempt?	b. What method was used to insert the PPIUD on the final attempt?

 Kelly forceps (NB: If Caesaren section deliver – Kelly's forceps cannot be used) 	 Kelly forceps (NB: If Caesaren section deliver – Kelly's forceps cannot be used)
☐ Ring/Sponge forceps	☐ Ring/Sponge forceps
☐ Inserted by hand	\square Inserted by hand
 Pregna device (NB: If Caesaren section deliver – Pregna device cannot be used) 	☐ Pregna device (NB: If Caesaren section deliver – Pregna device cannot be used)
☐ Other	☐ Other
	
12. Was a PPIUD inserted? ☐ Yes ☐ No → go to Q16	13. Date of insertion: DD / MM / YYYY _ → go to QError! Reference source not f ound.
immediate apply) complications of	re the complication(s)? (Please tick all that Heavy bleeding
insertion?	☐ Other (please specify)
☐ Yes ☐ Severe pain	
∐ No →go to Q18	
16. If PPIUD not inserted after initial consent	being given was it due to:
 a. Contraindicated because of: (Please circle all that apply) 	c. Due to problems at the time of insertion (Please circle all that apply)
☐ Ruptured membranes > 18 hrs	☐ Excessive bleeding
☐ PPH	☐ Perforation
Chorioamnionitis	☐ Abandoning procedure due to technical problem
☐ Complicated valvular heart disease	☐ Lack of equipment/IUD
☐ Copper allergy☐ Wilson's disease	☐ Lack of personnel
☐ Abnormal uterus	Other (please specify) -
Known STI current or during last 3 months	
Other (please specify)	d. Other
	☐ The doctoer did not know that a PPIUD was to be provided
b. Due to woman's change of mind:☐ Yes ☐ No	Other (please specify)

17.	If a PPIUD was not inserted, was action taken to offer the woman other family planning options? Yes No
18.	Date of first PPIUD follow-up visit (Please ensure women is informed of her follow up date): DD $/$ MM $/$ YYYYY .
19.	Name, designation and signature of the person completing the form:
a.	Name:
b.	Designation:
c.	Date: DD / MM / YYYY.
Ч	Signature

End of Part C

Thank you very much for your time. This information will be very useful to improve services in the future.

POSTPARTUM IUD FOLLOW UP

(To be completed at the Clinic/Hospital by the provider who is doing a 4-6 week postnatal check-up for a woman who opted for a postpartum IUD)

Please complete this short checklist after the postnatal check or if the woman attends after delivery with problems related to the PPIUD before the postnatal check

Select the response that applies. All items should be answered

1. First name of the woman:	Family name of the woman:	
2. Name of Facility:	3. Upazilla: 6	
4. Admission Card No: 5. Antenatal No: 6. Date of delivery: DD / MM / YYYY 8. Name, designation and signature of the part	Designation	
☐ Vaginal Discharge ☐ Threads not felt	☐ Irregular bleeding ☐ Family Planning method failure, client	
☐ Threads coming out of vagina ☐ Abdominal pain ☐ Painful intercourse ☐ Partner's complaint	pregnant Post-coital bleeding PID needing antibiotics Client has seen expelled IUD Other (please specify)	
Woman reported spontaneous expulsion pr	rior to the Yes No Not Applicable	
IUD had already been removed prior to the check	<u></u>	

A speculum examination was undertaken	□Yes □No □Not Applicable	
IUD thread seen at speculum examination	□Yes □No □Not Applicable	
	.,	
Ultrasound examination performed	□Yes □No □Not Applicable	
If Ultrasound examination performed, what result?	was the	
	☐ IUD not present at ultrasound	
	☐ IUD present but in the wrong place	
Thursd metric constraints in the control of		
Thread retrievers used to bring threads dow	n LYes LNo LNot Applicable	
IUD removed at the postpartum review at the	e woman's □Yes □No □Not	
request	Applicable	
What is the main reason for requesting the I	UD removed?	
\square Wants to have another baby	\square Husband/partner objected	
☐ Heavy menstrual bleeding	\square Family members objected	
☐ Inter-menstrual bleeding	\square Religious objection	
☐ Painful sexual intercourse	☐ Husband/partner away	
☐ Painful periods	\square Wants to use alternative family	
☐ Pain in between periods	planning method (specify below)	
Other (specify)		
Alternative method used:		
☐ Oral contraceptive pills	Periodic abstinence	
☐ Implants	☐ Withdrawal	
☐ Condom	☐ Female sterilization	
☐ Injectable	☐ Male sterilization	
☐ Natural Methods ☐ Emergency contraceptive p		
☐ Other (specify)		
IUD removed at the postpartum review for reasons	nedical Yes No Not Applicable	

Another IUD was inserted at the postpartum check	□Yes □No	\square Not
	Applicable	
Woman already using other contraception	□Yes □No Applicable	□Not
Other contraception was offered	□Yes □No Applicable	□Not

End of form

POSTPARTUM IUD FOLLOW UP

(To be completed by the DCO through a telephone follow-up interview at 4-6 weeks for a woman who opted for a PPIUD if she did not attend postnatal check-in person)

Questionnaire for telephone follow-up if woman does not attend postnatal check-up.

All items should be answered.

9. First name of the woman: Family nam	ne of the woman:				
10. Admission Card No:					
11. Antenatal No:					
12. Date of delivery: 13. Date of check-up: DD / MM / YYYY DD / MM / YYYY					
Did the woman provide a working phone number?	□Yes □No □Not Applicable				
Have you experienced problems in relation to PPIUD	□Yes □No □Not ? Applicable				
Are you aware that the PPIUD has fallen out?	□Yes □No □Not Applicable				
Have you had the IUD removed?	□Yes □No □Not Applicable				
Did you ask for the IUD to be removed?	□Yes □No □Not Applicable				
Did a doctor or nurse recommend that the IUD be removed?	□Yes □No □Not Applicable				
Are you using another method of contraception	□Yes □No □Not Applicable				

End of form

Example of Audit of Training on insertion in all 6 countries

Country	Do you have a training Agenda	How many days agenda	To which cadres is the agenda applicable if you have different agendas	If you follow one agenda is it applicable to all cadres. This agenda is for how many days?	Who is trained?
INDIA	YES	ONE DAY	OBSGYN, PG's,RESIDENTS, INTERNS & STAFF NURSES OF OB/GYN DEPT.	YES. ONE DAY. (Training for data operators and counsellors is done separately)	OBSGYN, PG's,RESIDENTS, INTERNS & STAFF NURSES OF OB/GYN DEPT.
SRI LANKA	YES	ONE DAY	FOR FACULTY COORDINATORS, HOUSE OFFICERS & REGISTRARS, NURSES, MIDWIVES & PERIPHERAL STAFF.	NO. ONE DAY AGENDA FOR BOTH GROUPS. AGENDA FOR NURSES ETC IS AWARENESS, COUNSELLING & FOLLOW UP.	GROUP 1: FACILITY COORDINATORS, HOUSE OFFICERS & REGISTRARS. GROUP 2: ANTE NATAL CLINIC STAFF & LABOUR ROOM NURSES.
BANGLADESH	YES	ONE DAY	OBSGYN & STAFF NURSES OF OB/GYN DEPT.	YES. ONE DAY.	OBSGYN & STAFF NURSES OF OB/GYN DEPT.
NEPAL	YES	THREE DAYS	FOR OBSGYN, OTHER MEDICAL OFFICERS & NURSES	YES. THREE DAYS	OBSGYN, DOCTORS, NURSES, ASSISTANT NURSES, MIDWIVES, SBA
KENYA	YES	THREE DAYS	No info given	YES.THREE DAYS	No info given
TANZANIA	YES	ONE/ THREE/ FIVE DAYS	ONE DAY - OBSGYN; THREE DAYS - ALL; FIVE DAYS - COMPREHENSIVE FOR ALL; COUNSELLING TRAINING - THREE DAYS; REFRESHERS - ONE DAY - FOR ALL	NO. ONE DAY - OBSGYN; THREE DAYS - ALL; FIVE DAYS - COMPREHENSIVE FOR ALL; COUNSELLING TRAINING - THREE DAYS; REFRESHERS - ONE DAY - FOR ALL	OBSGYN, JUNIOR DOCTORS, ROTATING INTERNS, NURSES, MIDWIVES (FINAL YR.), ANAESTHETISTS

Country	Selection Critieria	Training Batch Size	Competencies - number of mama U insertions practiced	Competencies - number of LIVE insertions practiced under supervision	Competencies - number of LIVE insertions practiced independently.
INDIA	ALL THOSE WHO ARE POSTED IN THE DEPARTMENT ARE TRAINED.	In each batch 20 members are trained by 2 - 5 trainers.	5 to 10 for all cadres.	For OB/GYN - none. PG's & RESIDENTS - 2 to 3. Nursing staff - 3 to 5.	Once live insertions are done under supervision they continue to do insertions whenever they are on duty
SRI LANKA	ALL THOSE WHO ARE SRI LANKA POSTED IN THE DEPARTMENT ARE TRAINED.		5 - 10 for doctors only	DONE	DONE
BANGLADESH CONDUCT DELIVERIES		In each batch, 20 - 40 are trained.(In case of a batch of 40 participants, 30 doctors & 10 nurses.)	5 - 10 for all cadres	2 - 3 for all cadres	2 for all cadres
ALL PROVIDING NEPAL DELIVERY SERVICES		In each batch , 9 are trained by 3 trainers. (1 + 2 Nurse trainees; 1 trainer for 3 participants)	Practiced until they are confident.	1 -2 for all cadres	10 for all cadres
KENYA Polivery of the training is taken by nurses as doctors are few.		5 to 10	3	2	
TANZANIA	ALL HCP WORKING IN LABOUR WARD, POST NATAL WARD, RCH CLINIC, ANC WARD, MATERNITY SERVICE PROVIDERS	For training & counselling, each batch consists of 15 trainees & 3 trainers. For insertions, each batch consists of 12 trainees & 3 trainers	5 for all cadres	5 for all cadres	All providers are tracked & data provided electronically.

Country	Certification - awarded for attendance	Certificati awarded Proficience insertion mama U	for cy in	award Profic		Certification - awarded for Proficiency in insertion LIVE independent	Quality - Random inspection during training	Quality - Random inspection when services are being provided.	Quality - how is it monitored?
India	YES	Certificat			ven only once after successfully pleting the training.		YES. PROJECT DIRECTOR / NATIONAL COORDIN ATOR	Yes. Chief Coordinator / Dy. Coordinator / Sr. OB/GYNAC.	Procedure followed for insertion, placement & infection control
Sri Lanka	NO	YES	NO		NO		YES. MT	Yes	No. of insertions, quality & placement
Bangladesh	NO	NO	NO		NO		YES. NC & DNC.	Yes. FC & DFC	By the number & quality of insertions, follow up & patient satisfaction.
Nepal	NO	NO	NO		YES. AFTER 10 INSERTIONS.		YES. NATIONAL HEALTH TRAINING CENTRE & NESOG - PPIUD	Yes. LOCAL TRAINER - OBSGYN / MATERNITY IN CHARGE	Number & quality of insertions, placement, expulsions & infection rate
Kenya	YES	NO	NO		YES		YES	Yes	No info given
Tanzania	NO	NO	NO		NO		YES	Yes	Number of insertions, techniques, quality, follow up reports & uterine infections.

Example of Audit of Structure

Counselling

Human Resources

Is the counselling done by Doctors?

Is the counselling done by Midwives?

Is the counselling done by PPIUD counsellors

Leaflets

Do they have leaflets covering all PPFP?

Does it cover PPIUD?

Are the leaflets in all the appropriate languages?

Are the leaflets approved by the government?

Flipcharts

Do they have flip charts with illustrations and reading material?

Do flip charts cover all forms PPFP?

Do flip charts cover PPIUD?

Posters

Do they have posters in ANC, wards (AN and PN) informing of PPFP

Do they have posters in ANC, wards (AN and PN) informing on PPIUD

Video

Do they have a TV with video being played in appropriate language

Does it cover importance of birth spacing

Does it cover all forms PPFP

Does it cover PPIUD

Consent

Do they have appropriate consent form with adv, disad, risks and side effects?

Is it in their language?

Insertion

Human Resources

Who is doing the insertion - are they government staff?

IUCDs

Does the clinic/Hospital have adequate supplies in pharmacy

Does the clinic/Hospital have adequate supplies in labour room

Does the clinic/Hospital have adequate supplies in operating theatre

PPIUD kit

Does the hospital have ready made up PPIUD kits? If so, how many?

Does PPIUD kit have: Kelly's, sponge forceps, kidney dish/gulley pot and speculum?

If no PPIUD kit, does facility have adequate supply of Kelly's forceps in the Labour Room

What is the turnaround for sterilisation?

Follow up

Do they have PPIUD follow up pack? If so how many?

Does follow up pack have speculum, uterine sound, artery forceps, thread retriever?

Can they refer for an ultrasound in the event of IUCD of unknown location?

Can they refer for an X-ray in the event of IUCD of unknown location?

Example Audit of Process

Coverage

Do we have a map demonstrating the flow of patients from peripheral units to referral hospitals

How many peripheral units are there which do ANC and refer to our facilities

How many of these do we cover in terms of training in counselling

What % of women delivering in our facilities have had ANC in that hospital or in a clinic that we cover?

What % of women counselled in our facilities delivered elsewhere?

Training in Counselling

Who is trained in Counselling?
Is it done routinely by the facilities or is it instigated by PPIUD?
Who does the training? Is the government involved?
Are there lectures and small group discussion or just one or the other?
Are there practical sessions?
Is a certificate given?
Is it part of CME?
Have all eligible staff been trained?

Training in insertion

Is training instigated by the initiative or by the facility itself Who does the training? Is the government involved? Is it part of CME? Have all eligible staff been trained?

Data

Do they have a register of women delivered in each unit

Do they have a register of women who were interviewed

Do they have a register of counselled women

Do they have a register of women who had insertions

Do they have a register of women who had follow up

When the initiative leaves what data will be available from the national health service?

Sustainability

Has PPIUD been accepted as a viable method FP in the country?

Is it part of normal medical training?

Is it part of normal nursing/midwifery training?

Is it part of normal training clinical officers/other relevant cadres of health professionals Will the government accept PPIUD insertion by non-medical staff?

Data Safety Monitoring Boards

Guidance on set up of DSMB/C (Data Safety Monitoring Board/Committee)

DSMC is to reassure the implementation team, the Government, the patients and public that the research project or any new initiative is safe to be continued.

The DSMC is an independent body with none of the implementers (i.e. the HQ PPIUD staff, the local national society or officers of involved). The implementers provide all the data needed for DSMBC to review and attend an open session of the DSMBC to answer questions from the DSMBC and give additional details. The closed session do not have implementers and the members of the DSMBC have to scrutinise whether the data collection is adequate and complete for them to declare the project can continue safely. DSMBC also reviews all adverse events to decide that there are no serious issues and the minor issues are not too numerous to be concerned of and that the project can continue. This should be stated clearly in the minutes of their meeting.

In brief DSMC looks at data quantity and quality and safety aspects of the project whilst the Implementation Advisory Group reviews the progress of the project against time lines, identifies blockers and enhancers and give advice and help to 'oil the machinery' for better implementation.

Functions of DSMC include:

- 1. Look into the completeness of the data in quantity and quality by looking at the returns at random with the help of the implementation group i.e. what % of women delivered are having the forms filled and are they being filled as complete as possible i.e. are the data missed out i.e. left blank. This is needed for the DSMC to say that it is safe to continue to project. With small proportion of numbers and incomplete data they cannot come to the conclusion.
- 2. In our project there are two components we assess from form 1 counselling and insertion and then complications and expulsions in form 2. If review of removals and expulsions are large numbers then we need to question whether it is safe to continue our initiative. Because the counselling part is not going to cause harm (or going to be unsafe) the cases that they have to concentrate are part C of form 1 and form 2 when they come for repeat visit.

At the end of each meeting the chair of the DSMC should write to the National coordinator to state that it is safe to continue the project.

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Co-authors' statements of contribution

Co-authors statement of candidate's contribution

PhD by publication, Warwick Medical School, University of Warwick

Statement of contribution by Anita Makins

Paper to be considered as part of PhD by published work

Study 3

Kusum Thapa, Rolina Dhital, Sameena Rajbhandari, Shreedhar Acharya, Sangeeta Mishra, Sunil Mani Pokhrel, Saroja Pande, Emily-Ann Tunnacliffe, Anita Makins. Factors affecting the behavior outcomes on post-partum intrauterine contraceptive device uptake and continuation in Nepal: a qualitative study. BMC Pregnancy and Childbirth 2019; 19: 148

Contribution of candidate

Anita Makins was deeply involved in the work described in this paper including in direct implementation of the research. She instigated the study question and co-designed the research project including regarding the chosen qualitative research methodology. Anita supervised implementation of the work from the UK but also through visits to Nepal. Once transcription and translation of the in depth interviews had occurred she participated in the analysis, and revision of the results and findings. She was instrumental in drawing the conclusions. She was greatly involved in the writing and revision of the manuscript. She also contributed to responses to expert reviewers' comments prior to publication in BMC Pregnancy and Childbirth.

Name	Signature	Date
Kusum Thapa		12/7/2021
Rolina Dhital		12/6/2021
Sameena Rajbhandari		12/20/2021
Shreedhar Acharya		12/16/2021
Sangeeta Mishra		12/21/2021
Sunil Mani Pokhrel		12/21/2021
Saroja Pande		12/6/2021
Emily-Anne Tunnacliffe		12/6/2021

Co-authors statement of candidate's contribution

PhD by publication, Warwick Medical School, University of Warwick

Statement of Contribution by Anita Makins

Paper to be considered as part of PhD by published work

Study 4

Kusum Thapa, Rolina Dhital, Sameena Rajbhandari, Sangeeta Mishra, Shanti Subedi, Bhogendra Raj Dotel, Sapana Vaidya, Saroja Pande, Emily-Anne Tunnacliffe, Anita Makins and Sabaratnam Arulkumaran. Improving post-partum family planning services provided by female community health volunteers in Nepal: a mixed methods study. BMC Pregnancy and Childbirth 2020; 20:123

Contribution of Candidate

Anita Makins was heavily involved in the research surrounding training of 'Female Community Health Volunteers' (FCHVs) in family planning counselling in Province 1 in Nepal. She co-designed the research project. She participated in planning the mixed methods methodology as well as in finalising the tools to be used in the study. Anita provided technical supervision with implementation of the FCHV training, the data collection undertaken as well as to the analysis. She provided this from London but also through visits to Nepal. She was key in interpreting the results and to drawing the final conclusions. She contributed to writing of the manuscript including support with revisions following expert reviewers' comments after successful submission at BMC Pregnancy and Childbirth.

Name	Signature	Date
Kusum Thapa		12/7/2021
Rolina Dhital		12/7/2021
Sameena Rajbhandari		12/13/2021
Sangeeta Mishra		12/13/2021
Shanti Subedi		
Bhogendra Raj Dotel		12/15/2021
Sapana Vaidya		12/19/2021
Saroja Pande		12/20/2021
Emily-Anne Tunnacliffe		12/6/2021
Sabaratnam Arulkumaran		12/6/2021

Co-authors statement of candidate's contribution

PhD by publication, Warwick Medical School, University of Warwick

Statement of contribution by Anita Makins

Paper to be considered as part of PhD by published work

Study 5

Rolina Dhital, Ram Chandra Siwal, Khem Narayan Pokhrel, Sabina Pokhrel, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins. Evaluating the impact of female community health volunteer involvement in a postpartum family planning intervention in Nepal: a mixed-methods study at one-year post-intervention. PLOS ONE. Published October 20, 2021. Available: https://doi.org/10.1371/journal.pone.0258834

Contribution of candidate

Anita Makins instigated the study question and lead the design of the research project. She finalised the mixed methods methodology and provided technical support to the design of the tools used. She supported implementation of the project from the UK predominantly using video conferencing, given the outbreak of the pandemic and the restrictions on travel. She was directly involved in the interpretation of the results of both quantitative and qualitative elements of the project. She was instrumental in drawing the conclusions and was greatly involved in the writing and revision of the manuscript. She also contributed directly to responses to expert reviewers' comments prior to publication.

Name	Signature	Date
Rolina Dhital		12/9/2021
Ram Chandra Siwal		12/6/2021
Khem Narayan Pokhrel		12/11/2021
Sabina Pokhrel		12/11/2021
Heera Tuladhar		12/9/2021
Suzanna Bright		12/8/2021
Emily-Anne Tunnacliffe		12/6/2021
Kusum Thapa		12/9/2021

Publications

SUPPLEMENT ARTICLE



FIGO postpartum intrauterine device initiative: Complication rates across six countries

Anita Makins^{1,2,*} | Neda Taghinejadi² | Maya Sethi¹ | Kazuyo Machiyama³ | Projestine Munganyizi⁴ | Elly Odongo⁵ | Hema Divakar⁶ | Parveen Fatima⁷ | Kusum Thapa⁸ | Gamini Perera⁹ | Sabaratnam Arulkumaran^{1,10}

²Oxford University Hospitals NHS Foundation Trust, Oxford, UK

³London School of Hygiene and Tropical Medicine, London, UK

⁴Association of Gynaecologists and Obstetricians of Tanzania, Dar es Salaam, Tanzania

⁵Kenya Obstetrical and Gyanecological Society, Nairobi, Kenya

⁶Federation of Obstetric and Gynecological Societies of India, Mumbai, India

⁷Obstetrics and Gynecology Department, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh

⁸Nepal Society of Obstetricians and Gynaecologists, Kathmandu, Nepal

⁹Sri Lanka College of Obstetricians and Gynaecologists, Colombo, Sri Lanka

¹⁰St George's, University of London, London, UK

*Correspondence

Anita Makins, International Federation of Gynecology and Obstetrics, London, UK. Email: anita@figo.org

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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. 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. 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

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¹International Federation Gynecology and Obstetrics, London, UK

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, the authors of a 2015 Cochrane review called for more research assessing expulsion rates. Existing studies vary hugely in their rates of expulsion after PPIUD insertion, from under 2% to over 25%. 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

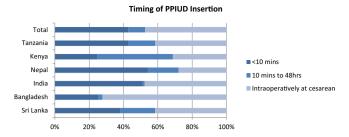


FIGURE 1 Timing of PPIUD insertion across the six countries participating in the initiative. [Colour figure can be viewed at wileyonlinelibrary.com]

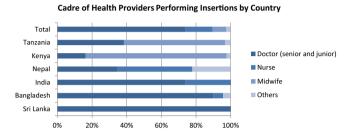


FIGURE 2 Cadre of health provider performing PPIUD insertion by country. [Colour figure can be viewed at wileyonlinelibrary.com]

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

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

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 (r	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	e responses allowed i	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)		

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

	Attendance a	t 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

^aMissing data in 850 from 18 960 reports collected on expulsion (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

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	e only: n=11 326)	
Strings visible	5940	71
Strings not visible	2405	29
(Missing data 2981)		

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.

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

^bMissing data in 526 from 18 960 reports collected on removals (rates calculated excluding missing data).

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

	Univariate analy	rsis		Multivariate and	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 delive	ry ^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			

^aMultivariate analysis adjusting for 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. Tasksharing 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.

^bMultivariate analysis adjusting for country and method of insertion.

^cMultivariate analysis adjusting for cadre and country.

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 countries³ 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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SUPPLEMENT ARTICLE



Factors influencing the likelihood of acceptance of postpartum intrauterine devices across four countries: India, Nepal, Sri Lanka, and Tanzania

Anita Makins^{1,2,*} | Neda Taghinejadi² | Maya Sethi¹ | Kazuyo Machiyama³ | Kusum Thapa⁴ | Gamini Perera⁵ | Projestine S. Munganyizi⁶ | Ajey Bhardwaj⁷ | Sabaratnam Arulkumaran^{1,8}

*Correspondence

Anita Makins, International Federation of Gynecology and Obstetrics, London, UK. Email: anita@figo.org

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Abstract

Objective: To examine the factors that positively influenced the likelihood of accepting provision of postpartum intrauterine devices (PPIUDs) across four countries: Sri Lanka, Nepal, Tanzania, and India.

Methods: Healthcare providers were trained across 24 facilities in counselling and insertion of PPIUDs as part of a large multicountry study. Women delivered were asked to take part in a 15-minute face-to-face structured interview conducted by incountry data collection officers prior to discharge. Univariate analysis was performed to investigate factors associated with acceptance.

Results: From January 2016 to November 2017, 6477 health providers were trained, 239 033 deliveries occurred, and 219 242 interviews were conducted. Of those interviewed, 68% were counselled on family planning and 56% on PPIUD, with 20% consenting to PPIUD. Multiple counselling sessions was the only factor resulting in higher consent rates (OR 1.30–1.39) across all countries. Odds ratios for women's age, parity, and cadre of provider counselling varied between countries.

Conclusion: Consent for contraception, specifically PPIUD, is such a culturally specific topic and generalization across countries is not possible. When planning contraceptive policy changes, it is important to have an understanding of the sociocultural factors at play.

KEYWORDS

Counselling; Family planning; FIGO initiative; LMICs; Postpartum contraception; Postpartum intrauterine device; PPIUD

1 | INTRODUCTION

In recent years, there has been increasing international recognition of the importance of offering effective contraceptive services to women immediately after childbirth. The benefits for women and their children are clear: contraceptive use has the potential to improve perinatal outcomes and child survival by widening the birth interval, and reduce maternal morbidity and mortality associated with high parity and unintended pregnancies. However, the ability of services to meet women's contraceptive needs postpartum has historically been

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¹International Federation of Gynecology and Obstetrics, London, UK

²Oxford University Hospitals NHS Foundation Trust, Oxford, UK

³London School of Hygiene and Tropical Medicine, London, UK

⁴Nepal Society of Obstetricians and Gynaecologists, Kathmandu, Nepal

⁵Sri Lanka College of Obstetricians and Gynaecologists, Colombo, Sri Lanka

⁶Association of Gynaecologists and Obstetricians of Tanzania, Dar es Salaam, Tanzania

⁷Avni Health Foundation, Mumbai, India

⁸St George's, University of London, London, UK

problematic, with estimates that around two-thirds of women have an unmet need for contraception in the first year after birth.³ The frequent tradition of deferring family planning services to the 6-week postpartum visit fails many women who may desire to postpone or limit childbearing but face barriers to accessing postnatal care⁴ or prioritize services for their newborn over their own care.⁵ Services are responding to these challenges at both a local and global level, with the development of initiatives offering contraceptive services immediately postpartum. These initiatives take advantage of prenatal care and delivery as opportunities to address the postpartum contraceptive needs of women.⁶ Effective contraceptive counselling lies at the core of these initiatives, and is essential to enabling uptake of contraception among postpartum women prior to discharge.

Despite this increased focus on offering effective methods to women immediately postpartum, there has been little corresponding research into how best to counsel women to make choices.⁷ Counselling factors such as timing and provider status have the potential to significantly impact on uptake of postpartum contraception⁸; however, there is a dearth of evidence exploring these associations. We were able to identify two studies that aimed to analyze the impact of timing on contraception uptake. One study, based in the USA, identified significantly increased rates of postpartum use of a more effective method of contraception among patients counselled in both the prenatal and postpartum period as opposed to one time period only; the authors did not however comment on the comparative impact of prenatal versus postnatal counselling. 9 Another study, based in Egypt, identified no significant difference in the effect of prepartum versus postpartum counselling on verbal acceptance of a receiving a postpartum intrauterine device (PPIUD). 10 Even less is known about the impact of the status of the counselling provider. Those providing counselling come from a wide variety of backgrounds, ⁷ and may operate in health systems where obstetrics and family planning services have traditionally been separate. 6 As part of their study, Mohamed et al. 10 commented that provider status had no impact on subsequent acceptance of PPIUD, but provided no data to support this claim, and no further detail on the backgrounds of the counselling providers included in their study. More research on the impact of the timing of counselling and provider status is needed to better understand how we can best assist women in making contraceptive choices postpartum.

The aim of the present study was to examine the factors that influenced the outcome of counselling for PPIUD, as part of a FIGO initiative, across four countries: India, Sri Lanka, Nepal, and Tanzania.

Although they are all low- or lower-middle-income countries, the profiles of the four countries selected in this study are different when contraceptive use is taken into account. This is likely to impact on the outcomes. Recent figures compiled by the UN on world contraceptive use, published in 2018,¹¹ are outlined in Table 1. IUDs relate mainly to interval IUDs as PPIUD was not significantly in practice in 2015–2016 when the surveys were collated. These figures show that IUDs are not popular, particularly in India, Nepal, and Tanzania, with contraceptive prevalence ranging from 0.9–1.5. If IUDs are not popular or common in the country, counselling will be

TABLE 1 Contraceptive prevalence and unmet need for family planning in India, Nepal, Sri Lanka, and Tanzania.

	India	Nepal	Sri Lanka	Tanzania
Date of survey	2016	2016	2016	2015
Contraceptive prevalence				
Any method, %	53.5	52.6	61.7	38.4
Any modern method, %	47.8	42.8	51.3	32.0
Intrauterine device, %	1.5	1.4	10.1	0.9
Unmet need for family plan	ning			
Total, %	12.9	23.7	7.5	22.1
Spacing, %	5.7	8.1	3.1	15.5
Limiting, %	7.2	15.6	4.4	6.6

Source: United Nations. 13

a key element of the implementation process, hence the need for a deeper understanding of its effects.

2 | MATERIALS AND METHODS

The present study forms part of a larger multicountry PPIUD initiative by the International Federation of Gynecology and Obstetrics (FIGO) (See de Caestecker et al. 12 in this Supplement). The study initiative commenced in 2013 and is ongoing at publication. Following agreement from the governments and national obstetrics and gynecology societies, referral hospitals with over 5000 deliveries a year were selected in each country. Local healthcare professionals, managers, and policy makers were educated on the value of birth spacing to reduce maternal and under-five mortality rates as well as in the safety and effectiveness of PPIUD. Medical and nursing staff in each facility were then trained in counselling and insertion of PPIUD via a "training-the-trainer" model using standardized lectures and practical sessions across the four countries. This involved training a pool of master trainers in each facility that could then go on to train their own staff on a regular basis. Emphasis during the training was placed on balanced counselling, where all methods available in the country should be outlined and explained to the woman. PPIUD should then be addressed separately as it was a new method. In Sri Lanka and Tanzania, all counselling was provided by clinical staff (doctors, nurses, and midwives) working in the chosen facilities. In India and Nepal, counselling on family planning and PPIUD was conducted not only by medical and nursing staff already present but also by designated counsellors employed by the initiative. These counsellors received 2 days of training that included family planning methods, counselling techniques, and specific information on PPIUD.

Women delivering in those facilities 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 discharge. All data were collected by the DCOs on tablets and stored using

CommCare software (Dimagi, Cambridge, MA, USA). Data were analyzed from the 24 facilities, six in each of the four participating countries: Nepal, Sri Lanka, and Tanzania and India. The timeframe analyzed was from January 2016 to November 2017 for India, and September 2016 to November 2017 for Nepal, Sri Lanka, and Tanzania. These dates were selected because more than 80% of all women delivering in the chosen facilities in each country had been interviewed by DCOs in these periods and data could then be considered representative. Although six countries participated in the initiative, Kenya and Bangladesh did not achieve high enough interview rates among delivered women to be included in this analysis. This was also the reason for not including the other 12 facilities in Sri Lanka, as interview rates in these units did not reach the required threshold. Factors analyzed included: age, parity, number of living children, number of episodes of counselling, and cadre of healthcare staff involved in the counselling. With cadre of healthcare staff, multiple answers were allowed as often women were counselled by various professionals. Factors excluded from the analysis were timing of counselling and involvement of the husband. Timing of counselling (prenatal, intrapartum, and postpartum) was not included in the analysis as very often women were counselled during all three periods of time and therefore it was difficult to establish any relationship with outcome. Discussion with the husband was also not analyzed as only one country had responses to this question. Counselling received across the countries was standardized. This was verified by including questions on knowledge of postpartum family planning, PPIUD, advantages and disadvantages, as well as satisfaction with the counselling they received.

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. Univariate analysis was performed using Stata

version 15.0 software (StataCorp LLC, College Station TX, USA) to investigate factors associated with acceptance of PPIUD. P < 0.05 was considered significant.

3 | RESULTS

Table 2 presents a summary of activities in the four countries. From the start of the initiative to November 2017, 4295 healthcare providers were trained in counselling and 2182 in counselling and insertion of PPIUD. A total of 239 033 deliveries occurred across the 24 facilities. The median age of women was 25 years and median parity was 2. A total of 219 242 women were interviewed, which equated to 92% of all women delivering across the 24 facilities. Of those interviewed, 68% were counselled on family planning and 56% were also counselled on PPIUD. Of those counselled, a total of 20% consented to PPIUD.

Table 3 summarizes the univariate analysis of specific factors that may have influenced uptake of PPIUD. In India, older women were less likely to accept PPIUD (OR 0.97), whereas in the other three countries women were more likely to accept the older they were. This was a similar situation when looking at parity—the higher the parity, the less likely Indian and Sri Lankan women were to accept PPIUD (OR 0.91 and 0.94, respectively); whereas in Tanzania, they were more likely to accept PPIUD the higher the parity (OR 1.16). In India, Sri Lanka, and Tanzania, women were more likely to accept PPIUD if the child from the immediate delivery was alive at the time of interview (OR 3.49, 3.38, and 2.58, respectively). In all four countries, women were more likely to accept PPIUD if they had been counselled multiple times (ORs 1.30–1.39). An association between cadre of health provider and consent to PPIUD varied from country to country. In India, women who had been counselled by counsellors were 1.17

TABLE 2 Key data on facilities, training, and counselling as part of the PPIUD initiative in India, Nepal, Sri Lanka, and Tanzania.

	India	Nepal	Sri Lanka	Tanzania	
	Jan 2016 to Nov 2017	Sept 2016 to Nov 2017	Sept 2016 to Nov 2017	Sep 2016 to Nov 2017	Overall
Number of facilities	6	6	6	6	24
Total number trained in counselling only	12	1178	1758	1347	4295
Total number trained in counselling and insertion	914	246	134	888	2182
Deliveries	76 381	70 098	36 367	56 187	239 033
Median age	25	24	28	26	25
Median parity	1	1	2	2	2
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Interviewed	73 830 (97)	65 256 (93)	33 536 (92)	46 620 (83)	219 242 (92)
Counselled on family planning	63 807 (86)	23 531 (36)	31 736 (95)	30 925 (66)	149 999 (68)
Counselled on PPIUD	63 782 (86)	20 679 (32)	18 100 (54)	19 575 (42)	122 136 (56)
Consented to PPIUD	21 934 (34)	2408 (10)	2043 (6)	3520 (11)	29 905 (20)

Abbreviation: PPIUD, postpartum intrauterine device.

TABLE 3 Factors influencing consent for insertion of postpartum intrauterine device.

	India (N = 56 021)	, 021)		Nepal (N = 23 433) ^a	3 433)ª		Sri Lanka (N = 31 607)	= 31 607)		Tanzania (N = 27 274)	- 27 274)	
	Crude OR	P>z	95% CI	Crude OR	P>z	95% CI	Crude OR	P>z	95% CI	Crude OR	P>z	95% CI
Demographics												
Age	0.97	<0.001	0.961-0.969	1.05	<0.001	1.033-1.060	0.99	0.056	0.984-1.000	1.03	<0.001	1.027-1.040
Parity	0.91	<0.001	0.894-0.934	na	na	na	0.94	0.017	0.895-0.989	1.16	<0.001	1.134-1.186
Survival of recent birth												
No living child	1.00						1.00			1.00		
≥1 child alive from this delivery	3.49	<0.001	2.378-5.112	na	na	na	3.38	0.227	0.468-24.513	2.58	<0.001	1.647-4.040
No. counselling episodes	S											
Once	1.00			1.00			1.00			1.00		
Multiple times	1.30	0.000	1.235-1.365	1.39	0.000	1.232-1.559	1.31	0.008	1.072-1.599	1.39	0.000	1.228-1.578
Counselling by differing cadres ^b	cadres ^b											
Counselled by doctor												
Yes	0.83	<0.001	0.804-0.865	1.48	0.003	1.147-1.906	1.01	0.884	0.907-1.120	1.39	0.000	1.172-1.638
oN	1.00			1.00			1.00			1.00		
Counselled by nurse/midwife	midwife											
Yes	0.71	<0.001	0.684-0.747	0.67	<0.001	0.552-0.823	0.21	<0.001	0.174-0.262	0.57	<0.001	0.433-0.750
No	1.00			1.00			1.00			1.00		
Counselled by counsellor	ellor											
Yes	1.17	<0.001	1.091-1.265	na	na	na	na	na	na	na	na	na
oN	1.00											

^aInformation was not available on parity, survival of recent birth, and counsellors for Nepal because this information was not available on their interview form.

^bInformation was not available on Counsellors for Sri Lanka and Tanzania as they did not employ this strategy for counselling women.

times more likely to say yes to PPIUD, whereas in Nepal and Tanzania those counselled by doctors were more likely to respond positively (OR 1.48 and 1.39, respectively). In Nepal and Sri Lanka, women who were seen by nurses/midwives were less likely to consent to PPIUD as a contraceptive option.

4 | DISCUSSION

Counselling had a much greater impact in some countries than in others and it is interesting to elucidate why that was the case. Across the six facilities in India, 86% of women were counselled and the proportion of women consenting to PPIUD was the highest at 34%. In 2016, the documented background interval IUD prevalence was reported as 1.5% at national level. Which factors may have influenced this success?

Odds ratios for women's age and parity in India suggest that women who had fewer children and were younger were more likely to agree to PPIUD. In the six Indian facilities included in the initiative, the only long-acting immediate postpartum contraceptive methods available are PPIUD and bilateral tubal ligation (BTL). The only other alternative is the progestogen-only pill and condoms. The government has been providing small financial incentives for providers, women, and their community health workers to take up contraception for many years. ¹³ Given that most women are encouraged to leave hospital with some form of long-acting contraception and there are limited choices, PPIUD becomes an attractive option for young women of low parity owing to its reversibility. Older women who are seeking birth-limiting options would be more likely to choose BTL.

Although this is not captured by the monitoring data, another factor that may have contributed to the success of the initiative in India is that counselling occurred a number of times throughout pregnancy. Due to the structure of the government health system, women typically attend for their minimum of four prenatal appointments in the same facility. With counselling set up in these facilities, multiple discussions with healthcare professionals about contraception were possible with each woman. Across all four countries, multiple counselling sessions were more likely to result in uptake of PPIUD than single encounters. Many of the other countries struggled to consistently achieve multiple counselling episodes at the same participating facility, especially owing to the nature of their population and the health services provided in government institutions. In Tanzania, women often had prenatal care in different units from where they would eventually deliver, making multiple counselling encounters at one of the participating facilities difficult. In Nepal, the migrant nature of the population and the fact that many women go to back to their family homes made multiple counselling encounters difficult.

The value of multiple encounters was clear, particularly in countries where the IUD is not popular. Multiple encounters also allowed for relatives to become involved in the counselling sessions, which is key in communities where family and relatives play a significant role in decision making around family planning. In India in particular, women were encouraged to come back with their husbands and mother-in-laws

at subsequent appointments so that they could also hear about the benefits of family planning, but particularly the value of PPIUD as an effective nonhormonal long-acting reversible contraceptive.

The value of the counsellor was also evident in India where the ORs of accepting PPIUD was 1.17 times greater among women who were counselled by a counsellor compared with those who were not. Reproductive Child Health (RCH) counsellors are part of the existing government healthcare system in Indian hospitals. They counsel not only on family planning but also other reproductive and child health topics. The value that counsellors add to clinical consultations is clearly evident when it comes to contraception—a topic requiring indepth, private conversations with every woman.

The initiative in Nepal saw smaller proportions of women receiving counselling in family planning and PPIUD (36% and 32% of those interviewed, respectively), and therefore the PPIUD consent rate was also lower (10%). The method mix was different in Nepal, where hormonal implants are on offer but only after 6 weeks. Fewer practitioners were trained in counselling and insertion and although counsellors were employed, this analysis could not demonstrate their impact on acceptance of PPIUD because the interview forms did not collect the relevant information.

Family planning counsellors in Nepal were employed directly by the initiative and so their sustainability remains in question. They were also a new cadre of health staff in the health system, and during monitoring visits it was evident that in some facilities they were not well accepted and sometimes viewed with suspicion. Nepali women tend to have more trust in medical staff, in particular doctors, and it was mentioned by providers that without the doctor's ratification women would be less likely to accept a new concept such as PPIUD. Further qualitative research into this aspect is currently underway.

The six Nepali facilities involved are large institutions with a relatively low staff to patient ratio. This meant that doctors simply did not have the time to spend counselling women at length. Interestingly, the odds ratio of consenting for PPIUD was 0.67 when women were counselled by nurses. On monitoring visits it was noticed that many nurse/midwives were not motivated to counsel or insert PPIUD. Often it was seen as an extra burden that had previously been undertaken by the family planning department and not maternity staff. In an already stretched and busy environment, these nurses were often not willing to take on an extra task. In many instances they were the gateway to knowledge and information for the patient and without their support, it is not surprising that counselling and consent rates were low. However, it should be reiterated that the national IUD prevalence in Nepal was 1.4% in 2016, 11 and therefore that a consent rate of 10% is still quite an achievement. Initiating new practices in an environment where the system is already under strain is not an easy task and is likely to take considerable time.

Sri Lanka is a country with much lower unmet need for contraception in comparison with the other three countries. Contraceptive prevalence for any method was 61.7% in 2016, 11 and unmet need for spacing (which is where PPIUID is particularly relevant) was relatively low at 3.1%. Method choice immediately postpartum is greater with hormonal implants being widely available for insertion prior to

discharge. There was some suggestion that this is a popular option for Sri Lankan women, with the prevalence of implants increasing over time. ¹¹ According to the same data, the prevalence of IUDs in 2016 was 10.1%. This would suggest that the method is popular and it is surprising to see consent rates as low as 6%. Either way, many countries reported that the initiative resulted in collateral beneficial effects such as increases in use of other methods of contraception as well as increase in the use of interval IUDs. The odds ratio suggests that counselling by nurses resulted in less likely acceptance of the method (OR 0.21).

There was some adverse publicity generated during implementation of the initiative in Sri Lanka over the period of time that these results were collected. The initiative became embroiled in the known ethnic tension issues in country where some believe that contraception is used as a political tool. This may have resulted in lack of support by some professionals and may explain the overall low consent rates. An article in this Supplement outlines the details of the initiative in Sri Lanka. ¹⁴

Tanzania's profile is very different from that of Sri Lanka's, with contraceptive prevalence virtually static since 1991 at 38.4% and the highest unmet need for spacing at 15.5%. 11 Tanzania has the highest infant and under-five mortality rates and a pronatalist culture, therefore persuading women to have fewer children can be difficult to justify. It is therefore not surprising that women are less likely to accept contraception the lower their age and parity, and survival of the last birth was found to be strongly associated with PPIUD acceptance (OR 2.58). Being counselled by a doctor was clearly associated with acceptance of PPIUD (OR 1.39). The national prevalence of interval IUDs was low in 2016 at 0.9%. Considering this prevalence, the proportion of women consenting to PPIUD in the six facilities was high at 11%. In Tanzania, counsellors were not employed by the initiative, and counselling and insertion were primarily conducted by midwives. The results suggest that despite the overall low modern contraceptive prevalence, there is demand for long-acting methods, such as PPIUD, in Tanzania. This study suggests that nationalization of PPIUD services predominantly through midwives has the potential to be a highly successful intervention in Tanzania.

The present study adopted a quantitative approach when looking at different factors influencing consent for provision of PPIUD. Clearly there are multiple variables: family structures and who is the decision maker, organization of health care in the country, alternative methods and adverse effects, as well as a woman's perceptions of her need for family planning. It is likely that further studies using a qualitative methodology in each country would help to better understand how these factors interact and hence help inform policy makers.

5 | CONCLUSION

It is not possible to generalize the results across all four countries with regard to factors that influence women to consent to provision of PPIUD. These appear to be very much context specific. The only consistent factor across all countries that resulted in a greater likelihood of acceptance of PPIUD was having multiple counselling episodes. This should be taken into account by policy makers when designing implementation programs.

AUTHOR CONTRIBUTIONS

AM wrote the manuscript with help from NT. Data cleaning, analysis, and tables were prepared by MS and KM. SA planned the initiative and directed implementation together with AM. PM, AB, KT, and GP coordinated activities in their respective countries. All authors reviewed the final version of the paper. 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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RESEARCH ARTICLE

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Factors affecting the behavior outcomes on post-partum intrauterine contraceptive device uptake and continuation in Nepal: a qualitative study



Kusum Thapa^{1*}, Rolina Dhital¹, Sameena Rajbhandari¹, Shreedhar Acharya^{1,2}, Sangeeta Mishra^{1,3}, Sunil Mani Pokhrel^{1,4}, Saroja Pande¹, Emily-Ann Tunnacliffe⁵ and Anita Makins⁵

Abstract

Background: The use of post-partum family planning (PPFP) methods such as post-partum intrauterine device (PPIUD) in general remains low despite its benefits for the women. The reasons or factors affecting the uptake and continuation of such PPFP methods in developing countries such as Nepal remains unclear. This qualitative research aims to explore the factors affecting PPIUD uptake and continuation related behaviors among post-partum mothers within 6 weeks of childbirth in Nepal.

Methods: This qualitative study was conducted through 43 in-depth interviews among post-partum mothers who delivered in 3 selected hospitals in Nepal. Data were analyzed through content analysis using the theory of planned behavior (TPB) as the theoretical framework.

Results: The themes and categories were structured around the three major components of the TPB on attitude, subjective norms, and behavioral control. Majority of the women in this study, irrespective of their behavioral outcome expressed a positive attitude towards PPIUD use. However, the women who expressed an unfavorable attitude towards PPIUD influenced their behavior to not choose or discontinue PPIUD. Subjective norms such as the family, peer, and societal influences against PPIUD negatively affected the women's intention and behavior related to PPIUD. Whereas, the positive influence of the health providers positively affected their behavior. Regarding the behavior control, women who had their own control over decisions tended to use PPIUD. However, external factors such as their husband's preference or medical conditions also played a prominent role in preventing many to use PPIUD despite their positive intentions.

Conclusion: As suggested in TPB, this study shows that multiple factors that are interlinked affected the behaviors related to uptake and continuation of PPIUD. The attitude helped in s'haping intention but did not always lead to the behavioral outcome of PPIUD uptake and continuation. Subjective norms had a strong influence on both intention and behavior. Behavior control belief also had an important role in the outcome with respect to PPIUD uptake and continuation. Thus, a more layered, multidimensional and interlinked intervention is necessary to bring positive behavior changes related to PPIUD.

Keywords: PPIUD, Uptake, Continuation, Post-partum mothers, Theory of planned behavior, Nepal

¹Nepal Society of Obstetricians and Gynaecologists, Paropakar Maternity and Women's Hospital, Thapathali, Kathmandu GPO: 23700, Nepal Full list of author information is available at the end of the article



^{*} Correspondence: kusumthapa2006@gmail.com

Background

The use of modern contraceptives in general remains low in low- and middle-income countries (LMICs) as compared to the high-income countries [1, 2]. Evidence suggests that myths and misconceptions regarding long acting modern contraceptives such as intrauterine contraceptive devices (IUDs) have attributed to the low usage of IUDs in LMICs [1]. Studies from African countries such as Ghana and Burundi have identified lack of adequate knowledge among users, socio-cultural influences, health providers' influences, and availability of the IUD as key barriers of uptake and continuation of IUD among users [3, 4].

LMICs in South Asia such as Nepal are no exception to the challenge of low uptake and continuation of IUDs including the ones used in the immediate post-partum period [5]. Post-partum intrauterine contraceptive device (PPIUD) is an effective and affordable long-acting post-partum family planning (PPFP) method which can be used immediately after childbirth within 48 h of post-partum period. It is known to be safe and has broad eligibility criteria for post-partum mothers [6, 7]. PPFP such as PPIUD was first introduced in Nepal between 2008 and 2009 [8]. Despite the decade-long effort, the country still lacks nationally representative data on the usage of PPIUD separately. Moreover, the overall usage of IUD remains as low as 1.4% in the country [9].

Since 2015, the Nepal Society of Obstetricians and Gynaecologists (NESOG) carried out the initiative on institutionalizing PPFP services in 6 referral facilities through immediate long-acting method such as PPIUD in Nepal [10, 11]. The initiative was supported by the International Federation of Gynaecology and Obstetrics (FIGO). The major interventions of the initiative includes training of the doctors and nurses working in the maternity units of the implementing facilities to provide timely and quality PPFP services to the women who give child birth in the facilities [11]. The interventions also include advocacy with the key family planning stakeholders in Nepal, and implementation of behavior change communication (BCC) strategies through counselling of women on PPFP as part of antenatal care (ANC) and immediate post-partum care with the use of BCC materials such as leaflets, posters and videos on benefits of PPFP including PPIUD use.

NESOG has been working closely with the government line agencies with the aim to sustain the progress and scale up the program nationwide. The initiative has been able to improve the acceptance of PPIUD among post-partum mothers above the national average rate in the 6 facilities involved. However, the uptake still remains low and discontinuation rate among the users persists. Previous study from the same initiative suggested that the total uptake of PPIUD was around 3% of

70,098 total deliveries and 10% of the 20,679 women who had been counselled on PPIUD in the 6 implementing facilities in Nepal between 2016 and 2017 [10].

Factors behind the behavioral outcomes related to uptake and continuation among the users for PPIUD are less understood. Understanding the underlying behavioral factors that has been directly or indirectly affecting the uptake and continuation could help improve the PPIUD program implementation strategies in Nepal and other LMICs with similar contexts. Therefore, this study intends to explore the factors affecting these behavioral outcomes using the theory of planned behavior (TPB) as a theoretical framework [12].

Theory of planned behavior (TPB)

TPB has been widely used in health research to predict and explain a wide range of health behaviors including health services utilization, breastfeeding, substance use, condom use, and fertility intention [13–17].

TPB states that behavioral outcomes depend on both intention and behavioral control. It distinguishes between the three types of beliefs - attitude, subjective norms, and behavioral control. Attitude is related to favorable or unfavorable perceptions towards behavior [12]. The subjective norms deal with how the opinions of others shape an individual's intention [10]. Behavioral control results in the actual control of the behavior that could be internal or external control which brings out an individual's ability to decide and take action [12].

According to TPB, the combination of attitude, subjective norms and behavior control would lead to the intention which subsequently leads to a behavior outcome. TPB provides a more holistic perspective towards behavior change and suggests that improving knowledge alone or focussing on one dimension does not change a behavior [12]. Application of TPB could provide an in-depth understanding to identify gaps and design more effective interventions to improve PPIUD uptake and continuation.

Methods

Study setting

This qualitative study is part of a larger parent study conducted between March 2017 and June 2018. The aim of the parent study is to assess the institutionalization process of the initiative and examine the trends of PPFP counseling coverage, and PPIUD uptake and continuation in the implementing facilities. The quantitative baseline data is collected from all the mothers who had given birth in the selected facilities. A part of the quantitative study has been published recently in a larger multi-country study [10]. The data collection for this qualitative study was conducted in April 2018 in three major government referral hospitals across Nepal which

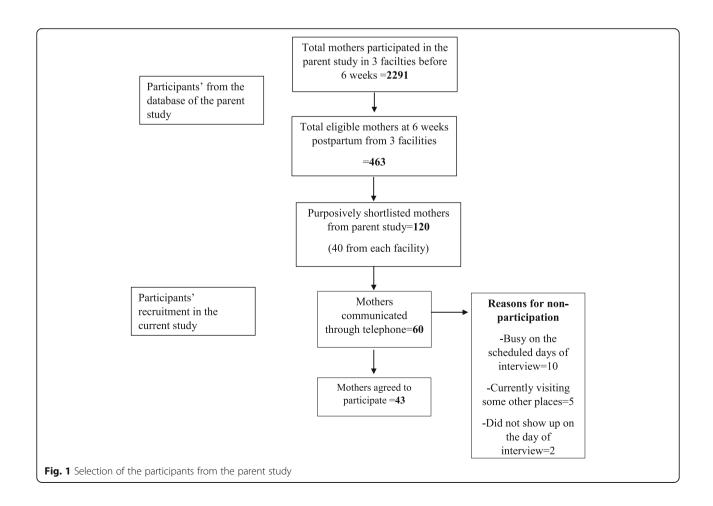
were implementing PPIUD initiative. The facilities included Lumbini Zonal Hospital, Koshi Zonal Hospital and Bharatpur Hospital representing three different regions of Nepal with high obstetric caseloads of around 10,000 deliveries per year for each.

Participants

The participants of this study were the post-partum mothers who had given birth in the selected facilities. The eligibility criteria included the mothers who had participated in the parent study during their immediate post-partum period, were at 6-weeks post-partum period and residing within the same district of the facilities. The mothers also represented four distinct PPFP related behavior outcomes which included continued PPIUD user, discontinued PPIUD user, choosing other PPFP methods, or did not choose any method.

Data collection

The research team first identified 2291 mothers who had given birth and participated in the parent study from the three facilities 6 weeks before the scheduled interview dates of the current study. From the database, the team then shortlisted 463 mothers representing different PPFP related behaviors and different age groups. The team then selected 120 mothers (40 from each facility) purposively based on their address that was within the same district as that of the facilities and the completeness of their responses in the parent study. The data collection officers from each facility then tried to contact these women through the telephone. However, not all women had their own phone or were not reachable. The research team intended to recruit the women until the information reached the point of saturation for each type of PPFP related behavior in each facility. Thus, the women were contacted further and invited to participate in the following days if the information didn't reach the point of saturation or if the invited mothers didn't show up on the scheduled day of the interview. As a result, the data collection officers communicated with 60 mothers in total to confirm their current status related to PPFP behavior outcomes and invited them to participate in the study. However, 15 mothers refused to participate citing their unavailability on the scheduled days of the interview and 2 mothers didn't show up on the



day of the interview. In total, 43 women participated in this qualitative study (Fig. 1).

The data was collected through in-depth interviews among the women in each facility until the information reached a point of saturation for each PPFP related behavior (Additional files 1, 2, 3 and 4). The interviews were conducted in PPIUD initiative office within each facility in a quiet and secure setup. All the in-depth interviews were taken by the researcher (RD) with the support from the researchers (SA, SM, SMP) and data collection officers in each facility. All the interviews were recorded with an audio record and the field notes were taken.

Data analysis

The audio records and field notes of all interviews were taken in Nepali language which were then translated into English language during the process of transcription by RD and the translation was reviewed by KT and SR. The transcribed information in English language was then entered into Dedoose software version 8.0.42 for data analysis. Data analysis was done through thematic content analysis using TPB as a theoretical framework [12]. The categories were identified by the researchers (KT, RD and SR) from the coding of the transcripts which were then fitted into three major themes of TPB. The analysed themes and categories were then shared with other authors (SA, SM, SMP, SP, ET and AM) for their review. Anonymous original quotes that reflected real opinions of the respondents were chosen to give more insight.

Ethical considerations

Ethical approval was obtained from Nepal Health Research Council. The written informed consent were collected from all the participants before the interview. The participation was voluntary and confidentiality was maintained.

Results

Characteristics of the participants

In total, 43 women who had given birth in the selected facilities participated in this study. (Table 1)

Table 1 PPFP related characteristics of women participating in the study from each facility

	Facility			
PPFP behaviors	Facility 1	Facility 2	Facility 3	Total
Continued PPIUD	5	4	3	12
Discontinued PPIUD	2	3	3	8
Other PPFP methods	2	3	4	9
No method	5	5	4	14
Total	14	15	14	43

The women included continued and discontinued PPIUD users and women who preferred other PPFP methods or no methods at all.

All the women who participated in this study were currently married. Among the women interviewed, the majority of them were in age group between 20 to 29 years followed by the women between 30 to 39 years of age and the least between the age of 18 and 19 years. More women in their twenties had just given birth for the first time, whereas more women in their thirties were multipara. All the adolescents interviewed had given birth just for the first time. (Table 2).

Themes and categories

The findings are structured around three major themes- attitude, subjective norms and behavioral control. (Table 3) The first theme on attitude was divided into perceived favorable and unfavorable outcomes that dealt with how the women perceived the use of PPIUD. The second theme on subjective norms represented various influences from the family, peers, society, and health providers in shaping their PPIUD related intention and behaviors. The third theme of behavioral control focussed on internal and external control. The original quotes of the women represents different age groups (adolescents, and women between the age groups 20–29 years and 30–39 years) and parities (primipara and multipara).

1. Attitude

It has been suggested that intentions of the individual largely reflects personal attitudes towards the favourability of a behavior. However, all positive attitudes do not necessarily lead to positive behaviors [12].

Perceived favorable outcomes

Majority of the women in this study, irrespective of their behavioral outcome expressed a positive attitude towards PPIUD use.

"PPIUD is a less painful method as compared to depot which is injected into the arms every 3 months. PPIUD also works for many years so I felt it was a good option for me." (20–29 years, multipara, PPIUD user)

Table 2 Characteristics of women based on parity and age

Age	Primi-para	Multi-para	Total
Adolescent (18–19) years	6	0	6
20–29 years	16	8	24
30–39 years	1	12	13

Table 3 Themes and categories of the study

	Themes	Categories
1.	Attitude	Perceived favorable outcomes
		Perceived unfavorable outcomes
2.	Subjective norms	Family's influence
		Peer's influence
		Society's influence
		Health provider' influence
3.	Perceived behavioral control	Internal control
		External control

"I married too soon and had a child really soon as well. But I wanted to delay my next pregnancy to complete my education. I thought PPIUD would be useful for me but I had heavy vaginal bleeding after using it and the doctor advised to remove it" (Adolescent, Primipara, Discontinued PPIUD user)

"I understood the benefits of PPIUD and think it is a good method. But my husband is away so I decided not to use any method." (20–29 years, Primipara, No methods)

"I understood about PPIUD and it is good for those who wish to use it. I discussed with my husband about different options and decided to use depot because it is available in the health post near our home which makes it more convenient for us" (20–29 years, Primipara, Other methods)

Perceived unfavorable outcomes

Most of the women who expressed unfavorable perceived outcomes were PPIUD non-users or those who discontinued PPIUD.

"Though I used PPIUD, I was just very worried about the side effects. I heard it can make you feel very weak, can cause heavy bleeding and even pierce the uterus. That is why I decided to remove it." (30–39 years, multipara, Discontinued PPIUD user)

"I refused using PPIUD because I didn't want to use a method as soon as I gave birth, I felt it would hurt me." (20–29 years, Primipara, No method)

2. Subjective norms

According to TPB, the individual's intentions are largely shaped by the opinion of family, friends, or any person the individual trusts [12].

Family influence

Strong family influence against PPIUD affected the intention and behavior of most women who were not currently using the method.

"Everyone back home, my mother-in-law, mother, sisters, and sisters-in-law, they all said that I should have consulted them before using PPIUD. They said it is not good. I felt so worried and couldn't bear the emotional pressure. I felt relieved after removing it." (20–29 years, Primipara, Discontinued PPIUD user)

A few of them who used PPIUD had a positive influence from their family. "During my pregnancy, I discussed the options with my husband and mother-in-law. Both suggested me to use PPIUD." (20–29 years, Primipara, PPIUD user)

Peer influence

Most of the women had strong peer influence on their behavior in particular for discontinuing PPIUD and choosing other methods.

"All my friends either use depot or pills. When I was using PPIUD, I was the only one using it which made me feel uncomfortable. I feel more comfortable now after switching to depot because I am not the only one using this method." (20–29 years, Primipara, Discontinued PPIUD user who switched her PPFP method)

Social influence

Majority of the women had a strong social influence over their behavior. The major barriers included myths surrounding PPIUD use.

"The Female Community Health Volunteer in our village asked me why I used PPIUD without consulting her. She said it has serious side effects and so many other methods were available. It just worsened my fear and I feel like removing it ever since." (20–29 years, Multipara, PPIUD user)

"They said IUD can pierce our body. They said a lady from a nearby village had such complications because of IUD." (20–29 years, Primipara, Discontinued user)

Health providers' influence

Many PPIUD users agreed to use the method because they liked and understood the counselling on PPFP from the health providers.

"I came to this hospital 4 times during my pregnancy and was counselled all the times. The health provider was so nice and explained everything very clearly. I understood different methods of PPFP and decided to choose PPIUD." (30–39 years, Multipara PPIUD user)

A few reflected their trust in health providers. However, they were not always counselled about PPFP."I went for a check-up in a nearby health post. I always listen to their advice. They told me how to take care of myself during pregnancy and prepare for childbirth. But they never counselled about PPFP. I didn't know about PPIUD or other methods." (Adolescent, Primipara, No methods)

Perceived behavioral control

Internal control

The internal control focussed on a woman's ability to take her own decisions irrespective of other influences or attitudes.

Many women who were currently using PPIUD reflected their own control over the decision.

"After understanding different options I decided to use PPIUD. It is comfortable and I plan to continue using it until I decide on a permanent method" (30–39 years, Multipara, PPIUD user)

A few of them who discontinued PPIUD or did not choose the method too reflected their own decision."It was my own decision to use as well as to remove PPIUD. I just didn't feel like continuing it from the bottom of my heart." (20–29 years, Multipara, Discontinued PPIUD User)

"I understood the method well. I would have used it if my husband was around. But he is working abroad and won't be able to come back for few years. He said I can still use it but I chose not to use it. I will think about a method when he comes back" (20–29 years, Primipara, No method)

External control

The external factors could be a decision made by family members on women's behalf or complications beyond the women's control. Most of them reflected external factors that prevented them to use PPIUD despite their own positive intentions towards it.

"I was OK with any method. But my husband had used the condom in the past and it was his decision that we continue using a condom." (20–29 years, Primipara, Other methods)

"I would have continued using PPIUD. But it was partially expelled. It wasn't 45 days yet after my childbirth so I couldn't reuse it immediately." (Adolescent, Primipara, Discontinued user)

"I had agreed to use PPIUD but told them to ask for my husband's opinion. My husband suggested not to use PPIUD but use depot instead. So I didn't use it and planning to use depot". (Adolescent, Primipara, No methods)

Discussion

As suggested in TPB [12], this study shows that multiple factors influence the behavioral outcomes related to uptake and continuation of PPIUD among the women. The findings highlighted the need for a multidimensional approach to improve the attitude, subjective norms and behavioral control to improve PPIUD uptake and continuation.

In this study, attitude had an influence in shaping a woman's intention in using PPIUD. However, it also highlighted that positive attitude alone was not enough to result in actual behavior outcome. Contrary to this, a negative attitude towards PPIUD was more likely to lead to women not choosing or discontinuing PPIUD. Though the beliefs about the effect of PPIUD played a crucial role in shaping either positive or negative attitudes, other factors such as intention to have a child immediately and family member's influence also played important roles. A study by Ajzen, on fertility intention too suggested that the reasons behind positive and negative attitudes may not entirely be the same and attitude alone may not lead to behavior [17].

As explained in TPB [12], subjective norms also played an important role in shaping one's intention and behavioral outcomes in this study. Influences from the family and society on women's family planning behaviors have been discussed widely [3, 4]. Similar to previous studies, myths over IUD were an important barrier that affected subjective norms [3, 4]. In this study, peer influence too affected PPIUD uptake and continuation which was related to the fear of being left alone among the peers rather than the direct effect of PPIUD. A study on PPIUD uptake

among African American adolescents has also shown the influence of peers on PPIUD behavior [18].

Moreover, this study also showed that lack of timely counseling on PPFP in the peripheral facilities led to missed opportunities. Health providers play a key role to address PPFP needs in a timely fashion [19, 20]. The previous quantitative study on PPIUD initiative indicated that multiple counseling by health providers had a significant influence on the uptake of PPIUD by women [10]. Another qualitative study focussing on the training of health providers on PPFP counseling service and PPIUD insertion techniques had suggested that regular mentoring had helped in motivating the health providers on improving their services [11]. Despite the efforts, the gap on counseling exists which is partly attributed to the low health providers to patients ratio in these busy hospitals [10]. The task shifting of PPFP services such as counseling by establishing community linkages could help address the gap to some extent. The female community health volunteers (FCHV) and the peripheral health facilities are often the first points of contact for most women in Nepal [21, 22]. Involvement of FCHVs by building their capacity has proven beneficial for many health interventions in Nepal [23, 24]. The capacity building process by integrating the training packages on PPFP counseling for them into the national health system and by strengthening the local leadership to drive these training activities would be pertinent. Further, their inclusion in the BCC activities is crucial to gaining women's trust in the family planning method.

In this study, both perceived internal and external control also played important roles in shaping the intention as well as the behavioral outcomes. Perceived behavior control is believed to have a direct influence over the behavioral outcomes irrespective of the attitude and subjective norms [12]. Internal control in this study reflected the personality attributes such as the women's self-confidence and her internal feelings. Whereas, external controls were related to subjective norms or health complications which had no influence on a woman's attitude or intention. It is clear from the responses that in many instances the husband is in fact in control of the chosen method of contraception. Migrant husbands are not keen to leave their wives behind with a method of contraception in situ which they do not perceive as necessary given their absence. Perhaps inclusion of partners in counselling sessions would result in a better understanding of the advantages of a one stop approach and the efficacy of PPIUD in preventing pregnancies when comparing to other methods requiring user input.

This study has certain limitations. First, this study was conducted in a small population and therefore may not be generalised to a wider population. However, as a qualitative study, this study provides an in-depth perspective of women of different age groups, parities and PPFP related behavior. Second, this study was conducted at 6 week post-partum period and does not provide a longitudinal perspective on the contraceptive choices and behaviors of the women in the long run.

Despite the limitations, the findings of this study have important program implications for stakeholders related to PPFP. The findings highlight existing gaps and will aid in designing more effective interventions through evidence based practice. Community awareness through innovative approaches using mass media and community mobilization is an effective intervention [25] which could help address attitude as well as subjective norms and behavior control. As with ANC group counselling [26], more focused group counselling on PPFP during ANC could also help in shaping positive peer influence. Moreover, involving family members such as husband or mother-in-law in the PPFP counselling could also be effective to overcome barriers surrounding subjective norms and external control [27]. Further, expansion of the institutionalization process to the peripheral facilities could help in capacity building of health providers and to reach out to more women in need of PPFP services. This would in turn widen the sphere of women using the method and hence make it more acceptable to the wider public [25].

This study is one of the few studies that have explored the factors affecting the behavior outcomes in LMICs such as Nepal. This study indicates that a more layered, multidimensional and interlinked intervention is necessary to bring out the ultimate outcome of improving the uptake and continuation of PPIUD among women in LMICs.

Conclusion

This study identified that the multiple factors as outlined in TPB influenced the behavior related to uptake and continuation of PPIUD among women and each factor was interlinked to the others. The attitude helped in shaping intention but did not always lead to the behavioral outcome of PPIUD uptake and continuation. Subjective norms had a strong influence on both intention and behavior. Behavior control belief also had an important role in the outcome with respect to PPIUD uptake and continuation. Further studies on larger population with a longer follow up could provide a broader and longitudinal perspective.

Additional files

Additional file 1: Interview guide for PPIUD continued user. (DOCX 30 kb)
Additional file 2: Interview guide for PPIUD discontinued user. (DOCX 31 kb)

Additional file 3: Interview guide for women who chose other PPFP methods. (DOCX 31 kb)

Additional file 4: Interview guide for women who chose no PPFP methods. (DOCX 31 kb)

Abbreviations

ANC: Antenatal care; BCC: Behavior change communication; IUD: Intrauterine contraceptive device; LMIC: Low and middle income countries; NESOG: Nepal Society of Obstetricians and Gynecologists; PPFP: Post-partum family planning; PPIUD: Post-partum intrauterine contraceptive device; TPB: Theory of Planned Behavior

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Availability of data and materials

The datasets and transcripts analyzed for this study will be available from the corresponding author on reasonable request.

Authors' contributions

KT was involved in conceiving the study design, finalizing the tools, analysis, writing, and revisions of the manuscript. RD was involved in designing the study, finalizing the study tools, data collection, analysis, and writing the first draft of manuscript and subsequent revisions. SR was involved in data analysis and revision of the manuscript. SA, SMP and SM were involved in coordination of the data collection and revision of the manuscript. AM instigated the study question and was involved in the revision of the manuscript. All authors have read and approved the final version of the manuscript.

Ethics approval and consent to participate

Ethical approval was obtained from Nepal Health Research Council. The written informed consent were collected from all the participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interest.

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Author details

¹Nepal Society of Obstetricians and Gynaecologists, Paropakar Maternity and Women's Hospital, Thapathali, Kathmandu GPO: 23700, Nepal. ²Department

of Obstetrics and Gynecology, Lumbini Zonal Hospital, Butwal, Nepal. ³Department of Obstetrics and Gynecology, Koshi Zonal Hospital, Biratnagar, Nepal. ⁴Department of Obstetrics and Gynecology, Bharatpur Hospital, Bharatpur, Nepal. ⁵International Federation of Obstetrics and Gynaecology, London, UK.

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RESEARCH ARTICLE

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Improving post-partum family planning services provided by female community health volunteers in Nepal: a mixed methods study



Kusum Thapa^{1*}, Rolina Dhital¹, Sameena Rajbhandari¹, Sangeeta Mishra², Shanti Subedi³, Bhogendra Raj Dotel⁴, Sapana Vaidya¹, Saroja Pande¹, Emily-Anne Tunnacliffe⁵, Anita Makins⁵ and Sabaratnam Arulkumaran⁵

Abstract

Background: Family planning services in the post-partum period, termed post-partum family planning (PPFP) is critical to cover the unmet need for contraception, especially when institutional delivery rates have increased. However, the intention to choose PPFP methods such as post-partum intrauterine devices (PPIUD) remains low in countries such as Nepal. Community health workers such as Female Community Health Volunteers (FCHVs) could play an important role in improving the service coverage of PPFP in Nepal. However, their knowledge of PPFP and community-based services related to PPFP remain unclear. This study aims to assess the effect on community-based PPFP services by improving FCHV's knowledge through orientation on PPFP.

Methods: We conducted this mixed-methods study in Morang District in Nepal. The intervention involved orientation of FCHVs on PPFP methods. We collected quantitative data from three sources; via a survey of FCHVs that assessed their knowledge before and after the intervention, from their monthly reporting forms on counseling coverage of women at different stages of pregnancy from the communities, and by interviewing mothers in their immediate post-partum period in two selected hospitals. We also conducted six focus group discussions with the FCHVs to understand their perception of PPFP and the intervention. We performed descriptive and multivariable analyses for quantitative results and thematic analysis for qualitative data.

Results: In total, 230 FCHVs participated in the intervention and their knowledge of PPFP improved significantly after it. The intervention was the only factor significantly associated with their improved knowledge (adjusted odds ratio = 24, P < 0.001) in the multivariable analysis. FCHVs were able to counsel 83.3% of 1872 mothers at different stages of pregnancy in the communities. In the two hospitals, the proportion of mothers in their immediate post-partum period whom reported they were counseled by FCHVs during their pregnancy increased. It improved from 7% before the intervention to 18.1% (P < 0.001) after the intervention. The qualitative findings suggested that the intervention improved their knowledge in providing PPFP counseling.

Conclusion: The orientation improved the FCHV's knowledge of PPFP and their community-based counseling. Follow-up studies are needed to assess the longer term effect of the FCHV's role in improving community-based PPFP services.

Keywords: Family planning services, Post-partum period, Contraception, Intrauterine devices, Community health workers

¹Nepal Society of Obstetricians and Gynaecologists, Paropakar Maternity and Women's Hospital, Thapathali, Kathmandu GPO: 23700, Nepal Full list of author information is available at the end of the article



^{*} Correspondence: kusumthapa2006@gmail.com

Background

Globally, there has been increasing recognition of the importance of providing contraceptive services to women immediately after childbirth. However, three in five women around the world face an unmet need for post-partum contraception in the first two years after childbirth [1]. The unmet need for post-partum family planning (PPFP) is much higher in low and middle-income countries (LMICs). In Nepal, one in two women face this unmet need during the post-partum period [2].

PPFP is defined as the prevention of unintended pregnancy and closely spaced pregnancies during the first 12 months following childbirth [3]. PPFP helps to space pregnancies and prevent unintended pregnancies but is often neglected by users and providers due to sociocultural influences and lack of knowledge and availability of services [4–6].

The copper intrauterine device (IUD) is a PPFP method that can be used in the immediate post-partum period. It can be used immediately after childbirth either within 10 min of placenta being removed or 48 h of childbirth and is termed post-partum IUD (PPIUD) [7]. Women who undergo cesarean section can also choose PPIUD where the route of insertion is intra-cesarean [8]. PPIUD can be used by women who want to limit or space their pregnancies, it can be used effectively for up to 12 years and if desired can be removed easily at any time after insertion with immediate return of fertility [9].

In Nepal, PPIUD is currently the only reversible PPFP method available in the immediate post-partum period. Despite the advantages of PPFP, the use of immediate PPFP methods such as PPIUD remains low in Nepal as compared to other countries [10]. A qualitative study from the earlier phase of implementation of this initiative identified societal norms, as well as peer and health provider influences as factors that affected women's behavior on choosing a PPFP method [11]. The community level awareness of PPFP in general and in particular on PPIUD was very low [11].

In low-income countries, such as Nepal, many women continue to give birth at home and those who give birth in facilities often do not return for follow-up [12]. Nevertheless, the number of women giving birth in health facilities such as hospitals, health posts, and birthing centers has increased from 18% in 2006 to 57% in 2016 [13]. This increase in health facility deliveries provides a one stop approach for women to receive maternity care as well as immediate PPFP services [12].

Institutionalization of PPFP/PPIUD initiative in Nepal

Since 2015, the government of Nepal and Nepal Society of Obstetricians and Gynecologists (NESOG) with the support from the International Federation of Gynecology and Obstetrics (FIGO) has implemented the

institutionalization of immediate PPFP services initiative in six major referral hospitals across Nepal. The initial phases of the Initiative focused on PPIUD and the institutionalization of services of facility-based activities [14] including a time-limited employment of a counselor that improved PPFP counseling coverage. However, the overall uptake of immediate PPFP methods such as PPIUD remained lower than in other countries [12]. Moreover, a qualitative study conducted during an earlier phase of this initiative identified Female Community Health Volunteers (FCHVs) as an important influencer of women's behavior in choosing a PPFP method [11]. However, FCHVs or community-based activities were not part of the implementation in the earlier phase of this initiative. Built upon the lessons learned from the earlier implementation, the initiative introduced community linkages through the involvement of FCHVs in 2018 within the catchment areas of two implementing hospitals in Morang District of Province One in Nepal. If successful, this intervention would provide a sustainable means of providing community-based PPFP counseling in the future.

Role of FCHV in community linkage

The FCHV program was introduced in 1988 to support Nepal's family planning (FP) program nationwide [15]. FCHVs are recognized as a pillar of the health system in Nepal and an important bridge linking the communities to health care services. They are often the first point of contact for people in their communities who are in need of health services. FCHVs are not certified health providers, instead, they are women of different educational levels selected within each community to volunteer and promote health in the communities. Currently, over 52, 000 FCHVs are actively volunteering in Nepal with each FCHV reaching around 500 people in their communities [15]. All FCHVs undergo 18 days of basic training on FP, Maternal Newborn and Child Health (MNCH), and nutrition when they join this voluntary service [15].

For MNCH related health promotion activities, FCHVs conduct mothers' group meetings in the communities every month and organize counseling sessions for pregnant women in the communities on FP, birth preparedness and the advantages of institutional delivery [16]. They also identify danger signs among pregnant and post-partum mothers and newborns through their antenatal and postnatal home visits, and refer any with complications to health facilities [16].

The involvement of FCHVs in community health interventions in Nepal has effectively improved population-based coverage for various health services [17–21]. A post disaster health promotion intervention study involving FCHVs in an earthquake affected district in Nepal showed that their involvement helped in

improving the facility delivery among the mothers from 63 to 83% [21]. The same study also identified the improved odds of mothers having better knowledge and behaviors related to MNCH after the intervention [21]. Another cohort study found that those who received follow-up visits by FCHVs had 84% less relative risk of infant deaths due to low birth weight compared to those who had no FCHVs' involvement [19]. Despite the FCHVs' role in improving MNCH indicators in the country, their specific role in promoting PPFP was unclear. This study assessed the effect of an intervention in improving the knowledge of FCHVs on PPFP as a primary outcome. We also assessed the early effect of the intervention on PPFP counseling coverage in the communities and in the major referral hospitals as secondary outcomes.

Methods

Study design

This is a mixed methods study following the sequential explanatory method [22] where the qualitative study followed the quantitative study and helped in explaining the quantitative findings in more depth. The study utilized three quantitative and one qualitative techniques. The quantitative methods included knowledge assessment of FCHVs before and after the intervention, cross-sectional study of post-partum mothers admitted in the hospital, and the review of monthly reporting forms on FCHV's service coverage. The qualitative method included focus group discussions (FGD) with the FCHVs. We followed consolidated criteria for reporting qualitative research (COREQ) to conduct FGD, analyze, and report the qualitative findings.

Study settings

We conducted this study in two major referral hospitals and their catchment communities in Morang district, Province One. We assessed the knowledge of FCHVs in communities that were within the catchment areas of 23 peripheral health facilities in Morang District, Province One. In Nepal, FCHVs are linked with the peripheral health facilities in the communities, whereby each peripheral health facility usually supervises around nine to ten FCHVs in their communities and facilitate a monthly FCHV meeting in the health facilities to document their monthly activities [15, 16].

The selected 23 peripheral health facilities in this study are also the major catchment areas of the two major referral hospitals in Morang District namely, Koshi Zonal Hospital (KZH) and Nobel Medical College Teaching Hospital (NMCTH). Both hospitals have high obstetric workloads. Though KZH and NMCTH were the two major hospitals in the district, there are many other private hospitals, non-for profit hospitals, and birthing

centers where women from the same district could go for childbirth. Similarly, the two study hospitals also provided obstetric services to a wider population of mothers from different regions across the country. However, these two hospitals were selected specifically for this study as these were the only two hospitals in Morang District that had implemented the FIGO and NESOG supported PPFP/PPIUD initiative. Some other birthing centers and a non-profit hospital in the region also provide PPFP/PPIUD services through the government, however, exact data is not available.

Intervention

The intervention activities for this study were designed based on the findings from the previous qualitative study [11], and feedback from key stakeholders of MNCH and FP programs in Nepal. The intervention was focused on a cascade process of orientation of FCHVs in the selected communities. Under the leadership of Provincial Health Directorate in Province One, a pool of 15 facilitators were trained for the orientation of PPFP programs. The provincial level facilitators then trained 92 health providers at the peripheral health facility-level from 23 peripheral health facilities in Morang District, Province One. In December 2018, these health providers then trained nine to ten FCHVs within their peripheral health facility catchment communities, totaling 230 FCHVs.

The content and process of delivery in the training session remained the same for each level. The facilitators at each level employed a simplified approach using the FCHV User's Guide developed by the government of Nepal. The facilitators delivered key messages on PPFP, displayed posters related to different methods of PPFP, and also demonstrated the examples and samples of PPFP methods. The contents covered different methods of PPFP along with the advantages and disadvantages of each method. The content focused on PPIUD in more detail as it was the only long acting reversible method available in the immediate post-partum period in Nepal.

The sessions were interactive in nature. The facilitators tested the knowledge of the FCHVs through a structured questionnaire on the five key messages for immediate PPFP to assess their knowledge before and after the intervention on the same day. The facilitators discussed the changes in FCHV's scores and tried to address any areas of confusion.

Both FCHVs and health providers agreed to discuss the progress with PPFP related activities in their regular monthly meetings in the peripheral health facilities. The FCHVs were also required to maintain monthly reporting forms following the intervention and report on counseling coverage of PPFP for mothers at different stages of pregnancy within their communities. They were also required to report on the number of mothers who chose PPIUD after giving birth in various health facilities including the two study hospitals.

Study participants

The study participants comprised of FCHVs and mothers in the immediate post-partum period from the two hospitals. FCHVs were from communities within the major catchment areas of the two referral hospitals. In order to be considered eligible for both the quantitative and qualitative studies, the FCHVs had to be residing within the same area during the time of intervention, and willing to participate in the intervention.

Mothers in their immediate post-partum period, who were still in hospital and willing to participate and were eligible for the quantitative study were selected through simple random sampling. The mothers who had suffered any major post-partum complication, those who were physically unable to answer the questions and those admitted to intensive care units were excluded from this study due to ethical reasons.

Study tools

We used three different study tools for the quantitative study.

FCHVs' pre-posttest questionnaire

For FCHVs, the quantitative study tool comprised of questions related to their general characteristics and their knowledge of PPFP (Additional file 1). The general characteristics included their age, level of education, number of years working as a FCHV, and their exposure to FP related trainings in the past. For knowledge, we adopted the questions from the FCHV User's Guide on PPFP developed by the government of Nepal. The questionnaire had a list of five questions that assessed the key concepts of immediate PPFP and specifically PPIUD. The FCHVs had to choose either "true" or "false" for each question. Considering the possibilities of limited literacy of the FCHVs, the tools were designed with pictorial responses for each question. Others could read out the questions to FCHVs and they could choose a happy face for a "true" response and a sad face for a "false" response. The same tools were used before and after the intervention.

FCHV's monthly reporting form on community counseling coverage

The FCHVs also provided their monthly reporting forms that included information on their PPFP counseling coverage in the post-intervention period between January and February 2019 (Additional file 2). The information included the total number of mothers at different stages of pregnancy in the communities and the proportion of these mothers counseled by FCHVs on PPFP.

The numbers also represented the women who had already given birth after they were counseled and the proportion of the counseled mothers who chose PPIUD after giving birth in different facilities. The FCHVs obtained this information through individual interaction with the women in their communities.

Mothers' interview questionnaire

We used mothers' questionnaires to assess if the effect of community counseling coverage was reflected amongst the mothers giving birth in the two referral hospitals (Additional file 3). For the purpose of this study, we asked two specific questions to the mothers in their immediate post-partum period. The questions focused on whether they had ever interacted with FCHVs during their pregnancy and if they had ever been counseled by the FCHVs during their pregnancy. The mothers were required to answer either "yes" or "no" to these two questions.

For the qualitative study, the researchers conducted FGD with the use of FGD checklists (Additional file 4). The FGD checklists included questions related to the FCHVs' knowledge of PPFP, their impression of the intervention, their community-based activities after the intervention and their recommendations.

Study variables

The primary outcome was FCHVs' knowledge of immediate PPFP. The intervention was the main exposure variable. The other covariates included FCHV's age, level of education, number of years working as a FCHV, and their exposure to FP related orientations in the past.

The secondary outcome was the counseling coverage of PPFP by FCHVs. The counseling coverage in the communities was measured directly through FCHVs' reports. It included the number of mothers at different stages of pregnancy being counseled by FCHVs and the uptake of PPIUD among the counseled mothers who had recently given birth in different facilities including the two hospitals. Not all the mothers counseled by FCHVs had given birth during the study period. Moreover, not all the mothers who had given birth had gone to the two referral hospitals as there are other health facilities in Morang District.

The counseling coverage was also measured indirectly with the aim to validate if counseling activities in the communities had started to be reflected amongst the mothers who gave birth in the two study hospitals. We measured if the mothers delivering in the hospitals had ever interacted with and been counseled by the FCHVs during their last pregnancy before they came for child-birth. The mothers delivering in the hospitals represented women from a wider population and not just limited to the FCHVs' working areas.

Sample size

For FCHVs, we calculated the size using the formula to compare two proportions [23]. We assumed that FCHVs would have a minimum of 22% knowledge before the intervention and would reach over 35% after the intervention. The minimum required sample size was calculated to be 201 for each phase of the intervention with 80% power for both groups to have significantly different proportions at 5% level of significance. However, considering incomplete response rates, the sample size was increased. In total data for 230 FCHVs was included in the analysis of both pre- and post-intervention data.

For post-partum mothers from the two referral hospitals, we used the same formula to compare the two proportions. We assumed that the intervention would increase the proportion of mothers being counseled by FCHVs by 5% to a minimum of 15% after the intervention. The minimum required sample size was calculated as 157 for each group before and after the intervention, with 80% power for both groups to have significantly different proportions at 5% level of significance. However, considering incomplete data and response rates, we increased the sample size to collect the data of 250 mothers from each hospital [23].

After initial review of the quantitative data, we purposively selected 6 groups of FCHVs to participate in the qualitative study until the information reached point of saturation.

Data collection

We collected both quantitative and qualitative data between November 2018 and February 2019. The intervention for FCHVs was conducted in the month of December 2018 across 23 peripheral health facilities. The quantitative data to assess FCHVs' knowledge of PPFP was collected before and after the orientation program on the same day of the intervention. Random sampling was not a feasible option, we therefore used convenience sampling to recruit FCHVs in the intervention as we had to coordinate with the peripheral health facilities to invite FCHVs.

We collected the data for FCHVs' counseling coverage from two different sources. The FCHVs' monthly reporting form for PPFP was introduced after the intervention and comprised of information from the post-intervention period only between January and February 2019.

The data from post-partum mothers in the facilities was collected before and after the intervention. The mothers recruited in the study during November and December 2018 were considered the pre-intervention group and those recruited during January and February 2019 were considered the post-intervention group. We used a simple random sampling method to recruit

mothers in their immediate post-partum period. Every day the data collection officers (DCO) created a sampling frame of all the bed numbers with mothers in their immediate post-partum period who had given birth in the selected facilities. They then randomly selected two-bed numbers in each hospital through the opaque lottery method from the list of bed numbers and requested the mothers to participate in the study. If the selected mothers refused to participate, the DCOs repeated the process of random sampling leaving out the bed numbers of the mothers who had refused to participate. DCOs then interviewed the mothers who gave consent from the randomly selected bed numbers to participate in the study using a structured questionnaire on a mobile tablet.

The data collection for the qualitative study was conducted in late February 2019 and was guided by the quantitative study. After initial review of the quantitative results on FCHV's knowledge and the counseling coverage, we purposively selected six peripheral health facilities where the intervention had taken place. Each facility represented a unique group of FCHVs who had participated in the intervention showing different levels of knowledge of PPFP. The FCHVs from the selected health facilities were approached via telephone and requested to be physically present in the health facilities to participate in the FGD on the assigned dates. All the FCHVs that were contacted attended a FGD. A welltrained female qualitative researcher (RD) moderated the FGD with assistance from a female note taker. All FGDs were conducted in closed meeting rooms of the respective health facilities. Only the moderator, note taker and the FCHVs were present in the FGDs to maintain confidentiality and reduce bias. The moderator first explained the objective of the FGD and introduced the research team to the participants. The FCHVs were familiar with the reasons for conducting the research and a relationship with the research team had already been established through their earlier participation in the intervention and quantitative study. The FGDs took around 40 to 45 min to complete. All FGDs were audio recorded and field notes were transcribed by hand. The moderator (RD) summarized the discussions based on the field notes with the FCHV for their feedback, to ensure that the research team had understood them correctly.

Data analysis

We analyzed three different quantitative data sets using SPSS version 23 and the significance level was considered to be a p value of less than 0.05.

 For FCHVs, we conducted the descriptive analysis of their general characteristics, and bivariate and multivariable analysis to assess their knowledge of PPFP. We used chi-squared test to assess the change in proportions of FCHVs correctly answering questions on each of the five key messages on PPFP before and after the intervention. We used a logistic regression model to assess factors associated with their PPFP knowledge score. The outcome variable for knowledge was dichotomized to less than 4 correct answers and 4 or more correct answers out of 5 questions on key PPFP messages.

- For the counseling coverage by FCHVs in the communities, we conducted descriptive analysis.
- For the post-partum mothers at the two referral hospitals, we used a chi-squared test to assess the differences between the pre- and post-intervention groups on their responses to two questions; if they had ever interacted with a FCHV and if they had been counseled by an FCHV during pregnancy.
- We used thematic analysis [24] for qualitative data based on the five priori themes generated from the findings of quantitative data. All FGDs were conducted in Nepali and was translated into English language during the process of transcription. The transcripts were then reviewed by KT and SR and analyzed with Dedoose software version 8.0.42. KT, RD and SR first read and re-read the transcripts to familiarize themselves with the broad ideas and generated initial codes. KT, RD and SR then gathered all the coded data and collated the codes with the relevant priori themes. The themes were then reviewed by all the authors and assessed to determine whether the data was consistent with the findings and the overall objective of the study. KT, RD and SR then selected original and vivid quotes from FCHVs for each theme to provide more insights.

Results

Quantitative results

General characteristics of FCHVs orientated on PPFP

Table 1 shows the general characteristics of the FCHVs who attended the orientation on PPFP in Province One. Among the 230 FCHVs, the median age was 48 years [range 19–70 years]. The median years of working as an FCHV was 21 [range 2 months – 28 years]. In total, 45.7% of the FCHVs (n=105) had primary level education, 33.9% (n=78) had secondary level education, and 19.1% (n=44) had no formal education though they were able to write their names and read some very basic information. The majority of the FCHVs (88.3%) had previously received a general orientation on different FP methods, however, the majority of them (73.9%) had never received orientation specifically related to PPFP.

Table 1 General characteristics of FCHVs oriented on PPFP

Characteristic of FCHVs	N = 230				
	Median	Minimum	Maximum		
Age, in years	48	19	70		
Years of working as FCHV, in years	21	< 1	28		
		n (%)			
Education					
Cannot read and write	44 (19.1)				
Primary	105 (45.7	")			
Secondary	78 (33.9)				
University	3 (1.3)				
FP orientation in the past					
No	27 (11.7)				
Yes	203 (88.3)			
PPFP orientation in the past					
No	170 (73.9))			
Yes	60 (26.1)				

Changes in knowledge scores on PPFP of FCHV before and after the orientation

Table 2 shows the proportion of FCHVs answering the PPFP questions correctly before and after the intervention. Prior to the orientation, the lowest score was observed for the first question on whether women can use a contraceptive method immediately after birth. The proportion of FCHVs answering this question correctly improved from 45.7 to 75.2% after the orientation. The second lowest score was observed for question 3 which stated that women who undergo a cesarean section can use PPIUD. The proportion of FCHVs answering this question correctly improved from 50.2 to 97.4% after the orientation. Overall, the proportion of FCHVs being able to answer 4 or more questions correctly improved from 46.5 to 95.2%.

Factors associated with improved knowledge scores among FCHV

Table 3 shows the logistic regression model assessing the factors associated with knowledge of PPFP among FCHVs. The knowledge of PPFP was divided into those with correct knowledge of less than 4 questions and those with correct knowledge of 4 or more questions. There was a 24 fold increase in FCHVs ability to correctly answer 4 or more questions (AOR = 24.0, p < 0.001). Other sociodemographic characteristics of FCHVs and their exposure to any previous FP related training had no significant association with their knowledge scores.

Community-based PPFP counseling by FCHVs

Table 4 shows data from the peripheral health facilities monthly meeting records, collected and submitted by FCHVs, on their community-based activities. The 230

Table 2 FCHVs Change in knowledge scores on PPFP

Knowledge of PPFP	Pre-orientation $(n = 230)$	Post-orientation $(n = 230)$	P-value
Key messages	n (%)	n (%)	
1. Immediately after delivery, mothers can use contraception	105 (45.7)	173 (75.2)	< 0.001
2. Post-partum Intrauterine devices can provide protection up to twelve years	205 (89.5)	255 (97.8)	< 0.001
3. Mothers who undergo a caesarean section can have post-partum IUD inserted	115 (50.2)	244 (97.4)	< 0.001
4. IUDs can be inserted immediately after giving birth	148 (64.3)	223 (97.0)	< 0.001
5. If IUD strings are seen outside vagina, they should go for follow-up immediately	180 (78.3)	215 (93.9)	< 0.001
Overall correct answers			
Less than 4 correct answers	123 (53.5)	11 (4.8)	< 0.001
4 or more correct answers	107 (46.5)	219 (95.2)	

FCHVs oriented on PPFP managed to reach 83.3% (1559) of the total number of registered pregnant mothers. They counseled them about different methods of PPFP along with other general information on safe pregnancy and childbirth in a period of two months. Among the mothers counseled, 5% chose to receive a PPIUD when they gave birth in facilities in Province One.

PPFP related counseling received by mothers

Table 5 demonstrates the responses from the mothers who had delivered in the two referral hospitals on the

Table 3 Factors associated with knowledge scores^a on PPFP among FCHVs

	$N = 460^{b}$)	
Characteristics	AOR	95% CI	<i>P</i> -value
Intervention			
Pre-intervention ^c	1		
Post-intervention	24.0	(12.37–46.97)	< 0.001
Age	0.98	(0.96-1.02)	0.985
Years of working as FCHV	0.99	(0.96-1.03)	0.934
Education			
No formal education	1		
Primary level and higher	0.67	(0.40-1.11)	0.124
FP orientation in the past			
Yes	1.19	(0.73-5.01)	0.186
No ^c	1		
IUD orientation in the past			
Yes	1.04	(0.56-1.90)	0.897
No ^c	1		
PPFP orientation in the past			
Yes	0.951	(0.53-1.68)	0.862
No ^c	1		

^aknowledge scores = less than 4 correct answers and 4 or more correct answers

FCHV interaction and FCHV PPFP counseling they received during their pregnancy. In total 243 post-partum mothers were randomly selected for this study in the pre-intervention period and 238 post-partum mothers in the post-intervention period.

The proportion of mothers reporting that they had interacted with FCHVs during their pregnancy in the communities was significantly higher in the post-intervention group (23.2%, p = 0.001) as compared to pre-intervention group (11.9%). Similarly, the proportion of mothers who have been counseled by FCHVs on PPFP methods was also significantly higher in the post-intervention group (18.1%, p < 0.001) as compared to the pre-intervention group (7%).

Qualitative results

The participants of the FGD comprised of a subgroup of FCHVs who had participated in the quantitative study. In total, 54 FCHVs participated in FGD representing 6 health facilities and each FGD group had nine participants. The FCHVs represented different age groups and working experiences. The oldest FCHV was above 60 years of age and had over 25 years of working experience. The youngest FCHV was 20 years old and had working experience of less than a year.

We had five major priori themes for the six FGDs conducted. The themes helped to explain in more depth the quantitative findings on changes in their knowledge and community-based counseling activities. The first two themes focused on their knowledge of PPFP and their perceptions about the orientation program. The third and fourth themes focused on the activities they conducted after the orientation and the challenges they faced when working in the communities. The fifth theme summarized their overall impression and their suggestions for similar orientation programs and the overall role of FCHVs (Table 6).

^bpooled data from pre- and post-intervention

creference group

Table 4 Proportion of mothers at different stages of pregnancy counseled by FCHVs in the communities and uptake of PPIUD in facilities

Description	Number	Percent
Total FCHVs	230	_
Total pregnant mothers in the catchment areas of FCHVs	1872	
Mothers counseled by FCHV on PPFP	1559	83.3
Uptake of PPIUD by the mothers counseled by FCHV	80	5.1

Knowledge of PPFP

The majority of FCHVs suggested that PPFP was a very new concept that they only learned of through the current orientation program. Despite the general concept of FP being quite familiar for them, the majority suggested they had never heard that FP methods can be used immediately after childbirth.

"I was very surprised that FP methods like IUD can be used immediately after birth, something I have never known or heard before in my 27 years of working as FCHV."-FCHV-1/Group-1.

Some FCHVs shared their personal experiences of hearing about PPFP from the mothers in the communities. They mentioned that they had never received formal orientation on PPFP.

"I had heard about women using IUD immediately after birth in some hospitals, but no one had actually taught me about it and didn't know that it can be used immediately. So I used to wonder how it is possible to insert so soon after birth."-FCHV-5/Group-3.

On further probing, some FCHVs shared misconceptions on the insertion of PPIUD during cesarean section. The responses also reflected misinformation they had received from untrained PPFP health providers and as a result of some gaps in the orientation session.

"I think it's not possible for women who undergo cesarean section to use PPIUD because when a woman undergoes surgery, she is under so much pain. She cannot use the IUD through vagina because it causes so much pain. This was also something told to us by a doctor in a private hospital. We don't remember being explained about this in the training"-FCHV-6/Group-1.

On a personal level, many of them replied that the newly acquired knowledge on PPFP had changed their personal perspectives. While many of them had previously been apprehensive about the side effects of PPIUD, following the thorough explanation during the orientation sessions, they were now more informed and confident about this method. Some reflected that they could have helped more mothers sooner including those in their own family had they known about it earlier.

"Had we known about PPFP and in particular about PPIUD sooner, we could have suggested it to so many women. Would have made a difference in our own lives too."-FCHV-5/Group-4.

Perception of PPFP orientation program

All the FCHVs suggested that the orientation program was very effective and had helped in improving their knowledge. However, some had constructive criticisms on the process of the orientation, such as, its duration.

"The training is very useful and effective but felt the duration of the training was a bit short. If it was longer we could have discussed in more depth in a more relaxed manner."-FCHV-1/Group-1.

"The training was very useful. The duration was adequate, neither long nor short. We had enough time to discuss and learn in detail that's why we are able to answer your questions clearly now. It was also interactive and they cleared our doubts."-FCHV-3/Group-2.

Some responded that the best part of the orientation was the pre- and post-tests on their knowledge about PPFP. It allowed for self-assessment, and the improved scores post-orientation had helped them internalize that they had learnt something new.

Table 5 Interaction and counseling coverage by FCHVs among the post-partum mothers in the two referral hospitals

Community-based counseling	Pre-intervention $n = 243$	Post-intervention $n = 238$	<i>P</i> -value
Interaction with FCHV	29 (11.9)	55 (23.2)	0.001
Counseling by FCHV on PPFP	17 (7)	43 (18.1)	< 0.001

Table 6 Theme from Focus Group Discussions of FCHVs

Themes	Categories	Codes
1. Knowledge on PPFP	General knowledge of PPFP	New concept Personal experience
	Applied Knowledge on PPIUD	General Knowledge Misconceptions on PPIUD Personal perspective
2. Perception of PPFP orientation program	Impression on the process	Length Content
	Usefulness	Most useful/impressive aspect
3. Activities conducted by FCHVs on PPFP	Process of Counseling coverage	Introducing PPFP
		Complimenting facility-based counseling
	Reflection of the activities	Agent of change
4. Challenges	Societal barriers	Misconceptions
		Social disparity
	Personal Fear	Personal fear
5. FCHVs' suggestions	Process of orientation	Length of orientation
		Content delivery
		Opportunities for peer teaching /learning
	Sustainability	Involving other stakeholders
		Continuity

"They also distributed the papers to assess our knowledge, we were so nervous in the beginning, but then they explained everything in detail after we filled in the questions and then they took the test again after orientation. We could answer better and when the trainer said we all passed, we were so happy and felt we accomplished something significant."-FCHV-4/Group-4.

Activities conducted by FCHVs on PPFP

The FCHVs reflected upon their community-based activities following the orientation. All FCHVs reported having reached out to the pregnant mothers in the communities. On average, they counseled 7–8 pregnant mothers each, per month, on healthy pregnancy, safe childbirth and PPFP methods. The FCHVs took pride in their role as a pillar of their society and in bridging the gaps in health care.

"We are the pillars of the community. We help spread the awareness about the PPFP as a pillar too. We counsel mothers through Ama Samuha (mothers' group), Gaun Ghar (village-home) clinic and by meeting mothers individually through home to home visits."-FCHV-6/Group-1.

The FCHVs also suggested that their counseling complemented that done by the health providers in the facilities. They felt that being a point of contact for mothers

in the communities helped in providing additional reassurance to those who had already received counseling in the facilities.

"Those who go to these hospitals for antenatal care regularly are counseled about different methods of PPFP including PPIUD, when they talk to us they feel more reassured. Sometimes they want a second opinion from us whether they should use it or not."-FCHV-3/Group-5.

All the FCHVs perceived themselves as agents of change in their communities. They believed that they were able to influence the PPFP perspectives of the people in the communities. Their responses also reflected the social commitment and sense of responsibility ingrained in them.

"As the name suggests, we are the Swayam Sewikas (volunteers). That's what the government suggests too. Whenever we learn something new, we just can't wait to spread the message in the communities. Sometimes when I see a pregnant woman pass by my house, I stop cooking and run towards her and share new information." FCHV-3/Group-4.

Challenges

Despite all the positive feedback they had about PPFP and the positive work they have been doing in the

communities, many of them also reflected on the challenges they face. Some of the challenges were directly related to PPFP whereas others were more general.

The biggest barrier the FCHVs perceived were the deep-rooted misconceptions and beliefs that people in the communities have in general about modern contraceptives. Though they try to change people's perspectives, they believe that they are not always able to convince the women.

"The major challenge we often face is that many women have this misconception that temporary methods can cause cancer."-FCHV-4/Group-4.

The FCHVs also shared that although their voluntary role is well acknowledged by the government and most people; disadvantaged people tend to rely on them more for information, whereas people with higher social status avoid listening to them. The FCHVs believed that this puts disadvantages to those women as they have less knowledge and reduced access to free services.

"It is easier for us to reach out to more disadvantaged and poorer communities. They are more receptive. The toughest communities to reach are the people who think they are superior, are better off and have some level of education. The sad part is that they are too prejudiced to approach us to understand about free services but also cannot afford to pay for contraceptives in private medical stores. So they are at a disadvantage."-FCHV-2/Group4.

Some FCHVs reflected their personal fears in approaching mothers for counseling. They shared that there have been past instances of community members forcing them to take responsibility for complications they had experienced in the health facilities. They feared similar episodes might re-occur if the mothers they had counseled faced complications with the PPIUD.

"I am a bit worried that after we counsel these women to use PPIUD, if they decide to use it and face some complication they would come and scold us. There has not been such an incident yet. But you know as FCHVs sometimes there are ignorant people who tend to threaten us for every health consequence they face. Sometimes they say you tend to preach a lot, are you going to take the responsibility!! So that's a concern that I have with the use of PPIUD."-FCHV-5/Group-3.

FCHVs' suggestions

The FCHVs also provided suggestions for the implementers and other stakeholders on improving the FCHV orientation and community linkages.

Most suggested an increase in the real-time demonstrations of the entire process of PPIUD insertion, they specifically suggested showing an audiovisual aid or using a dummy to show insertion techniques.

"Showing us a video during the orientation about the details of PPFP methods and insertion of PPIUD would have been more effective."-FCHV-3/Group2.

While some had active ideas on the list of things to do to enhance the activities, a few of them, in particular, the older FCHVs with over 20 years of experience shared their words of wisdom. They believed that it takes time to bring change in the community and suggested that if activities are continued un-interruptedly, it may be more effective.

"It takes time. It's not a rapid process. When the awareness spreads gradually, the impact would be higher."-FCHV1/Group1.

"Anything new will take time for people to understand. So it will take time. The concept of PPFP especially PPIUD is still new so we must be patient."-FCHV5/Group4.

Many of the FCHVs recommended involving wider stakeholders beyond health workers. They suggested involving local leaders, representatives of mothers' groups and wider family members in dissemination and orientation activities. They believed such involvement would allow for a wider reach, enable task-shifting and increase awareness.

"To make this program more effective, the program implementers should also be present in the Gaun Ghar (village-home) clinics to provide the orientation of PPFP. Direct presence would help reach out to more women. Or if not you, maybe some representatives from the health centers could also help. If some authorized people could tell these women that FCHVs are telling the truth and their counseling is effective, then the women in the communities could be more convinced."-FCHV-3/Group-5.

Discussion

In this study, the intervention improved FCHV's know-ledge of PPFP significantly. After the intervention, the FCHVs were able to provide wide coverage of counseling on PPFP to women at different stages of pregnancy in the communities. Within two months of the intervention, the proportion of post-partum mothers reporting that they were counseled by FCHVs during their pregnancy improved significantly. The qualitative findings provided more depth into FCHVs' knowledge, their

impression of the intervention and further details about the activities and challenges they faced.

The quantitative findings suggested that the know-ledge of PPFP among FCHVs improved significantly after the intervention. Qualitative findings supported this and the majority of mothers were able to explain PPIUD. A previous qualitative study from the same initiative had identified the lack of knowledge among FCHVs as an important barrier to women's uptake of immediate PPFP methods [11]. FCHVs are often the first point of contact for women in the communities to seek correct information and timely health care. Thus, the findings from this study are encouraging as the improved knowledge of PPFP among FCHVs would enable them to provide correct and timely information to the women in need of PPFP services.

The qualitative findings indicated that the majority of FCHVs perceived the intervention to be useful. However, some FCHVs also highlighted certain gaps in the intervention process. Some FCHVs wished that the duration of the intervention was longer and more interactive, while some reflected on the lack of use of audiovisual aids such as videos on PPFP methods and in particular on PPIUD insertion. It was a conscious decision made by the implementers to simplify the content delivery considering the limited education levels among FCHVs. It indicates the need for the implementers not to under-estimate use of technology when interacting with people with limited literacy. Studies suggest that interactive sessions with adequate time provide more knowledge retention [25]. Thus, the feedback from the FCHVs is important to take into consideration to improve the delivery of the intervention in the future.

In this study, both the quantitative and qualitative findings suggested that FCHVs were able to reach out to many mothers at different stages of pregnancy in the communities and counsel them on PFPP. Though FCHVs have managed to conduct many MNCH related activities in the past [19–21], PPFP related activities were almost non-existent before the intervention. With the improved knowledge of PPFP, FCHVs were able to encourage women to go to facilities for childbirth [21] and also inform them about the contraceptive choices available immediately after giving birth in facilities.

FCHVs reported that 5% of the pregnant women they had counseled had chosen PPIUD when they gave birth in various hospitals including the two study hospitals in Morang District, Province One. Nepal does not have specific PPIUD nationally representative data, however, the overall uptake of IUD was found to be just 1.4% [13]. Therefore, the early findings of the effect of FCHV's involvement in PPFP is quite encouraging.

The quantitative findings also found an increased proportion of mothers delivering in the hospitals had been counseled by FCHVs during their pregnancy. This finding validates the community-based activities conducted by the FCHVs by reflecting their work in the experiences of women delivering at the facilities. Though still early to assess the longer term impact of the intervention, this finding indicates that a significant proportion of mothers reaching the health facilities for childbirth are already informed about the PPFP options they can choose after the childbirth. The increase in institutional delivery provides an increased opportunity for women to receive PPFP services such as PPIUD [12]. This enables women to receive both obstetric care and PPIUD services in the same setting around the same time. Thus, FCHVs role in PPFP provides an opportunity to increase the demand and access to PPFP services in the health facilities.

The qualitative findings also provided more information about the challenges FCHVs face while working in the communities. Some challenges were similar to those faced by community health workers (CHW) in other countries, such as Brazil, which included lack of understanding among the people and lack of respect of their work in communities [26]. FCHVs in this study, also pointed out the social barriers and deep-rooted misconceptions among the mothers about modern contraceptives making it difficult for them to convince the people in the communities of their benefits. Studies from LMICs have indicated multiple barriers among mothers on the uptake of PPFP methods, such as PPIUD, which include social taboos, lack of knowledge, lack of autonomy to make decisions and many more [4-6]. As indicated by some FCHVs in the FGD, change could take time and consistency in providing community awareness could be the most important solution to overcome barriers related to PPFP in communities.

Overall, this study indicates that the intervention has helped in improving FCHVs' knowledge on PPFP and enabled them to include PPFP counseling in their MNCH related activities in the communities. A systematic review on CHW's role in FP services in LMIC has indicated positive results in improving the use of modern contraception and in improving knowledge and attitude related to FP [27]. However, these studies have focused on FP in general and have not explored the roles of CHW specifically in PPFP. This study provides important baseline information on CHW's role in PPFP.

Limitations

This study has certain limitations. Firstly, the length of the study is too short due to the time limitation of the initiative. A longer duration would have provided an opportunity to carefully follow-up the FCHVs to evaluate any changes in their knowledge and behaviors related to community-based counseling in the longer run. Moreover, it could have provided enough time to assess the

long-term impact of the FCHV's role in changing PPFP related intention and behaviors of mothers. Secondly, this study lacked control groups of FCHVs who had not received the orientation program. Having a control group for pre- and post-intervention periods could have provided a better comparative perspective. Thirdly, this study does not have information from other stakeholders involved in the intervention, such as, the health providers who were involved as facilitators in the orientations. Furthermore, no data related to the coverage of the facility-based counseling in the peripheral health posts was available. This information could have provided a more complete picture of the roles at each layer of the health system.

Despite the limitations, this is the first study that has assessed the role of FCHV in delivering communitybased PPFP counseling services in Nepal. The findings indicate that involving FCHVs in PPFP programs is beneficial and they also indicate the inadequacies in existing PPFP programs. Although PPFP was introduced in Nepal over a decade ago, it is still a new concept for FCHVs; this reflected the lack of community-level interventions and awareness activities. Despite the short period of time, these FCHVs were able to reach out to a large number of mothers. As for many other health interventions, FCHVs could be a sustainable medium for community mobilization for PPFP programs. Follow-up studies are necessary to assess the long term impact of such interventions in the communities and similar studies involving CHW from other LMICs could provide a global perspective.

Conclusion

This study showed that the orientation of PPFP improved the knowledge of FCHVs on PPFP which in turn improved their counseling coverage on PPFP in the communities. The orientation improved the FCHV's knowledge of PPFP and the quality of their community-based counseling. The increased proportion of mothers being counseled by FCHVs has also been reflected in the facility-based results. Longer follow-up studies are warranted to provide a longitudinal perspective on the effect of FCHV's community-based activities on mother's uptake of PPIUD.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10. 1186/s12913-020-4969-1.

Additional file 1. Interview Questionnaire for Female Community Health Volunteers.

Additional file 2. Checklist for FCHVs monthly reporting forms.

Additional file 3. Interview Questionnaire for post-partum mothers.

Additional file 4. FGD checklists for FCHVs.

Abbreviations

CHW: Community health workers; DCO: Data collection officer; FCHV: Female Community Health Volunteer; FGD: Focus group discussions; FIGO: International Federation of Gynecology and Obstetrics; FP: Family planning; IUD: Intrauterine contraceptive device; KZH: Koshi Zonal Hospital; LMIC: Low and middle income countries; MNCH: Maternal newborn and child health; MOHP: Ministry of Health and Population; NESOG: Nepal Society of Obstetricians and Gynecologists; NHTC: National Health Training Center; NMCTH: Nobel Medical College Teaching Hospital; PPFP: Post-partum family planning; PPIUD: Post-partum intrauterine contraceptive device

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Authors' contributions

KT was involved in conceiving the study design, finalizing the tools, analysis, writing, and revisions of the manuscript. RD was involved in designing the study, finalizing the study tools, data collection, analysis, and writing the first draft of manuscript and subsequent revisions. SR was involved in coordination of data collection, data analysis and revision of the manuscript. SM, SS and BD were involved in coordination of the data collection and revision of the manuscript. SV and SP were involved in revision of the manuscript. ET, AM and SA provided the technical guidance and revisions of the manuscript. The authors read and approved the final manuscript.

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Availability of data and materials

All anonymized quantitative data will be available in Figshare repository upon acceptance of the manuscript. Qualitative data will be available from the corresponding author only upon reasonable request as it contains personal quotes from the respondents which maybe identifiable.

Ethics approval and consent to participate

This study was approved by the ethical review board of the Nepal Health Research Council under Regd. 502/2018. The written informed consent was collected from all the participants. The participation was voluntary and confidentiality was maintained for all the participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

¹Nepal Society of Obstetricians and Gynaecologists, Paropakar Maternity and Women's Hospital, Thapathali, Kathmandu GPO: 23700, Nepal. ²Koshi Zonal Hospital, Biratnagar, Morang District, Province One, Nepal. ³Nobel Medical College Teaching Hospital, Biratnagar, Morang District, Province One, Nepal. ⁴Health Directorate-Province One, Dhankuta, Nepal. ⁵International Federation of Obstetrics and Gynecology, London, UK.

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RESEARCH ARTICLE

Evaluating the impact of female community health volunteer involvement in a postpartum family planning intervention in Nepal: A mixed-methods study at one-year post-intervention

Rolina Dhital 10, 1,20, Ram Chandra Silwal 10, Khem Narayan Pokhrel 1,30, Sabina Pokhrel 1, Heera Tuladhar 40, Suzanna Bright 50, Emily-Anne Tunnacliffe 50, Kusum Thapa 40, Anita Makins 50

- 1 Green Tara Nepal, Kathmandu, Nepal, 2 Health Action and Research, Kathmandu, Nepal, 3 Tropical Health and Education Trust, Kathmandu, Nepal, 4 Nepal Society of Obstetricians and Gynecologists, Paropakar Maternity and Women's Hospital, Kathmandu, Nepal, 5 International Federation of Gynecology and Obstetrics, London, United Kingdom
- These authors contributed equally to this work.
- * rolina.dhital@gmail.com

Abstract

Introduction

This is a one-year post-intervention study following an initiative to provide orientation to female community health volunteers (FCHVs) on postpartum family planning in Nepal. In light of positive results in the earlier post-intervention study, this study was designed to provide a more long-term perspective on sustainability by assessing the effect at one-year post-intervention.

Methods

This mixed-methods study was conducted in January 2020 in Morang district, Nepal. We collected quantitative data from a knowledge assessment of FCHVs who had participated in the intervention on postpartum family planning, data on their community-based counseling coverage and through interviews with postpartum mothers in two selected hospitals. Qualitative data were collected through six key informant interviews with health providers and four focus group discussions with FCHVs involved in the intervention. We performed descriptive and multivariate analyses for quantitative data and thematic analysis for qualitative data.

Results

In total, 206 FCHVs participated in the one-year post-intervention study with significant improvement in knowledge of postpartum family planning as compared to pre-intervention period. The adjusted odds ratios (AOR) for knowledge of the 5 key messages on postpartum

family planning as compared to the pre-intervention period included 1) knowledge on post-partum family planning can be used immediately after birth (AOR = 18.1, P<0.001), 2) post-partum intra-uterine device (PPIUD) can provide protection up to 12 years (AOR = 2.9, P = 0.011), 3) mothers who undergo cesarean section can use PPIUD (AOR = 2.3, P<0.001), 4) PPIUD can be inserted immediately after birth (AOR = 6.2, P<0.001), and 5) women should go for follow-up immediately if the IUD strings are seen outside vulva (AOR = 2.0, P = 0.08). The FCHVs answering 4 or more questions correctly was 10 times higher (AOR = 10.1, P<0.001) at one-year post-intervention, whereas it was 25 times higher at immediate-post-test (AOR = 25.1, p<0.001) as compared to pre-intervention phase.

The FCHVs had counseled 71% of the pregnant women (n = 538) within their communities at one-year post-intervention. The postpartum mothers in hospitals had a 2 times higher odds of being counseled by FCHVs during their pregnancy at one-year post-intervention (AOR = 1.8, P = 0.039) than in pre-intervention phase. The qualitative findings suggested a positive impression regarding the FCHV's involvement in postpartum family planning counseling in the communities, however, supervision and monitoring over a longer term was identified as a key challenge and that may influence sustainability of community-based and hospital-based postpartum family planning services.

Conclusion

The FCHVs' knowledge and community-based activities on postpartum family planning remained higher than in the pre-intervention. However, it declined when compared to the immediate post-intervention period. We propose regular supervision and monitoring of the work of the FCHVs to sustain progress.

Introduction

In low and middle-income countries such as Nepal, not all women give birth in health facilities, and among those who do deliver in health facilities, return for follow-up remains a challenge [1]. In Nepal, the proportion of women giving birth in health facilities in the presence of skilled birth personnel has increased from 18% to 57% between 2006 and 2016 [2]. Despite the increase in facility deliveries, the utilization of postnatal care services remains low in the country [3].

The barriers to low utilization of postnatal care in Nepal are attributed to socio-cultural factors, difficult geographical and transportation barriers to visiting health facilities in the postnatal period, lack of adequately trained health professionals, and lack of quality care in the health facilities. The low utilization of postnatal care services has also acted as a barrier for uptake of family planning methods during the postpartum period among women in Nepal [3].

Postpartum family planning is the family planning method available for women for the first 12 months of the postpartum period [4]. The family planning methods available after six weeks of childbirth in Nepal for breastfeeding mothers include progesterone-only contraceptives such as oral contraceptive pills, implants, and injectable, non-hormonal methods such as copper intrauterine device (IUD), and female sterilization [5]. The options available for men include condoms and male sterilization throughout the women's postpartum period [5]. The contraceptive methods available only six weeks after childbirth limit the choices for women who may resume their sexual activities sooner, and the options available for their male partners might not be reliable when women lack autonomy [5,6]. Moreover, for a country with low

postnatal care coverage, it limits women's options for family planning, especially when the women are less likely to return to the facilities [1]. Therefore, postpartum family planning options available immediately after childbirth provide a one-stop solution for those giving birth in the health facilities [1,5,6]. The immediate postpartum family planning services available for women in Nepal include female sterilization and postpartum IUD (PPIUD) [5].

The postpartum family planning initiative was implemented in Nepal jointly by the Nepal Society of Obstetricians and Gynecologists and the International Federation of Gynecology and Obstetrics between 2015 and 2020 [7]. The initiative was primarily hospital-based that focused on training health care providers on the skills of providing immediate postpartum family planning services [7]. The initiative also included hospital-based counseling of pregnant women during their antenatal care (ANC) visits on different postpartum family planning methods [7,8]. However, the awareness and uptake of postpartum family planning methods among postpartum mothers remained lower in Nepal than in other countries [1]. Previous studies from the same initiative identified a lack of community activities as a barrier to the low uptake of immediate postpartum family planning services in Nepal [6,7]. The studies also suggested that female community health volunteers (FCHVs) could play a role in raising awareness about postpartum family planning methods among women in the communities and link the women to the services provided in the hospitals [6,7].

Therefore, an intervention study was designed and implemented as part of the postpartum family planning initiative focusing on FCHVs in Nepal in December 2018 [8]. The goal of the intervention with FCHV was to suffice the existing hospital-based postpartum family planning initiative and link the women in the communities to the hospitals providing postpartum family planning services [8]. The intervention was incorporated into the national FCHV programs and was piloted in Morang district, Nepal. The intervention focused on improving FCHVs' knowledge of postpartum family planning through an orientation program and supervision of their community activities [8].

The initial intervention study showed that FCHVs had a significant improvement in their knowledge of postpartum family planning as assessed by a post-test on the same day of the training [8]. However, the study lacked a perspective on knowledge retention and the sustainability of the intervention. The follow-up period after two months of the intervention was too short to provide a longitudinal perspective [8]. Therefore, this study aims to assess the effect of the FCHV's intervention one year after its completion, in terms of FCHV knowledge retention and their community counseling activities in Morang district, Nepal. Comparisons were made with the earlier post-intervention study results [8]. This study could provide a longer-term perspective before expanding FCHVs' involvement in promoting postpartum family planning at the provincial and national levels in Nepal.

Methods

This is a one-year post-intervention study that employed a mixed-methods research design. The study followed a sequential explanatory method [9] where the qualitative approach intended to provide insights to the quantitative approach. The Consolidated Criteria for Reporting Qualitative Studies (COREQ) was used to collect, analyze, and report the qualitative findings [10]. The COREQ checklist is provided in the supporting file (S1 Table).

Study settings

This study was conducted in Morang District, Province One in eastern Nepal. To be in line with the initial post-intervention evaluation [8], this study was conducted at two major referral hospitals in Morang District namely, Koshi Zonal Hospital and Nobel Medical College Teaching

Hospital, and the catchment communities of the 23 peripheral health facilities covered by the FCHVs who received the postpartum family planning orientation in December 2018.

The hospitals, peripheral health facilities, and FCHVs represent different layers of the health system in Nepal. The peripheral health facilities represent the primary care centers. However, not all peripheral health facilities are birthing centers and the health providers were not trained on immediate postpartum family methods such as PPIUD at the time of data collection. The peripheral health facilities are linked to the referral hospitals and serve as catchment areas for the hospitals. The two hospitals included in this study were the major referral hospitals in the Morang district providing maternity care and immediate postpartum family planning services [5,8]. Koshi Zonal Hospital is a government hospital and a part of the hospitals implementing the postpartum family planning initiative since 2015. Nobel Medical College Teaching Hospital is a private teaching hospital that started implementing the postpartum family planning initiative in 2018 [5].

Study participants

Quantitative study. The quantitative study participants included FCHVs from the communities and postpartum mothers from the two hospitals. All 230 FCHVs who had participated in the intervention were contacted and invited to participate in the study [8].

The postpartum mothers who had given birth and were admitted at the time of data collection in the two hospitals between January 10, 2020, and February 9, 2020 were considered eligible. We included all women of reproductive age who had delivered at the two hospitals including mothers with newborns who had complications. Mothers with severe maternal postpartum complications, those physically unable to respond to the questions, and those admitted in the intensive care units were excluded.

Qualitative study. Qualitative assessment was conducted through key informant interviews (KII) and focus group discussions (FGD). We conducted four FGD with 40 FCHVs who were a subgroup of the 230 FCHVs who had participated in the quantitative study to gain better insights into their knowledge and community-based activities. We purposively selected two facilities with FCHVs having higher knowledge scores and two facilities with FCHVs having lower knowledge scores based on the posttest knowledge scores from previous evaluation study [8]. All the FCHVs approached for FGD agreed to participate.

We also conducted six KII with the stakeholders involved in delivering the intervention for FCHVs. The key informants included:

- 1. a former director of the Provincial Health Directorate of Province One,
- 2. a senior public health administrator of Morang district health office who was involved in planning and coordination of the intervention,
- 3. a doctor and a nurse from the two referral hospitals who were providing postpartum family planning services, and
- 4. personnel in charge of the health facility from two of the peripheral health facilities supervising FCHVs.

The KII participants were selected purposively based on their active involvement in the intervention.

Study tools

Quantitative tools. For comparison, the same quantitative study tools were used as in the previous post-intervention evaluation study [8]. The tools are provided in the supporting information (\$2 and \$3 Tables). The tools included:

Knowledge of postpartum family planning	T1	T2	Т3	T3-T1	T3-T2
	(n = 230)	(n = 230)	(n = 206)		
Questions	n (%)	n (%)	n (%)	(%)	(%)
1. Can mothers use contraception immediately after delivery?	105 (45.7)	173 (75.2)	193 (93.7)	64.0***	0.2***
2. Can Postpartum Intrauterine devices provide protection for up to twelve years?	205 (89.5)	255 (97.8)	198 (96.1)	7.4***	-0.02
3. Can mothers who undergo a caesarean section have postpartum IUD inserted?	115 (50.2)	244 (97.4)	144 (69.9)	39.2***	-28.2***
4. Can IUDs be inserted immediately after giving birth?	148 (64.3)	223 (97.0)	189 (91.7)	17.6***	42.6*
5. Should women go for follow up immediately if the IUD strings are seen outside vulva?	180 (78.3)	215 (93.9)	181 (87.9)	12.3***	-5.6*
Overall correct answers					
4 or more correct answers	107 (46.7)	219 (95.6)	186 (90.3)	93.4***	-5.5*

T1 = Pre-test before the orientation, T2 = Post-test immediately after the orientation, T3 = 1-year post-intervention.

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- FCHVs' knowledge questionnaire: This included five questions which assess knowledge of the key concepts of immediate postpartum family planning and specifically PPIUD (Details in Table 1). The tool was adopted from the government of Nepal's FCHV User's Guide on postpartum family planning. The tool was designed to be simple by the government and experts of postpartum family planning in Nepal considering the possibilities of limited literacy of the FCHVs [8].
- FCHVs' monthly reporting form: Information on counseling coverage was collected for a period of two months prior to the start of data collection for this study from November to December, 2019. Indicators included the total number of pregnant mothers in the communities and the proportion of pregnant mothers counseled on postpartum family planning by FCHVs (Table 3).
- Mothers' interview questionnaire: We used the same questionnaire used in previous study [8] to assess if the effect of community counseling coverage by FCHVs was reflected amongst the mothers giving birth in the two referral hospitals. To fulfill the objective of this study, we specifically asked if they had been counseled on postpartum family planning by FCHVs in their community during their pregnancy.

Qualitative tools

• For the qualitative study, the researchers used FGD and KII guides. We used the same FGD guide used in previous study [8] which did not require pretesting. We developed a new KII checklist for this study (S2 Table) which was similar to FGD. Both the tools were reviewed by the qualitative research experts. The guides included the following topics: knowledge of postpartum family planning; impression of the intervention; community-based counseling activities on postpartum family planning; perspectives on the challenges of sustainability; and their suggestions for how to increase long-term impact.

Study variables

The primary outcomes were FCHVs' knowledge retention on each of the 5 key messages of postpartum family planning at one year. Other covariates included FCHVs' age and number

^{*}P<0.05.

^{**}P<0.01.

^{***} P-value<0.001.

of years working as an FCHV. The characteristics of the same population of FCHVs has been described in detail in the previous evaluation study [8].

The secondary outcome was the proportion of women provided counseling on postpartum family planning by FCHVs. The ultimate goal was to prepare and inform the women about the postpartum family planning choices they can use immediately after childbirth. The responses from the postpartum mothers admitted in the hospitals validated the community linkage with the hospitals and reflected the community-based activities conducted by the FCHVs. The exposure variables for the mothers from the two hospitals included the district they came from for delivery and the hospitals where they delivered.

The counseling coverage in the communities was self-reported by FCHVs. The FCHVs' reports reflected the pregnant women at different stages of pregnancy in the communities in the past two months before data collection.

Sample size

For FCHVs, we attempted to follow the 230 FCHVs who had participated in the previous evaluation study in pre and post-tests [8]. The details of sampling for the early evaluation has been described in the previous study [8]. A total of 206 FCHVs participated in this one-year post-intervention study, out of the 230 FCHVs with a follow-up rate of 89.6%. Among the 24 FCHVs who did not participate in the follow-up study, two had just retired from their role as FCHV, and 22 did not attend the interview (S1 Fig).

For postpartum mothers, with the assumption that counseling coverage would increase from 7 to 15% between pre and post-intervention, to detect a difference at 80% power and a 5% level of significance [11], a minimum sample of 237 postpartum women was required for one-year follow-up. Allowing for potential incomplete responses a sample size of 300 was adopted with 150 women from each hospital.

Data collection

Quantitative data collection. Quantitative data were collected through face-to-face interviews using smart phones and mobile tablets. The structured data collection tools were developed using Open Data Kit (ODK) software [12]. All the tools were available in both English and Nepali [8]. All study participants were interviewed in Nepali. Data enumerators were trained on data collection techniques, use of the ODK application for smart phones and mobile tablets, ethical considerations, and were provided with an overview of postpartum family planning methods. Data enumerators used the smart phones and mobile tablets to read out the questions to participants and enter their responses.

The 23 peripheral health facilities involved in the training and supervision of the 230 FCHVs coordinated for the data collection. Each facility invited the 9–10 FCHVs who had participated in the intervention within their catchment communities to attend their regular monthly meeting. We chose the same day of the monthly meeting for our data collection at each facility. The FCHVs were provided with travel incentives to attend the monthly meetings as part of the government norms. Data collection for FCHVs took place in January 2020 across 23 peripheral health facilities. All the FCHVs who attended their monthly meeting agreed to participate in the study and gave written informed consent, and were interviewed in a separate room maintaining confidentiality.

For postpartum mothers, we collected the data of the admitted mothers from the two hospitals. We chose the simple random sampling method to recruit the mothers admitted to the two hospitals at the time of data collection. As the healthy mothers and their newborns were discharged within a few days of their childbirth, the enumerators created a sampling frame every

day of all the bed numbers of the mothers admitted in the postpartum wards. The enumerators then randomly selected 5 mothers from the list of numbers based on computer-generated random bed numbers for each hospital on each day. The enumerators would request the selected mothers to participate in the study and if they refused, they'd rule out the particular bed numbers and regenerate a new random bed number. The postpartum mothers included in this study represented 30% of an estimated 1000 deliveries over 1 month across the two hospitals. All mothers were provided with an information sheet and their participation was entirely voluntary. Written informed consent was obtained. Mothers were interviewed at their bedside, prior to discharge, without the presence of their caretakers or family members in order to maintain confidentiality.

Qualitative data collection. A qualified researcher, independent from the intervention, moderated all the FGD and conducted the KII using the interview checklists. The independent researcher was accompanied by another female researcher who assisted with taking field notes and audio-recording the discussions. Only the two qualitative researchers, and the FCHVs or KII respondents were present in each FGD and KII sessions respectively. The moderator first explained the objectives of the FGD and KII and introduced the research team to the participants. The FGD and KII took around 40 to 45 minutes to complete. The moderator summarized the discussions based on field notes to the FCHVs and stakeholders for their feedback and to ensure that the research team had understood them correctly.

Ethical considerations

Ethical approval was obtained from Nepal Health Research Council under Ethical Review Board protocol number 823/2019. The written informed consent was collected from all the participants and their privacy and confidentiality were ensured for both quantitative and qualitative studies. Their participation was voluntary and at no point were they pressurized or coerced.

Data analysis

Quantitative analysis. We analyzed three different quantitative datasets using SPSS version 23 with a significance level set at a P-value < 0.05. Bivariate and multivariable analyses were conducted to assess FCHV knowledge retention on postpartum family planning. Chisquared tests were completed to assess the change in proportions of FCHVs correctly answering questions on each of the five key messages on postpartum family planning (details provided in Table 1), at the post test questionnaire held immediately after the intervention, and one year after the intervention as compared to pre-intervention. Logistic regression models were used to assess the association between the time of the intervention phases and knowledge of each of the five key messages on postpartum family planning, controlling for FCHVs' age and years of working experience.

Descriptive analysis of counseling coverage by FCHVs in the communities was completed, based on their monthly records of postpartum family planning as reported by FCHVs. Indicators included: total number of pregnant women and the proportion of pregnant women counseled by FCHVs on postpartum family planning.

We compared the proportions of postpartum mothers being counseled by FCHVs during their pregnancy between two-month and one-year follow-up assessments using a chi-squared test.

We then used a multiple logistic regression model to examine the association between the assessment phases and the proportion of mothers reporting to have received postpartum

family planning counseling by an FCHV. The logistic regression models controlled for districts the women came from and the hospitals they delivered.

Qualitative analysis. Thematic analysis [13] was conducted on the qualitative data based on the five priori themes generated from the two-month post-intervention study [8]. All FGDs were conducted in Nepali and were translated into English language during the process of transcription. The first author and the third author reviewed the transcripts. The first four authors then analyzed the qualitative data using Dedoose software version 8.0.42. The authors first read and re-read the transcripts to familiarize themselves with the broad ideas and generated initial codes. They then gathered all the coded data and collated the codes with the relevant priori themes from the previous study and then selected original quotes from FCHVs and KII for each theme to provide further insight. The first author then compared the responses from the one-year post-intervention study with the responses from the two-month post-intervention study for each theme. The themes were then reviewed by all the authors and assessed to determine whether the data was useful in addressing the overall objective of the study.

Results

Quantitative results

Table 1 shows the proportion of FCHVs answering the postpartum family planning questions correctly before the orientation (pre-test), immediately after the orientation (post-test), and one-year after the intervention. A total of 206 FCHVs participated in this one-year post-intervention study, out of the 230 FCHVs who had participated in the intervention at the start (89.6%).

The proportion of FCHVs answering the questions correctly at one-year post-intervention remained significantly higher than pre-intervention for all five questions. However, the proportions of correct answers were lower as compared with the immediate post-test for all but one question.

At one-year post-intervention, the lowest proportion of correct answer was observed for the question on whether a mother who undergoes cesarean section can use a PPIUD. The proportion of FCHVs answering this question correctly decreased by 28% at one-year post-intervention as compared to 39.2% increase in the post-test immediately after the orientation. The percentage of FCHVs answering overall 4 or more questions correctly at one-year post-intervention had decreased by 5.5% than immediate posttest. However, it has increased by 93.4% as compared to pre-test.

Table 2 shows the logistic regression models examining the association between the different phases of assessment of knowledge on each of the 5 key messages of postpartum family planning knowledge among FCHVs. Knowledge of postpartum family planning was also assessed among those with fewer than overall 4 correct answers and those with overall 4 or more correct answers.

In the adjusted model, a 25-fold increase in FCHV knowledge had been observed at the post-test [AOR = 25.4 (CI 12.6–50.2), P<0.001], and at one-year post-intervention it remained approximately 11 fold higher [AOR = 10.7(CI 6.3–18.1), P<0.001] as compared to the pre-intervention phase.

The knowledge for each of the five key questions had significantly improved as compared to the pre-intervention phase. The knowledge on postpartum family planning can be used immediately after birth was 18 folds higher (AOR = 18.1, P<0.001) in one-year post intervention which was higher than the increase in knowledge at immediate post-test (AOR = 3.6, P<0.001) as compared to the pre-test before the intervention. The knowledge on PPIUD can provide protection for up to 12 years was 3 folds higher at one-year post-intervention

Table 2. Association between intervention phases and knowledge on key messages of postpartum family planning among FCHVs.

	Knowledge of postpartum family planning		All 3 phases of assess	sment
	Characteristics	Assessment	UOR (95% CI)	AOR ^a (95% CI)
1	Can mothers use contraception immediately after delivery?	Pre-test	1	1
		Post-test	1.4 (0.9–2.1)	3.6 (2.4-5.4)***
		1-year post-intervention	9.7 (5.4–17.6)***	18.1 (9.7–33.6)***
2	Can Postpartum Intrauterine devices provide protection for up to twelve years?	Pre-test	1	1
		Post-test	3.6 (1.4-9.3)**	5.3 (1.9-14.1)**
		1-year post-intervention	1.7 (0.7-3.7)	2.9 (1.3-6.6)**
3	Can mothers who undergo a caesarean section have postpartum IUD inserted?	Pre-test	1	1
		Post-test	25.3 (11.0-58.4)***	37.6 (16.0-88.2)***
		1-year post-intervention	0.82 (0.6-1.2)	2.3 (1.6-3.5)***
4	Can IUDs be inserted immediately after giving birth?	Pre-test	1	1
		Post-test	9.4 (4.3-20.5)***	17.7 (7.9-39.3)***
		1-year post-intervention	2.7 (1.5-4.6)***	6.2 (3.5–10.8)***
5	Should women go for follow up immediately if the IUD strings are seen outside vulva?	Pre-test	1	1
		Post-test	3.2 (1.7-5.7)***	4.3 (2.3-7.9)***
		1-year post-intervention	1.7 (0.7-1.9)	2.0 (1.2-3.4)**
	Overall correct answers	Pre-test	1	1
	4 or more correct answers	Post-test	10.6 (5.5-20.6)***	25.4 (12.6-50.2)***
		1-year post-intervention	3.8 (2.3-6.2)***	10.7 (6.3–18.1)***

UOR = unadjusted odds ratio, AOR = adjusted odds ratio.

1 = reference.

NA = not included in the analysis.

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(AOR = 2.9, P = 0.011) as compared to pre-test, whereas it had increased by 5 folds at immediate post-test (AOR = 5.3, P = 0.001). The knowledge on mothers who undergo a cesarean section can have PPIUD inserted had retained at 2 folds higher (AOR = 2.3, P<0.001) at one-year post-intervention, whereas it had increased by 38 folds at immediate post-test (AOR = 37.6, P<0.001). The knowledge on PPIUD can be inserted immediately after birth had retained at 6 folds higher at one-year post-intervention (AOR = 6.2, P<0.001) as compared to 18 folds higher at immediate post-test (AOR = 17.7, P<0.001). The knowledge on women should go for follow-up when the IUD strings are seen outside of vulva was retained by 2 folds higher at one-year post-intervention (AOR = 2.0, P = 0.08) whereas it had increased by 4 folds at immediate post-test (AOR = 4.3, P<0.001).

Table 3 shows the descriptive data collected from the peripheral health facilities of the monthly meeting records collected and submitted by FCHVs, on their community-based activities. It shows the service coverage for a period of two months before the data was collected for each phase—at two-months post-intervention and at one-year post-intervention. At two-months post-intervention, all the 23 peripheral health facilities had maintained monthly records of postpartum family planning service coverage by FCHVs [8]. At one-year post-intervention, 13 out of 23 facilities had maintained the monthly reporting forms. At one-year post-intervention, the proportion of pregnant women counseled by FCHVs was 71.5% (n = 538) as compared to 83.3% (n = 1559) at two-months post-intervention.

^{* = &}lt; 0.05

^{*** = &}lt; 0.001.

^aAdjusted for FCHVs' age and years of experience.

Table 3. Proportion of pregnant mothers counseled by FCHVs in the communities and uptake of PPI	UD in
facilities.	

Description	2-months post- intervention	1-year post- intervention
No. peripheral health facilities maintaining FCHV records	23	13
No. recorded pregnant mothers in the catchment areas of FCHVs	1872	752
Proportion of all the recorded pregnant mothers counseled by an FCHV on postpartum family planning	1559 (83.3%)	538 (71.5%)

https://doi.org/10.1371/journal.pone.0258834.t003

Fig 1 shows the proportion of postpartum mothers in the hospitals who were counseled by an FCHV during their pregnancy in the community. In total, data was collected from 244 women in the pre-intervention phase, 238 at two-months post-intervention and 300 at one-year post-intervention.

The proportion of women that reported they were counseled by FCHVs at one-year post-intervention was 12.3% (n = 37) of 300 women, which was higher than the pre-intervention phase of 7% (n = 17) of 244 women. However, it was lower than 18.1% (n = 43) of 238 women interviewed at two-months post-intervention (Fig 1).

<u>Table 4</u> demonstrates the logistic regression model examining the relationship between time period from intervention and the number of postpartum mothers reporting receiving counseling from an FCHV during their pregnancy.

In the adjusted model, there was an almost 3-fold increase [AOR = 2.9, (CI 1.6-5.4), P<0.001] in the number of women reporting being counseled by an FCHV at two-months

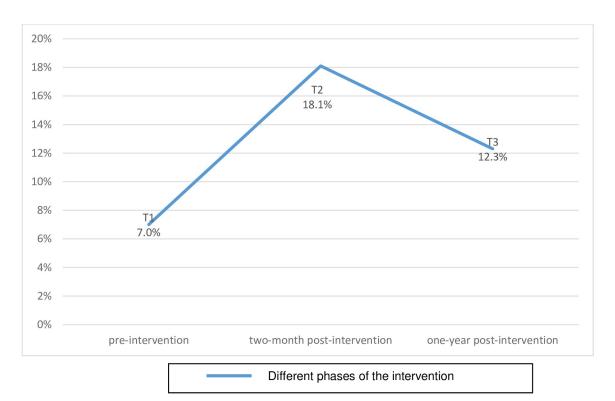


Fig 1. Counseling coverage of PPFP among the postpartum mothers by FCHVs in the two referral hospitals. (T1) pre-intervention, (T2) two-month post-intervention, (T3) one-year post-intervention.

https://doi.org/10.1371/journal.pone.0258834.g001

	Counselled by FCHV		
Characteristics	UOR (95% CI)	AOR (95% CI)	
Assessment			
Pre-intervention	1	1	
2-month post-intervention	2.0 (1.3-3.1)**	2.9 (1.6-5.4)***	
1-year post-intervention	0.9 (0.6-1.5)	1.9 (1.0-3.5)*	
Facility			
Nobel Medical College teaching hospital	1	1	
Koshi Zonal Hospital	1.5 (1.0-2.4)*	1.5 (0.9-2.5)	
District			
Other	1	1	

1.1 (0.7-1.7)

1.01 (0.6-1.6)

Table 4. Association between intervention phases and FCHV counseling among postpartum mothers delivering in the two hospitals.

UOR = unadjusted odds ratio.

AOR = adjusted odds ratio.

1 = reference.

Morang

NA = not included in the analysis.

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post-intervention, and an almost 2-fold increase [AOR = 1.9, (1.0-3.5), P = 0.036] at one-year post-intervention, when comparing to the pre-intervention phase.

Qualitative results

Table 5 summarizes the key themes of the qualitative study comparing the findings between the two-month post-intervention evaluation study, and the one-year post-intervention study. These include the FGD findings for the two-month post-intervention, and FGD and KII findings for one-year post-intervention. There were no KII in the earlier study. Comparisons were made on the five key themes which included knowledge of postpartum family planning, perception on the postpartum family planning orientation, activities conducted by FCHVs in the communities, challenges of maintaining their work, and suggestions to improve sustainability. Original quotes from the responses of the participants at one-year post-intervention are included in the description of the findings to provide more context.

1. Knowledge of postpartum family planning. At one year, almost all FCHVs still considered postpartum family planning as a new concept. Most were able to list out different methods of postpartum family planning and also explain the time of insertion of PPIUD as well as its benefits, as had been true at the two-months post-intervention study [8].

"In my knowledge, PPIUD is a convenient method to be inserted in uterus of a recently delivered woman. This protects a woman from unwanted pregnancy. The merit of this method in my view is that one does not need to wait until the next menstrual cycle after childbirth."-FCHV, FGD 1-year post-intervention

Some FCHVs lacked adequate knowledge about certain aspects of PPIUD at one year. During the orientation, FCHVs were taught that the uterus involutes over time and therefore, it is important to refer the PPIUD users to the hospital for follow-up as well as to cut the thread

^{*** = &}lt;0.001.

^{* = &}lt;0.05.

^{** = &}lt;0.01.

Table 5. Comparison between two-month and one-year post-intervention qualitative findings.

	Themes	2-months post-intervention FGD	1-year post-intervention FGD and KII
1	Knowledge on postpartum family planning	Majority of FCHVs were able to mention timing of insertion and benefits correctly.	Majority of FCHVs were able to mention timing of insertion and benefits correctly.
		Some FCHVs were confused about whether PPIUD can be used among women who had undergone the Cesarean section.	The confusion regarding PPIUD use among women who underwent Cesarean section persisted. Some FCHVs were also confused about follow-up among PPIUD users and lacked knowledge about referring women with PPIUD strings seen or felt outside the vulva to the health facilities.
2	Perception of postpartum family planning orientation program	The majority of FCHVs considered the postpartum family planning program to be useful.	The majority of FCHVs and stakeholders still considered postpartum family planning program useful.
3	Activities conducted by FCHVs on postpartum family planning	Almost all the FCHVs had actively conducted activities in the communities and raised awareness about postpartum family planning in healthy mothers' groups and counseled pregnant women in the communities. All FCHVs had actively maintained their monthly reporting forms.	Not all FCHVs were actively involved in counseling activities for pregnant women in the communities. Many FCHVs had stopped maintaining the monthly FCHV reporting forms citing lack of supervision and support.
4	Challenges of sustaining their work	FCHVs were concerned about the potential threats they may have to face while counseling women in the communities. Many FCHVs considered women to face societal barriers to choosing postpartum family planning/PPIUD	No threats were encountered by FCHVs in their community-based activities since the 2-month study. Many FCHVs still considered societal barriers to exist, preventing women from choosing postpartum family planning/PPIUD FCHVs suggested that a change of new peripheral 'facility incharge' may have interrupted the regular monitoring of FCHV activities related to postpartum family planning services. Stakeholders highlighted concern regarding a lack of refresher courses and monitoring.
5	FCHVs' suggestions on improving sustainability	Strong request for additional refresher courses for their knowledge retention.	Many FCHVs and KII highlighted the need for refresher courses and better monitoring and supervision of FCHV related activities. Stakeholders highlighted the need for local greater government involvement for sustainability.

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when it is seen outside the vulva. Contrary to this, some FCHVs considered having a string seen or coming out of the vulva, to be normal.

"When the thread/string is seen or felt by the women coming out of vulva outside the body, it is normal. They don't need to worry about it or go for follow-up to the hospital."-FCHV, FGD 1-year post-intervention

Perception about postpartum family planning orientation. FCHVs during the two-month post-intervention study suggested that the orientation had helped to improve their postpartum family planning knowledge [8] and at one-year post-intervention, all FCHVs from the FGD and stakeholders from KII still considered this to be the case. All participants believed that efforts in continuing the orientation activities must be expanded and refresher orientations should be initiated to maintain the momentum of FCHV led community-based activities on postpartum family planning.

"It was one of the best trainings that I have ever had! The contents were understandable, trainers motivated everyone to learn, and overall I liked the training session."-FCHV, FGD 1-year post-intervention

"There is no doubt that FCHV initiated counseling is effective in terms of finding women in ANC and discussing their need for the PPIUD. Training helped them by motivating and

identifying new knowledge regarding the method and the need to counsel pregnant women in their communities."- Public Health Administrator, Health Office, Morang, KII

2. Activities conducted by FCHVs in the communities. In the two-month post-intervention study all FCHVs appeared to be motivated and had shared their postpartum family planning related activities in the communities enthusiastically, however at a one-year post-intervention, activities appeared to have slowed down. All the FCHVs at two-month post-intervention mentioned that they had been maintaining the FCHV monthly reporting forms on postpartum family planning. Whereas, at one-year post-intervention, almost half of the FCHVs acknowledged that they had stopped maintaining the monthly reporting forms. They cited discontinuation of supervision from those in charge of the health facilities and a lack of reporting forms since the start of the new fiscal year (mid-July, 2019) as some of the key reasons for their discontinuation. A few, mentioned that they still counsel women about postpartum family planning methods as needed even though they had stopped maintaining a record.

Major changes in the stakeholders working at different levels of the health system had occurred since the last evaluation. More than 50% of the peripheral health facilities had newly assigned health facility 'in-charges' and staff. Whilst most of the peripheral health facilities which had retained the same people in charge, were able to continue monitoring the FCHV activities on postpartum family planning, those with newly assigned supervisors (who were not involved in the initial intervention) were unaware of the FCHV activities regarding postpartum family planning and had therefore not been monitoring their activities. It seemed that there was little monitoring of activities at a central level.

"Projects come and go. So we thought it's the same with this one too. When the project is active everybody is active. Once it phases out no one really asks us to report it either. Our new health facility-in-charge too stopped asking about the data. So we discontinued filling the monthly data for postpartum family planning."-FCHV, FGD 1-year post-intervention

3. Challenges of sustaining their work. In the two-month post-intervention research, the key challenges expressed by the FCHVs included societal barriers for women to accept immediate postpartum family planning methods such as PPIUD and the fear of potential threats from people in the communities when providing counseling. At one-year post-intervention, most of the participants still cited the low acceptability of PPIUD due to societal barriers. However, none of the FCHVs had faced challenges from the communities, allaying their earlier fears.

One of the major challenges indicated by most of the FCHVs and KII participants at one year was the lack of monitoring and supervision since the intervention ended. Some FCHVs also highlighted the gap in linking their counseling to the actual services women would receive in the two hospitals.

The stakeholders from the two hospitals highlighted that while FCHVs involvement in the communities is useful, they also felt that designated counselors are needed in the hospitals to help bridge the gap and to supplement community-based counseling services.

"Counseling of the pregnant women in the communities is very useful and it supplements the counseling services in the hospital. However, the women also need thorough counseling again when they come to the hospital. Due to high workload, not all the trained providers in the hospital are able to provide counseling..."-Nursing in-Charge-Hospital, KII

Other challenges highlighted by FCHVs and stakeholders alike included a lack of clarity in the referral of mothers for postpartum family planning services and a lack of postpartum family planning services in lower level facilities.

"Sometimes when we counsel pregnant mothers it's difficult for us to decide where to advise them to go for delivery. It would have been easier if the postpartum family planning/PPIUD facilities were available in nearby places. Not all women are ready going to the two big hospitals for delivery and the place of their choice does not have those facilities."-FCHV, FGD 1-year post-intervention

Former director of the Provincial Health Directorate, who had been recently transferred to work at central level in Kathmandu, indicated additional challenges for sustainability such as: the short implementation phase of FCHV involvement in the project; inadequate exit strategy for FCHV activities after the project ended; and a lack of involvement of birthing centers who could also have provided postpartum family planning services.

"Involving FCHVs for postpartum family planning was the first project of its kind for the government too. But the duration of implementation was too short. Such projects require a minimum period of one or two years of implementation to be sustainable. But this project ended without a detailed exit strategy."-Former Director of Provincial Health Directorate of Province 1, KII

4. Suggestions on sustainability. In the two-month post-intervention study, FCHVs had requested a refresher course. At one-year post-intervention, both FCHVs and other stakeholders highlighted that refresher orientation for FCHVs had not taken place and continued to highlight the importance of such ongoing orientation. Many FCHVs also suggested that having additional counseling materials such as flipcharts on postpartum family planning and sample IUDs would help their counseling to be more effective.

"There has been no follow-up or refresher orientation for FCHVs. It would be better if they could receive such refresher course in every 6 months. It would also have been helpful if the (government) health office would follow-up and monitor the FCHV activities on a regular basis even though the project has ended."-health facility-in-charge, KII

Almost all FCHVs focused on the need for follow-up of activities, which ended after the completion of the project. Many FCHVs and many stakeholders also urged for an expansion of postpartum family planning services into nearby health facilities for increased sustainability and equity of service access.

"For sustainability, services for PPIUD should be provided in our nearby health facility as the majority of our clients come from poor and unreached backgrounds and not everyone goes to those two hospitals where postpartum family planning services are provided."-FCHV, FGD 1-year post-intervention

Discussion

The intervention in this study assessed the knowledge retention of FCHVs about postpartum family planning so that they could counsel the women in the communities and link them to the hospitals providing immediate postpartum family planning services [8]. Retained

knowledge at one-year post-intervention among FCHVs in this study was higher as compared to the pre-intervention period which is encouraging for this cadre of community health workers who do not have a professional degree in health sciences. However, knowledge had decreased when compared to the earlier evaluation highlighting the challenges of sustainability. For FCHVs to retain knowledge in the long-term, refresher trainings would be advisable.

A review of the existing literature on long-term retention of knowledge suggests that 66 to 75% of knowledge will be retained after one year in general education as well as in medical education [14]. The FCHVs in this study had a higher retention rate than this. However, knowledge is likely to decrease further by 50% or more in the next five years without any further ongoing training or education [14]. Another review of ongoing trainings for community health workers from various low- and middle-income countries on different health topics has shown positive results for knowledge retention following refresher trainings [15]. A study on refresher training for community health workers in India suggested the knowledge retained among them following the refresher training at one-year post-intervention was higher than the knowledge retained two months after the initial training [16]. Thus, it would be important for the local and provincial government to identify strategies to conduct refresher courses and regular supervision to help the FCHVs retain their knowledge of postpartum family planning.

The secondary goal of the FCHV intervention was to suffice the existing postpartum family planning counseling services in the hospitals and establish a community linkage with the hospitals. In this study, the proportion of women counseled by FCHVs remained higher than the pre-intervention period for women giving birth in the two hospitals, however, no improvement was observed as compared to two-months post-intervention period. Lack of improvement in the proportion of women being counseled as compared to early post-intervention phase reflect the challenges of sustaining the intervention and inadequate linkage between FCHV's community activities with the hospitals. The two hospitals included in this study were implementing hospital-based interventions on postpartum family planning services as part of the larger postpartum family planning initiative in Nepal. The unadjusted logistic regression model suggested that the postpartum mothers in Koshi Zonal Hospital were 1.5 times more likely to have been counseled by FCHVs during their pregnancy in the communities than the women from Nobel Medical college. Koshi Zonal Hospital is a major referral government hospital in Morang district and therefore, is directly linked to the government peripheral health facilities and community-based activities by FCHVs [7]. Moreover, the hospital had been implementing the postpartum family planning initiative since 2015 [7]. Likewise, Nobel Medical College Teaching Hospital is a private teaching hospital that had started implementing the postpartum family planning initiative only in 2018 [5]. As a private hospital, the linkage with the FCHV's community-level activities might not have been as strong as a government hospital would have. However, previous study on service coverage from the same initiative had indicated a better hospital-based counseling coverage and acceptance of postpartum family planning methods in the private hospital which could balance the weaker community linkage to some extent [5].

The descriptive data collected from the FCHVs' monthly reporting forms on their community-based postpartum family planning counseling coverage showed incomplete recording and reporting of their activities. FCHVs conduct health awareness programs every month within the catchment areas of their peripheral health facilities through monthly mother's group meetings [8]. They also counsel pregnant women in the communities on birth preparedness, identify danger signs, and encourage pregnant women to go to health facilities for child-birth [17,18]. They are provided with a monthly reporting book by the government and use it as a tool to record their activities and report it to the peripheral health facilities towards the end of every month. As part of the intervention for postpartum family planning, an additional

simple checklist was introduced by the implementers of the intervention [8]. However, the new checklist has not yet been incorporated within the national system for FCHV's monthly reporting book. This could have been one of the reasons behind some FCHVs not continuing recording and reporting activities for postpartum family planning.

Moreover, the qualitative findings also indicated that many peripheral health facilities had newly assigned health facility in-charges who were unaware of the intervention and didn't supervise the FCHVs' postpartum family planning related activities. At the time of this study, we identified that more than 50% of the peripheral health facilities had newly assigned health facility-in-charges who were not part of the intervention. The changes in the peripheral health personnel has been part of the larger reshuffling process taking place in the health system in Nepal [19]. Although there are no studies looking into the effects of this reshuffling on the sustainability of health programs; it could have interrupted the recording and reporting activities among FCHVs. It is postulated that the new staff may not have recorded activities accurately and therefore the actual counseling of expectant mothers by FCHVs could have been underreported. Given the retention in their knowledge at one year, particularly regarding the value of immediate postpartum family planning, it is not unreasonable to assume that counseling would have continued albeit un-recorded. Moreover, the trained health personnel who had moved on to new facilities may have helped in training new FCHVs who were not part of this intervention. Future follow-up studies focusing on the activities of providers who moved to new facilities could provide an interesting perspective on sustainability.

The qualitative findings of this study showed that FCHVs and the stakeholders regarded PPIUD as the most useful postpartum family planning method and believed that the FCHV activities must be expanded. They also considered that the orientation of FCHVs was a useful component of the intervention and their continued involvement would support hospital-based postpartum family planning services. However, it was also highlighted that the lack of refresher orientation for FCHVs and inconsistent monitoring of their activities after one-year was problematic for sustainability. The World Health Organization recommends the need for ongoing training activities with regular supervision and refresher training for community health workers [4]. The lack of consistent supervision of the activities among FCHVs identified in this study is also likely to affect sustainability of the intervention in years to come. The ongoing training activities have also been regarded as a neglected aspect of most training programs for community health workers in low-and middle-income countries [20]. The United States Agency for International Development Health Care Improvement Project has recommended that community health workers should be updated every six months from their initial training to sustain the practice of their skills [21].

The previous studies from the initiative had identified the need of coordinated efforts from different levels of health system and society to bring positive behavior changes related to acceptance of postpartum family planning [6,7] FCHVs represent the community level and their role was to counsel the women in the communities about the immediate postpartum family planning choices they will have in hospitals [8]. However, FCHVs are not the direct service providers and are only a dimension of the larger intervention [1,6,8]. Thus, their role in acceptance of PPIUD and other postpartum contraception among women would remain limited. Therefore, the acceptance of PPIUD or other contraceptives were not considered as an outcome for FCHV intervention on postpartum family planning.

The ultimate goal of this intervention was to improve the acceptance of immediate postpartum family planning methods through a coordinated effort involving different tiers of the health system in Nepal including FCHVs. FCHVs have played an important role in mobilizing the communities and strengthening the maternal and newborn health and family planning coverage in Nepal [22–24]. Globally, community health workers have also played crucial roles

in improving the knowledge, attitude, and uptake of modern contraceptives in general [25]. However, the intervention studies on training community health workers to improve immediate postpartum family planning acceptance and uptake remain scant. The intervention involving FCHVs for postpartum family planning was the first of its kind in Nepal. The findings on knowledge retention on postpartum family planning at one-year post-intervention are encouraging. However, further studies are warranted to assess the specific roles of FCHV in improving the acceptance and uptake of immediate postpartum family planning methods such as PPIUD.

Policy implications

Community health workers all around the world have a unique role to play in health care, as they are not government employees and yet are often expected to undertake specific health counseling roles which in many high-income countries would be the remit of salaried, formally trained nurses or midwives. Perhaps one of the issues with community health workers is that they fall into a vacuum of responsibility-because they are not officially recognized salaried government staff, they are often trained and supported by the government tasked with filling in the gap. This can result in a fragmented approach to their training and function. This is unfortunate, given they are highly respected by their communities and so hugely influential, particularly in remote communities such as rural Nepal and therefore could be instrumental in changing the behavior of communities. One suggestion could be to recognize the value of this cadre of health personnel by remunerating their work appropriately, providing regular training and mentoring as well as monitoring their outputs.

The continued efforts of FCHVs was reflected amongst the mothers giving birth in the two major referral hospitals. At one-year post-intervention, the odds of a postpartum mother in one of the hospitals having been counseled by an FCHV during their pregnancy remained two times higher as compared to the pre-intervention period. Moreover, the knowledge retention of postpartum family planning among FCHVs at one-year follow-up and their continued efforts with community-based counseling have both remained higher than in the pre-intervention phase. Despite the lack of continued supervision, the activities are still functioning which is remarkable. However, in order to sustain the progress, the suggestions from the study participants must be taken into account such as the need to provide refresher orientations for the FCHVs and providing orientations for newly assigned health facility personnel. Timely acknowledgement of such potential barriers by the concerned policymakers of Nepal is essential. Further, lobbying for the continuation of refresher courses for FCHVs, ensuring better monitoring, recording, and reporting of postpartum family planning activities to enable datadriven decision making, and incorporating postpartum family planning activities into the national FCHV program are necessary next steps to ensure sustainability of postpartum family planning activities already embarked upon. Moreover, efforts in coordinating between different layers of health system and strengthening the community linkages with the hospitals is essential to improve women's access and utilization to the services provided in the higher level hospitals. Follow-up studies to evaluate the intervention after a longer period are also necessary to assess the progress and sustainability.

Limitations

This study has certain limitations regarding its study design. It has no control group, which could have provided a comparative perspective on postpartum family planning services in areas without any intervention. However, it would not have been feasible to recruit control groups from the same setting as other FCHVs beyond the intervention catchment area had

also received orientations on postpartum family planning at some point and the spill-over effect of the intervention couldn't be ruled out. Due to feasibility issues, it was also not possible to recruit FCHVs from other districts.

Secondly, the recording and reporting of the postpartum family planning counseling activities by FCHVs may not reflect the true picture of the actual counseling activities by FCHVs. Thus, the under-reporting of the postpartum family planning activities is highly likely given the fact that the correct forms were not issued and there was a change of supervisory staff at many peripheral health facilities. Interviewing the women or potential clients of FCHVs could have provided a more direct perspective from the clients' point of view. However, it was beyond the scope of our study as the primary contacts of the FCHVs are women in the communities for which we would have had to do a more extensive community-based household survey. However, we did assess a subset of the women from the community who had gone to the selected two facilities for childbirth. A wider community-based survey in the future could help reflect the sustainability in the communities in the long-term.

Thirdly, the tool we used for assessing FCHV's knowledge was not able to assess experiences and awareness at a deeper level. However, FCHVs in Nepal mostly have limited literacy and henceforth we had to use a simple questionnaire which was a validated tool used by the government as part of their training guideline. Moreover, qualitative research complemented the quantitative study where the study participants were able to share experience, awareness, and technical understanding.

Fourthly, as a longitudinal study, regression errors could have been affected by repeat observations. It would have been ideal to perform statistical analyses with models such as generalized estimating equation modeling to minimize the errors for repeated observations. However, the participants were not assigned the same identification numbers for each assessment which was a limitation during data collection.

Fifthly, the odds ratio was quite large with relatively wide confidence intervals when the follow-up results were compared with the baseline results for FCHVs' knowledge. Though the increase in knowledge after the intervention was remarkable, the possibility of sparse data bias leading to a large odds ratio and wide confidence intervals cannot be completely ruled out.

Lastly, the findings of qualitative studies at two months and one year after the interventions provide a perspective of changes taking place but may not be directly comparable. The people interviewed are different and the time the interviews took place is also different. Similarly, KII was not undertaken in the first 2 months' post-intervention study and so comparisons are not like for like.

This study nevertheless, provided a longitudinal perspective on the changes taking place over time. Moreover, as a mixed-methods study, the qualitative findings helped to provide more context to the results obtained from the quantitative study.

Conclusion

This study showed that the knowledge of postpartum family planning among FCHVs and their counseling activities remained higher at a one-year follow-up as compared to the pre-intervention phase. However, it had decreased as compared to the earlier evaluation highlighting the challenges of sustainability. The proportion of women being counseled by FCHVs remained higher than in pre-intervention phase and no significant difference was observed between two- month post-intervention and one-year post-intervention assessments. Continued supervision and monitoring was identified as a way to maintain postpartum family planning activities amongst FCHVs and refresher trainings would likely help in maintaining knowledge and sustaining progress in the long-term. In view of these findings, incorporating

postpartum family planning activities into the national FCHV program would be strongly advised.

Supporting information

S1 Fig. Timeline of the postpartum family planning initiative and the intervention. (DOCX)

S1 Table. COREQ checklist.

(PDF)

S2 Table. Study tools in Nepali.

(PDF)

S3 Table. Study tools English.

(DOCX)

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Author Contributions

Conceptualization: Rolina Dhital, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins.

Data curation: Rolina Dhital, Ram Chandra Silwal, Khem Narayan Pokhrel, Sabina Pokhrel, Suzanna Bright.

Formal analysis: Rolina Dhital, Ram Chandra Silwal, Khem Narayan Pokhrel, Sabina Pokhrel.

Investigation: Rolina Dhital, Ram Chandra Silwal, Khem Narayan Pokhrel, Sabina Pokhrel, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins.

Methodology: Rolina Dhital, Ram Chandra Silwal, Khem Narayan Pokhrel, Sabina Pokhrel, Heera Tuladhar, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins.

Project administration: Ram Chandra Silwal, Sabina Pokhrel, Heera Tuladhar, Suzanna Bright, Anita Makins.

Resources: Ram Chandra Silwal, Sabina Pokhrel, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins.

Software: Rolina Dhital, Khem Narayan Pokhrel, Sabina Pokhrel.

Supervision: Rolina Dhital, Ram Chandra Silwal, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins.

Validation: Ram Chandra Silwal, Khem Narayan Pokhrel, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins.

Visualization: Khem Narayan Pokhrel, Sabina Pokhrel, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins.

Writing - original draft: Rolina Dhital.

Writing – review & editing: Rolina Dhital, Ram Chandra Silwal, Khem Narayan Pokhrel, Sabina Pokhrel, Heera Tuladhar, Suzanna Bright, Emily-Anne Tunnacliffe, Kusum Thapa, Anita Makins.

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ORIGINAL ARTICLE

Economic Evaluation of Provision of Postpartum Intrauterine Device Services in Bangladesh and Tanzania

Gillian Eva, a* Judy Gold, b* Anita Makins, c,d,e* Suzanna Bright, Katherine Dean, Emily-Anne Tunnacliffe, Parveen Fatima, Afroja Yesmin, Projestine Muganyizi, Grasiana F. Kimario, Kim Dalzieli

Key Findings

- In public health facilities in Tanzania and Bangladesh, postpartum family planning (PPFP) is rarely available until the 6-week follow-up visit.
- Delivering family planning counseling and offering the immediate postpartum intrauterine device (PPIUD) was found to be cost-effective compared to the standard PPFP practice.
- The PPIUD program resulted in an incremental costeffectiveness ratio (ICER) of US\$14.60 per CYP in Bangladesh and US\$54.57 per CYP in Tanzania.
- It is likely that national rollout of PPFP counseling and PPIUD delivery will save costs to the health care system in both countries.

Key Implications

- There is a strong case for governments and donors to invest in providing high quality family planning counseling during antenatal care and around the time of delivery and to include PPIUD within PPFP provision immediately following delivery.
- National provision of PPIUD could produce long-term savings in health care costs due to the decrease in unplanned pregnancies resulting from increased PPFP uptake.
- PPIUD could be even better value if health care providers receive preservice training in this method, and if PPIUD delivery was rolled out nationally.
- ^a Independent consultant, Washington, DC, USA.
- ^b Independent consultant, Melbourne, Australia.
- ^c International Federation of Gynecology and Obstetrics, London, UK.
- $^{\rm d}$ Oxford University Hospitals NHS Foundation Trust, Oxford, UK.
- ^e Nuffield Department Women's and Reproductive Health, Oxford University, Oxford, UK.
- f Obstetrical and Gynaecological Society of Bangladesh, Dhaka, Bangladesh.
- ^g Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania.
- ^h Tanzania Midwives Association, Dar es Salaam, Tanzania.
- ⁱ Melbourne School of Population and Global Health, The University of Melbourne, Melbourne, Australia.
- * Joint first authors.

Correspondence to Gillian Eva (gillian.eva@gmail.com).

ABSTRACT

Introduction: Postpartum family planning is an effective means of achieving improved health outcomes for women and children, especially in low- and middle-income settings. We assessed the cost-effectiveness of an immediate postpartum intrauterine device (PPIUD) initiative compared with standard practice in Bangladesh and Tanzania (which is no immediate postpartum family planning counseling or service provision) to inform resource allocation decisions for governments and donors.

Methods: A decision analysis was constructed to compare the PPIUD program with standard practice. The analysis was based on the number of PPIUD insertions, which were then modeled using the Impact 2 tool to produce estimates of cost per coupleyears of protection (CYP) and cost per disability-adjusted life years (DALYs) averted. A micro-costing approach was used to estimate the costs of conducting the program, and downstream cost savings were generated by the Impact 2 tool. Results are presented first for the program as evaluated, and second, based on a hypothetical national scale-up scenario. One-way sensitivity analyses were conducted.

Results: Compared to standard practice, the PPIUD program resulted in an incremental cost-effectiveness ratio (ICER) of US\$14.60 per CYP and US\$91.13 per DALY averted in Bangladesh, and US\$54.57 per CYP and US\$67.67 per DALY averted in Tanzania. When incorporating estimated direct health care costs saved, the results for Bangladesh were dominant (PPIUD is cheaper and more effective versus standard practice). For Tanzania, the PPIUD initiative was highly cost-effective, with the ICER (incorporating direct health care costs saved) estimated at US\$15.20 per CYP and US\$18.90 per DALY averted compared to standard practice. For the national scale-up model, the results were dominant in both countries.

Conclusions/implications: The PPIUD initiative was highly cost-effective in Bangladesh and Tanzania, and national scale-up of PPIUD could produce long-term savings in direct health care costs in both countries. These analyses provide a compelling case for national governments and international donors to invest in PPIUD as part of their family planning strategies.

INTRODUCTION

Postpartum family planning (PPFP) is widely recognized as an important approach to achieving progress towards improved health outcomes for women and children. The World Health Organization (WHO) advises a minimum of 24 months between a live birth and trying for the next pregnancy owing to the

Provision of immediate PPIUD leads to a lower risk of future unintended pregnancies and higher continued use at 6 months, versus IUD provided later.

increased risks to the mother and child of short interpregnancy intervals (the definition of which differs across studies), including miscarriage, induced abortion, stillbirth, preterm birth, low birth weight, infant mortality, and child malnutrition. 5-9 Many contraceptive methods are now considered safe to use postpartum, even among breastfeeding women. 10,11 In addition, the increasing number of women in low- and middleincome countries (LMICs) attending antenatal care and delivering in health facilities means that discussing PPFP during antenatal care and at the time of delivery and offering effective postpartum contraception immediately postpartum are now key ways to reduce the risk of unintended pregnancies.3,5,7,12

Although many women who give birth do not want another pregnancy within 12 months, 13 births at short interpregnancy intervals are not uncommon, especially in LMICs. 14 PPFP use remains low and is mostly unchanged over the last decade, particularly across Africa, 15 resulting in high unmet need among postpartum women for both spacing and limiting births. 13,14,16 Institutional delivery and child immunization are the factors most correlated with voluntary uptake of modern PPFP, 15,17 and several studies have demonstrated the importance of good-quality counseling and community involvement to increasing PPFP acceptance. 18-20 Challenges identified for PPFP uptake include perceived low risk of pregnancy during the postpartum period among both providers and women, low rates of facility deliveries, and (perceived or real) cultural resistance to family planning, particularly during the postpartum period.^{2,21} The latest WHO Medical Eligibility Criteria (MEC) guidance in 2015 included several additional methods that can be initiated immediately postpartum. 10 Before this guideline change. PPFP was often not discussed until the 6week follow-up visit, which many women do not attend and which comes after the return of fertility for women who are not exclusively breastfeeding.

Long-acting reversible contraceptives (LARCs) have the potential to be an important component of PPFP programs, especially because they have very low failure rates, do not require resupply visits, and can be reversed. Women who do use PPFP mostly use short-acting methods, and very few use a postpartum intrauterine device (PPIUD). ^{13,14} The WHO MEC guidance states that long-acting methods (intrauterine devices [IUDs], intrauterine systems (IUSs), and implants), can be used immediately postpartum. ¹⁰ They are also appropriate for breastfeeding women; IUDs can be used without

restrictions, and implants and IUSs are methods for which the advantages of use generally outweigh the risks. ¹⁰ IUSs and implants have high costs, which means that IUSs are rarely available in LMICs, and the availability of implants frequently depends on subsidies or donor supplies rather than national government purchasing. ^{22–24}

The copper IUD has been available in both LMICs and high-income countries for decades as an interval method (after 6 weeks postpartum), but it has not been routinely used immediately postpartum.²⁵ Provision of immediate PPIUD leads to a lower risk of future unintended pregnancies and higher continued use at 6 months, compared with IUD provided at a later time.²⁶ Although previous studies reported higher expulsion rates for immediate PPIUD compared with insertions at other times, 26-28 2 recent studies showed that when Kelly forceps are used to ensure correct placement at the fundus of the uterus, expulsion rates of immediate PPIUD insertion are comparable to interval insertion (<5%). 29,30 Several programs in both high- and low-income countries have demonstrated that immediate PPIUD is a safe method with low expulsion and discontinuation rates and high acceptance among providers and clients. 11,27,31–34 Immediate PPIUD also offers cost and time savings to women since they do not have to return to the facility to receive their PPFP method and can combine their followup visit with their routine postpartum checkup.

Recent global efforts have focused on expanding family planning access, including PPFP, through programs such as FP2020. 12,35 However, the funding landscape is changing, with uncertainty in the continuity of donor funding and increasing expectation for LMICs to financially sustain their own health services, such as through national health insurance schemes. 36,37 Advocating for sufficient investment for widescale provision of PPFP counseling and PPIUD provision is hindered by a limited number of studies and a consequent gap in the evidence base on the cost-effectiveness of these approaches.

The International Federation of Gynecology and Obstetrics (FIGO) conducted a PPIUD initiative between 2013 and 2020 across 6 countries in Africa and Asia. Published analyses from the initiative have demonstrated the feasibility and safety of immediate PPIUD provision, with almost 37,000 PPIUDs inserted between May 2014 and September 2017 in the 6 countries, a low expulsion rate of 2.6% overall, and no cases of uterine perforation.²⁹ Our study presents an economic evaluation based on the implementation of the PPIUD initiative in Bangladesh and Tanzania,

This economic evaluation of the PPIUD initiative in Bangladesh and Tanzania aims to inform efforts to increase access to PPFP counseling and PPIUD provision.

which was led by FIGO and its national member societies—the Obstetrical and Gynaecological Society of Bangladesh, the Association of Gynaecologists and Obstetricians of Tanzania, and the Tanzanian Midwifery Association. The aim of the evaluation is to inform future national and global efforts to increase access to PPFP counseling and PPIUD provision.

METHODS

Target Population, Setting, and Location

The target population was women in Tanzania and Bangladesh attending the facilities participating in the FIGO PPIUD initiative for delivery (6 facilities in each country). All the participating facilities were large tertiary teaching and referral hospitals. In both countries, counseling on postpartum contraception was offered when women were admitted for delivery, as well as during antenatal care at these facilities. In Tanzania, it was also offered during antenatal care at 26 satellite facilities linked to the participating hospitals.

Intervention (PPIUD Initiative and Context)

The most recent Demographic and Health Surveys (DHS) found that in Bangladesh, 12% of married women of reproductive age have an unmet need for family planning and 52% use modern

contraception.³⁸ In Tanzania, 22% of married women have an unmet for family planning and just 32% use a modern contraceptive method.³⁹ In both countries, less than 1% of women choose to use an IUD (Table 1).^{38–42} Most women in both countries receive at least one antenatal care visit, and almost half of women in Bangladesh and two-thirds of women in Tanzania deliver at a health facility.

The economic evaluation focused on the second phase of the FIGO PPIUD initiative, which ran from January 2015 to June 2018. Full details of the FIGO PPIUD initiative were published previously.33 In short, the PPIUD initiative included training on and the provision of PPFP counseling (on all postpartum methods), PPIUD insertion (if eligible and voluntarily chosen), and follow-up at 6 weeks. Each country established a central project team at national professional societies to develop and roll out the PPIUD initiative at 6 large tertiary teaching and referral hospitals. In both countries the national teams consisted of 6 project staff, although not all were employed full-time by the PPIUD project. One facility coordinator and one deputy facility coordinator, both clinicians, oversaw the project at each participating facility in each country.

Based on shared lessons learned among the 6 countries involved in the PPIUD initiative, an

TABLE 1. Country Demographic and Health Data^a

	Bangladesh ³⁸	Tanzania ³⁹
2018 population, millions ⁴⁰	161.4	56.3
2018 population density, people/km² of land area ⁴⁰	1,240	64
Total fertility rate, births per woman	2.3	5.2
Use of modern method of contraception, b %	51.9	32
Family planning uptake at 1–2 months postpartum, % ⁴¹	13.2	9.2°
Unmet need for family planning, b %	12.0	22.1
Use of intrauterine device, b %	0.6	0.9
Received antenatal care at least once from a medically trained provider, d,e %	81.9	98.0
Delivered at a health facility, d,e %	49.4	62.6
Deliveries attended by a skilled provider, d %42	52.7	63.6

^a Source: Demographic and Health Survey, unless otherwise stated.

^b Among currently married women aged 15-49 years.

^cTabulations based on use of family planning obtained from the reproductive calendar (average of use in time span postpartum), births 12–23 months preceding the interview, based on Bangladesh DHS 2011 and Tanzania DHS 2010.

d Among women aged 15–49 years who had a live birth within 3 years of the survey.

^e Medically trained providers include qualified doctor, nurse, midwife, family welfare visitor, and community skilled birth attendant. For antenatal care, medically trained providers also include paramedics, medical assistants, or subassistant community medical officer.

Immediate PPFP, including provision of IUDs at or around the time of delivery, is not currently standard practice in government health facilities in Bangladesh or Tanzania.

initial "training of trainer" session was held, after which all training of trainer and cascade trainings were conducted by national staff on the PPIUD project team. Existing clinical staff at the participating facilities were trained on PPFP counseling and immediate PPIUD insertion. In Bangladesh, 1,160 providers (predominantly doctors) were trained in PPIUD insertion and training lasted 1 day (note this number includes some providers who were trained more than once). Due to the high flow of clients in the Bangladesh facilities, 28 dedicated postpartum contraceptive counselors were also recruited and received an initial 2.5-day training followed by a half-day refresher training the following year. In Tanzania, 1,113 providers received a 3-day PPIUD insertion training, and 1,515 received a 3-day PPFP counseling training. The health care providers trained in PPIUD insertion in Tanzania were a mix of doctors, nurses, and nurse-midwives, and the training content was adapted to suit all cadres and to align with national requirements.

No community-level demand generation activities were included as part of the initiative in these 2 countries, although leaflets and informative videos were produced as an adjunct to counseling in the hospitals as part of the PPIUD initiative. Voluntary insertion of a Copper T 380A IUD was available to any woman who was medically eligible, voluntarily consented to receive an IUD, and attended a PPIUD initiative facility for delivery.

For the initiative and this evaluation, a PPIUD was defined as an IUD inserted immediately following delivery, before the woman was discharged. This could be within 10 minutes of delivery of the placenta (post placental) or between 10 minutes and 48 hours following placental delivery (immediately postpartum).

Ethical approval for the overall FIGO PPIUD initiative was obtained in both countries and from the London School of Hygiene and Tropical Medicine for overall analysis of the data.

Comparator (Standard Practice)

Standard practice PPFP in both countries was assumed to be no provision of immediate PPFP. The only immediate postpartum contraceptive method available at the facilities during the timeframe of the initiative was tubal ligation during cesarean delivery, which was not routinely available to all women (and very rare in Tanzania). Where PPFP counseling was provided, it typically occurred at the 6-week follow-up postnatal care visit (i.e.,

outside the defined period of immediate postpartum contraception).

The governments of both countries have expressed official support for increasing access to postpartum contraception, for example, through the 2017 National Action Plan for Family Planning in Bangladesh⁴³ and the 2015 Postpartum Family Planning Action Plan and 2019 National Family Planning Costed Implementation Plan in Tanzania. However, a shortage of trained providers, inconsistent availability of products, and poor infrastructure limit the extent to which these services can be accessed. Immediate PPFP, including provision of IUDs at or around the time of delivery, is not currently standard practice in government health facilities in either country.

Although no immediate PPFP (within 48 hours of delivery) is routinely available in either country, PPFP from 6 weeks onwards is offered and it is likely that some of the women who adopted a PPIUD would otherwise have taken up an alternate method during the extended postpartum period. Due to the lack of direct comparators and a lack of available data on uptake of other PPFP in the extended postpartum period, we did not include any alternate methods as the comparator in our main analysis. We have instead included a sensitivity analysis testing the impact of different proportions of women taking up alternate PPFP methods, based on the national uptake rate of PPFP. See the Supplement for full details.

Economic Evaluation Perspective, Design, and Time Horizon

The economic evaluation involved a decision analysis that compared the new PPIUD initiative with standard practice. A decision analysis was used because it was able to reflect whether women voluntarily accept contraception provided in the immediate postpartum period. The economic evaluation was composed of the incremental costs of the PPIUD initiative (relative to standard practice) and uptake of the PPIUD. This included costs for recruitment; project staff; meetings; equipment; training; development of information, education, and communication materials; clinical supervision; and sharing of data and learning. Full details can be found in the Supplement.

For each country we defined an initial setup period of 4 months; March to June 2015 in Bangladesh and December 2015 to March 016 in Tanzania. The setup period included 3 months of initial project establishment and 1 month in which the first training of trainers was conducted. The setup period thus included fixed

costs but no impact (no PPIUDs inserted). The implementation period, based on the actual timing of the PPIUD initiative, was July 2015 to June 2018 for Bangladesh (36 months) and April 2016 to June 2018 for Tanzania (27 months); the implementation period included ongoing costs of implementation as well as impact (number of PPIUDs inserted).

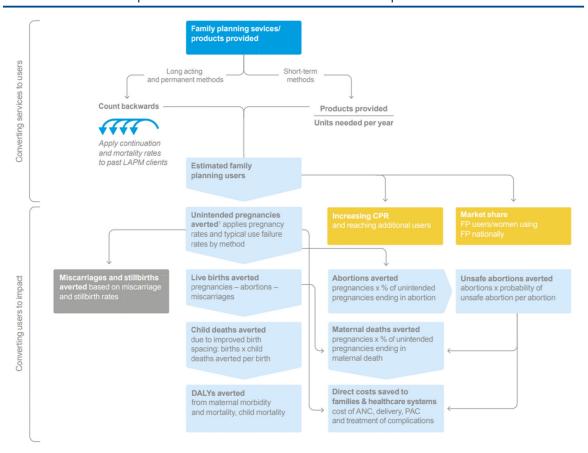
The analyses were conducted from the government's perspective. Cost-effectiveness was reported within the time frame of program operation and was also modeled using the existing Impact 2 tool (Figure 1). 46,47 In brief, the Impact 2 tool uses national- and regional-level data on typical pregnancy rates and rates of maternal deaths, unsafe abortions, child deaths, and similar outcomes to estimate the impact on key health outcomes of contraceptive services delivered,

based on the number of pregnancies and pregnancy-related deaths or illnesses that are averted because a woman is using contraception (Figure 1). The Impact 2 tool also estimates the direct cost savings to the health care system as a result of these health outcomes being averted, based on cost of antenatal care, delivery, postabortion care, and treatment of complications that are averted. The estimated impact of the services will occur over the lifetime of the contraceptive method provided.

To maximize the usefulness of the evaluation for national governments, we repeated the economic evaluation based on a hypothetical national scale-up. In Bangladesh, we modeled the cost of scaling up the PPIUD initiative to all 36 Government Medical College Hospitals nationally.⁴⁸ In Tanzania, we modeled the cost of scaling

The economic analyses were conducted from the government's perspective.

FIGURE 1. Overview of Impact 2 Tool Used to Assess Cost-Effectiveness of Postpartum Intrauterine Device Initiative



Abbreviations: ANC, antenatal care; CPR, contraceptive prevalence rate; DALYs, disability-adjusted life years; FP, family planning; LAPM, long-acting permanent method; PAC, postabortion care; PPIUD, postpartum intrauterine device.

Source: Weinberger et al. 47

up the PPIUD initiative to all 28 Regional Referral Hospitals nationally, ⁴⁹ as well as to 140 satellite facilities (assuming an average of 5 per hospital). PPIUD insertion rates for the national scale-up model were based on the insertion rates during the PPIUD initiative. Full details of the adjustments and assumptions made for this analysis can be found in the Supplement.

This manuscript has been prepared in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS).⁵⁰

Effectiveness Measures

The measure of effectiveness of the PPIUD initiative was based on the number of immediate PPIUDs inserted, taken directly from the recorded data in the 2 countries, during implementation of the initiative. This measure is relevant for family planning and as an input to the existing Impact 2 tool, which quantifies the relationship between number of insertions, couple-years of protection (CYP), health outcomes, and future costs averted. The primary outcomes for this economic evaluation are cost per PPIUD inserted, cost per CYP, and cost per disability-adjusted life year (DALY) averted.

Estimating Resources and Costs

Costs that were provided in local currencies were first adjusted to 2018 local currency costs based on available national inflation data.^{52,53} The resulting 2018 local currency costs were then converted to US\$using the average exchange rate for the year. Costs that were provided in US\$ were adjusted to 2018 US\$using the annual average US inflation rates.⁵⁴ No discount rate was applied to the costs of conducting the PPIUD program or its associated uptake due to the short timeframe of the initiative.

A bottom-up, micro-costing approach was used with inputs as described in the Supplement. Data on costs and PPIUD insertions were primarily sourced from existing project narrative and financial reports, with additional cost data collected as needed from the national project teams. The economic evaluation included the following costs:

- Training of providers in PPIUD insertion and PPFP counseling;
- Staff salary and honorarium payments for facility level staff;
- · Reusable clinical equipment;

- Lifetime direct PPIUD service delivery costs: cost of insertion, follow-up visit (if any), and removal; and
- Costs of supporting activities: behavior change materials, advocacy, project management, and monitoring.

A 10% overhead rate was applied, as per the overhead rate used by the government in each country. See the Supplement for further information on costs included.

We included costs for all postpartum contraception counseling sessions delivered at the participating facilities during the initiative, regardless of whether the counseled woman adopted a PPIUD, because more women will need to receive counseling than eventually receive a PPIUD. We included costs for people to attend 1 follow-up visit at a health facility, using an attendance rate of 25%, based on follow-up rates achieved during the initiative.

The Government of Bangladesh pays reimbursements for uptake of LARCs; part of the reimbursement is paid to the woman and part to the provider. For IUDs (including PPIUD), up to US\$6.24 is available as reimbursement (email communication, July 13, 2020). However, due to administrative challenges, payment of these reimbursements was not consistent during the evaluation timeframe. No reimbursements are paid to women or providers for attendance at follow-up visits in either country.

Costs associated with the initiative being an international, donor-funded project and the costs of the research component of the initiative were excluded from the analysis since these are not reflective of the true cost of government-led introduction of PPIUD. Costs to the women or to society were not included, other than where fees charged to women offset the cost to the government. Consistent with sector standards, costs to treat complications are not included in the analysis. ⁵⁵

Analysis

Incremental cost-effectiveness ratios (ICERs) were generated for the PPIUD initiative as it was conducted in the 6 facilities in each country compared with standard practice using the formula below. The PPIUD initiative was considered as standard postpartum practice *plus* PPFP counseling and PPIUD service delivery, meaning that the cost of standard practice can be estimated as 0 for both the initiative and for standard practice alone.

ICERs are reported both with and without the estimated direct health care savings from the Impact 2 tool factored in; when these estimated savings from the Impact 2 tool are factored in, we refer to "ICER with cost offset."

ICER =

Cost PPIUD — Cost of Standard Practice
Outcomes PPIUD — Outcomes of Standard Practice

The incremental costs and incremental benefits (outcomes) of the PPIUD initiative can be interpreted through a cost-effectiveness plane representing the 4 potential outcomes of the analyses (Figure 2). ⁵⁶

One-way sensitivity analyses were conducted to test the robustness of estimates included in the economic evaluations and describe the impact of uncertainty on parameter values (costs of direct service delivery and training costs, and varying the proportion of government reimbursements paid in Bangladesh).

RESULTS

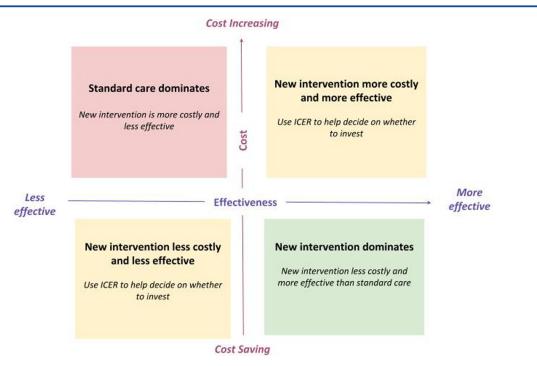
Outcomes

In Bangladesh, the 6 participating facilities delivered 8,031 PPIUDs over the 36-month implementation period; in Tanzania the 6 participating facilities delivered 7,448 PPIUDs over the 27-month implementation period (Table 2).

Service Provision and Total Cost

Table 2 displays the main results of the costing analysis. The direct service costs of a PPIUD include cost of insertion, follow-up visit, and removal. In Bangladesh, the counselors were employed full-time, so their costs were included in staff costs not direct services costs, whereas for Tanzania counseling was done by existing staff, so costs were calculated per PPIUD and are included here. The cost of direct service provision was estimated to be US\$1.71 per PPIUD in Bangladesh (excluding government reimbursements) and US\$2.05 in

FIGURE 2. Cost-Effectiveness Plane Representing 4 Potential Outcomes of Cost-Effectiveness Analyses of Postpartum Intrauterine Device Initiative



Abbreviation: ICER, incremental cost-effectiveness ratio. Source: Cost-effectiveness plane figure adapted from Cohen et al.⁵⁰ Tanzania. It was estimated that the reimbursement paid by the Government of Bangladesh (see above) would be paid 50% of the time during the implementation period, thus US\$3.12 was added to the base cost, resulting in a cost per PPIUD with reimbursements included of US\$4.83 in the Bangladesh analysis. In Bangladesh, the main cost driver was facility-level staffing, followed by national-level staffing. In Tanzania the main cost driver was training.

The direct health care costs saved by the PPIUD initiative, based on estimates from the Impact 2 tool, were US\$802,368 in Bangladesh and US\$1,348,744 in Tanzania (Table 2).

National Scale-Up Model

The direct health

care costs saved

by the **PPIUD**

initiative were

\$802,368 in

Tanzania.

estimated to be US

Bangladesh and

US\$1,348,744 in

In the analysis for the national scale-up model, a 36-month implementation period was used for both countries. For Bangladesh it was estimated that the 36 facilities would deliver 26,507 PPIUDs, while for Tanzania it was estimated that the 28 facilities (plus 140 satellite facilities) would deliver

43,928 PPIUDs (Table 2). The analysis for the national scale-up model estimated direct health care costs saved of US\$2,648,284 in Bangladesh, and US\$7,954,649 in Tanzania (as estimated by the Impact 2 tool) (Table 2).

Cost-Effectiveness

Table 3 displays ICER results for the PPIUD initiative presented both with and without the cost offset of the estimated direct health care savings from the Impact 2 tool.

In both countries, the PPIUD initiative was found to be more expensive and more effective than standard practice, before offsetting the direct cost savings to the health care system. In Bangladesh, the cost per outcome was estimated to be US\$14.60 per CYP and US\$91.13 per DALY averted, while in Tanzania the cost per outcome was estimated to be US\$54.57 per CYP and US\$67.67 per DALY averted compared with standard practice. When the cost offset generated from the Impact 2 tool was incorporated (from estimated

TABLE 2. Results of Costing Analysis in Bangladesh and Tanzania

	Bang	ladesh	Tanzania		
	PPIUD Initiative	National Scale-Up Model	PPIUD Initiative	National Scale-Up Model	
Program design					
Number of facilities ^a	6	36	6	28	
Setup period, months	4	4	4	4	
Implementation period, months	36	36	27	36	
Number of PPIUDs inserted	8,031	26,507	7,448	43,928	
Costing analysis					
Estimated total cost	US\$539,285	US\$1,979,140	US\$1,869,507	US\$6,910,494	
Estimated cost of direct PPIUD service provision ^b	US\$1.71	US\$1.71	US\$2.05	US\$2.05	
Cost per facility per year	US\$27,986	US\$17,373	US\$130,697	US\$79,223	
Main cost driver	Facility staff ^c (58% total cost)	Facility staff ^c (53% total cost)	Training (76% total cost)	Training (80% total cost)	
Estimated direct health care costs saved (Impact 2)	US\$802,368	US\$2,648,284	US\$1,348,744	US\$7,954,649	
Estimated total costs after including estimated health care costs saved (Impact 2)	-US\$263,083	-US\$669,144	US\$520,763	-US\$1,044,156	

Abbreviation: PPIUD, postpartum intrauterine device.

^a Note the facilities included in the national scale-up model include the facilities in the PPIUD initiative plus additional facilities at the equivalent level of the public health care system. For Tanzania, each hospital in the scale-up model is assumed to have 4–6 associated satellite facilities that are trained in postpartum family planning counseling and given IEC materials to distribute and that refer clients to the hospitals, as was done in the PPIUD initiative.

b Includes cost of initial insertion, follow-up visit, and eventual removal using weighted averages. Cost of counseling is included for Tanzania but not for Bangladesh (cost of counselors in Bangladesh is included in staff costs, not direct service costs). Government reimbursements paid in Bangladesh are not included here.

^c Facility staff in Bangladesh include counselors and honorariums in the PPIUD initiative. Counselors only are included in the national scale-up model.

TABLE 3. Cost-Effectiveness of PPIUD Initiative

	Bangladesh		Tanzania			
Outcome of interest ^a	Estimated Number	ICER Without Cost Offset ^b	ICER With Cost Offset	Estimated Number	ICER Without Cost Offset ^b	ICER With Cost Offset ^c
PPIUDs inserted	8,031	67.2	PPIUD dominates	7,448	251.1	69.9
CYPs	36,943	14.6	PPIUD dominates	34,261	54.6	15.2
Unintended pregnancies averted	16,683	32.3	PPIUD dominates	15,471	120.8	33.7
Maternal deaths averted	11	50,731.0	PPIUD dominates	30	62,316.9	17,358.8
Child deaths averted	63	8,613.0	PPIUD dominates	306	6,109.5	1,701.8
Total DALYs averted (maternal + child DALYs)	5,918	91.1	PPIUD dominates	27,626	67.7	18.9

Abbreviations: CYP, couple-years of protection; DALYs, disability-adjusted life years; ICER, incremental cost-effectiveness ratio; PPIUD, postpartum intrauterine device.

direct cost savings to the health care system), in Bangladesh PPIUD "dominated" (i.e., PPIUD is cheaper and more effective). For Tanzania, the ICER with cost offset was estimated to be US\$15.20 per CYP and US\$18.90 per DALY averted compared with standard practice, meaning it remained more effective and more costly than standard care.

Table 4 displays ICER results for the national scale-up model. In Bangladesh, the cost per outcome was estimated to be US\$16.23 per CYP and US\$106.64 per DALY averted, while in Tanzania the results were estimated to be US\$34.20 per CYP and US\$43.31 per DALY averted. Once the estimated savings from direct health care costs averted were factored in (as estimated by the Impact 2 tool) PPIUD dominated for all outcomes in both countries, meaning that it would be both cheaper and more effective to provide the PPIUD intervention compared with standard care. Full results of the national scale-up model can be found in the Supplement.

Sensitivity Analyses for Cost Adjustments

In Bangladesh, the ICER was most sensitive to the rate of payment of government reimbursements (Figure 3). With all the parameters and scenarios tested, the PPIUD intervention remained cheaper and more effective than standard practice,

indicating it was the dominant strategy. In Tanzania, the ICER was most sensitive to variations in costs of training (Figure 3). For both scenarios tested, the PPIUD intervention remained highly cost-effective. The scenario with the highest cost per DALY was an increase of 10% of training costs, which resulted in a cost per DALY of US \$72.83 before estimated health savings were factored in.

For the national scale-up analysis, the models were most sensitive to changes in rate of payment of government reimbursements (Bangladesh) and training costs (Tanzania). However, the models remained cheaper and more effective than standard care, indicating the PPIUD intervention was the dominant strategy in all scenarios tested. Details can be found in the Supplement.

Sensitivity Analyses for Uptake of Alternate PPFP

A number of scenarios were tested to estimate the effect on the ICER of different proportions of PPIUD adopters taking up an alternate family planning method during the extended postpartum period (see Figure 4). The scenarios tested were based on the national PPFP uptake rate at either 1–2 months or 9–11 months postpartum. Details of the different scenarios and assumptions made can be found in the Supplement.

^aOutcomes are the estimated service lifespan impacts from the Impact 2 tool.

^b The ICER without cost offset is equivalent to the cost per outcome because the cost of standard practice is estimated as zero cost in both study groups without any impact on the ICER.

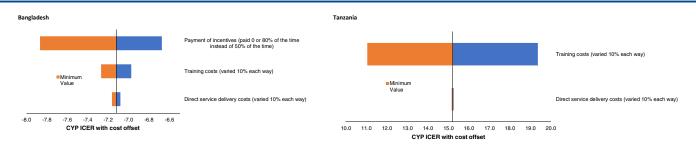
^cWhen neither the intervention nor standard care "dominates," the ICER should be used to decide whether or not to invest (see Figure 2).

TABLE 4. Cost-Effectiveness of National Scale-Up Model

	Bangladesh			Tanzania		
Outcome of Interest ^a	Estimated Number	ICER Without Cost Offset ^b	ICER With Cost Offset	Estimated Number	ICER Without Cost Offset ^b	ICER With Cost Offset
PPIUDs inserted	26,507	74.7	PPIUD dominates	43,928	1 <i>57</i> .31	PPIUD dominates
CYPs	121,932	16.2	PPIUD dominates	206,064	34.2	PPIUD dominates
Unintended pregnancies averted	55,062	35.9	PPIUD dominates	91,248	75.73	PPIUD dominates
Maternal deaths averted	18	107,057.9	PPIUD dominates	120	57,587.45	PPIUD dominates
Child deaths averted	207	9,576.2	PPIUD dominates	1,804	3,830.65	PPIUD dominates
Total DALYs averted (maternal $+$ child DALYs)	18,558	106.6	PPIUD dominates	159,561	43.31	PPIUD dominates

Abbreviations: CYP, couple-years of protection; DALYs, disability-adjusted life years; ICER, incremental cost-effectiveness ratio; PPIUD, postpartum intrauterine device.

FIGURE 3. Sensitivity Analyses for Cost Adjustments Showing Incremental Cost-Effectiveness Ratio for Postpartum Intrauterine Device Initiative in Bangladesh and Tanzania



Abbreviations: CYP, couple-years of protection; ICER, incremental cost-effectiveness ratio.

For all scenarios in both countries, the PPIUD intervention remained more costly and more effective than standard care (before estimated direct cost savings to the health care system were factored in), and is likely cost-effective. Even in the most extreme scenarios (the 9–11 month PPFP uptake rate in Bangladesh, and 4 times the 1- to 2-month PPFP uptake rate in Tanzania), the ICER did not change substantially from the base case results (14.6 in Bangladesh, 54.6 in Tanzania). Details can be found in the Supplement.

DISCUSSION

Summary of Key Findings

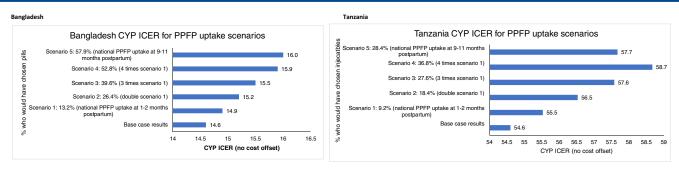
The cost per CYP of the PPIUD initiative was US\$14.60 in Bangladesh and US\$54.57 in

Tanzania before considering longer-term cost savings. In both countries, the PPIUD initiative was found to be more effective than standard PPFP practice. In Bangladesh, once the costs savings for the health care system were factored in, the PPIUD initiative was also found to be cheaper than standard practice. Despite the overall higher costs in Tanzania, cost per outcomes related to deaths averted and DALYs averted were less in Tanzania compared with Bangladesh because overall maternal health outcomes in Tanzania were much poorer, ³⁹ thus the estimated impact of averting a pregnancy was much greater. In both countries, when PPIUD insertion was modeled to nationallevel scale-up, the estimated direct health care savings to the government exceeded the estimated

^aOutcomes are the estimated service lifespan impacts from the Impact 2 tool.

^bThe ICER without cost offset is equivalent to the cost per outcome because the cost of standard practice is estimated as zero cost in both study groups without any impact on the ICER.

FIGURE 4. Sensitivity Analyses for Uptake of Alternate Postpartum Family Planning Methods During the Extended Postpartum Period in Bangladesh and Tanzania



Abbreviations: CYP, couple-years of protection; ICER, incremental cost-effectiveness ratio; PPFP, postpartum family planning.

cost of rolling out PPIUD services. In other words, these analyses suggest that rolling out PPIUD services nationally would save costs in the long run.

International thresholds state that interventions that avert 1 DALY for less than the average per capita GDP for a given country are considered very cost-effective (see the limitations to these thresholds outlined below),⁵⁷ while country-specific cost-effectiveness thresholds for Bangladesh and Tanzania range from 3% to 77% and from 4% to 86% of GDP per capita, respectively.⁵⁸ Our cost per DALY estimates are cost-effective under all proposed thresholds. In Bangladesh, the cost per DALY averted was US\$91.13 (5.4% of the 2018 GDP per capita of US\$1,698), and in Tanzania the cost per DALY averted was US\$67.67 (6.4% of the 2018 GDP per capita of US\$1,501).

Assumptions and Limitations

Due to the lack of direct comparability between immediate PPFP and family planning in the extended postpartum period, as well as the lack of necessary data, we did not factor into our analysis the proportion of PPIUD adopters who would otherwise have taken up an alternate PPFP method at a later date. As such, we may have overestimated the impact of the PPIUD initiative. We ran sensitivity analyses to test the impact of different proportions of women taking up alternate methods (see the Supplement for details). In all scenarios, when the estimated direct cost savings to the health care system from the PPIUD initiative were not factored in, the PPIUD initiative remained more expensive and more effective than standard practice and was likely cost-effective. The change in ICER was not substantial from our base ICER,

suggesting only a small impact from women taking up alternate methods in the extended postpartum period. This outcome is because the most commonly used family planning methods in both countries are short-acting (and so lead to fewer CYPs) and are more expensive per CYP than the PPIUD.

Additional limitations of the evaluation include reliance on self-reported data and estimates for some measures, for example, time spent on the PPIUD initiative by project management staff and time spent on PPIUD delivery by clinical staff. We minimized reporting error by collecting multiple estimates, removing outliers, and reporting averages. We used sector standard CYP factors that do not account for services being delivered postpartum, when fertility may be lower than at other times due to abstinence or lactational amenorrhea, ⁵¹ although this effect is dependent on women breastfeeding exclusively and only applies for the first 6 months postpartum.

The WHO guidance from 2001 to determine cost-effectiveness thresholds based on a country's per capita GDP has been criticized for not reflecting opportunity cost⁵⁸ and lacking country specificity. It should be used alongside other country-specific information, such as the overall budget available for health.⁵⁹ To address this issue, we also compared our findings with available country-specific thresholds (Summary of key findings above).

Certain costs, such as costs of demand generation activities and costs of treating complications, were not included in the analysis, which may have led to an underestimate of the true cost of scaling up PPIUD. Demand generation activities were not included because they were not part of the PPIUD initiative. Costs of treating complications

were not included because there are insufficient data on the rate, type, and severity of PPIUD complications; however, these costs are not likely to be substantial and therefore likely would not impact the final analysis significantly. Similarly, there may have been additional benefits to the PPIUD initiative that were not captured in this evaluation. These possible benefits include increased uptake of other contraceptive methods during the immediate postpartum period and increased uptake of any contraceptive method after the immediate postpartum period due to improved PPFP counseling, uptake of PPIUD at nonparticipating facilities by providers trained through the initiative, and personal cost and time savings to women that take up a PPIUD. For the national scale-up model we needed to make several assumptions regarding costs and activities, which are described in full in the Supplement.

A further limitation of our analysis is that we only considered what was done in the PPIUD initiative, and this may differ if PPIUD rollout is run by the government or if the national context changes. For example, government-run PPIUD training might be longer than that used during the initiative, staff may already be in place and trained to provide PPFP counselling, and if different types of facilities were included, these would likely have different levels of uptake and costs. To explore these possibilities, we repeated the analyses with some adjustments to the intervention design. Details of this analysis and the results are in the Supplement.

Comparison With Existing Literature

Although LARCs have been consistently demonstrated to be more cost effective than short-acting methods in high-income countries, ^{60,61} there are few comparable studies on the cost-effectiveness of delivering postpartum contraception and even fewer specifically on immediate postpartum IUD. ⁶² In addition, comparisons with other studies are of limited use due to different implementation approaches, different methodology for calculating cost, and different costs in different countries.

Previous studies comparing contraceptive methods have consistently found IUD to have a lower cost per CYP compared with other methods of contraception. One study in Kenya (not of postpartum contraception) reports an estimated cost of US\$1.37 per CYP for IUD, US\$1.60 for female sterilization, US\$4.06–US\$6.17 for implants, US\$6.34 for IUS, US\$6.88 for oral contraceptives, and US\$7.07–US\$12.47 for injectables (ranges represent different types of implant and

injectables). ⁶³ A study from Rwanda reports an estimated cost of US\$6 per CYP for PPIUD compared with US\$21 per CYP for postpartum implant. ⁶⁴

The only known studies to have considered the cost-effectiveness of immediate PPIUD provision are Wall et al.⁶⁴ in Rwanda and Washington et al.⁶⁵ in the United States. The latter found that immediate PPIUD results in cost savings of US\$282,540 per 1,000 women and a gain of 10 quality adjusted life years. Wall et al.⁶⁴ used a micro-costing approach similar to our analyses to estimate the incremental cost of PPIUD and postpartum implants compared with standard methods, from the perspective of the health system, in Kigali, Rwanda. The authors included and excluded similar costs as our analyses, but unlike the PPIUD initiative, they conducted and included the costs of promotional activities. The resulting cost per PPIUD inserted was US\$25 and cost per CYP for PPIUD was US\$5, lower than the results in our analyses. However, the Rwanda initiative did include reimbursements paid directly to providers and community health workers referring women to providers and had a higher uptake rate of PPIUDs of 16% (compared with 5%-8% uptake in our analyses), making direct comparisons difficult.

Significance of Results

Compared with previous analyses, our estimates of cost per PPIUD inserted and cost per CYP for PPIUD were generally higher than those reported in peer-reviewed publications, which could reflect our very detailed micro-costing approach as well as differing costs between countries. Nonetheless, our results indicate that even with these higher costs, national introduction and scale-up of PPIUD in Bangladesh and Tanzania are expected to be highly cost-effective or even cost saving. Both the cost-effectiveness and the impact of PPIUD may improve over time as some costs will decrease (for example, no repeat setup costs, and all facilities having trained providers in place), while the impact may increase as awareness and acceptability of the method improve among providers, women and their families, and communities. In addition, potential future national rollout of the PPIUD initiative may be positively affected by ongoing efforts in both countries to encourage births in facilities and improve the capacity of lowerlevel facilities, as well as efforts to increase awareness and availability of a range of postpartum contraceptive methods. 42,45

While the PPIUD initiative was found to be cost-effective in both countries, the main cost drivers and actual costs differed. In Bangladesh, the

National
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largest cost driver was the staff employed at the facility level to counsel women on PPFP. Although more costly to the government, the inclusion of dedicated counselors was a highly effective way of providing quality counseling, which contributed to the success of the initiative, ¹⁹ and has now been incorporated into the latest Bangladesh Costed Implementation Plan (2020–2022). 42 Alternatively, this counseling role could be taken over by the new midwifery cadre of health worker, which could increase access to PPIUD services, while simultaneously reducing salary costs. In Tanzania, the main cost driver was training, partly because the training course was several days longer than in Bangladesh and also due to higher associated travel and meeting costs. PPIUDs in Tanzania are predominantly inserted by midwives, as opposed to doctors in Bangladesh,66 and so a longer training period was deemed necessary. The practice of frequently rotating providers to different clinical departments also meant that training had to be repeated frequently; the same challenge of high rotation of providers was also observed in a program to introduce PPIUD in Malawi.67 In the future, approaches such as on-the-job training could be used to reduce costs while maintaining quality, as has been demonstrated in other countries.⁶⁸

FIGO shared the findings of the PPIUD initiative with the national societies of obstetricians and gynecologists and key government departmental heads in both countries, and they were received with much interest. In Bangladesh, there is an inprinciple agreement to engage with the Obstetrical and Gynaecological Society of Bangladesh in the national rollout of PPIUD as part of a broader PPFP package, although the costs of this have not vet been ascertained. The Tanzanian government is currently seeking donor funding to progress national rollout of PPIUD. Furthermore, in both countries the PPIUD initiative has instigated changes to the preservice training curriculum of midwives and doctors; over time, this will lead to decreased need for detailed in-service training specifically for PPIUD provision.

It is estimated that making family planning widely accessible could reduce maternal mortality by one-third globally.⁶⁹ As well as the health benefits arising from reduced risks to subsequent pregnancies, the newborn, and the wider family,^{5–9} there are additional benefits such as an increase in productivity and the economic value women can contribute to their societies when able to control their fertility.^{70,71} Offering immediate PPFP is an efficient way of giving women the

choice to space or limit their pregnancies. Following the change in WHO MEC criteria, there are now more methods potentially available to women postpartum, each of which has advantages and disadvantages. Making available a broad contraceptive method mix allows women to choose the method most appropriate for them, increasing uptake and reducing the chances of discontinuation.⁷² The FIGO PPIUD initiative and many others have demonstrated that IUD insertion immediately postpartum is safe and feasible to implement.²⁹ However, in practice many countries cannot consistently supply all LARC methods, and difficult cost-benefit decisions have to be made by governments when allocating resources. Information on cost-effectiveness can help guide government and policy resource allocation decisions to maximize value and impact. This economic evaluation estimated that from an implementation perspective, the provision of quality PPFP counseling and insertion of immediate PPIUD if chosen, is highly cost-effective in 2 LMICs, including when modeled to a national scale.

CONCLUSION

The PPIUD initiative was found to be highly costeffective in Bangladesh and Tanzania, with national scale-up of PPIUD estimated to produce
long-term savings in health care costs. The true
benefits to national governments are likely to be
even greater than our analysis suggests owing to
additional likely benefits not quantified. These
analyses provide a compelling case for national
governments and international donors to invest
in the provision of quality contraceptive counseling before and around the time of delivery and
for the routine inclusion of PPIUD within the suite
of contraceptive methods made available during
the immediate postpartum period in Bangladesh
and Tanzania.

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economic evaluation of the initiative in Bangladesh and Tanzania, and FIGO contracted GE, JG, and KD to conduct the economic evaluation. All authors contributed to the design of the evaluation. With support from SB, EAT and KD, FP and AY collated the data required from Bangladesh and PM and GK from Tanzania. The data were analyzed and the economic evaluation constructed by GE, JG and KD. The paper was written by GE, JG and AM with direction for the economic analysis from KD, and then reviewed by all authors.

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