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Original Research Article

The effect of antenatal counseling and intrauterine device insertion services on postpartum contraceptive use in Nepal: Results from a stepped-wedge randomized controlled trial ☆,☆☆,☆☆☆

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ABSTRACT

Objective: There is high unmet need for family planning in the postpartum period in Nepal. The current study assessed the effects of a contraceptive counseling and postpartum intrauterine device (PPIUD) insertion intervention on use of contraception in the postpartum period.

Study design: We utilized a cluster, stepped-wedge design to randomly assign two hospital clusters (compromised of six hospitals) to begin the intervention at time one or time two. From 2015 to 2017, women completed surveys after delivery but before discharge (n = 75,893), and then at one year and two years postpartum. We estimated the intent-to-treat effect of the intervention using weighted, linear probability models and the adherence-adjusted effect (antenatal counseling) using an instrumental variable approach. Outcomes included modern contraceptive use and method mix measured at one and two years postpartum in a sample of 19,298 women (year I follow-up sample) and a sample of 19,248 women (year II follow-up sample). We used inverse probability weights to adjust for incomplete follow-up and bootstrap methods to give correct causal inference with the small number of six clusters.

Results: The intervention increased use of modern contraceptives by 3.8 percentage points [95% CI: −0.1, 9.5] at one-year postpartum, but only 0.3 percentage points [95% CI: −3.7, 4.1] at two years. The intervention significantly increased the use of PPIUDs at one year and two years postpartum, but there was less use of sterilization. Only 42% of women were counseled during the intervention period. The adherence-adjusted effects (antenatal counseling) were four times larger than the intent-to-treat effects.

Conclusions: Providing counseling during the antenatal period and PPIUD services in hospitals increased use of PPIUDs in the one- and two-year postpartum period and shifted the contraceptive method mix.

Implications: In order for antenatal counseling to increase postpartum contraceptive use, counseling may need to be provided in a wider range of prenatal care settings and at multiple time points. Healthcare providers should be trained on contraceptive counseling and PPIUD insertion, with the goal of expanding the available method mix and meeting postpartum women's contraceptive needs.

1. Introduction

Postpartum contraceptive use is critical for maternal and child health [1], but women may not adopt contraceptive methods soon after delivery and become pregnant again, leading to high-risk short birth intervals [2–4]. One reason for high rates of unmet need for postpartum family planning (PPFP) [5] is that counseling about PPFP is typically provided during postnatal care [6]; yet, utilization of postnatal care is low, creating missed opportunities for service provision [7].

Many women in low resource contexts come into contact with health systems during pregnancy and for delivery. A potential approach to overcoming the challenges of counseling women during postnatal care is to provide counseling during the antenatal period and offer immediate insertion of the postpartum intrauter-

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ine device (PPIUD). However, evidence is inconclusive on whether PPFP counseling during the antenatal period improves contraceptive uptake in the postpartum period [8–14]. These studies have short observation periods, no longer than one year after delivery; thus, we know little about whether counseling during the antenatal period impacts the use of contraception in the extended postpartum period of two years, during which women are at risk for short-birth intervals [15]. Additionally, PPIUD use remains low in many countries [16], and it is difficult to know if PPIUD-focused interventions have an effect on contraceptive method mix, as most studies do not follow women who do not obtain a PPIUD [16–18].

Providing PPFP counseling prior to birth and offering PPIUD insertion may be a promising intervention to meet the contraceptive needs of postpartum women in Nepal, where 50% of women have unmet need for contraception within the two years following a birth [19]. Although the postnatal period is the most common time for PPFP services, most mothers tend to make contact with health services for infant health services [20], rather than to obtain contraception. Thus, it is no surprise that in Nepal only 13% of women are provided information about PPFP during postnatal care [19]. Antenatal care, in contrast, is widespread (84% of women had at least one antenatal visit), and the vast majority of antenatal care is from a skilled provider (84%) [19]. However, it is a historically uncommon practice to provide PPFP counseling prior to birth in Nepal. Further, over half of births (57%) take place in health facilities [19].

To provide rigorous evidence about whether PPFP counseling during the antenatal period impacts contraceptive use in the postpartum period, we studied the effects of a facility-based intervention in Nepal providing PPFP counseling and offering PPIUD insertion as newly added services to the healthcare system. Pradhan et al. (2019) studied the effect of the intervention in Nepal on uptake of PPIUD immediately following birth and found a small but significant effect [21]. However, the effects of the intervention on modern contraceptive prevalence and method mix in the one and two year postpartum period remains uncertain. Thus, in this analysis, we focused on all contraceptive methods, rather than PPIUD alone, because the counselors were expected to cover information about all available family planning methods, including how they work, duration of use, effectiveness, and possible side effects, to enable informed and free choice [22]. This may have led to the adoption of other contraceptives, especially in Nepal where IUD use is uncommon (1% among married women of reproductive age) [19], and women face substantial geographical barriers in obtaining care. On the other hand, some of the women wanting to adopt PPIUD may have used other methods if PPIUDs were not available, and PPIUD uptake may therefore reflect a change in the method mix, rather than an increase in modern contraceptive prevalence. Thus, we aimed to fill the aforementioned gaps by assessing the impact of the intervention on (1) modern contraceptive use, (2) use of long-acting reversible contraception (LARC), (3) use of PPIUD, (4) use of non-PPIUD LARC (i.e., interval IUD and sub-dermal implant [both inserted six or more weeks after delivery]), (5) short-acting contraception (SAC), and (6) sterilization at one year and two years post-partum.

2. Material and methods

2.1. Intervention description

In 2013, the International Federation of Gynecology and Obstetrics (FIGO) launched the Postpartum Intrauterine Device (PPIUD) Initiative in six countries: Nepal, Sri Lanka, India, Kenya, Tanzania, and Bangladesh [22]. In Nepal, FIGO collaborated with the Nepal Society of Obstetricians and Gynecologists (NESOG) and the Nepal Ministry of Health and Population to design the intervention in adherence with the national health system and training guidelines. The intervention involved five components:

(1) female community health volunteers and hospital staff were trained on PPFP counseling,
(2) maternity care providers were trained on PPFP counseling and PPIUD insertion and complications management,
(3) counseling aids and informational tools, specially leaflets, wall charts, and videos, were provided and to be distributed during counseling and displayed in hospital waiting areas,
(4) Kelly's forceps for vaginal PPIUD insertion and PPIUDs were provided,
(5) one provider in each hospital was designated as the facility coordinator to provide on-going support for the initiative.

In total, 417 female community health volunteers, 372 nurses/midwives, and 381 general hospital staff were trained on counseling. A total of 43 medical doctors and 92 nurses were trained on counseling and PPIUD insertion. Only doctors and nurses who provided labor and delivery services, and would have the potential to insert PPIUDs, were trained to insert PPIUD due to time and resource constraints.

Providers were trained to counsel women during routine antenatal care and at labor and delivery (only in early labor and never during active labor). Providers received refresher trainings, as needed, and were expected to train rotated-in providers regularly. Counselors were expected to provide information about all available family planning methods. Available methods included male condoms, contraceptive pills, Depo-Provera injectable, IUDs, implants, and sterilization, and were provided by the Nepal Ministry of Health and Population's Family Planning Programme at no cost. Within the range of available and appropriate methods, providers placed additional emphasis on the advantages of PPIUD [22]. IUDs were already included in Nepal's method mix; however, the method was only available at a limited number of hospitals, where trained health care providers were available. Providers were expected to demonstrate how the PPIUD is inserted using visual aids. PPIUD services, including the device, insertion and removal, were offered to women free of charge. Providers covered removal services in the counseling, and women were instructed to return to the facility at any time if they wanted the PPIUD removed. Pregnant women who received counseling in the antenatal period had the option to provide advance consent to PPIUD insertion, and their medical charts were marked with their stated decision. These women were consented again at the time of delivery to confirm their choice for PPIUD insertion.

2.2. Study setting and evaluation design

The evaluation of the FIGO PPIUD intervention in Nepal was conducted in six hospitals: Bharatpur Hospital, Bheri Zonal Hospital, BP Koirala Institute of Health Sciences (BPKIHS), Koshi Zonal Hospital, Lumbini Zonal Hospital and Western Regional Hospital. The inclusion criteria for hospital sites were: (1) tertiary care facility, (2) high volume of obstetric caseloads ($\geq$6000 per year), (3) large catchment area (patients from at least six or more districts), (4) not located inside of the capital city of Kathmandu, and (5) not already providing PPIUD services. Hospitals were selected based on eligibility criteria and with input from the national government. The intervention targeted counseling during antenatal care in large, tertiary hospitals primarily for feasibility. Many women in Nepal likely receive antenatal counseling at local facilities, if available. However, the goal of the intervention was to assess the feasibility of introducing and institutionalizing counseling and PPIUD services as routine maternal health care. Thus, women who deliv-

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ered in these hospitals may not be representative of women in Nepal, as a whole, and are likely better served than other women.

Ethical approval as exempt was granted by the Office of Human Research Administration, as only de-identified data were provided to [Blinded for Review] for analysis. The study received approval from the [Blinded for Review]. The protocol was also reviewed and approved by the Nepal Health Research Council and implementation was supervised by an independent data national safety monitoring committee.

The evaluation followed a stepped-wedge cluster randomized design, consisting of a baseline survey of women after delivery but before discharge from the hospital and two follow-up surveys, one year and two years after delivery. The six hospitals were pairwise matched based on geographic location and annual delivery caseload following which one hospital within each pair was randomly assigned to Group 1 and the other to Group 2. The three pairs were: (i) Western Regional and BPKIHS, (ii) Lumbini Zonal and Bharatpur, and (iii) Koshi Zonal and Bheri Zonal. Group 1 hospitals were Lumbini Zonal, Koshi Zonal, and Western Regional. Baseline data collection started in all six hospitals at the same time, September 8, 2015, and ended on the same date, March 8, 2017. Group 1 hospitals initiated the intervention after three months of baseline data collection, while Group 2 hospitals initiated the same intervention after nine months of baseline data collection.

All women who gave birth in study hospitals in the 18-month study period and whose primary residence was in Nepal were eligible for participation in the baseline survey (see Fig. 1). After giving birth and before discharge from the hospital, site-based trained Nepali female enumerators approached women, introduced themselves, stated their affiliation as researchers with [Blinded for Review], informed women they were conducting a study about PPFP, and screened them for eligibility. Women were provided details about the study in their own language, including the nature of the study, research objectives, benefits and risks, contact information for study investigators, and how their privacy would be maintained. The informed consent script was read aloud to women, including a portion on women's rights to refuse or withdraw from the study. The portion said, "You are completely free to take part in this study or to refuse to do so. The choice is completely yours. Participation in this study is voluntary and you can choose not to answer any individual questions or all of the questions, if you don't like. Even after you agree to participate in the study, you will be free to leave the interview at any time you wish and/or to refuse to answer any question that you are uncomfortable with." Enumerators asked participants to provide written consent to take part in the study. Participants who were unable to sign their names provided a thumbprint along with a witness' signature. Women were not provided compensation for baseline interviews. Of the 75,893 eligible women, 75,583 (99.8%) consented to be interviewed. While our consent rate is high, consent rates in the 2016 Nepal Demographic and Health Surveys are also high at 98%, which suggests that women in Nepal are willing to participate in voluntary surveys.

Enumerators interviewed women in their spoken language using hand-held tablets. Interviews were conducted in private locations that provided visual and audio privacy, such as a private room. Only the enumerator and the respondent were present during the interview. Enumerators were instructed to end the interview or change the discussion if anyone interrupted the interview and/or entered the private location. The baseline survey included questions about women's socio-demographic background, reproductive and contraceptive history, antenatal contraceptive counseling, and uptake of PPIUD. At the end of the survey, women were given the opportunity to make comments and ask questions.

The year one follow-up survey occurred between May 30, 2016 and April 30, 2018. The year two follow-up survey occurred between March 17, 2017 and December 31, 2018. The baseline study was powered to detect an effect size in the pre-specified, primary outcome of "percentage uptake of PPIUD" (see ClinicalTrials.gov, NCT02718222) of five percentage points [23]. The overall study was not only interested in the uptake of PPIUD but also

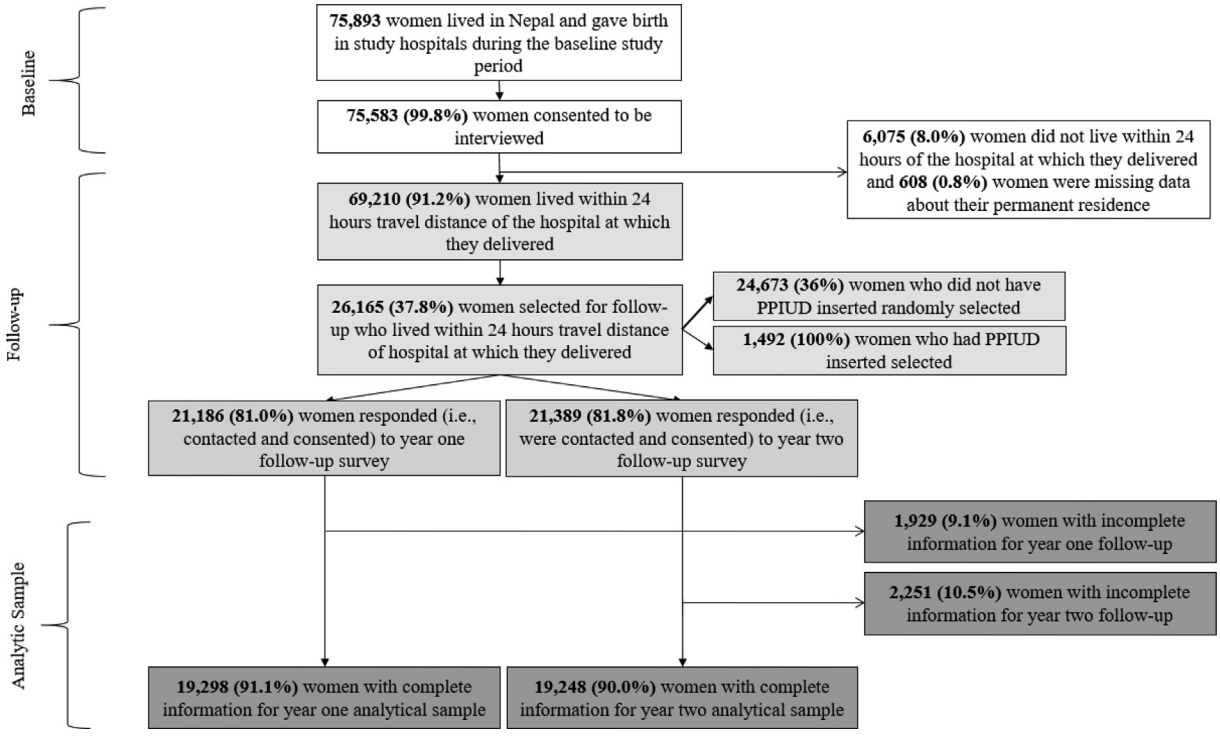

Fig. 1. Flow chart of the analytical sample, Stepped-wedge randomized controlled trial, Nepal, 2015–2018.

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continuation and expulsion of PPIUD, and thus, power calculations for follow-up were based on the outcome of percentage continuation of PPIUD. We assumed that a proportion of women would discontinue the PPIUD, and thus powered to detect an effect size in PPIUD continuation of 3.96% in the follow-up surveys [23]. The sampling frame for follow-up was limited to those who lived within 24 h travel distance of the hospital at which they delivered with the aim of reducing travel costs of follow-up. Based on the power calculation and in consideration of the costs of follow-up, 36% of women who met inclusion criteria and did not have the PPIUD inserted at baseline were randomly selected for follow-up. All women who met inclusion criteria and had the PPIUD inserted at baseline were selected for follow-up to measure continuation, expulsion, and side effects. In total, 26,165 women were selected for follow-up.

Trained Nepali female enumerators contacted women selected for follow-up to schedule interviews. Similar to the baseline, women were provided details about the study in their own language, and enumerators read the informed consent script aloud to women. The voluntary nature of the study was described in detail, and participants were informed that they could skip any question they did not want to answer or end the survey when they pleased. Enumerators asked participants to provide written consent. Participants who were unable to sign their names provided a thumbprint along with a witness' signature. Women were provided 340 Nepalese Rupees (equivalent to $3 USD) as compensation for their participation in follow-up surveys. Interviews occurred in private settings in or near women's homes and in their spoken language, using hand-held tablets. Only the enumerator and the respondent were present during the interview.

The follow-up surveys included questions about women's socio-demographic background, reproductive and contraceptive use history, uptake of contraception, and satisfaction with contraception. Women were provided the opportunity to ask questions or make comments at the end of the survey. Of those selected for follow-up, the response rate (i.e., rate of contact and consent) for year one was 81.0% ($n = 21,186$) and for year two was 81.8% ($n = 21,389$). The analytical samples used in this study consisted of 19,298 women for year one and 19,248 women for year two with complete information.

2.3. Exposure and outcome measures

The key exposure for this analysis was delivering in a hospital during the intervention period (i.e., the treatment group; coded as 1). The control group (coded as 0) included women who delivered in a hospital before the intervention started in that hospital. We also considered receipt of counseling about postpartum contraception an exposure in this analysis (coded 1; if women did not receive counseling, they were coded 0). Receipt of counseling about postpartum contraception was measured by asking women two questions: (1) "Were you counselled about family planning/birth spacing during your pregnancy?" and (2) "Were you counselled about family planning/birth spacing after admission for delivery to the hospital?" If women self-reported that they had been counseled, women were asked in an open-ended fashion to detail which methods they were counseled about. Women were able to provide more than one response, and interviewers could indicate on the form whether the woman was counseled about female sterilization, male sterilization, IUD, injectables, implants/norplant, pill, condom, emergency contraception, calendar method, lactational amenorrhea method, withdrawal, or other (and specify other). We did not consider the location, the content, or the quality of the counseling, rather the measure is an indication of whether or not counseling was received about any family planning method as perceived and reported by women. Our intention was that this measure captured counseling prior to delivery, but the questions were asked of women after delivery but before discharge from the hospital. It is possible that some women received counseling in the postnatal ward and reported this as "counseling after admission to the hospital." However, counseling in the postnatal period was not a part of our intervention and it is unlikely that women were counseled in the postnatal ward, as this was not a standard practice.

Our outcome measures were pre-specified in the trial registered with ClinicalTrials.gov, NCT02718222. The primary outcome was "percentage uptake of PPIUD," and that outcome was examined in previously published work [21]. In this analysis, we focus on pre-specified, secondary outcomes three ("percentage of women using modern contraception at 9 months postpartum") and four ("percentage of women using modern contraception at 18 months postpartum"). While our follow-up surveys were planned to occur at nine and 18 months, in practice the average time of follow-up was closer to one and two years, and we report our results as one and two years follow-up.

Outcomes included modern contraceptive use, long-acting reversible contraception (LARC) use, short-acting contraception (SAC) use, and sterilization. LARC use was further sub-divided into PPIUD use and other LARC use. All outcomes were binary. Women were defined as modern contraceptive users if they reported that they were using condoms, oral contraceptive pills, emergency contraception, injectable Depo-Provera, sub-dermal implants, IUDs, or sterilization at the time of the follow-up survey [24]. Women who reported using implants or IUDs (i.e., PPIUD and interval IUD) were considered LARC users. Women were defined as PPIUD users if they reported that they were currently using PPIUD, which was inserted at baseline. Women who reported using implants and interval IUD were considered non-PPIUD LARC users. Women were defined as users of SAC if they reported using condoms, pills, emergency contraception, or injectables. Finally, women were defined as users of sterilization if they, or their partners, were sterilized.

2.4. Statistical analysis

Our main approach was an intent-to-treat (ITT) analysis; we assessed the effect of the intervention on women who delivered in hospitals after the start of the intervention, compared to women delivering in hospitals that had not yet started. While the intervention called for counseling of all women, we found that, in practice, not all women delivering in the intervention period received counseling [21]. Thus, we also conducted an analysis of contraceptive use among women who were counseled due to the intervention (i.e., the adherence-adjusted effect).

We conducted separate analyses for data collected at year one and year two follow-up surveys. Since the probability of being followed-up varied by PPIUD insertion status, we calculated sampling weights to create a sample which was representative of the study population at large. Sampling weights were defined as the inverse of the probability of being selected for follow-up based on a model of follow-up on baseline characteristics (see Appendix A, Table A.1., Table A.2., Fig. A.1., and Fig. A.2.). For women who did not get the PPIUD inserted at baseline, their predicted probability of follow-up was multiplied by 0.36 to account for the fact that only 36% of this population was selected for follow-up. Our weighted sample was therefore representative of women living within 24 h travel distance of the hospital at which they delivered. We accounted for potentially correlated outcomes among women who delivered at the same hospital by using wild cluster bootstrap with a six-point bootstrap weight distribution to estimate standard errors [25]. This approach has been shown to have good properties with six clusters using Monte Carlo simulations [26].

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We conducted the ITT analysis by fitting weighted linear probability models. We fit models both with and without additional controls for women's background characteristics, including: parity, age, education, ever had abortion(s), ethnicity, male child born at the index birth, marital status, and ever used family planning. We also included a variable indicating the time since delivery, measured in months. All regression models included hospital and month fixed effects to control for time-invariant hospital effects and underlying time trends, respectively.

We calculated an adherence-adjusted effect of the intervention (i.e., the impact of being counseled about postpartum contraception due to the intervention) on our outcome measures using an instrumental variable (IV) approach [27]. ITT is the common approach to analyze randomized control trials, but it ignores treatment noncompliance. It is often the case in randomized control trials that subjects do not follow the protocol for their assigned treatment. Thus, IV can be used to adjust for treatment adherence and study the effect of the treatment on those study participants who actually received it [28]. In our analysis, the intervention period is the instrumental variable – the intervention was mediated by counseling. We used the Kleibergen-Paap rk Wald F statistic to test for weak instruments [29].

Appendix B provides detailed information about the analysis. We used Stata version 15 to manage and analyze the data (StataCorp LLC, College Station TX, USA).

3. Results

Table 1 reports the descriptive statistics of the woman-level variables used in the analysis disaggregated by year of follow-up survey and intervention arm. Approximately 62% of women in the year one follow-up sample and about 63% of women in the year two follow-up sample delivered in a hospital after the start date of the intervention, and were thus potentially exposed to the intervention. In both year one and year two samples, about 43% of women in the intervention arm reported receiving counseling on postpartum contraception, and about 10% of women in the intervention arm had the PPIUD inserted at baseline. In general, women who were and were not followed-up at year one and two did not differ greatly in baseline sociodemographic characteristics (not shown; see Appendix A, Table A.3.). Baseline sociodemographic characteristics of women in our samples did not differ between year one and two follow-up, except for receipt of PPFP counseling and PPIUD insertion. Further, in general, covariates were balanced across the groups of hospitals [21].

At year one, 36.2% of women reported using a modern contraceptive method (Fig. 2). At year two, 39.1% were using a modern method. The proportion of women using non-PPIUD LARC and sterilization increased between year one and two (3.0% vs. 5.5%, and 3.1% vs. 3.7%, respectively). Conversely, the proportion of women using SAC was relatively stable between the surveys, and the proportion of women using PPIUD decreased from 4.5% at year one to 3.9% at year two.

Table 2 shows the ITT effect of delivering in hospital during the intervention, compared to delivering in a hospital before the intervention. Effects with and without women level controls were similar. One year after delivery, women who delivered in a hospital during the intervention period had 3.8 percentage point (pp) [95% CI: −0.1, 9.5 pp] higher probability of using modern contraception than women who delivered before the intervention. In terms of method mix, the increase in contraceptive use reflected a corresponding rise in the use of PPIUD but a small decline in sterilization; the probability of sterilization fell by 1.0 pp [95% CI: −2.2, −0.2 pp]. In the two-year follow-up, the effect of the intervention on the probability of modern contraceptive use was 0.3 pp [95% CI: −3.7, 4.1 pp], a much smaller increase relative

Table 1
Baseline demographics of postpartum women included in the follow-up study samples, by intervention arm, Stepped-wedge randomized controlled trial, Nepal, 2015–2018.

Baseline Characteristics	Year 1 follow-up (n = 19,298)		Year 2 follow-up (n = 19,248)	
	% Intervention	% Control	% Intervention	% Control
Delivered in hospital during the intervention period	100.0	0.0	100.0	0.0
Received postpartum contraceptive counseling	42.8	10.0	42.7	9.9
PPIUD inserted at baseline	10.0	0.1	9.7	0.1
Age				
Less than 20	12.4	13.6	11.6	12.5
20–24	45.8	45.6	45.6	45.3
25–29	30.0	29.0	30.6	29.8
Greater than 29	11.9	11.8	12.2	12.5
Education				
No schooling	1.3	0.6	1.2	0.6
Some primary	4.7	5.1	4.5	4.7
Completed primary	4.8	4.6	4.6	4.2
Some secondary	30.9	29.3	30.5	28.3
Completed secondary	19.2	18.3	19.4	18.7
More than secondary	39.2	42.0	39.9	43.5
Parity				
1	55.2	58.8	54.7	58.4
2	35.6	33.5	36.0	34.0
3 or more	9.3	7.7	9.3	7.6
Ethnicity				
Hill Brahmin	26.3	23.4	27.0	24.0
Chhetri	14.9	16.8	15.0	16.7
Janajaati	34.5	39.4	34.7	40.0
Madhesi	6.3	5.2	5.8	5.1
Dalit	14.2	11.8	13.7	11.1
Muslim	2.0	1.7	1.8	1.6
Others	1.9	1.7	2.0	1.6
Married	99.9	99.9	99.9	99.9
Had abortion(s) before	4.7	4.8	5.0	4.9
Male child born at index birth	54.7	55.0	54.6	54.9
Ever used family planning	31.5	33.4	31.9	33.9

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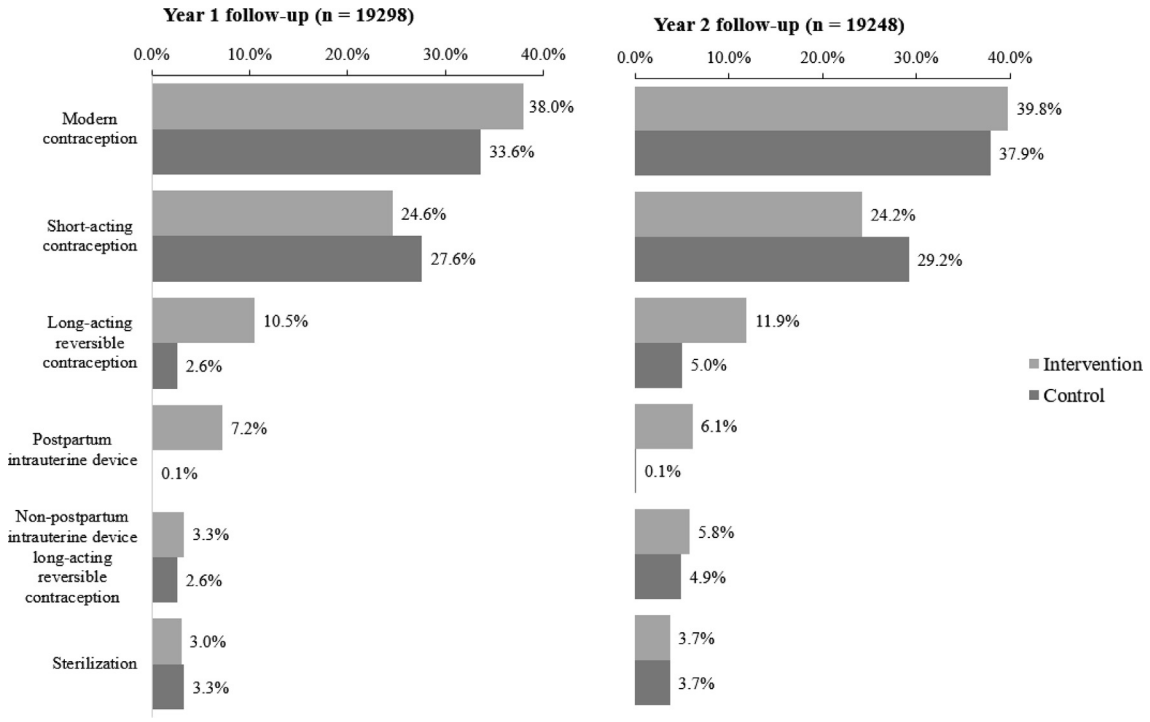

Fig. 2. Outcomes measured at year one and two follow-up surveys, Stepped-wedge randomized controlled trial, Nepal, 2015–2018.

Table 2
Intent-to-treat effect of delivering in a hospital during the intervention compared to the historical control, on key outcomes at year one and two follow-up, Stepped-wedge randomized controlled trial, Nepal, 2015–2018.

Outcomes	Year 1 follow-up sample (n = 19,298)		Year 2 follow-up sample (n = 19,248)	
	Adjusted Coef.	95% CI	Adjusted Coef.	95% CI
Modern contraception	0. 04	[−0.00, 0.10]	0.00	[−0.04, 0.04]
Short-acting contraception	0.02	[−0.02, 0.07]	−0.01	[−0.04, 0.02]
Long-acting reversible contraception	0.03*	[0.01, 0.05]	0.02	[−0.00, 0.04]
Postpartum intrauterine device	0.03*	[0.02, 0.04]	0.02*	[0.01, 0.03]
Non-postpartum intrauterine device long-acting reversible contraception	−0.00	[−0.01, 0.01]	−0.01	[−0.02, 0.01]
Sterilization	−0.01*	[−0.02, −0.00]	−0.01	[−0.02, 0.00]

*$p < 0.05$, **$p < 0.01$

Note(s): Difference from zero effect tested using wild cluster bootstrap method. Sampling weights constructed using inverse probability weighting. Adjusted models control for time since delivery, male child born at index birth, had abortion(s) before, ethnicity, parity, education, marital status, ever use of family planning, and age. All regression models adjusted for hospital and month fixed effects.

to the intervention's effect at year one. In terms of method mix at two years follow-up, we witnessed a similar pattern with a rise in PPIUD and a decline in sterilization and some evidence that PPIUD was a substitution for SAC; however, these effects were not significant.

Fig. 3 illustrates contraceptive counseling rates during the antenatal period at baseline among women in the analytic sample disaggregated by month of delivery and hospital group. There was a substantial increase in counseling following the start of the intervention. Prior to the intervention, counseling rates were around 10%, while after the intervention they rose gradually to over 40%.

Our estimate of the adherence-adjusted effect of the intervention accounts for imperfect compliance. Table 3 displays the effect of being counseled on the probability of contraceptive use, and method mix, one and two years postpartum. The effect of the intervention on the probability of PPIUD use was 12.0 pp [95% CI: 6.1, 16.4 pp] at year one and 10.5 pp [95% CI: 4.7, 15.8 pp] at year two. The large, and highly significant, rise in the use of PPIUD among counseled women was partially offset by a decline in other methods. Thus, the intervention did not produce a significant effect in use of modern contraception among those who were counseled. There is no evidence of bias more than 15% based on the Kleibergen-Paap rk Wald F statistic [29].

4. Discussion

The findings from this study showed that the intervention had a significant effect on use of PPIUD at both one and two years postpartum. This effect was about four times larger in women who were counseled about PPFP. However, the intervention had no impact on increasing modern contraceptive use among women who delivered during the intervention period.

The rate of PPFP counseling was lower than expected. However, integrating counseling into antenatal care is difficult in settings in which this is not the norm [16]; similar interventions have found

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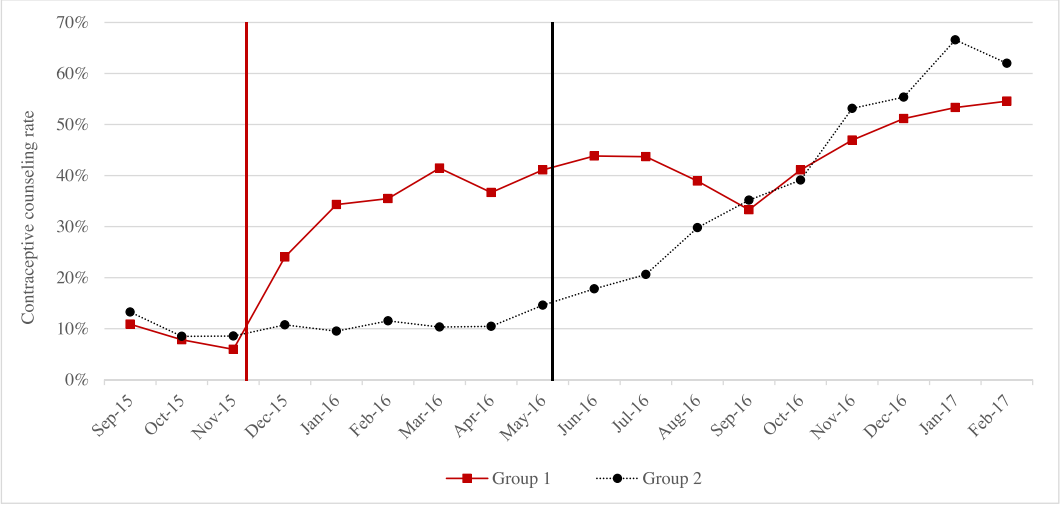

Fig. 3. Trends in counseling rate for any family planning method, Stepped-wedge randomized controlled trial, Nepal, 2015–2018. The red and black vertical lines represent the approximate intervention start dates in Group 1 and Group 2 hospitals, respectively.

Table 3
Adherence-adjusted effect of being counseled on postpartum contraception due to the intervention among women who delivered in a hospital during the intervention compared to the historical control, on key outcomes at year one and two follow-up, Stepped-wedge randomized controlled trial, Nepal, 2015–2018.

Outcomes	Year 1 follow-up sample (n = 19,298)		Year 2 follow-up sample (n = 19,248)	
	Adjusted Coef.	95% CI	Adjusted Coef.	95% CI
Modern contraception	0.16	[−0.05, 0.39]	0.01	[−0.15, 0.18]
Short-acting contraception	0.08	[−0.12, 0.29]	−0.03	[−0.15, 0.10]
Long-acting reversible contraception	0.12**	[0.05, 0.19]	0.07	[−0.02, 0.17]
Postpartum intrauterine device	0.12**	[0.06, 0.16]	0.11**	[0.05, 0.16]
Non-postpartum intrauterine device long-acting reversible contraception	−0.00	[−0.03, 0.03]	−0.04	[−0.10, 0.02]
Sterilization	−0.04	[−0.11, 0.01]	−0.03	[−0.09, 0.02]
Kleibergen-Paap rk Wald F statistic (15% maximal IV size)	13.8 (9.0)		11.3 (9.0)	

*$p < 0.05$, **$p < 0.01$

Note(s): Difference from zero effect tested using wild cluster bootstrap method. Sampling weights constructed using inverse probability weighting. Adjusted models control for time since delivery, male child born at index birth, had abortion(s) before, ethnicity, parity, education, marital status, ever use of family planning, and age. All regression models adjusted for hospital and month fixed effects.

rates as low as 13% [16]. Although, implementation strategies may influence the success of these programs and should be considered when comparing results. It is also possible that women counseled during antenatal care delivered at facilities outside of the intervention. However, all women in the study sample lived within 24 h of the hospital. It is unlikely that over 50% of women who received antenatal care and planned to deliver at the facility, delivered elsewhere. Providers likely did not counsel all women, suggesting lack of compliance to the protocol. Providers who participated in the study reported that hospital management issues, limited supplies, and human resource constraints created barriers in adopting the intervention [31]. Expanding coverage may require addressing these barriers and providing additional support [32]. Given that antenatal care is traditionally void of PPFP counseling, more effort may be required to increase providers' confidence and knowledge on counseling techniques [32,33].

Coverage of counseling may not improve contraceptive utilization without improvements in quality [21,34]. Further, sociocultural barriers, such as gender norms and societal pressure to have children, may prevent women from using postpartum contraception, and lack of desire to use methods which require a provider to remove may dissuade women from uptake of PPIUD. In a related study, we asked Tanzanian women who participated in the intervention and opted not to get the PPIUD why they did not want one. Women reported they did not want PPIUD because of side effects, unfamiliarity, and lack of in-depth knowledge about the method [30]. We also interviewed women who adopted PPIUD, but discontinued. Women reported that they chose to discontinue PPIUD because of side effects and lack of support, or their expectations were not met [35].

Whether antenatal counseling can improve postpartum contraceptive use is inconclusive. The integration of PPFP counseling during antenatal care visits was associated with postpartum contraception use at one year or less in Mexico [9], Nigeria [13], and Ghana [14]. However, evidence from China, South Africa, and Scotland suggests that PPFP counseling in the prenatal period has no impact [8]. To our knowledge, no studies follow women longer than a year. Thus, our study supports the latter literature in that we found no increase in postpartum contraceptive use at one year, and this null effect was sustained at two years.

The intervention significantly increased PPIUD use at both one and two years postpartum. Similar interventions tend to focus on rates of immediate acceptance of the PPIUD, rather than the effect on use in the extended postpartum period [16–18,21], and thus comparability is difficult. However, an intervention that counseled women at hospital admission and offered the injectable, PPIUD, or sterilization prior to discharge found that while rates of PPIUD use were low, it increased use of interval IUD at one year postpartum [36]. We found the opposite effect, but women in our study were also counseled prior to admission.

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Tertiary level hospitals with high obstetric caseloads were used for the study. Thus, we excluded women who delivered outside of formal healthcare systems or at small, primary healthcare centers. Women in our study samples were not nationally representative; they tended to be younger and have more years of schooling than reproductive age women in Nepal [19]. We also focused on women who lived within 24 h travel distance of the hospital, and effects are likely different for women in remote areas. Given that healthcare access is difficult for women in rural areas [31], women may be reluctant to obtain PPIUD since it requires a facility visit to have it removed. However, in contrast, women may want to use the PPIUD, rather than short-acting methods, so that they do not have to visit facilities for resupply. Women's preferences for methods and fertility desires must be considered and actively met in any counseling intervention.

It is possible that women who were counseled about PPFP explicitly expressed an interest in contraception, leading to the receipt of counseling and possible selection bias in the adhere-adjusted analysis. However, it is unlikely that the significant change in counseling rates can be attributed to greater demand alone. The initiative did not include any woman-level demand-generation activities, and instead focused on training providers. Thus, it seems unlikely that selection bias influenced all the change in these rates. Further, we did not consider women's desires to avoid pregnancy or return to fertility, and instead focused on contraceptive use as per our pre-specified, secondary outcomes. Although the WHO recommends waiting at least 24 months before attempting another pregnancy, women may desire additional children sooner and become pregnant before this time.

Adherence to the protocol may have differed by provider. However, we did not account for clustering by provider, because we did not ask women the name of the provider who counseled them about PPFP. It is possible that we violated the excludability and monotonicity assumptions required by the instrumental variable approach. Women who were counseled may have told women who were not counseled about contraception, resulting in a spillover effect. In this case, we overestimated the effect of counseling on contraceptive use. While it is possible that receiving contraceptive counseling could result in a woman being less likely to use contraception, we generally assumed the reverse to be true for all women.

Over half of pregnancy intervals among women in low- and middle-income countries are too short [4], often a result of high unmet need for postpartum contraception [3]. Renewed interested in PPFP has inspired initiatives to integrate contraceptive services into routine maternal care. However, progress at meeting new mother's contraceptive needs is slow [4,37]. The implementation of the PPIUD Initiative significantly raised the proportion of women using PPIUD by two years postpartum, but had no effect on the proportion of women using modern contraception. New developments are needed to understand how to meet women's contraceptive needs until they are no longer at-risk of short-birth intervals or desire an additional pregnancy.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.contraception.2019.12.014.

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