Provision of immediate postpartum intrauterine contraception after vaginal birth within a public maternity setting: Health services research evaluation

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Abstract

Introduction: Expanding access to postpartum intrauterine contraception (PPIUC) can reduce unintended pregnancies and short inter-pregnancy intervals; however, provision across Europe is limited. Our aim was to determine the feasibility, clinical outcomes and patient satisfaction of providing immediate PPIUC after vaginal birth using a health services research model.

Material and methods: Phased introduction of PPIUC across two Lothian maternity hospitals; all women intending vaginal birth during the study period without a contraindication to use of the method were eligible to receive PPIUC. Midwives and obstetric doctors were trained in vaginal PPIUC insertion using Kelly forceps. Women received information antenatally and had PPIUC insertion of either a levonorgestrel intrauterine system or a copper intrauterine device within 48 hours of vaginal birth. Follow-up was conducted in-person at 6 weeks postpartum and by telephone at 3, 6 and 12 months. Primary outcomes were: uptake, complications (infection, uterine perforation), expulsion and patient satisfaction at 6 weeks; and method of continuation up to 12 months. Secondary outcomes included hazard ratio for expulsion adjusted for demographic and insertion-related variables.

Results: Uptake of PPIUC was 4.6% of all vaginal births; 465/447 (96.1%) of those requesting PPIUC successfully received it and most chose a levonorgestrel intrauterine system (73%). At 6 weeks postpartum, the infection rate was 0.8%, there were no perforations and 98.3% of women said they would recommend the service. The complete expulsion rate was 29.8% (n = 113) and most had symptoms (n = 79). Of the additional 121 devices removed, 118 were because of partial expulsion. The rate of complete/partial expulsion was higher for insertions by midwives compared with those by doctors. The re-insertion rate after expulsion/removal was 87.6% and method continuation at 12 months was 79.6%.

Abbreviations: IUC, intrauterine contraception; NHS, National Health Service; PPIUC, postpartum intrauterine contraception; RCOG, Royal College of Obstetricians and Gynaecologists

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Conclusions: Routine PPIUC at vaginal birth is feasible. Complications were extremely rare. High expulsion rates may be observed in early stages of service introduction and with inexperienced providers. Re-insertion and therefore longer-term continuation rates of intrauterine contraception were very high. In settings with low rates of attendance for interval postpartum intrauterine contraception insertion, PPIUC could be a useful intervention to prevent unintended and closely spaced pregnancies.

KEYWORDS

intrauterine contraception, postpartum contraception, postpartum intrauterine contraception, postpartum intrauterine device, service delivery

1 | INTRODUCTION

Unintended pregnancy in the postpartum period is common. One UK study found that at least 1 in 13 women attend for termination of pregnancy within 12 months of childbirth.¹ For women who continue a pregnancy following a gap of less than 12 months between childbirth and subsequent conception-known as a short interpregnancy interval-there is an increased risk of preterm labor, fetal growth restriction and stillbirth.² Initiation of effective contraception has been shown to reduce the incidence of unintended pregnancy and short inter-pregnancy intervals, especially when started immediately postpartum.³ As this is also a convenient and desirable option for women,¹ there is now an increasing requirement for maternity centers to offer a range of contraceptive services. Although both contraceptive and maternity care are provided free-of-charge in the UK under the National Health Service (NHS), there are still challenges in integrating these services, particularly for contraceptive methods requiring trained personnel to fit, such as intrauterine contraception (IUC).

NHS Lothian (Edinburgh and surrounding region) has two large maternity centers (two hospitals; approximately 9000 annual births) and has led numerous recent initiatives to improve access to post-partum contraception. This included the introduction of routine antenatal contraceptive counseling⁴ and the successful provision of IUC insertion at planned cesarean delivery.⁵ However, most women have a vaginal birth and those intending to use IUC postpartum are required to attend their general practitioner or local sexual clinic several weeks after childbirth. Local data suggest that <50% of women attend for interval IUC insertion, even when provided with an appointment.¹

Current clinical guidelines from UK, USA and World Health Organization⁶⁻⁸ all support immediate postpartum intrauterine contraception (PPIUC) insertion. This can be performed in the 10 minutes following placental delivery (post-placental insertion) and up to 48 hours after vaginal birth.⁹ Although there is good evidence to support the safety of PPIUC,^{10,11} until recently much of the clinical experience originated from low- and-middle-income settings.

Key message

Vaginal postpartum intrauterine contraception (PPIUC) provision is feasible in a public maternity setting. Complications are low, but expulsion may be increased with inexperienced providers. High continuation suggests that PPIUC is a useful intervention to reduce unintended pregnancies, especially where attendance for interval insertion is poor.

Although some high-income settings such as the USA now offer PPIUC, it is not yet routinely available. The recommended technique for vaginal PPIUC insertion is one with which most European maternity providers are unfamiliar. In a publicly funded maternity setting such as the UK, the need to train large numbers of multi-disciplinary providers to ensure sufficient availability of fitters therefore presents challenges.

We sought to train maternity providers in vaginal PPIUC insertion in NHS Lothian and subsequently introduce and evaluate a routinely available service, using a health services research model appraising both clinical and qualitative outcomes. Primary clinical outcomes of interest included uptake, complications (infection, perforation), expulsion and satisfaction at 6-weeks postpartum, and method continuation up to 12 months. Based on previous studies we anticipated a higher expulsion rate with vaginal PPIUC insertion,^{10,11} so our secondary aim was to determine the patient and insertion-related characteristics associated with expulsion. The acceptability and experience of women and healthcare staff were evaluated through a separately reported qualitative study.

2 | MATERIAL AND METHODS

The study was conducted across both NHS Lothian maternity services comprising St Johns Hospital (Hospital A; smaller regional 600 AOGS

center) and the Royal Infirmary of Edinburgh (Hospital B; large tertiary center). The vaginal PPIUC service was intentionally introduced in a phased manner, first to Hospital A in January 2017 and 9 months later to Hospital B (October 2017). The recruitment period for both hospitals continued until June 2019.

Any pregnant woman anticipating vaginal birth in the region, interested in using IUC for postpartum contraception and without a contraindication to the method (as per UK Medical Eligibility Criteria for Contraceptive Use⁹) was eligible to participate. Information about PPIUC and the study was provided by community midwives to all pregnant women during their 20-week antenatal visit, when contraception counseling routinely occurs in Lothian. Those who were eligible and wished to receive PPIUC completed a structured self-assessment form containing detailed information about the insertion procedure, risks and available methods; as well as consent to follow-up by clinical research staff. Women could choose to receive either a 52-mg levonorgestrel intrauterine system (Mirena[®]; Bayer plc) or a 5-year 380-mm² copper intrauterine device (UT380[®]; Durbin). PPIUC intention and method choice were recorded in the women's electronic maternity record, and a designated sticky label was applied to the case notes to assist in identifying them on admission to the birth unit.

Before service introduction, all obstetric doctors and a cohort of labor ward midwives were trained in vaginal PPIUC insertion using 33-cm Kelly forceps (Roberts Surgical Healthcare Ltd). This technique has been widely described in the literature¹² and is advocated by the Royal College of Obstetricians and Gynaecologists (RCOG).¹³ After delivery of the baby and placenta, ring forceps are applied to the anterior cervix to straighten the utero-cervical canal. The IUC device is removed from its pre-packaged inserter and advanced into the uterine cavity using Kelly forceps. After the forceps have reached the fundus (confirmed by external palpation with the non-dominant hand), the device is released from the forceps, which are then removed, and the threads are trimmed flush with the cervix.

Training workshops in vaginal PPIUC insertion were facilitated by clinical research staff (MC and colleagues) and consisted of education about risks and benefits of PPIUC, insertion training video (supplied by RCOG) and practical simulation using postpartum uterus models (Mama-U[®]; Laerdal). One-to-one and small-group workshops were conducted regularly throughout the study period. Following workshop attendance, inserters were required to maintain a logbook and perform a minimum of three competent procedures under supervision. A 'train-the-trainers' model¹⁴ was used to increase the pool of available supervisors. Supervision was initially provided by the research team, who also delivered subsequent coaching for on-site trainers. To become a 'trainer', an individual was required to have sound knowledge of the clinical and educational aspects of PPIUC, to have performed at least five 'live' insertions successfully and participated in at least one observed episode of supervision.

Alongside training for in-hospital staff, educational sessions were provided for community healthcare staff, the main providers of antenatal care. All community midwifery 'teams' (10 in total, consisting 10-20 midwives covering designated geographical areas) were visited individually and given information about PPIUC and the study to enable them to counsel women about this option during routine antenatal contraceptive discussion.⁴ Similar sessions were provided for local general practitioners and family nurses. This also included dissemination of patient resources and visual aids to support PPIUC counseling. A full list of the resources developed to support training and implementation are detailed in a previous paper.¹⁵

Women desiring PPIUC received routine antenatal and intrapartum care. After delivery, a trained PPIUC inserter and a supervisor were contacted. A second eligibility assessment was performed by attending staff to identify any intrapartum contraindications to PPIUC insertion. Exclusion criteria included: (a) prolonged rupture of membranes (more than 36 hours); (b) clinical suspicion or treatment for chorioamnionitis; (c) unresolved postpartum hemorrhage (as defined by blood loss >1000 mL). Insertion procedures were performed in the birth unit (or a designated area of the postnatal ward) within the first 48 hours after delivery depending on the availability of trained staff; concomitant clinical workload; and clinical needs and preference of the woman. This was felt to reflect a 'normal' clinical environment for maternity centers offering PPIUC. An ultrasound was not performed routinely after insertion. All insertion procedures were recorded in a designated PPIUC logbook and in the woman's maternity record. Following insertion, women were provided with written and verbal advice about possible signs of expulsion and infection, along with contact information for research staff.

Details of insertion procedures (timing, location, staff member, analgesia), participant demographics and delivery information were obtained from maternity records. All women who received PPIUC were contacted within the first postpartum week and provided with a follow-up appointment at or around 6 weeks postpartum. At the follow-up visit, women underwent pelvic examination to visualize and trim threads (if required) and a transvaginal ultrasound to confirm IUC location. They also completed a structured survey about relevant symptoms (pain, bleeding, thread issues), infant feeding status, resumption of sexual activity and their PPIUC experience (including main source of information, perceived coercion and if they would recommend PPIUC). Clinical outcomes recorded at this visit included complications (infection, uterine perforation), device expulsion and removal.

Complete expulsion was defined as a device that had been fully expelled from the uterine cavity before the initial follow-up (self-reported). Partial expulsion was defined as a device found to be located within the cervical canal (either wholly or in part) on clinical examination or ultrasound at initial follow-up, and these were removed. Where no device was seen on ultrasound, an abdominal/pelvic X-ray was performed to exclude uterine perforation. Infection was recorded if there was a self-reported or documented history of receiving antibiotics (and/or device removal) for suspected intrauterine/pelvic infection at or before the initial follow-up. Women were offered re-insertion of IUC following expulsion or removal. Where immediate re-insertion was not possible, for example because of recent unprotected sex, women were offered a further appointment and an alternative interim method. Further contact was made by research staff 3, 6 and 12 months after the initial PPIUC insertion and a short telephone survey was completed. Data collection included self-reported complications and continued IUC use.

2.1 | Statistical analyses

To determine PPIUC uptake under 'normal conditions', a convenience sample was chosen with no minimum sample size. The characteristics of the women who had IUC inserted and those who experienced an outcome of interest were described using counts and proportions (with 95% confidence intervals). We further reported those experiencing an expulsion by the characteristics of the women and insertion procedure, including the device type. Where the time to expulsion was unknown (in the absence of symptoms), times were treated as interval censored with the expulsion assumed to have occurred sometime between the date of insertion and initial follow-up. We fitted parametric survival models assuming the time to expulsion followed a Gompertz distribution, which allowed for the time to expulsion to be interval censored, right censored or known. The fit of the model was assessed by plotting the Cox-Snell residuals. As an individual clinician may perform multiple insertions, we allowed for this clustering by calculating robust standard errors. We also stratified the survival models by hospital to allow for possible differences in baseline hazards. Calculations were performed using STATA 15.1 (StataCorp).

2.2 | Ethical approval

South-East Scotland Research Ethics Service provided written confirmation (December 2017) that the study met the criteria for 'health services research' and as such full NHS ethical review was not required. NHS Lothian quality improvement team approval was granted.

3 | RESULTS

3.1 | Uptake and insertion procedure

During the recruitment periods (Hospital A: 31 January 2017 to 31 May 2019; Hospital B: 1 October 2017 to 31 May 2019), 465 women requested PPIUC and were eligible at the time of delivery (Figure 1). This represented an uptake of 4.6% of all women who had a vaginal birth (assisted, unassisted or breech) in the region over the study periods (n = 10 119). Of these, 447 insertion procedures were successfully completed (96.1%) (Table 1).

The mean age of participants was 30 years (range 16-44 years) and most (73%) opted for a levonorgestrel intrauterine system insertion. The mean delivery-to-insertion interval was 6.6 hours (range 0-47 hours); 28.2% (n = 126) of insertions were performed within

the first hour, increasing to 77.0% (n = 342) within 6 hours. None were performed within 10 minutes of placental delivery. Sixty-three percent of insertions (n = 240) were by midwives, and all except 13 occurred in the labor ward.

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Eighteen women did not receive PPIUC (4.0%) for the following reasons: insertion abandoned because of technical difficulty (n = 8) or patient discomfort (n = 2), significant bleeding before insertion (n = 6), woman changed her mind at insertion (n = 1) and no staff available (n = 1).

3.2 | Complications, expulsion and satisfaction

Initial follow-up information was available for 379 women (84.8%) (Table 2). Three women (1.1%) were treated with antibiotics for suspected intrauterine infection (all within 10 days of delivery): two had their devices removed and further IUC inserted later. There were no cases of uterine perforation. Before the initial follow-up, 113 women (29.8%) spontaneously expelled their device. Of these expulsions, most were identified by the woman (n = 79), but the remainder (n = 34) were only confirmed following ultrasound and X-ray. At initial follow-up, 118 (31.0%) women were found to have a partial expulsion. Of these, 68 (57.6%) were diagnosed clinically with the device visibly extruding from the cervix. All partially expelled devices were removed. One other removal was performed at patient request. All removal procedures were performed easily within an outpatient clinic setting. Of the 231 women whose device was expelled or removed, 205 (88.7%) chose to have another device inserted at (or shortly after) initial follow-up.

In multivariate survival models, the rate of expulsion was associated with type of staff inserting, analgesia during delivery and previous IUC use (Table 3). Higher rates of expulsion were observed for insertions by midwives (vs doctors) and for non-regional anesthesia (P < .05). Parity did not appear to affect the expulsion rate.

Of the 148 women with a correctly sited device at initial follow-up, threads were visible in 120 (81.1%) and 79 of these were trimmed (53.4%). Table 4 summarizes information regarding satisfaction and PPIUC decision-making. Almost all women (98.3%) said they would recommend PPIUC.

For women who did not attend initial follow-up (n = 68), it was not possible to determine clinical outcomes and they were excluded from this analysis. If contact was made at a later time-point, then method continuation and pregnancy status were recorded (Figure 1).

3.3 | Continuation

Of the 265 potential participants who had reached the 12-month time-point, contact was made with 230 (86.8%) and 183 (79.6%) reported continued use of IUC.



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FIGURE 1 Overall participant flow and device status including uptake and insertion, initial clinical review and continuation rates of intrauterine contraception (3, 6 and 12 months). PPIUC, postpartum intrauterine contraception

TABLE 1 Characteristics of women enrolled who had device successfully inserted and who have initial review data available (n = 379)

Characteristic	Number of insertions (%)
Hospital	
A	171 (45)
В	208 (55)
Staff inserting	
Doctor	139 (37)
Midwife	240 (63)
Supervised	
No	245 (65)
Yes	134 (35)
Number of previous insertions carried out by	clinician
0	78 (21)
1	56 (15)
2	42 (11)
3, 4 or 5	92 (24)
6, 7, 8 or 9	65 (17)
≥10	46 (12)
Age of woman (years)	
16-19	14 (4)
20-24	60 (16)
25-29	89 (23)
30-34	118 (31)
35-39	81 (21)
≥40	17 (4)
Scottish Index of Multiple Deprivation	
1	73 (19)
2	95 (25)
3	79 (21)
4	75 (20)
5	57 (15)
Body mass index (kg/m²) ^a	
<18 (underweight)	5 (1)
18-24 (normal)	172 (46)
25-29 (overweight)	106 (28)
≥30 (obese)	93 (25)
Woman has previously used intrauterine cont	raception
No	295 (78)
Yes	84 (22)
Number of previous births	
0	108 (29)
1	149 (39)
2 or more	122 (32)
Mode of delivery	
Operative vaginal delivery	41 (11)

TABLE 1 (Continued)

Characteristic	Number of insertions (%)	
Spontaneous vaginal delivery	338 (89)	
Analgesia used during delivery		
Non-regional	320 (84)	
Regional	59 (16)	
Type of device inserted		
Copper	101 (27)	
Intrauterine system	278 (73)	
Number of hours after delivery when device was inserted		
1 or less	106 (28)	
>1 and ≤6	179 (47)	
>6 and ≤12	33 (9)	
>12 and ≤24	30 (8)	
>24 and ≤48	31 (8)	
Feeding mode reported at initial review		
Bottle	178 (47)	
Breast	167 (44)	
Mixed	34 (9)	
1 or less >1 and ≤6 >6 and ≤12 >12 and ≤24 >24 and ≤48 Feeding mode reported at initial review Bottle Breast Mixed	106 (28) 179 (47) 33 (9) 30 (8) 31 (8) 178 (47) 167 (44) 34 (9)	

^aThree women with missing data.

TABLE 2 Summary of recorded complications and outcomes ofpostpartum intrauterine contraception insertion in those with initialfollow-up data available (n = 379)

Outcome/complication	Number of cases (%)	95% confidence interval
Uterine perforation	O (O)	0-0.1
Infection (suspected and/or confirmed)	3 (0.8)	0.2-2.3
+ Device retained	0	0-0.1
+ Device removed	2 (0.5)	0.1-1.9
Complete device expulsion	113 (29.8)	25.3-34.7
Identified before initial review (preceding symptoms)	79 (20.8)	16.9-25.3
Identified at initial review (no preceding symptoms)	34 (9.0)	6.3-12.3
Removal of device	121 (31.9)	27.3, 36.9
Partial expulsion and/or placement concern	118 (31.1)	26.5-36.1
Other reason	3 (0.8)	0.2-2.3
Re-insertion following expulsion/removal (n = 234)	205 (87.6)	82.7-91.5

Among those who initially received PPIUC (n = 379), eight pregnancies to date have been recorded within 12 months (2.1%). Six occurred in women who either did not attend initial follow-up (n = 2) or declined re-insertion (or alternative method) following

(Continues)

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TABLE 3 Estimated hazard ratios for expulsion among women enrolled who had device successfully inserted and who have initial review data available (n = 376^a)

	Partial or complete expulsion		Complete expulsions only	
Characteristic	Adjusted hazard ratio	Pavalue	Adjusted hazard ratio	P-value
Staff inserting	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
Doctor	1 (reference)	045	1 (reference)	056
Midwife	1 //6 (1 01_2 12)	.0-13	1 84 (0 99-3 42)	.030
Supervised	1.40 (1.01 2.12)		1.04 (0.77 0.42)	
No	1 (reference)	77	1 (reference)	150
No	1 07 (0 7 1 62)	.//	1 64 (0 92 2 25)	.157
Number of provious insort	ions corried out by clinician		1.04 (0.02-5.25)	
		70	1 10 (0 01 1 57)	20
1 VS 0	1.05 (0.91–1.22)	./0	1.19 (0.91–1.57)	.29
2 VS 1	1.05 (0.91-1.20)		1.18 (0.91-1.52)	
3 vs 2	1.04 (0.93-1.16)		1.15 (0.93-1.42)	
4 vs 3	1.03 (0.95–1.11)		1.11 (0.95–1.30)	
5 vs 4	1.01 (0.96–1/07)		1.08 (0.97–1.19)	
7 vs 6	1.00 (0.97–1.03)		1.03 (0.99–1.07)	
10 vs 9	0.99 (0.94–1.03)		1.00 (0.94–1.05)	
Age of woman (years)				
25 vs 20	0.88 (0.66–1.17)	.093	1.04 (0.67–1.60)	.82
30 vs 20	0.86 (0.53–1.40)		1.09 (0.53–2.24)	
35 vs 20	1.04 (0.60–1.80)		1.19 (0.56–2.55)	
40 vs 20	1.39 (0.73–2.65)		1.33 (0.54-3.31)	
Body mass index (kg/m ²)				
25 vs 20	1.10 (087–1.39)	.50	1.21 (0.86-1.68)	.31
30 vs 25	1.07 (0.95-1.21)		1.15 (0.96-1.38)	
Woman has previously use	d intrauterine contraception			
No	1 (reference)	.28	1 (reference)	.034
Yes	0.82 (0.57-1.18)		0.57 (0.34-0.96)	
Number of previous births				
0	1 (reference)	.18	1 (reference)	.55
1	0.94 (0.65-1.36)		1.18 (0.64-2.16)	
≥2	0.68 (0.42-1.1)		0.91 (0.48-1.76)	
Mode of delivery				
Operative vaginal delivery	1 (reference)	.50	1 (reference)	.62
Spontaneous vaginal delivery	1.21 (0.69–2.12)		1.25 (0.52–2.98)	
Analgesia used during delivery				
Non-regional	1 (reference)	.033	1 (reference)	.034
Regional	0.61 (0.38-0.96)		0.43 (0.2-0.94)	
Type of device inserted				
Copper	1 (reference)	.13	1 (reference)	.99
Intrauterine system	0.83 (0.64-1.06)		1.00 (0.66-1.52)	

(Continues)

TABLE 3 (Continued)

	Partial or complete expulsion		Complete expulsions only	
Characteristic	Adjusted hazard ratio (95% CI)	P-value	Adjusted hazard ratio (95% CI)	P-value
Number of hours after delivery when device was inserted				
6 vs 1	0.93 (0.64–1.34)	.19	1.02 (0.61–1.68)	.30
12 vs 1	0.85 (0.49-1.46)		0.96 (0.45-2.05)	
24 vs 1	0.70 (0.42-1.18)		0.77 (0.38–1.56)	
48 vs 1	0.58 (0.32-1.05)		0.59 (0.28-1.27)	
Feeding mode reported at initial review				
Bottle	1 (reference)	.83	1 (reference)	.73
Breast	0.94 (0.67–1.31)		0.84 (0.5–1.4)	
Mixed	0.87 (0.53-1.42)		1.05 (0.51-2.18)	

^aThree out of 379 women had body mass index missing and were not included in the above analysis.

TABLE 4 Outcomes for satisfaction and decision-making at initial follow-up after postpartum intrauterine contraception (PPIUC) insertion (n = 346^{a})

	Number (%)
Timing of decision for PPIUC	
Several weeks before delivery	303 (87.6)
Within 1 wk before delivery	9 (2.6)
During labor	0 (0)
Postnatal period (up to 48 h)	29 (8.4)
Not recorded	5 (1.4)
Main source of information about PPIUC	
Community midwife	232 (67.0)
Antenatal clinic	28 (8.1)
Labor ward staff	18 (5.2)
Friend/family	12 (3.5)
Poster/leaflet/website	26 (7.5)
Other	3 (0.9)
Not recorded	27 (7.8)
Felt pressure or coercion towards PPIUC	
No	345 (99.7)
Yes	0
Unsure	1 (0.3)
Would recommend PPIUC to friend/family	
No	0
Yes	340
Unsure	6

^a33 women with missing data at initial follow-up.

confirmed expulsion (n = 4). One was a planned pregnancy after device removal at 10 months postpartum. Another pregnancy followed device removal for colposcopy at 8 months postpartum. Pregnancy outcomes included: continuing pregnancy or live birth (n = 5), early miscarriage (n = 2) and surgically managed ectopic pregnancy (n = 1).

4 | DISCUSSION

This study demonstrates that it is feasible to provide routine vaginal PPIUC in a publicly funded maternity setting. Almost 1 in 20 women having a vaginal birth chose PPIUC, comprising women of all ages and socio-economic backgrounds, most of whom had not used IUC before. Most PPIUC insertions were successful despite relatively low rates of regional anesthesia, and women were satisfied with their experience. Our separate qualitative paper reports further on the high acceptability of PPIUC in this cohort. (N. Boydell, M. Cooper, S.T. Cameron, et al, submitted)

This is one of the few studies from a high-income country to train both doctors and midwives in vaginal PPIUC insertion. Unlike previous studies, which have focused predominantly on clinical outcomes of PPIUC within a trial setting using a small number of highly trained 'inserters', this study addresses the translation gap to demonstrate the feasibility and outcomes of providing PPIUC in a 'real-world' context. The study findings are supported by a robust follow-up pathway and a low rate of participant loss.

There was a very low incidence of insertion-related complications in line with existing evidence.^{10,11} Infection/suspected infections were rare, and there were no cases of perforation. The overall expulsion rate observed was higher than generally reported elsewhere, although rates in the literature do vary considerably (0%-50%).^{10,11} Direct comparisons are also difficult because of variability in insertion techniques, follow-up and definitions of expulsion between studies. Recently published findings from a large-scale PPIUC initiative across 6 low- and middle-income countries reported combined expulsion rates of under 4%¹⁶ (similar to standard IUC insertion). This program involved training midwives, doctors and nurses using the same insertion technique as ours, with no apparent difference in expulsion between provider groups.

In contrast, our analysis suggested a possible increase in the risk of partial and complete expulsion following insertion by a midwife compared with that by a doctor. This more likely reflects the relative inexperience with IUC insertion in our midwife population and therefore a steeper learning curve. More generally, inserter experience has previously been linked to a reduction in expulsion rate.¹⁷ We did not observe a reduction in the expulsion rate with an increasing number of insertions, perhaps because of the relatively small number of overall procedures performed by any individual. Our methodology involved a continuous accumulation of newly trained providers throughout the study period (80 in total) to ensure adequate provision. A higher number of providers 'in-training' combined with an overall lower uptake of PPIUC compared with low- and middle-income country settings, meant less frequent insertion opportunities and a longer time-frame to achieve similar competency. In this situation, a higher minimum number of supervised insertions may be needed, particularly as 'on-the-job' mentoring has been noted to be integral to the success of PPIUC services.¹²

The timing of insertion is another important factor in service provision. Immediate post-placental insertion (within 10 minutes of placental delivery) has been associated with a lower risk of expulsion in other studies compared with early postpartum insertion.¹⁰ This could not be evaluated here because none of our insertions were truly 'post-placental' and only a small proportion (28%) were performed within the first hour. Again, this likely reflects some of the early challenges of service introduction, including timely access to a trained inserter and supervisor. Although we did observe a reduction in the delivery-to-insertion interval as the study progressed, further improvement is needed because earlier postpartum insertion has logistical advantages, such as preventing the need to return to the birth unit (from postnatal ward) for insertion and facilitating earlier hospital discharge.

No other patient or insertion-related variables were found to be significant in relation to expulsion risk. Some studies have suggested a higher expulsion rate for the intrauterine system compared with the copper intrauterine device,¹⁸ although the overall evidence is conflicting. Most women in our study received an intrauterine system and we found little evidence of a difference in expulsion rate between the two devices, although further research from larger comparative trials is needed.

As mentioned previously, the major limitation to our approach was that both the introduction and evaluation of vaginal PPIUC provision were conducted concurrently. Hence, the early outcomes observed here may not fully reflect those once the service has become fully 'embedded', particularly in relation to the expulsion rate, which should therefore be interpreted with some caution. Moreover, although these findings reflect the experience from a large UK maternity service, they may not be applicable to all settings. The use of routine ultrasound at follow-up may also have led to higher removal rates due to the detection and removal of devices defined as 'partially expelled'. Routine ultrasound is rarely included in PPIUC studies from low-income settings, and indeed the clinical significance of a non-fundally located IUC is unknown but can lead to removal, which may in some instances be unnecessary.¹⁹ Within routine service provision, access to ultrasound is likely to be more limited unless indicated on clinical grounds, eg non-visible threads.

Some studies have included the use of immediate post-insertion ultrasound, but this has not been shown to reduce subsequent expulsion¹⁹ and could be a barrier to service provision.

Several lessons can be learned from this translational study. It is important that women are fully informed about procedural risks (including expulsion), ideally during the antenatal period, and that providers continue to monitor outcomes to provide accurate estimates of risk. Although an important counseling point, most women in our study chose re-insertion of IUC following expulsion, indicating an ongoing acceptability and motivation towards the method. However, it is acknowledged that IUC insertion is provided at no cost to women in our setting. Where contraception is not provided freeof-charge, the initial costs of PPIUC and possible re-insertion may limit the uptake and acceptability. The importance of a follow-up visit is strengthened given the observed pregnancies in those who did not attend, and the small number of women who did not recognize that their device had expelled and could have been at-risk of pregnancy. We have modified our service in light of the high expulsion risk including individualized feedback for staff, provision of 'refresher' training and a more prolonged period of supervision. A dedicated postpartum IUC inserter has been developed, which more closely resembles the standard non-postpartum IUC inserters that are widely in use. In a recently conducted randomized controlled trial by Blumenthal et al,²⁰ the dedicated postpartum inserter was favored by healthcare professionals over forceps for ease of insertion. It is possible that such a device could overcome some of the challenges linked to training and insertion, and may also lead to fewer expulsions.

In public health terms, the high continuation rate following PPIUC is arguably the most important outcome. IUC use 3 months after PPIUC was 88.3%, which given that only 50% of women are expected to attend for interval insertion^{1,21} suggests that PPIUC addresses a key gap in provision. This high continuation rate was maintained at 12 months after PPIUC, with almost four out of five women still using the method. Provided expulsion can be readily identified and early re-insertion facilitated if desired, PPIUC is a useful intervention to reduce unintended and closely spaced pregnancies. Although there are no current health economics data from the UK, a US study has reported the high cost-effectiveness of PPIUC, even up to expulsion rates exceeding those more widely reported in the literature.²² Therefore, the benefits of PPIUC are likely to persist, particularly in settings with low attendance rates for interval IUC insertion.

5 | CONCLUSION

There is demand for PPIUC among women and despite the complexities associated with introducing this service, it is inherently achievable. To be successful, PPIUC programs require effective antenatal counseling, availability of appropriately trained providers and a robust follow-up pathway that includes access to ultrasound and the option for device re-insertion. New services may observe an initially high expulsion rate, particularly among those less familiar with IUC insertion. Shared learning from early-adopter sites can help to expand access to PPIUC. This may help to prevent unintended and closely spaced pregnancies and reduce the unmet need for effective contraception in the postpartum period.

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CONFLICT OF INTEREST

None.

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