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Increasing Access to Immediate Postpartum Intrauterine Contraception in the UK

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Doctor of Philosophy (PhD)

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2020

Declaration

I declare that the thesis has been composed by myself and that the work has not be submitted for any other degree or professional qualification. I confirm that the work submitted is my own, except where work which has formed part of jointly-authored publications has been included. My contribution and those of the other authors to this work have been explicitly indicated below. I confirm that appropriate credit has been given within this thesis where reference has been made to the work of others.

Chapters 1 and 2

These chapters are comprised entirely of my own work.

Chapter 3

The original idea and study design were conceived by STC and AG. I was directly involved in service implementation and training; follow-up of participants, all data collection and analysis. Additional statistical support and analysis was provided by KM. I prepared the original manuscript. The final version was reviewed by all authors and journal peer reviewers prior to publication.

Chapter 4

I led all aspects of the training programme and conceived the idea for the evaluation approach. RCOG resources included used with permission. I designed local training resources; delivered staff training workshops and clinical supervision; developed the evaluation survey and conducted all of the data collection and analysis contained in this chapter.

Chapter 5

I conceived the idea for the research along with SC. I developed and piloted the survey with RH. I performed data collection and all quantitative analysis. I conducted qualitative response analysis with NB and prepared the original manuscript. The final version was reviewed by all authors and journal peer reviewers prior to publication.

Chapter 6

I conceived the idea for the research, performed the literature review and developed the original framework. I prepared the original manuscript with SC. The final version was peer reviewed prior to publication.

Chapter 7

This chapter is comprised entirely of my own work.

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Publications arising from this work

Cooper M. Expanding access to postpartum long-acting reversible contraception (LARC): how can we deliver? *BMJ Sex Reprod Health*. 2020;46(1):75-7.

Cooper M, McGeechan K, Glasier A, Coutts S, McGuire F, Harden J, Boydell N, Cameron ST. Provision of immediate postpartum intrauterine contraception after vaginal birth within a public maternity setting: health services research evaluation. *Acta Obstetricia et Gynecologica Scandinavica*. 2019; 00:1-10

Cooper M and Cameron S. Successful implementation of immediate postpartum intrauterine contraception services in Edinburgh and framework for wider dissemination. *Int J Gynecol Obstet*. 2018; 143: 56-61.

Cooper M and Cameron S. Postpartum Contraception. *The Obstetrician & Gynaecologist*. 2018; 20:159-166.

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Cooper M, Boydell N, Heller R*,* Cameron S. Community sexual health providers' views on immediate postpartum provision of intrauterine contraception. *BMJ Sex Reprod Health* 2018;44**:**97-102.

Cooper M and Cameron S. Postpartum Contraception. *Obstetrics, Gynaecology and Reproductive Medicine,* 2018; 28(6): 183-5.

Abstract

Background

Early resumption of fertility after childbirth can lead to unintended pregnancy (UIP), with short interpregnancy intervals linked to poorer obstetric and neonatal outcomes. Barriers exist for women accessing contraception during the postpartum period, particularly long-acting reversible methods such as intrauterine contraception which are the most effective at preventing UIP. Immediate postpartum intrauterine contraception (PPIUC) insertion is known to be safe and effective but is not widely available in the UK. In the few maternity centres offering this, it is generally restricted to women having a caesarean birth. Improving access to PPIUC after vaginal birth could reduce UIP in the postpartum period and expand contraceptive choice and convenience for women after childbirth.

Aims and objectives

The aim of this research was to investigate the routine provision of PPIUC after vaginal birth in the UK. Firstly, to determine the feasibility and clinical outcomes of the technique in this setting, and secondly to increase knowledge of service implementation in order to increase access.

Methods

A variety of methods were used to achieve the research objectives. Using a health services research model, vaginal PPIUC was newly introduced and evaluated across Lothian maternity services. This initially involved the design and delivery of a training package for midwives and obstetricians. After service introduction, all pregnant received information about PPIUC during antenatal contraceptive discussion. Eligible women received their choice of PPIUC method (52mg LNG-IUS or CU-IUD) within 48 hours of vaginal birth. After insertion, women were invited to attend a follow-up visit at six weeks (questionnaire, clinical examination and pelvic ultrasound) and further

telephone surveys were conducted at three, six and 12 months. Clinical outcomes of interest included the uptake, complications (infection, perforation), expulsion and patient satisfaction at six weeks' postpartum. Method continuation up to 12 months was also determined. Key aspects of service provision, namely training and aftercare, were further evaluated by means of two structured surveys conducted with multi-professional staff groups. Knowledge gained through local service introduction was consolidated using an implementation science framework to aid wider dissemination.

Results

During the 18-month study period, the overall uptake of vaginal PPIUC was 4.6%. Of the 465 eligible women who requested PPIUC, 447 (96.1%) had a successful insertion. There were no cases of uterine perforation and the overall infection rate was 0.8%. The complete expulsion rate was 29.8% (n=113) and most had symptoms (n=79). Of the additional 121 devices removed, 118 were due to partial expulsion. The reinsertion rate after expulsion or removal was 87.6% and overall method continuation was 79.6% at 12 months. Median satisfaction scores were 10/10 and 98% of women said they would recommend the service. All staff who received training rated the complexity as 'easy' or 'about right.

Conclusions

It was feasible to train midwives and obstetricians to provide PPIUC after vaginal birth and to introduce this service within a UK maternity care model. PPIUC was associated with a good uptake, low risk of complications and high patient satisfaction. Although there was a moderately high expulsion rate, method continuation at 12 months remained high. Access to follow-up and the opportunity for reinsertion after expulsion were important service delivery considerations. Staff were positive about offering vaginal PPIUC, but several challenges were identified in relation to training and service introduction. Structured training and a clear implementation framework may aid the wider availability in UK maternity settings.

Lay Summary

Women can become pregnant again within weeks of having a baby and for many, another pregnancy is not planned or wanted at this time. While there are many contraceptive options available to prevent this, and most are safe to start soon after having a baby, it can be difficult for new mothers to start these after they leave the hospital or birth unit. This is especially true for intrauterine contraception, also known as an “IUD” or “coil”, which needs to be inserted by healthcare staff. At present in the UK, this is often done in a GP surgery or sexual health clinic several weeks after giving birth.

Research from other countries has shown that it is safe to insert an IUD immediately after giving birth. It may also be less painful and more convenient for women to have an IUD inserted at this time. However, this option (also known as postpartum intrauterine contraception or ‘PPIUC) is not available to women in most UK maternity hospitals. This is partly due to a lack of training and experience with the procedure.

The purpose of this research was to make PPIUC available to women after giving birth in a UK maternity service in Lothian. This firstly involved training midwives and doctors to perform the procedure. All pregnant women had the opportunity to discuss their contraceptive wishes and, if desired, could have their choice of IUD (either the hormonal or non-hormonal type) fitted before they left the birth unit. After the IUD was inserted, they were invited to attend a check-up six weeks later and contacted again by telephone at three, six and 12 months.

We found that receiving PPIUC insertion within 48 hours of giving birth vaginally was very safe, and problems such as infection or injury to the womb were extremely uncommon. For around one in three women, the IUD was subsequently expelled from the womb. This was discovered either by the woman herself or at the check-up appointment, and three-quarters of women chose to have another IUD inserted at

that time. Overall women were very happy with the option of PPIUC, and four of out five women were still using the method one year after giving birth.

Other aspects of this research involved conducting surveys with healthcare staff about their views and experiences in relation to providing PPIUC. While staff were generally positive about offering PPIUC, they predicted some challenges in relation to widespread training and service availability in the UK. Through our experience of setting up a new PPIUC service in Lothian during this research, we have been able to develop tools and resources to help other maternity centres who wish to offer the option of PPIUC to women.

Acknowledgements

This research project was made possible through a jointly-funded grant from Wellbeing of Women and the Chief Scientist's Office, who continue to enable remarkable advancements in women's health through their generous support.

I would like to express my deepest gratitude to my supervisors, Professor Sharon Cameron and Professor Anna Glasier, for the opportunity to complete this PhD and for their endless support and guidance throughout. I am incredibly thankful for the many opportunities it has given me, and for their continued mentorship and inspiration.

As part of a small research team, I could not have asked for better colleagues than Anne Johnstone and Karen McCabe. For them, and for the endless supply of baked goods, I am eternally grateful.

This research would not have been possible without the amazing women who took part and so generously shared their time and experiences with us. I also need to thank the wonderful midwives, doctors and support staff across NHS Lothian who embraced this opportunity and worked hard to help make it a reality. You are truly 'champions'.

I am fortunate to have the unending support of an incredible group of friends who have encouraged and sustained me through this journey. My biggest thanks go to my ever-supportive family, both present and passed, who inspire me every day to work hard and pursue my dreams.

Finally, a special mention to my sister who gave birth to my beautiful niece during the course of this PhD, and who continues to reap the benefits of immediate postpartum LARC. In her words: "*I mean it just makes sense, doesn't it?*"

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Abbreviations

CMW	Community midwife
CU-IUD	Copper intrauterine device
FSRH	Faculty of Sexual and Reproductive Healthcare
GP	General practitioner
IUC	Intrauterine contraception
IUD	Intrauterine device
LAM	Lactational Amenorrhoea Method
LARC	Long acting reversible contraception
LMIC	Low-and-middle-income country
LNG-IUS	Levonorgestrel intrauterine system
NHS	National Health Service
NMC	Nursing and Midwifery council
PPC	Postpartum contraception
PPIUC	Postpartum intrauterine contraception
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised controlled trial
UK	United Kingdom
US	United States
WHO	World Health Organization

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Chapter 1 Background and statement of the problem

1.1 Introduction

This chapter details the background and rationale for the research described in this thesis. I will discuss the role of postpartum contraception (PPC) in reducing unintended pregnancies after childbirth and then outline the current provision of PPC in the UK, including barriers to access and the role of maternity providers.

1.2 The effects of unintended pregnancy

Unintended pregnancy remains a significant public health challenge in the 21st century. An unintended pregnancy can be defined as one which is either unwanted and/or mistimed. It is estimated that up to 45% of pregnancies in the UK are unplanned at conception (Wellings *et al.*, 2013). Extrapolated data from Western Europe suggests that around 56% of unintended pregnancies end in abortion (Bearak *et al.*, 2018), which remains one of the most commonly performed gynaecological procedures in the UK. The cost of unintended pregnancy to the UK health service has been estimated at £193 million each year (Montouchet and Trussell, 2013).

There is increasing recognition that the pre-conception period is a key determinant of obstetric performance, neonatal outcomes and childhood development (Poston *et al.*, 2018). The weeks and months prior to a planned conception present an opportunity to minimise modifiable risk factors such as smoking cessation, alcohol reduction and weight optimisation. It also allows women to engage in positive health behaviours such as physical activity and dietary supplementation to optimise

pregnancy outcomes and positively influence the health of future offspring (Colbourn *et al.*, 2018).

When a pregnancy is unplanned, this unique opportunity for intervention is lost. This may be particularly significant for women with concurrent medical conditions, such as diabetes or epilepsy; where the role of pre-pregnancy counselling, disease optimisation and ratification of long-term medications before conception is linked to improved maternal and neonatal outcomes.

Beyond the pre-conception period, unintended pregnancy has additional consequences which may further compound these adverse effects. Women who did not plan to conceive are more likely to initiate antenatal care at a later stage in their pregnancy or to receive no antenatal care at all (Dibaba, Fantahun and Hindin, 2013). Unintentional pregnancy is also independently linked to obstetric complications such as preterm labour, intrauterine growth restriction and stillbirth (Shah *et al.*, 2011; Hall *et al.*, 2017). It can later affect maternal bonding with the neonate; the likelihood of breastfeeding (Cheng *et al.*, 2009); and is associated with a two-fold increase in perinatal depression (Abajobir *et al.*, 2016).

The potential negative effects of unintentional pregnancy on the offspring range from low birthweight and prematurity in the neonate (Shah *et al.*, 2011; Hall *et al.*, 2017) to reduced cognitive development in the infant (Carson *et al.*, 2011). It is also recognised as both a cause and consequence of social deprivation; with associated lower educational attainment, poor diet and suboptimal infant feeding continuing the potential cycle of poor health into future generations (Wellings *et al.*, 2013).

1.3 The role of birth spacing

As well as pregnancy intention, the timing of conception can also play an important role in determining outcomes. When a pregnancy occurs soon after childbirth, the resulting short 'interpregnancy interval' – defined as the time between delivery and subsequent conception – has been linked to a higher rate of complications.

Many early studies in this area failed to account for potential confounding factors such as maternal age and socioeconomic status which in themselves could account for the adverse findings. In 2006, a systematic review sought to address this potential bias by excluding studies which failed to account for such confounding (specifically maternal age and poor socioeconomic status) (Conde-Agudelo, Rosas-Bermúdez and Kafury-Goeta, 2006). For the studies subsequently included, meta-analysis supported an association between preterm birth, small for gestational age infants and low birthweight with interpregnancy intervals of 18 months or less. The highest risk was seen with intervals of less than six months, a finding which has been replicated in other studies (Ahrens *et al.*, 2019). For women intending a vaginal birth after a previous caesarean, the risk of scar rupture is also highest for repeat pregnancies occurring within 6 months (Stamilio *et al.*, 2007).

On account of the evidence for potential maternal and fetal harm resulting from inadequate birth spacing, the World Health Organisation (WHO) recommends a gap of at least 24 months between consecutive pregnancies (World Health Organization, 2005).

Many theories exist to explain the negative consequences of short interpregnancy intervals, including maternal nutritional depletion (King, 2003) and the effects of starting a new pregnancy with unresolved weight gain or impaired glucose tolerance (Hanley *et al.*, 2017). While the interval itself may not be directly causative, it is concluded that encouraging planned and optimally-spaced pregnancies can lead to

improved maternal and neonatal outcomes. But is this at odds with women's desire for rapid repeat pregnancy?

Indeed, the converse seems to be true. Most women do not intend another pregnancy soon after giving birth. Two surveys of postpartum mothers from separate areas of the UK (Scotland and England) found that respectively, 97% and 91% of women were not planning another pregnancy within the next 12 months (Heller *et al.*, 2016; Thwaites, Tran and Mann, 2019). And yet in spite of these findings, and the aforementioned WHO recommendations, short inter-pregnancy intervals are common.

A UK population-based study by Heller et al reported that one in 13 women giving birth had conceived following an inter-pregnancy interval of 12 months or less (Heller *et al.*, 2016). The same study found that one in 13 women attending abortion services in the region did so within the year after giving birth. For parous women, the figure rose to one in eight.

Short interpregnancy intervals are also more likely to occur in younger and more socially deprived women (Smith, Pell and Dobbie, 2003; Yang *et al.*, 2019). These demographics are similar to those most at risk of experiencing an unintended pregnancy. In one US study of 384 women with a short interpregnancy interval, 76% reported that the pregnancy had been unintended (Brunner Huber *et al.*, 2018). It follows that unintended pregnancy and short inter-pregnancy intervals are closely linked. There also appears to be disparity between women's reported fertility intentions after childbirth, and the rates of unintentional and closely spaced pregnancies in the postpartum period.

In the rest of this chapter, I will explore some of the possible explanations for this. Firstly, the under-recognition of fertility potential after childbirth; secondly, the effect of contraceptive method choice on unintended pregnancy risk; and finally, the barriers that may exist in relation to PPC access.

1.4 Fertility and sexual activity after childbirth

There is a rapid return of fertility after childbirth. In non-breastfeeding women, the average reported time for resumption of ovulation is 45 days, although it can occur from as early as three to four weeks (Jackson and Glasier, 2011). In breastfeeding women, the high levels of prolactin required to maintain milk production may be adequate to inhibit ovulation. It is for this reason that many women rely on breastfeeding as a form of contraception, otherwise known as the lactational amenorrhoea method (LAM). However, in order to maintain ovulatory suppression and therefore fertility control, LAM criteria state that the woman should breastfeed 'exclusively'; should have absent menstruation; and that their baby should be less than six months' old. In this situation, LAM is known to be 98% effective (Faculty of Sexual & Reproductive Healthcare, 2017). However, fertility can resume quickly if bleeding returns or breastfeeding frequency declines. In one of the earliest studies of ovulation in breastfeeding mothers, all of the 48% who were found to have ovulated reported a reduction in either the frequency or duration of breastfeeding (Howie *et al.*, 1982).

The number of women intending to breastfeed their baby has increased in UK in the last decade, with between 50-60% babies born in England receiving breastmilk for their first feed (NHS Digital, 2020). This is largely in response to public health messages promoting the known benefits of breastfeeding for maternal and neonatal health. However, breastfeeding rates tend to decline in the early weeks after giving birth. In both Scotland and England, less than a third of women are still exclusively breastfeeding at six to eight weeks postpartum (Public Health England, 2017; NHS Scotland Information Services Division, 2019). For women under the age of 20 in Scotland, this figure falls to 13%. Therefore, while there are many benefits of breastfeeding for improving maternal and neonatal health, it may not provide reliable contraception, particularly for those women at highest risk of an unintended pregnancy such as the young and more socially deprived.

The risk of unintended pregnancy in the postpartum period depends not only on the return of ovulation and fertility, but also on the resumption of sexual activity. One Australian prospective cohort study of over 1500 nulliparous women recruited antenatally found that 41% reported resumption of vaginal intercourse by six weeks' postpartum, increasing to 65% by eight weeks (McDonald and Brown, 2013). Younger women in this study (under 25 years) were more likely to have resumed sexual activity earlier compared to older women. In another prospective study of 370 postpartum women in the US, four out of 10 women had resumed sexual activity by six weeks (Sok *et al.*, 2016).

Given the large number of women not intending to conceive soon after childbirth, it appears as though sexual activity at this time is not linked to a desire for pregnancy. In light of the rapid resumption of both fertility and sexual activity for many women, there is a need for early contraception use in the postpartum period if an unintended pregnancy is to be avoided. However, women may not be aware of this, or indeed perceive there to be a significant risk pregnancy at this time.

In a UK survey of 272 postnatal women, only 31% were able to correctly identify the earliest possible time to become pregnant after childbirth, and 43% were unaware of the recommended interpregnancy interval (Thwaites *et al.*, 2018). This study also found that many women believed hormone-containing contraceptives were unsafe for use during the postpartum period and while breastfeeding. This indicates that as well as a lack of awareness of fertility potential, misconceptions also exist about the safety of certain contraceptive methods at this time.

1.5 Efficacy and choice of contraceptive methods

In the UK, the Faculty of Sexual and Reproductive Healthcare (FSRH) produce much of the evidence-based contraception guidance for clinicians. This includes the UK

Medical Eligibility Criteria for contraceptive use (UKMEC) - an adapted version of the WHO MEC – which summarises eligibility for the use of each contraceptive method based on a woman's personal and health characteristics (Faculty of Sexual & Reproductive Healthcare, 2016). Recognising the need to provide additional guidance specifically for postpartum women, the FSRH also released a dedicated 'Contraception After Pregnancy' guideline in 2017 (Faculty of Sexual & Reproductive Healthcare, 2017).

This includes the recommendation that women who do not intend to conceive soon after giving birth should initiate contraception by day 21 postpartum (before ovulation is likely to occur)(Faculty of Sexual & Reproductive Healthcare, 2017). The guideline also states that it may be practically more convenient for women to start their chosen contraceptive method earlier than this and indeed supports this option.

With the exception of combined hormonal contraception (containing both oestrogen and progestogen), most methods of contraception are safe for use during the postpartum period (Faculty of Sexual & Reproductive Healthcare, 2016). This includes all of the progestogen-based hormonal contraceptives. But while most methods are safe to use at this time, not all are equal in terms of efficacy. The comparative failure rates for the most commonly used contraceptive methods are shown in Table 1.

The failure rate of any method is determined by the mode of action and inherent efficacy, as well its duration of action and user-dependency. Efficacy is often represented by the Pearl Index – the number of women experiencing a pregnancy within 12 months of use (Trussell, 2011). However, the measured efficacy of a method in the artificial setting of clinical trials (known as 'perfect' use) can differ from the 'typical' failure rate observed under normal conditions.

Table 1-1: Comparative efficacy of contraceptive methods: percentage of women experiencing an unintended pregnancy within the first year of use (adapted from (Trussell, 2011))

Method	Typical use (%)	Perfect use (%)
LARC methods		
Progestogen-only implant	0.05	0.05
Levonorgestrel intrauterine system	0.2	0.2
Copper intrauterine device	0.8	0.6
Progestogen-only injectables	6	0.2
Other methods		
Vasectomy	0.15	0.1
Female sterilisation	0.5	0.5
Progestogen-only pills	9	0.3
Combined hormonal contraception[1]	9	0.3
Female diaphragm	12	6
Male condom	18	2
Fertility awareness methods	24	0.4-5[2]
No method	85	85

LARC = long-acting reversible contraception

[1] Includes combined pill, transdermal patch and vaginal ring
[2] Lower range refers specifically to sympto-thermal method

In general, methods which require less action of the part of the user often have little difference between their 'typical' and 'perfect' use efficacy. The non-permanent or reversible methods which fall into this category are collectively known as the 'long acting reversible contraceptives' or 'LARC'. These are methods which require administration less than once per menstrual cycle. They include progestogen-based injectables and implants, and intrauterine devices (both hormonal and copper-based forms). As well as offering the convenience of a longer duration of action and therefore less frequent administration, LARC methods have also been shown to be the most effective at preventing unintended pregnancy (Trussell, 2011).

In the postpartum setting, LARC use is also associated with a lower incidence of short inter-pregnancy intervals (Yang *et al.*, 2019). In one prospective study of women receiving immediate postpartum implant insertion, the pregnancy rate at 12 months was 2.6% compared to 18.6% in the control group who used either no method or a less effective method (Tocce, Sheeder and Teal, 2012). In another study, a retrospective cohort of 340 adolescent mothers followed up for two years, repeat pregnancy was significantly less likely in those who had received a LARC method by eight weeks' postpartum (OR 0.118, CI 0.035-0.397) (Damle *et al.*, 2015). This was not the case for those who only indicated an intention to receive LARC, as the highest risk of rapid repeat pregnancy was seen in those where the method was not initiated prior to discharge from the birth unit (OR 2.447, CI 1.326-4.515). This suggests that as well as the choice of contraceptive method, the timing of initiation is also crucial, and for many methods is not entirely within a woman's control.

1.6 Access to postpartum contraception services

Starting a method of contraception after childbirth is not always straightforward. Beyond some of the least effective methods such as condoms which are easily accessible, the more effective methods generally require discussion and prescription or insertion by a healthcare professional. In the previously mentioned survey of postnatal women in the UK, almost two thirds reported an intention to acquire contraception from their GP (Thwaites *et al.*, 2018).

GPs have long been the 'traditional' source of postpartum contraception advice and provision in the UK. This frequently takes place during a postnatal 'check-up' six weeks after giving birth, when other matters such as maternal wellbeing and newborn health are often also addressed. The views of GPs about their role in the provision of postpartum contraception, and in particular LARC, was the focus of a qualitative study published in 2016 (Lunniss, Cameron and Chen, 2016). Interviews with GPs revealed that contraception was frequently viewed as a lesser priority in the context of other aspects of postnatal and neonatal care. As such, they reported that it was often discussed last during the consultation and in some cases, not at all. They also commented on the high non-attendance rates by women at these visits. These observations are further compounded by the fact that in many parts of the UK, GPs are no longer able to offer routine postnatal consultations due to funding and service constraints.

Women's experience of the GP postpartum discussion is also variable, as reported by Glasier et al who conducted semi-structured interviews with 174 women following childbirth (Glasier, Logan and McGlew, 1996). While most women indicated that their GP was their main source of information about contraception, almost 50% indicated dissatisfaction with this discussion. The most commonly cited reason for this was a lack of information about methods other than oral contraception and condoms. In

effect, this indicates an under-discussion of LARC methods; which as highlighted earlier are significantly more effective at preventing unintended pregnancy.

There is a growing sense that a short and often customary discussion during a six-week postnatal GP check-up is inadequate to fully address women's contraceptive needs after childbirth. Indeed, when considered alongside the early resumption of sexual activity and fertility, a six-week visit may also be too late for many.

One solution may be to include an earlier or additional postpartum visit to allow for a more thorough discussion. Attendance and contraceptive initiation were compared in a study of 512 new mothers allocated to attend either a six-week or three-week postpartum visit (Chen *et al.*, 2017). Although more women assigned to the earlier visit attended (90.2% vs 81.6%; $p<0.01$), there were no difference in contraceptive use or LARC initiation six months later. In a similar study, 200 women were randomly assigned to receive either an additional three-week postpartum visit or standard care of a single visit at six weeks (Bernard *et al.*, 2018). Again, no difference in LARC initiation was observed between the two groups (34% vs 41%; P0.56). Furthermore, only 43% attended the earlier visit in this study.

Therefore, even for women who have decided on their chosen method and are motivated to obtain it, the need to make and attend additional appointments in the weeks after childbirth can be a barrier. This is a particular challenge for LARC methods which may require more than one additional visit, further delaying initiation of effective contraception at a time when women can be at risk of unintended pregnancy. In a survey of 403 women in Texas, a higher rate of unintended pregnancy in the two years after childbirth was observed amongst those who reported experiencing barriers in accessing their preferred method (Potter *et al.*, 2016). Notably, in the study by Chen et al which evaluated the outcomes of an earlier postpartum visit, the highest rates of LARC use were seen in those who received this immediately postpartum (Chen *et al.*, 2017) i.e. before leaving the birth unit.

Immediate postpartum provision may be a more effective way of meeting women's contraceptive needs. Whilst contraception is not strictly required before three weeks' postpartum, there may be practical advantages to providing it at this time. As mentioned previously, current clinical guidance in the UK supports this practice (Faculty of Sexual & Reproductive Healthcare, 2017). As well as being a convenient option for women, this would also overcome the aforementioned challenges of attending later postpartum visits and provide contraceptive cover prior to resuming sexual activity.

Although in the study by Thwaites et al 61% of the women surveyed were intending to see their GP for postpartum contraception, almost half said they would have preferred to receive this from the postnatal ward before they left hospital (Thwaites *et al.*, 2018). Interestingly, women with children were significantly more likely to demonstrate this preference, perhaps indicating past personal experience of some of the challenges encountered after leaving hospital. Another survey of 250 postnatal women in Edinburgh found that 43% of women would hypothetically choose to receive a LARC method before their discharge from hospital if available (Heller *et al.*, 2016).

Expanding access to LARC in this way could remove barriers for women and reduce the rates of unintended pregnancy after childbirth. Offering immediate postpartum contraception in the UK would require changes to current pregnancy care models and an expansion of the role of maternity providers.

1.7 The role of maternity providers

In this UK, most of the direct care of women before, during and immediately after childbirth is provided by midwives; with additional support from obstetricians for more complex pregnancy and delivery. It is an expectation of the Nursing and

Midwifery Council (NMC) in the UK that all pre-registration midwives should be able to 'provide advice about contraception'. The earlier study by Glasier et al found that, in addition to GPs, midwives working on the postnatal ward were also a frequently reported source of information about contraception (Glasier, Logan and McGlew, 1996). However, many women said they found the information provided in this setting to be brief and 'perfunctory' in nature. This indicates that there are several challenges to delivering contraceptive advice effectively in this clinical environment.

In 2014, McCance et al conducted qualitative interviews with 12 postnatal midwives in Scotland to determine their views about providing contraceptive advice (McCance and Cameron, 2014). Most agreed that it was important for women to receive this information but felt that as midwives they were not adequately trained to provide it, suggesting obstetricians and GPs as more suitably qualified. Furthermore, they felt that the lack of time and privacy of a hospital ward setting were additional barriers to postpartum discussion. The issue of inadequate training is one that appears elsewhere in the literature. In a mixed methods study of final-year UK midwifery students, knowledge about contraception was found to be highly variable and often poorly applied in practical contexts. Furthermore, it tended to be limited to the least effective methods (Walker and Davis, 2014).

As well as a lack of clarification over *who* should provide postpartum contraceptive advice, there is also an issue around *when* this should be offered. In conjunction with the data presented earlier in relation to GPs, there is already a sense that the postpartum period – either immediately on the postnatal ward, or several weeks' later in the community – may not be the optimal time to introduce a lengthy discussion about contraception. One of the conclusions of the McCance study was that the antenatal period may be more suitable; although some of the midwives interviewed raised concerns about how acceptable this would be to women (McCance and Cameron, 2014).

The antenatal period presents a unique time when women are in contact with a variety of different healthcare providers for a protracted course. Unlike the

postpartum period, when much of the focus is on the newborn and recovering from childbirth, the antenatal period may offer a better opportunity to discuss and consider future fertility intentions and contraception. However, it is also a time when women already receive a large amount of health-related information, and there may be apprehension among maternity providers around introducing discussion about contraception with women while they are still pregnant.

In 2015, Cameron et al conducted the first feasibility pilot investigation of routine antenatal contraceptive counselling in the UK, known as the 'APPLES" study (Cameron *et al.*, 2017). Community midwives received additional training in contraception and a formal discussion was introduced with women during their routine 20-week antenatal visit. This discussion was supplemented with specially designed patient information sheets detailing all of the available methods and how these could be accessed. The women surveyed found the antenatal contraceptive discussion highly acceptable and 44% expressed an intention to use a LARC methods after childbirth. Focus group discussions found that maternity staff were also supportive of the intervention. Obstetricians noted that women seemed more certain about their method choice and midwives were generally positive about introducing this discussion, with many commenting that following the pilot study they considered contraception to be a 'routine' part of their role.

Following the success of the APPLES pilot, routine antenatal contraceptive counselling was rolled-out across the region and is now a standard part of maternity care in Lothian (Edinburgh and surrounding areas). But this is not commonplace in the UK, and studies continue to demonstrate an unmet need for postpartum contraception within maternity services (Thwaites *et al.*, 2018). In some areas, provision is 'targeted' at those women whom healthcare providers deem at greater risk of experiencing an unintended pregnancy or its consequences, such as adolescents or those with complex medical or social problems (Smith, Pell and Dobbie, 2003; Yang *et al.*, 2019). While this approach may reduce unintended pregnancy in those most at risk, it does raise concerns about LARC coercion in more

vulnerable groups of women. As noted earlier, women of all ages and social backgrounds can experience unintended pregnancy in the months after childbirth and as such, there is a need to support improved contraceptive access for all.

While antenatal contraceptive counselling may have a role in dispelling myths and facilitating informed discussion and choice, it does not necessarily translate into increased uptake of methods. In the aforementioned APPLES study, despite 44% of women indicating a preference for a LARC method during pregnancy, only 14% of those in the study actually left hospital with a method (Cameron *et al.*, 2017). Even amongst adolescent women in this cohort (a group identified as at increased risk of unintended pregnancy) only 32% initiated a method of contraception before leaving the maternity unit despite 80% indicating a desire for this when surveyed antenatally (Gallagher *et al.*, 2019). Similarly, in a US study of postpartum women keen to avoid another pregnancy for two years, only 13% were using LARC at 6 months despite 78% expressing the desire for a more long-term or permanent method immediately after birth (Potter *et al.*, 2014). These findings suggest a disparity between women contraceptive desire for immediate postpartum contraception, and what is currently available to them within maternity settings.

While information provision, either during or immediately after pregnancy, is an important and valued component of contraceptive care within maternity services, alone it is not enough. Unless this is delivered alongside simplified access to methods, the benefits for both individual women and wider public health is limited. In order for any discussion around the time of pregnancy to be fully effective, it needs to be coupled with increased access to the full range of contraceptive options, and available to women before they are discharged home. In further support of this holistic approach, higher rates of method initiation immediately postpartum have been observed when contraception advice is provided both before and after delivery (Zapata *et al.*, 2015). However, as many of the earlier studies indicate, there are challenges in providing contraception at the time of childbirth, particularly for LARC.

1.8 Provision of LARC in the postpartum period

While short-acting methods (condoms, pills, injectables) can be relatively easy to stock and dispense from a postnatal ward, LARC initiation requires access to specially trained healthcare providers. A survey of over 1200 obstetricians in the US found that only 1 in 5 offered same-day implant or IUC insertion in the postpartum period, despite this being a recommendation from the American College of Obstetricians and Gynaecologists (ACOG) at the time (Castleberry *et al.*, 2019). Other studies have identified factors such as funding and staff education as key barriers in the provision of immediate postpartum LARC (Holden *et al.*, 2018).

For midwives and obstetricians in the UK, the ability to provide LARC is not currently a mandatory training requirement. Even if trained individuals are available in maternity centres, they need to be present in sufficient number to meet the unique 24/7 demands of providing this in a labour and delivery setting. This is a considerable challenge for maternity services aiming to provide universal access to LARC and explains why many women currently leave hospital without it despite requesting it. However, the benefits of striving for immediate postpartum LARC provision are clear and its availability should be prioritised in the maternity setting as a means to reduce both short interpregnancy intervals and unintended pregnancy (Yang *et al.*, 2019).

In addition, it presents the most convenient option for women. Unlike other methods, postpartum LARC initiation is more likely to require attendance at additional appointments which as previously noted, can be a barrier for women (Potter *et al.*, 2016). This may deter them from accessing contraception altogether or encourage them to opt for a 'simpler' but less effective method (Zerden *et al.*, 2015). Two separate studies from different parts of the UK have found that almost 50% of the postnatal mothers surveyed indicated a preference for LARC provision before discharge from hospital after childbirth (Heller *et al.*, 2016; Thwaites *et al.*, 2018). At the time these studies were conducted, immediate postpartum LARC was not

routinely available in either region and therefore the question was largely hypothetical. But the findings indicate a desire amongst women for these services to become available.

In order to offer immediate postpartum LARC provision within maternity services, healthcare professionals will require additional training in order to provide it. One of the concerns raised about this by midwives in the McCance study was a lack of time in their already busy roles, along with the time commitment and complexity of training (McCance and Cameron, 2014). The traditional training pathway for clinicians to be accredited to provide subdermal contraceptive implant and IUC insertion in the UK is to undertake a formal and somewhat lengthy qualification with the FSRH. This may be a barrier in itself to those working in more unique settings such as maternity to undertake the training.

To meet the specific training needs of maternity providers in LARC provision, in recent years some maternity centres in the UK have developed locally approved pathways to simplify and expedite the number of trained implant inserters. Subsequently in 2018, the FSRH introduced a new 'insertion-only' certificate in implant insertion, recognising the unique training needs of maternity providers and removing the aspects of training unnecessary for their clinical roles. There are now several examples in the literature of successful implant insertion programmes across a range of maternity settings, including at-home provision by community midwives in the UK (Croan *et al.*, 2018).

While these services are still not widespread across all parts of the UK, their development signals positive steps towards immediate postpartum LARC provision; at least for women desiring implant insertion. However, what remains a significant challenge is increasing access to other LARC methods, namely immediate postpartum intrauterine contraception or 'PPIUC", which is still a relatively under-utilised option in the UK.

1.9 Immediate postpartum intrauterine contraception (PPIUC)

The UKMEC supports immediate insertion of IUC within the first 48 hours after childbirth (Faculty of Sexual & Reproductive Healthcare, 2016). If insertion is not performed in this time frame, current guidance suggests that this should be delayed until at least four weeks' postpartum. Therefore, compared to most other contraceptive methods, there is an even narrower window of opportunity to provide it within the immediate postpartum setting. At the time of commencing this research in 2016, to our knowledge immediate PPIUC insertion was not routinely available to women (regardless of mode of delivery) in any UK maternity service.

In 2017, following the success of the APPLES project (Cameron *et al.*, 2017), the Lothian research group published the first observational study of routinely available PPIUC insertion at elective caesarean section the UK (Heller, Johnstone and Cameron, 2017). In this study, women could choose to receive insertion of either a 52mg LNG-IUS or CU-IUD during their planned caesarean section. In keeping with pre-existing evidence (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015), provision of PPIUC at this time was shown to be safe and effective. Furthermore, 84.8% of women were still using the method at 12 months indicating its potential to reduce rapid repeat pregnancy. The researchers concluded that it was feasible to train maternity providers in the previously unfamiliar insertion technique, and to introduce this service successfully within an NHS setting. As such, it has now become routine practice in the area to offer PPIUC insertion to all women having a planned caesarean birth. However, similar to other parts of the UK, only around a third of women in the region currently deliver by caesarean section (NHS Digital, 2017; NHS Scotland Information Services Division, 2017). This still means that the majority of women remain unable to benefit from access to immediate PPIUC.

1.10 Conclusions

Fertility and sexual activity can resume early after childbirth and for many women, the postpartum period presents additional barriers to accessing effective contraception. There is an increasing focus on maternity services to streamline this process and provide contraception to women in the immediate postpartum setting, ideally following discussion during the antenatal period. However, this is not without its challenges, particularly in relation to LARC methods. For PPIUC in particular, there is a lack of familiarity with the technique in the UK. As such there is a need for increased education and awareness about PPIUC, supported by currently available evidence.

In the next chapter I will review and summarise the literature on immediate postpartum intrauterine device insertion, with a particular focus on PPIUC provision after vaginal birth as a basis for the subsequent research contained within this thesis.

Chapter 2 Immediate postpartum vaginal insertion of intrauterine contraception: a review of the literature

2.1 Introduction

In Chapter 1, I outlined the scale of unintended pregnancy and its potential consequences for women and their offspring, along with the rationale for expanding current provision of postpartum contraception in the UK to include access to immediate PPIUC.

In this chapter I will review the available literature around PPIUC provision at the time of vaginal birth. This will include a summary of the historical aspects of PPIUC provision followed by an appraisal of the current evidence relating to the clinically important outcomes of safety, efficacy and patient experience.

2.2 Justification for methods

As my research aim was to conduct one of the first clinical studies of vaginal PPIUC insertion in the UK, it was essential to explore the existing literature on this topic. This is not a formal systematic review designed to answer a specific research question. It was my intention to read as widely as possible around the topic to inform the evidence base for my practical research, as detailed in the chapters that follow. This literature review will therefore summarise the scope of clinical research in PPIUC to date, identifying key areas for further investigation and outlining lessons learned from previous work in the field.

The review strategy is described in detail followed by an overview of the evidence. The available literature on PPIUC dates back to the 1960s but there has been a significant increase in the number of relevant publications in the last two decades. The first systematic review of PPIUC, published by Cochrane in 2001 (Grimes *et al.*, 2001), included only eight studies and commented on the lack of available RCTs on this topic. Furthermore, seven of these eight studies investigated intrauterine devices which are no longer in clinical use in the UK. Therefore, while a short summary of the historical evidence will be included at the start of this review, the main body will focus predominantly on studies published in the last 20 years, as these were felt to be most relevant to current practice.

The population of interest is women who received insertion of an intrauterine device after vaginal birth. Unless otherwise indicated, the term 'PPIUC' refers to both hormone (levonorgestrel-containing) and non-hormone (copper-containing) IUDs, however any key differences in outcomes between the two types of device are explored. It was noted that several studies reported the outcomes of vaginal and caesarean PPIUC insertion together. Due to the emergent differences in outcomes of these two techniques, they are delineated where possible in this review, with a focus on vaginal PPIUC provision as the primary topic of this thesis.

The findings are presented under the following key themes: safety, efficacy and patient experience. These themes have been selected as they are the most frequently reported outcomes in PPIUC studies and are the most clinically relevant. Non-clinical literature relating to wider aspects of service development such as provider experience and training did not form part of this review and will be discussed in the relevant later chapters to avoid repetition. At the end of this chapter I will identify current gaps in literature and explain the justification for my own research as contained within the subsequent chapters of this thesis.

2.3 Review strategy

The PubMed, Cochrane library, EMBASE and Medline databases were searched for articles examining immediate PPIUC insertion. Search terms were initially formulated using published search strategies from previous systematic reviews (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). The following terms were included and modified according to the specific database: (((((postpartum OR postnatal OR postplacental OR puerperium OR caesarean OR cesarean OR delivery OR childbirth))) AND ((((intrauterine) AND ((device OR system OR contracept*)))) OR ((IUCD OR IUD OR IUS))))) NOT ((animals NOT humans)). The search was limited to human studies published in English.

The search was initially conducted in January 2017, and due to the submission timeline for this thesis, an updated search was performed in June 2020 to identify any recently published works. For the purpose of this review, studies which reported solely on outcomes of intra-caesarean PPIUC were excluded, as were those evaluating early outpatient postpartum insertion i.e. insertion beyond the first 72 hours postpartum.

The initial search yielded 4023 papers. Following abstract and title review of titles, 3586 studies were excluded as they did not meet the inclusion criteria. The full texts of the remaining 437 papers were appraised. This was not a formal systematic review as the aim was to encompass the breadth of research in this area, rather than answer a specific research question. Both qualitative and quantitative studies were included and therefore data pooling and meta-analysis was not feasible. Thematic analysis was used to describe and evaluate the included studies.

2.4 Overview of the literature

Most of the early available literature originates from low-and-middle-income countries in South-East Asia and Africa and relates to the CU-IUD. There has been a significant increase in research output from the United States in the past 20 years and this includes data on the 52mg LNG-IUS. No previously published clinical trials investigating modern vaginal PPIUC techniques were identified from the UK.

Seven systematic review and meta-analyses have been published, dating from 2001 to 2020 (Grimes *et al.*, 2001; Kapp and Curtis, 2009; Grimes, Lopez, Schulz, Van Vliet, *et al.*, 2010; Lopez *et al.*, 2015; Sonalkar and Kapp, 2015; Jatlaoui *et al.*, 2018; Averbach *et al.*, 2020). Two of these were updated versions of a previously conducted Cochrane review and focused primarily on RCTs. The remaining studies included largely observational studies and some but not all included comparator groups. Available qualitative research specific to this topic was found to be limited.

Although there are considerable variations in the methodological approach in these studies, the primary research question in quantitative trials of PPIUC generally relate to the timing of insertion, mode of delivery (vaginal or caesarean) or type of device (LNG-IUS or CU-IUD); with the outcomes of interest involving an assessment of safety and/or efficacy. As mentioned earlier, many studies do not disaggregate vaginal and caesarean PPIUC insertion in results reporting. There were also variations noted in insertion techniques, experience of providers and the use of ultrasound in study protocols.

To reduce some of the variability in outcome reporting noted in earlier PPIUC studies, in 1983 the WHO suggested definitions in relation to postpartum IUC insertion (World Health Organization, 1983). These have evolved over subsequent decades to provide more accuracy and clinical relevance. Unless otherwise stated, the following definitions will be used throughout this chapter and in the remainder of this thesis (Table 2-1).

Table 2-1: Definitions of intrauterine device insertion in the postpartum period - adapted from (World Health Organization, 1983)

Timing of insertion	Definition
Post-placental	Within 10 minutes of placental delivery
Early postpartum	Within the first week after delivery (often referred to as 'immediate postpartum' between 10 minutes and 72 hours)
Interval postpartum	Several weeks after delivery (usually between 4 and 8)
Non-postpartum	Insertion not related to the postpartum period

2.5 Historical aspects of PPIUC insertion

Soon after the widespread availability of intrauterine devices for contraception in the 1960's, the possibility of immediate postpartum insertion was explored. Early studies reported on the feasibility of the technique and favourable complication rates in terms of infection, uterine perforation and postpartum bleeding problems (Rosenfield and Castadot, 1974; Chi and Farr, 1989). Insertion was reported as easy (due to the dilated cervix after vaginal birth) and well-tolerated by women. However, the problem of expulsion after insertion was quickly observed. There was ongoing recognition of the potential value of PPIUC as an intervention and over subsequent decades investigators sought to find ways of reducing the risk of expulsion. This included modifying either the device itself or the insertion technique. However, none of these proved particularly beneficial (Grimes *et al.*, 2001).

In the 1980 the WHO published the results of a multi-centre international trial of immediate PPIUC insertion (Annus *et al.*, 1980), the largest of its kind to date at that time. The study was terminated early because of the high expulsion rate and PPIUC consequently fell out of favour. However, there were a number of issues with this study. Three different intrauterine devices were compared and one of which, the

Lippes loop (an inert device), was already known to have a higher expulsion rate even in non-postpartum settings. Furthermore, the findings included results from six different countries, using a number of different insertion techniques (manual, forceps, inserter) and varying levels of provider experience.

With the arrival of newer intrauterine devices and modified insertion techniques in the 1990s, interest in intrauterine methods and PPIUC provision was renewed. Summarising the evidence accumulated to date, the first Cochrane systematic review of immediate PPIUC insertion was published in 2001 (Grimes *et al.*, 2001). The review included results from only eight comparative clinical trials and noted the absence of RCTs comparing immediate insertion with the then accepted practice of interval postpartum insertion.

As evidence continued to emerge around global unintended pregnancy rates and the risks of short inter-pregnancy intervals, the postpartum period was increasingly recognised as an opportune time for intervention, particularly in relation to LARC provision. As such, the number of studies reporting on PPIUC outcomes since 2000 has increased considerably and will form the main focus of the rest of this literature review.

2.6 Safety of PPIUC

The 'safety' of PPIUC, and indeed intrauterine contraception in general, is frequently described in terms of the rate of the most commonly occurring or serious complications; namely uterine perforation, infection and bleeding problems which will each be discussed in turn. In the postpartum setting, the 'safety' of PPIUC in women who are breastfeeding is also of particular interest.

Some of the earliest studies in relation to immediate or early postpartum IUC insertion reported very favourable safety outcomes (Rosenfield and Castadot, 1974; Chi and Farr, 1989). These findings were confirmed in clinical trials over subsequent decades and are supported by meta-analysis in more recent systematic reviews (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). While these focused primarily on copper and non-hormonal IUDs, more recent trials included levonorgestrel-containing devices, and showed similar findings for both intra-caesarean and vaginal insertion. Key safety outcome (infection, uterine perforation, bleeding problems, breastfeeding) will be considered in turn with the accompanying evidence.

2.6.1 Infection

Infection is an infrequent complication of IUC insertion in the non-postpartum setting, with accepted rates of less than 1% (Faculty of Sexual & Reproductive Healthcare, 2015). There may be concern that the intrapartum environment presents many risk factors for intrauterine infection, and the insertion of a foreign body at this time may introduce or exacerbate this. However, even some of the earliest clinical trials of IUC insertion immediate after delivery reported rates of this complication comparable to standard use (Rosenfield and Castadot, 1974; Chi and Farr, 1989).

That being said, most clinical trials include strict exclusion criteria for those receiving PPIUC. Insertion is generally avoided in those with clinical evidence or suspicion of intrauterine infection, or those at particularly increased risk such as following prolonged rupture of membranes. Based on these criteria, infection rates following immediate PPIUC insertion compare well to standard interval insertion on meta-analysis for both vaginal and caesarean insertion (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015).

Randomised trials have not demonstrated a significant difference based on the timing of insertion in the postpartum period. In the 2010 RCT by Chen et al, of the 202 women randomised in equal number to immediate versus delayed vaginal insertion, there was only reported case of infection in each group (Chen *et al.*, 2010). Both cases were diagnosed with pelvic inflammatory disease secondary to a confirmed sexually transmitted infection. However, around 20% of women in the immediate group did receive broad—spectrum antibiotic prophylaxis during delivery (Chen *et al.*, 2010). This is routine practice in some countries (including the UK) for women at increased risk of Group B Streptococcal infection (Royal College of Obstetricians & Gynaecologists, 2017), or those having a planned caesarean delivery (National Institute for Health & Care Excellence (NICE), 2011).

Equally low rates have been reported in other RCTs. In another US study, 259 women were randomised to receive either immediate or delayed insertion of the 52mg LNG-IUS at vaginal birth, and there were no reported cases of infection in either group by six months (Turok *et al.*, 2017). In an earlier study, Dahlke and colleagues randomised 46 women to one of three groups – immediate (within 10 mins delivery), early (within 72 hours) or interval postpartum insertion – and again no cases of infection were recorded throughout the six-month follow-up period (Dahlke *et al.*, 2011). These studies generally involved clinical criteria for diagnosing infection based on patient-reported symptoms and/or examination findings.

Other studies have utilised more objective tools in an attempt to diagnose true infective cases with greater accuracy. For example, Welkovic et al evaluated infection using both clinical and biochemical markers in two non-randomised groups of women following a vaginal birth; one group (n=145) who received a post-placental CuT380A and the other (n=157) who did not (Welkovic *et al.*, 2001). At 10 days' postpartum, there was no significant difference between IUC acceptors and non-acceptors in either clinical signs of infection (3.4 vs 4.5%; p=0.65) or in left shift of the leukocyte ratio (15.4 vs 16.1%; p=0.99), a biochemical marker suggestive of infection.

In a Turkish prospective cohort study comparing immediate versus interval postpartum insertion of the CuT380A, routine vaginal swabs were performed at the one-month and 12-month follow-up visits along with a symptom assessment (Eroğlu *et al.*, 2006). Of the 257 women followed up to one year, there were six cases of microbiologically confirmed infection recorded (2.3%), five of which occurred in the interval insertion group. While this suggests that immediate post-placental insertion compares favourably in terms of infection, this study also included post-placental caesarean insertion and it was unclear if routine antibiotic prophylaxis was used in these cases. However, a later prospective cohort study also from Turkey compared complications of PPIUC insertion across three mode of delivery groups: elective caesarean, emergency caesarean and vaginal birth. Of the 160 women included, the were no recorded cases of infection (Sucak *et al.*, 2015).

Overall it can be concluded that the rate of infection following immediate vaginal PPIUC insertion is similar, or certainly no higher, than the accepted rate for interval or non-postpartum insertion. There is also no significant difference in infection rates with mode of delivery. Therefore, while increasing infectious morbidity in the intrapartum population has been of concern in recent decades (MBRRACE-UK, 2019), women receiving PPIUC appear no more likely to experience an infective complication. In addition, the more 'at risk' population are generally excluded from receiving this intervention.

2.6.2 Uterine perforation

Uterine perforation is defined as an injury to the uterine wall which may be partial (affecting the endometrium and or/myometrium) or full thickness, where the outer serosal layer of the uterus is breached. It is a potential complication of any procedure which involves instrumentation of the uterus, including intrauterine device insertion. However, perforation is an infrequently reported complication of non-postpartum

IUC insertion with rates of around 1-2 per 1000 (Heinemann *et al.*, 2015). There has been concern for some time around the risk of perforation during immediate postpartum insertion, however published rates are reassuringly low (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015).

The International Federation of Gynecology and Obstetrics (FIGO) led one of the largest international population-based studies of PPIUC insertion to date which included 36,766 women from six different hospitals (Makins *et al.*, 2018). Of the 53% who received immediate postpartum insertion (within 48 hours) of CU-IUD at vaginal birth, there were no reported cases of perforation. Although this is reassuring from such a large cohort, the follow-up rate was only around 50% and relied on self-reporting of outcomes.

Other studies have directly compared complication rates between PPIUC and insertion in the non-postpartum or 'interval' postpartum period. In one large prospective study of 8343 women who received CU-IUD insertion at different postpartum time periods, there was only one case of uterine perforation among the 460 women who received this post-placentally (Caliskan *et al.*, 2003).

In a small RCT by Eroglu et al (Eroğlu *et al.*, 2006), which used routine ultrasound during the follow-up of women after postpartum insertion in three different time periods (post-placental, early and interval), a total of three cases of perforation were reported, all of which occurred in the interval insertion group (2.3%). However due to the small numbers in each arm, this finding did not reach statistical significance.

As smaller studies are often under-powered to detect this rare outcome, systematic reviews can provide the most accurate assessment of risk. All of these have concluded that uterine perforation is rare following immediate postpartum insertion (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). However, there is the variability in the insertion techniques used to achieve PPIUC insertion in the included studies. It could be hypothesised that instrument-facilitated insertion could lead to a higher incidence

of perforation compared to manually placing the device. Different techniques are also employed to insert devices following vaginal and caesarean birth.

In a small prospective cohort study of 114 participants, metal forceps were used to achieve post-placental IUD insertion following both vaginal and caesarean delivery and there was one documented case of uterine perforation (Hinz *et al.*, 2019). In a randomised trial of 384 women comparing two different vaginal PPIUC insertion techniques, manual versus ring forceps, there were no reported cases of uterine perforation in either group (Xu *et al.*, 1996). Even when a specially designed postpartum IUD inserter is used, which more closely resembles a standard CU-IUD inserter, no cases of perforation were reported in an RCT of 500 women assigned to either the forceps or inserter-guided vaginal insertion (Blumenthal *et al.*, 2018).

When comparing insertion during caesarean section with vaginal insertion, an observational study of 235 post-placental IUD insertions again reported no cases of perforation in either group by 12 months (Celen *et al.*, 2004). This study included formal ultrasound assessment at the initial follow-up visit. It can be concluded that immediate postpartum insertion is associated with a low overall rate of perforation and compares favourably to insertion in the non-postpartum setting. Indeed, the evidence suggests that the current standard practice of delaying insertion until four or six weeks' postpartum may in fact increase the risk of this complication occurring.

One of the largest cohort studies to explore risk factors for uterine perforation following standard IUC insertion to date is the European Active Surveillance Study on Intrauterine Devices (Heinemann *et al.*, 2015). In this study, 61448 women completed questionnaires at baseline and 12 months after receiving IUC. A total of 81 perforations were reported, with slightly higher rates in IUS users (RR 1.3; 95% CI 0.8-2.2). Breastfeeding and postpartum status (up to 36 weeks) were found to be independently associated with perforation; with a relative risk of 6.1 (CI 3.9-9.6) among breastfeeding women. Although the timing of postpartum insertion is not specifically reported in this study, the countries involved did not have active PPIUC programs at the time of study, and thus it can be assumed that any postpartum

insertions were 'interval' in nature. Furthermore, the increased relative risk conferred by postpartum status was shown to be maintained up to 36 weeks after delivery. A similar finding was noted in the Caliskan study mentioned earlier, which found no increased risk of expulsion in the post-placental setting, or beyond six months' postpartum, but an increased relative risk with insertion in the first six months (OR 11.7-13.2) (Caliskan *et al.*, 2003).

Due to the overall low incidence of perforation in PPIUC trials, secondary analysis in relation to breastfeeding status is rarely possible. In one RCT designed to determine the effect of immediate versus delayed postpartum IUS insertion on breastfeeding outcomes, no cases of perforation were found in either arm of the study among the 259 women enrolled, all of whom were breastfeeding at the time of insertion (Turok *et al.*, 2017). The lower risk of perforation observed during immediate postpartum insertion is likely to be more a reflection of the insertion technique and uterine anatomy, than of factors relating to early lactogenesis.

2.6.3 Bleeding problems

Breastfeeding and the puerperium itself lead to physiological changes in a woman's bleeding pattern. In addition, both types of IUC are known to cause changes in menstrual bleeding. Therefore, the effect of immediate PPIUC insertion on bleeding outcomes has clinical importance. While it is generally accepted that immediate postpartum intrauterine insertion does not increase the rate of bleeding problems compared to interval or non-postpartum insertion (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015), this is a more challenging 'safety' outcome to investigate in PPIUC studies.

Firstly, not all studies investigate bleeding as an outcome. In those that do, it is either directly as a self-reported outcome, or indirectly as an underlying cause for removal

of the device. Secondly, assessing bleeding in this manner is often highly subjective and not all studies record the specific reasons for device removal.

One Turkish study aimed to compare the rate of complications between those receiving immediate or early postpartum insertion of a CU-IUD versus interval insertion (Eroğlu *et al.*, 2006). Both intra-caesarean and vaginal PPIUC was included. A total of 286 participants were followed up for one year and questioned directly about 'excessive bleeding' at each study visit during this time. A total of 12 women reported 'excessive bleeding' during follow-up (4.6%), and two thirds of these (n=8) were in the interval insertion group. Due to the small numbers involved, this study did not include subgroup analysis for this outcome based of mode of delivery.

However, in a retrospective cohort study of 593 women receiving post-placental IUC insertion from India, there was no difference in self-reported 'irregular' bleeding between the caesarean and vaginal insertion groups for the 171 women with follow-up visits recorded (Hooda *et al.*, 2016). Overall, the most common reported change in bleeding pattern was increased blood loss, which was reported in 10.5% of women overall. Notably this study only included use of the CU-IUD, which is widely known to be associated with this side effect (Faculty of Sexual & Reproductive Healthcare, 2015).

One of the concerns associated with increased blood loss is the potential risk of device expulsion. In a study of 114 women who received post-placental insertion of either the C-IUD or 52mg LNG-IUS, there were a total of seven IUC removals, five of which were reportedly due to bleeding (Hinz *et al.*, 2019). However, the study failed to demonstrate bleeding pattern as a predictor of device expulsion at six months (OR 0.81-1.49; p0.27-0.54).

Perhaps the most useful data in relation to differences in bleeding between both device types in the immediate postpartum setting comes from a 2012 study by Elsedeek (Elsedeek, 2012). This prospective cohort study of 191 women sought to compare bleeding patterns after intra-caesarean insertion of either the 52mg LNG-

IUS or CU-IUD with a control group. To reduce the subjectivity of self-reporting, participants completed a contemporaneous menstrual diary to record the number of bleeding days (duration) along with semi-quantitative assessment of pad soiling (heaviness). Outcomes were recorded at monthly intervals for one year, to further reduce the impact of recall bias. The mean duration of bleeding was greater in the CU-IUD group compared to the control (33.4 +/- 9.5 days versus 27 +/- 11.4; $p<0.03$). While those in the LNG-IUS group had both shorter and lighter bleeding (20.2 +/- 7.7 days and 3.1 +/- 1.6 pads/day respectively; $p<0.0001$), and a higher duration of amenorrhoea. Of particular importance, breastfeeding rates were similar (and high) in all groups, removing an important possible source of confounding.

The reduction in postpartum bleeding seen with insertion of the LNG-IUS immediately after delivery has also been observed in other studies (Sonalkar and Kapp, 2015). It is postulated that this is likely due to the progestogenic effect on the puerperal endometrium (Elsedeek, 2012); similar to its effect in non-postpartum women, and in women who receive early post-abortion IUS insertion (Sääv, Stephansson and Gemzell-Danielsson, 2012). Thus, bleeding outcomes following PPIUC insertion are most likely to be determined by the choice of device rather than the timing or mode of postpartum insertion.

2.6.4 Breastfeeding

An additional safety consideration specific to IUC insertion in the postpartum setting is the potential effect on breastfeeding, particularly in relation to hormone-containing devices. It may be postulated that the synthetic progestogen contained within the IUS could limit the fall in natural progesterone that occurs in the first few days after childbirth and is responsible for initiation of lactation. Confirmation of this hypothesis would present a considerable disadvantage of immediate IUS insertion for women who intend to breastfeed, particularly given the significant maternal and

infant benefits of doing so. Systematic review evidence supports the safety of progestogen-only contraceptives by breastfeeding women (Phillips *et al.*, 2016), however studies which specifically focus on immediate PPIUC use are more limited and early trials of this type produced mixed results.

One pilot RCT found similar breastfeeding continuation rates at 6 months irrespective of postpartum insertion timing among three groups (immediate, early and interval) of 52mg LNG-IUS users (80% vs 80% vs 63% respectively; p=0.372) (Dahlke *et al.*, 2011). Another comparative trial of immediate versus interval postpartum LNG-IUS insertion by Levi et al reported no difference in the proportion of women breastfeeding at six, 12 or 24 weeks after delivery (Levi *et al.*, 2018). However, this was a secondary analysis of only a small sample of women (n=63) for whom breastfeeding outcomes were actually recorded.

Conversely, in a secondary analysis of the Chen RCT, women continued to breastfeed for longer following delayed (interval) insertion compared to immediate postpartum insertion, and exclusive breastfeeding was also more common in the former group (Chen *et al.*, 2011). While participant demographics did not vary considerably between the two groups and the rate of breastfeeding initiation was similar in each, women were not asked about breastfeeding intention at the time of study enrolment and as with many of these studies, breastfeeding outcomes were self-reported. In addition, overall breastfeeding rates were relatively low in this study, which itself was under-powered to detect a difference in this outcome.

More conclusive evidence can be drawn from a larger non-inferiority RCT where breastfeeding was the primary outcome of interest among the 259 participants randomised to either immediate or delayed (between four and 12 weeks) postpartum insertion of the 52-mg LNG-IUS (Turok *et al.*, 2017). Outcomes included continuation of breastfeeding at eight weeks and time to lactogenesis. Rates of breastfeeding at eight weeks' postpartum were 79% (CI 75-90%) and 84% (76-91%) (p=0.28) respectively, indicating non-inferiority with immediate postpartum

placement. There was also no significant difference in the time to onset of lactation between the groups.

2.6.5 Summary

Immediate postpartum insertion of IUC appears to be a very safe intervention. Infection rates are comparable with non-postpartum insertion when those with other risk factors for this complication are excluded. The absolute risk of uterine perforation is very low during immediate postpartum insertion, regardless of the specific insertion technique employed, and may be lower than for interval insertion. There is no good evidence that postpartum bleeding problems are more likely following immediate insertion, and they may be reduced with insertion of the LNG-IUS. Irregular bleeding which can occur in the early weeks following LNG-IUS insertion are also likely to be masked by normal postpartum lochia. Currently available evidence does not indicate a significant detrimental effect on breastfeeding performance when the LNG-IUS is inserted immediately after delivery.

2.7 Efficacy of PPIUC

The primary efficacy of a contraceptive method is often determined by its failure rate, as measured by the number of unintended pregnancies occurring in women who use the method over a fixed period of time, usually one year i.e. the Pearl Index. While IUC itself is known to have a low inherent failure rate, its ability to effectively reduce unintended pregnancy at population level depends on the long-term continuation of the method. This is in turn affected by whether or not the device remains in place after insertion. As such expulsion and continuation are often described as important measures of 'efficacy' of PPIUC and will be addressed here separately.

2.7.1 Expulsion

One of the earliest observations from PPIUC studies was the higher expulsion rate compared to non-postpartum IUC insertion (Rosenfield and Castadot, 1974; Annus *et al.*, 1980; Chi and Farr, 1989). Theoretically, postpartum vaginal insertion through an already dilated cervix was thought to predispose to the increased likelihood of subsequent expulsion.

The most recent Cochrane review of immediate postpartum IUC insertion (Lopez *et al.*, 2015), which included meta-analysis of only RCTs, confirmed a higher expulsion rate at six months compared to standard interval insertion (17% vs 3%; OR 4.89; 95% CI 1.47-16.32). However, as it the wide confidence interval indicates, the size of effect from the included trials varied considerably.

One of the RCTs included in the analysis was the aforementioned study by Chen et al in 2010 (Chen *et al.*, 2010), where 102 women were randomised to receive either immediate post-placental insertion of the 52mg LNG-IUS, or delayed insertion six to eight weeks later. The rate of expulsion was found to be significantly higher in the immediate insertion group (24% vs 4%; p0.008). However, 10 out of the 12 women who experienced an expulsion in the immediate group opted to have another IUC inserted at the initial follow-up visit, therefore rates of method continuation at six months were similar regardless of initial insertion timing (84% vs 77%; p0.032).

As the risk of expulsion is believed to be directly linked to the insertion process itself, many factors have been investigated in relation to expulsion. These include the timing of insertion, mode of delivery (vaginal or caesarean) and insertion technique, which will each be considered in turn.

2.7.1.1 Timing of insertion

As summarised in **Table 2.1**, postpartum IUD insertion can occur at different times following delivery. 'Post-placental' insertion usually occurs in the labour room (or theatre) within ten minutes of placental delivery. 'Immediate' insertion describes IUC insertion within the first few days after birth, and usually before the woman is discharged from the maternity setting.

In an early study investigating post-placental insertion, Chi et al found that insertion within 10 minutes of delivery was associated with a lower expulsion rate than when insertion was performed later in postpartum period (Chi, Wilkens and Rogers, 1985). However, the IUC devices included in this study are no longer widely used, namely the Lippes loop and Copper T-220.

Two more recent studies have sought to compare IUC insertion across different postpartum insertion periods. In the first, a prospective cohort study of 286 women in Turkey, expulsion rates of the CuT380-A were compared across three different postpartum insertion times: post-placental (< 10 minutes), early (up to 72 hours) and interval (after six weeks) (Eroğlu *et al.*, 2006). The lowest rate of expulsion was observed in the interval group (3.8%) but was also lower in post-placental compared to the early insertion groups (14.3% and 18.6% respectively; p0.003). Of particular note in this study, women were given the option of choosing their insertion timing and almost twice as many women opted for post-placental versus early insertion.

In the second study by Dahlke et al, which involved a more robust study design, 53 women were randomised to one of three similar insertion timing groups for receiving the 52mg LNG-IUS (Dahlke *et al.*, 2011). The primary outcome was the rate of expulsion at six months. No expulsions occurred in the interval insertion group and the expulsion rate for both the post-placental and immediate groups were the same (27%). One of the critiques of this study, as noted by the authors, is that only one woman actually had a true 'post-placental' insertion within 10 minutes of delivery;

the remainder in the 'post-placental' group actually had insertion within 30 minutes. Therefore, these were all 'immediate' postpartum insertions as defined by pre-existing WHO criteria. In effect, this study found that there was no significant difference in complete expulsion rates between devices inserted earlier (>10 minutes) or later within the accepted 48-hour period for immediate postpartum insertion.

The difference in expulsion rates between post-placental and 'early' postpartum placement has important clinical considerations. It may not always be practical to insert devices within the 10-minute time frame (as discovered in the pilot study by Dahlke and colleagues). This was the focus of a 2016 observational study by Blumenthal et al (Blumenthal *et al.*, 2016). Of the 305 who completed follow-up after vaginal PPIUC insertion of CU-IUD, the expulsion rate at six months was 10.8% in those who received post-placental insertion and 4.1% in those who received insertion up to 48 hours after delivery. The difference was not found to be statistically significant (p0.10) and indeed the overall expulsion rate in this study was lower than in others (5.6%). However, the findings are limited by a higher loss to follow-up (almost 50%) and that insertion timings were self-reported, which may have introduced an element of bias.

However, these studies suggest that the difference in expulsion between immediate and early insertions may not be as significant as previously thought. Some argue that waiting longer than the prescribed 10 minutes after placental delivery may allow for further uterine contraction which may reduce the likelihood of subsequent expulsion (Goldthwaite *et al.*, 2018). It has also been proposed that the 10-minute insertion 'window' may present a barrier to insertion as it can be practically more difficult to achieve in routine clinical practice (Goldthwaite *et al.*, 2018; Lerma *et al.*, 2020).

One of the ongoing challenges in determining the effect of insertion timing on the expulsion rate of PPIUC is that many studies do not delineate between post-placental and immediate insertions, and the definitions used within these time frames vary. Since publication of the Cochrane review in 2015, there have been two more recent

systematic reviews and meta-analyses published (Jatlaoui *et al.*, 2018; Averbach *et al.*, 2020). These sought specifically to determine factors associated with expulsion after PPIUC insertion and provide further clarification around rates for different insertion timings. Unlike the earlier Cochrane review, both of these included studies of any design in their analysis, provided that expulsion was included as a primary outcome measure in the original study.

The first of these reviews, published in 2018, comprised the pooled results of 48 studies (Jatlaoui *et al.*, 2018). They found that the expulsion rate varied by insertion timing, with a rate of 10.0% for post-placental placement and 29.7% for what they defined as 'early postpartum' placement. This included all devices inserted between 10 minutes and four weeks after insertion. Compared to interval insertion, the risk of expulsion was found to be considerably increased with both immediate and early insertions (aRR 7.63, 95% CI 4.31-13.51; aRR 6.17, 95% CI3.19-11.93). However, this study did not distinguish between those insertions provided in the early hours after delivery i.e. within 48 or 72 hours; and those insertions performed in the early weeks after leaving the birth unit. For the latter, the current evidence base is considerably more limited. They also included studies investigating some older forms of IUC (such as the Copper 7 and TCu200) which are no longer in clinical use throughout most of Europe and the US.

The follow-up systematic review published in 2020 addressed some of these concerns (Averbach *et al.*, 2020). This focused solely on IUC devices currently in use in the US (and indeed most of Europe) and included evidence from five new studies published between 2018 and 2020. As such it can be considered as the most up to date review of the evidence. They found a similar pooled expulsion rate for post-placental insertion of 10.2%. However, when only 'early inpatient' insertions were considered, the pooled expulsion rate was in fact very similar (13.2%). As in the previous review, the risk of expulsion remained higher for both immediate and early IUC placement, compared to interval insertion (aRR 8.33 and 5.27 respectively).

From this evidence, it is clear that vaginal PPIUC provision is associated with an increased likelihood of expulsion, and that insertion timing may be an important factor; with earlier post-placental placement possibly conferring a small reduction in the risk of subsequent expulsion. However, this has to be balanced against the practical aspects of providing true 'post-placental' insertion. As well as timing of insertion, the mode of delivery and insertion technique may also play an important role.

2.7.1.2 Mode of delivery

There are inherent differences in the insertion method used to achieve PPIUC insertion following a caesarean or vaginal birth. Most intra-caesarean insertions are performed during elective procedures, when the woman is not in labour and as such the cervix is undilated. For vaginal insertion to be possible, the cervix must have reached full dilatation and therefore theoretically, it might be expected that this would increase the likelihood of the IUD being later expelled.

Due to the difficulties in randomising women to a specific mode of delivery, it is impossible to test this theory directly through an RCT comparing intra-caesarean with immediate vaginal PPIUC. Most of the currently available evidence has been generated from observational studies. In the 2015 systematic review by Sonalkar et al, five cohort studies were identified comparing post-placental CU-IUD insertion between both modes of delivery. Overall, most studies showed a higher rate of expulsion following vaginal insertion (13-23%) compared to insertion at the time of caesarean section (0-14%) (Sonalkar and Kapp, 2015).

More recent studies have continued to support these findings. A study by Colwill et al investigated IUD retention at six weeks among women receiving a CU-IUD within 10 minutes of either caesarean or vaginal delivery (Colwill *et al.*, 2018). All women (56/56) who received intra-caesarean insertion retained their device, compared to

84% of those who had a vaginal insertion. Just under half or those who did not retain their device (7.7%) experienced an expulsion. Mode of delivery was found to be the only factor associated with device retention ($p<0.01$).

The most recently published systematic reviews provide perhaps the most detailed information in terms of expulsion and mode of delivery, including pooled expulsion rates and an estimation of adjusted risk ratios for this variable. For immediate postpartum insertions, the expulsion risk was higher for vaginal compared to caesarean birth (aRR 4.57; 95% confidence interval 3.49-5.99) (Averbach *et al.*, 2020). Therefore, although there are no RCTs directly comparing the mode of delivery in terms of PPIUC expulsion, the current evidence strongly suggests a higher expulsion rate following vaginal PPIUC insertion. However, vaginal PPIUC insertion itself can be achieved in a number of different ways.

2.7.1.3 Insertion technique

Techniques described to achieve vaginal PPIUC insertion include manual insertion with the clinician's hand, using metal instruments such as forceps or via the pre-packaged device inserter. More recently, the use of a specialised postpartum inserter has also been investigated (Singh *et al.*, 2016). In one of the earliest studies to investigate expulsion after vaginal PPIUC by insertion method, Xu et al found no difference between manual or forceps insertion (Xu *et al.*, 1996). In a study which compared the forceps insertion technique to the new dedicated inserter, no difference was observed in complete expulsion rate between the two methods (Blumenthal *et al.*, 2018). What has consistently been emphasised in these studies, and in other PPIUC guidance (O'Hanley and Huber, 1992), is the importance of high fundal placement of the device regardless of the specific insertion technique.

In attempt to support correct fundal placement and potentially reduce the expulsion rate, some researchers have investigated the use of ultrasound either during or

immediately after PPIUC insertion (Hayes *et al.*, 2007; Dias *et al.*, 2015; Goldthwaite *et al.*, 2017). In one study, Dias et al found that the location of the IUC device on immediate post-insertion ultrasound was predictive of subsequent expulsion (sensitivity 65%; specificity 81%) (Dias *et al.*, 2015). As such, the authors proposed that routine use of ultrasound should be performed following PPIUC insertion. However, this study was limited by a small sample size and lack of inter-observer correlation on ultrasound measurements which could have affected the validity. They also included both caesarean and vaginal insertions in their analysis and concluded that mode of delivery was not associated with their overall observed expulsion rate of 25%. This contradicts most of the evidence from other larger studies and meta-analyses (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). Furthermore, their findings in relation to ultrasound as a predictor of expulsion have not been consistently replicated in other studies.

For example, in a US study which compared expulsion rates at 12 weeks following post-placental vaginal insertion of either the CU-IUD or 52mg LNG-IUS, ultrasound was not found to be predictive of subsequent expulsion (Goldthwaite *et al.*, 2017). The mean measured distance from the fundus in those who went on to expel their device did not differ significantly from those who did not expel their device (4.6cm vs 2.9cm; P 0.17). Indeed, there were women with a mean distance which exceeded clinically 'accepted' parameters (frequently 2-3cm from fundus) who did not go on to expel their device.

While post-insertion ultrasound may be a useful adjunct in some circumstances, its use a tool to predict or reduce expulsion is unclear at present. Many experts also argue that it is an unnecessary component of successful insertion which could in fact present an additional barrier to women actually receiving PPIUC (Goldthwaite *et al.*, 2018).

However, ultrasound has frequently been utilised in the follow-up protocols of PPIUC studies, and its routine use may also increase the detection of 'partial' expulsions or misplaced devices; the clinical significance of which remains unknown (Golightly and

Gebbie, 2014). This is an important outcome measure as in many studies those identified with a 'partial' expulsion often have their device removed.

In the Dahlke RCT mentioned earlier, the post-placental insertion group had a significantly lower rate of partial expulsion compared to those in the early insertion group (22.6% vs 51.2%) (Dahlke *et al.*, 2011). The authors propose insertion technique as the underlying explanation for this, arguing that higher fundal placement is possible when the device is inserted immediately after delivery.

2.7.1.4 Type of device

Most of the historical evidence around PPIUC relates to the CU-IUD, in part because it is cheaper and more widely available in low resource settings where many of the larger PPIUC trials have taken place. However, in most high-income settings women seeking IUC are able to choose between the CU-IUD or LNG-IUS. More recently, immediate postpartum insertion of the LNG-IUS has also been investigated.

The 2010 systematic review was the first to include studies of immediate postpartum insertion of the 52mg LNG-IUS and reported that while expulsion rates appeared higher with the LNG-IUS compared to the CU-IUD, the available evidence was limited (Grimes, Lopez, Schulz and Stanwood, 2010). Subsequently, two randomised trials investigating postpartum insertion timing of the 52mg LNG-IUS reported similar expulsion rates in the region of 24-27% at six months (Chen *et al.*, 2010; Dahlke *et al.*, 2011). However, both of these studies were limited by a relatively small sample size. While an RCT comparing expulsion rate specifically by device type would be the most scientifically rigorous way of determining any difference in expulsion rate, most women will have a method preference and there may be ethical challenges with such a randomisation process. However, there have been several non-randomised observational studies comparing the two devices in this setting from which some conclusions can be drawn.

In one US prospective observational study of postpartum LARC provision 350 women requesting immediate insertion of the either an implant or intrauterine device after delivery were enrolled (Eggebroten, Sanders and Turok, 2017). Of these, 123 opted for a 52mg LNG-IUS and 88 for a CU-IUD, and around three quarters of the women in each group received insertion following a vaginal birth. The hazard ratio of expulsion for the LNG-IUS compared to CU-IUD was 5.8 (adjusted for mode of delivery). Of note was the wide confidence interval (1.3 to 26.4), with the lower extremity close to the point of no effect.

There are also conflicting findings in the literature. A 2019 prospective cohort study by Hinz et al sought to compare the six-month expulsion rate after post-placental insertion by device type (Hinz *et al.*, 2019). After controlling for mode of delivery and other patient characteristics (such as breastfeeding), the odds of expulsion did not differ by device type alone (aOR 0.98, 95% CI 0.22-4.48). However, a higher risk of expulsion was observed with vaginal versus caesarean delivery, and this was found to be even higher for those who received the LNG-IUS. A similar finding has been observed elsewhere (Goldthwaite *et al.*, 2017).

In the 2018 systematic review by Jatlaoui et al, postpartum insertion of the LNG-IUS was associated with a higher expulsion rate than for the CU-IUD (RR 1.91; 95% CI 1.50-2.43) (Jatlaoui *et al.*, 2018). However, as the authors acknowledge, more than 90% of the data included in this review related to the CU-IUD.

In addition to PPIUC studies including the LNG-IUS being more limited in number, they also tend to originate from high-income settings where ultrasound frequently features in the follow-up protocol. This can lead to over-diagnosis of expulsion (in particular 'partial' expulsion) which may not always be reported separately in expulsion data. Therefore, while the LNG-IUS may be associated with an increased risk of expulsion following immediate postpartum insertion, further robust evidence is still required.

2.7.2 Continuation

The rate of expulsion following PPIUC is inextricably linked to the continuation rate, which many suggest is the more clinically relevant outcome in a public health context. At population level, if a highly effective method is continued for a longer time period then the overall number of pregnancies prevented is expected to be greater.

High continuation rates have been observed consistently in those who receive and retain PPIUC, and insertion during the immediate postpartum period compares favourably with delayed insertion in this respect (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). In the 2015 Cochrane review and meta-analysis, despite the higher expulsion rate in those who received immediate insertion compared to interval insertion (17 vs 3%), IUC method continuation at six months was more likely in the former (81% vs 67%; OR 2.04, 95% CI 1.01-4.09) (Lopez *et al.*, 2015). High continuation rates also appear to persist beyond six months although the available data is more limited. Follow-up periods vary considerably between PPIUC studies with only a few reporting continuation rates at 12 months or beyond (Averbach *et al.*, 2020).

In one such study, a prospective cohort of 235 women who received post-placental insertion of the CU-IUD (vaginal or caesarean), continuation rates at six and 12 months were 87.6% and 76.3% respectively (Celen *et al.*, 2004). A high number attended the 12-month follow-up visit (183/235; 78%) which included both clinical and ultrasound assessment.

The 12-month outcomes of post-placental vaginal and caesarean insertion were also directly compared in an observational study by Sucak et al (Sucak *et al.*, 2015). Of the 62/160 who received vaginal insertion, 77% were still using the method at 12 months. There was no difference in continuation rate when compared to those who receiving intra-caesarean insertion either electively or during labour (87%, p0.31; and 84%, p0.51 respectively).

Even when different postpartum timings are compared for each method (such as in the Eroglu and Dahlke studies mentioned earlier), despite the higher expulsion rate in the immediate and early insertion groups, long-term continuation and pregnancy rates were comparable with those who received interval insertion (Eroğlu *et al.*, 2006; Dahlke *et al.*, 2011). Therefore, despite the higher expulsion rates reported following vaginal PPIUC insertion, it performs favourably compared to both non-postpartum and intra-caesarean insertion in terms of long-term continuation. But in almost all of these studies women were able to receive IUD reinsertion following expulsion or removal.

In general, PPIUC also compares favourably to the postpartum initiation of other LARC methods in terms of long-term continuation. One study by Woo et al, enrolled women to either immediate postpartum insertion of the implant or IUC (Woo *et al.*, 2015). When accounting for reinsertion after expulsion among the 76 women who opted for IUC insertion, 81% still had their device in place at one year compared to 84% of implant users (p 0.96). While these findings are limited by a relatively low follow-up rate (51%), they have been replicated elsewhere. In a similar study where the follow-up rate was considerably higher (89%), continuation rates at six months were high among the 202 participants who received immediate postpartum insertion of the LNG-IUS, CU-IUD or implant (88%, 86% and 90% respectively), with no difference observed between methods (p0.85) (Eggebroten, Sanders and Turok, 2017).

Continuation of IUC following an expulsion depends on two key factors: the ability to identify an expulsion and the ability to access IUC reinsertion if desired. Patient recognition of expulsion is not always reported in PPIUC trials. Where this has been recorded, most women experiencing a complete expulsion were aware of it and most of these occurred early in the follow-up period (Goldthwaite *et al.*, 2017). This is less frequently the case for partial expulsion, which often relies on identification through clinical and/or ultrasound detection.

When the option of reinsertion after expulsion is available, the continuation rates following immediate PPIUC insertion are similar to interval insertion. Indeed, due to the high rates of non-attendance for interval insertion alluded to in the previous chapter, they are often higher. However, the high rates of IUC reinsertion following expulsion in clinical trials may not be translatable to non-research settings, where there may be less rigorous follow-up and potentially more difficulty in accessing appointments.

2.7.3 Summary

As an intervention, PPIUC insertion performs well in terms of efficacy. However, it is limited by a higher expulsion rate compared to non-postpartum insertion. Women having PPIUC insertion after a vaginal birth appear to at a higher risk of this outcome compared to those receiving it at the time of caesarean section. While immediate 'post-placental' insertion may confer a small reduction in the expulsion risk compared to insertion between 10 minutes and 48 hours after delivery, this warrants further investigation. More robust data are also needed regarding the risk of expulsion between device types, but current evidence suggests that this is higher for the LNG-IUS compared to the CU-IUD. Despite the higher expulsion rate with immediate PPIUC, long-term continuation rates are very high. Indeed, in populations where attendance for interval insertion is known to be low (such as the UK), the higher continuation rates with immediate provision may outweigh the reported expulsion rates.

2.8 Women's experience of PPIUC

In contrast to other clinical outcomes of PPIUC, women's experience of the intervention has been less widely reported. In quantitative studies it is most commonly evaluated using satisfaction scores. Where this has been included as an outcome measure, high satisfaction rates are seen among PPIUC recipients.

Only one randomised trial could be found where the primary outcome measure was patient satisfaction between women receiving either immediate or delayed postpartum insertion of the 52mg LNG-IUS (Braniff, Gomez and Muller, 2015). Satisfaction was measured on a five-point Likert scale at three time points during study follow-up (six weeks, three months, six months). There was no significant difference in satisfaction scores between the two groups, with 90.5% in the immediate insertion group and 88.2% in the control group either very or somewhat satisfied at six months ($p>0.99$).

Along with satisfaction scores, the 'uptake' of a contraceptive intervention can also provide a surrogate measure of how successful a new contraceptive intervention is likely to be among certain populations and is a useful evaluation tool in health services research. In the first observational study of a routinely-available PPIUC service in the UK, the overall uptake of IUC was 14% and 93% of recipients were either 'very' or 'fairly' satisfied (Heller, Johnstone and Cameron, 2017).

However, both of these studies assessed satisfaction specifically following intra-caesarean insertion, which may not be directly comparable to post-placental vaginal insertion. There are considerable differences in birth experience and analgesia between an elective operative delivery and a vaginal birth following labour, which may also exert significant bias on how women perceive their experience and satisfaction with PPIUC insertion at this time.

A large observational study from India (n=2733), which included both immediate vaginal and intra-caesarean insertion of the CU-IUD, found that 99.6% of women

were reportedly 'satisfied' at the time of insertion (Kumar *et al.*, 2014). However, this study did not assess satisfaction at later time points, and as with the aforementioned studies, was limited only to quantitative measures of satisfaction. Often these do not allow for detailed exploration of women's views and experiences and in this respect, qualitative research is a much more useful tool.

However, there is a paucity of qualitative research directly relating to women's experience of PPIUC insertion. Only one mixed methods study from the US could be identified where the primary objective was to explore this (Carr *et al.*, 2018). Pain scores (using visual analogue and Likert verbal rating scales) were collected from women before and after vaginal PPIUC insertion using ring forceps and compared between those with or without regional anaesthesia in place at the time of the procedure. A subset of women from each group then took part in semi-structured interviews before hospital discharge. Pain scores were low and similar across both groups. Similar themes emerged among the 21 women who took part in interviews. Their main motivation towards PPIUC insertion was 'convenience' and an awareness of perceived difficulty in accessing the method after leaving hospital. Most felt the pain was less than expected, even among those with greater quantitative pain scores, and high levels of satisfaction with PPIUC were expressed from both groups.

Pain as a measure of patient experience was also included as an outcome in the Dahlke RCT, where it was also evaluated using a visual analogue scale (VAS) (Dahlke *et al.*, 2011). Significantly lower VAS scores were observed with immediate compared to interval insertion (1.07 vs. 3.13, $p<0.001$).

2.8.1 Summary

In addition to performing well in terms safety and efficacy, patient satisfaction levels with PPIUC are high and at least comparable to those having interval insertion. Insertion-related pain is well tolerated, even in those without regional anaesthesia,

and may be less than that experienced during interval insertion. The limited qualitative data that exist suggest that convenience is a key motivator for accessing PPIUC, and that most women feel positive about their overall experience.

2.9 Areas for further research

One of the ongoing challenges in relation to vaginal PPIUC insertion is the expulsion rate. While it is important to consider this in the context of a high continuation rate and safety profile, more evidence about the specific factors which affect the expulsion rate and how these could be modified would be helpful in order to maximise the benefits of PPIUC.

Currently available PPIUC outcome data are largely derived from clinical trials, which may not be replicable in 'real life' settings. There are very few studies which report findings from routinely available services, particularly from high-income countries. Furthermore, PPIUC has not been widely adopted into clinical practice in many of these areas despite current recommendations. This suggests that we do not fully understand the barriers to more widespread availability of these services, which is necessary for translating this research into practice. More qualitative research into both patient and provider experience of PPIUC is needed.

The interplay between service delivery and efficacy is especially important in the context of PPIUC. For example, due to the effect of training on correct device placement and the role of formal follow-up in diagnosing expulsion. As such further research into how PPIUC is implemented within complex healthcare systems could support its increased availability, and therefore the efficacy of the intervention at a population level to reduce unintended pregnancy.

2.10 Literature review in the context of this thesis

At the time of commencing this research, there were no previous studies from the UK evaluating PPIUC provision after vaginal birth. Previous health services research conducted in Lothian focused on the routine provision of PPIUC during elective caesarean section (Heller, Johnstone and Cameron, 2017). While this was shown to be feasible and had favourable outcomes in terms of safety and efficacy, it was only available to those having a planned caesarean birth, which accounts for less than a quarter of all women.

Given the similarly favourable evidence that exists around vaginal PPIUC provision, it was felt that this warranted further investigation within a UK setting. The main aim of the research contained within this thesis was to determine the feasibility and outcomes of introducing a new vaginal PPIUC service. By utilising a mixed methods health services research approach, we also sought to explore some of the barriers and facilitators involved in introducing PPIUC as a routinely available service within the NHS.

In next chapter I will present the findings from a 12-month observational study of vaginal PPIUC insertion before going on to explore and evaluate key aspects of service delivery in Chapters 4 and 5. In Chapter 6, I will propose an implementation science framework to summarise the collective approach to service development, and potentially support the wider dissemination of PPIUC within the UK and beyond.

Chapter 3 Provision of immediate postpartum intrauterine contraception after vaginal birth

Published in full: **Cooper M**, Boydell N, Heller R, Cameron S. Community sexual health providers' views on immediate postpartum provision of intrauterine contraception. BMJ Sexual & Reproductive Health. 2018 Apr 1;44(2):97-102. (*Reproduced with permission*)

3.1 Introduction

In the opening chapters I presented information about the current unmet need for postpartum contraception in the UK, particularly in relation to LARC methods. A previous survey of postnatal women found that one in three were keen to receive immediate postpartum insertion of IUC if available (Heller *et al.*, 2016). Although contraception and maternity care are both free in the UK, there are still challenges in integrating these services into clinical practice, particularly for LARC methods which require trained personnel to fit. At the time of writing, no maternity units in the UK were offering immediate PPIUC insertion routinely to women. Although some other European centres had started to offer PPIUC, it was still not widely available. Indeed, immediate PPIUC insertion is not included as part of the RCOG or RCM curricula for those training in obstetrics or midwifery, and most clinicians were unfamiliar with the specific techniques used to achieve successful IUC insertion at this time.

Locally in the Edinburgh region, there was a limited PPIUC service available only to women delivering by elective caesarean section (around 20% of all annual births). A paper published by Heller et al reported that the overall uptake of this service amongst those eligible was 14% (Heller, Johnstone and Cameron, 2017). For women having a vaginal birth, the routine care pathway for receiving IUC prior to this study was for women to attend either their GP or local sexual health clinic from four weeks'

postpartum. Data collected locally indicated that only around 50% attended for interval postpartum insertion in these circumstances (Cameron *et al.*, 2017). It was therefore hypothesised that the providing PPIUC at the time of vaginal birth could address an unmet need. In this chapter, I will discuss our approach to introducing and evaluating vaginal PPIUC provision through a health services research model.

3.2 Justification for methodology

As discussed in Chapter 2, there have been a significant number of clinical trials of PPIUC dating back to the 1960's. More recently, published evidence has also included randomised controlled trials and systematic reviews and included data from high (mainly US) as well as low-and-middle-income countries. The favourable results from these studies have prompted the increased interest towards PPIUC in the UK and other countries.

Based on the available evidence, it was our hypothesis that offering women the option of immediate PPIUC insertion after vaginal birth would be associated with a good uptake, a low rate of complications and a high continuation rate. The most robust way to determine these outcomes would be through an RCT, comparing outcomes to standard care i.e. interval postpartum insertion. Most of the early studies investigating PPIUC provision were observational in nature. However, since 2015 there have been two published RCTs, both from high income settings, which were also included in two updated systematic reviews in 2015 (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). The overall findings were largely conclusive: vaginal PPIUC is safe and effective however, may be associated with in increased risk of device expulsion compared to interval postpartum insertion.

Many of these studies were published several years prior to the conception of this research, and the favourable results had not yet been translated into widespread clinical practice. It was also noted by several authors that some of the challenges with

PPIUC provision related to 'implementation' factors, which had been relatively under-researched at the time. Therefore, our aim was to design a more translational study to explore the logistical and well as clinical factors related to PPIUC provision in our setting.

Health services research is: '*a multidisciplinary scientific endeavour that studies and generates knowledge to facilitate improved translation of medical discoveries into practice to improve the health of patients and the public*' (Schwartz, 2017). Based on this principle, the aim of our study was not simply to introduce and evaluate the clinical outcomes of PPIUC, but to investigate the systems and processes necessary for successful service introduction with a view to disseminating this knowledge more widely. Therefore, this methodology was the most appropriate to achieve our broader aims.

3.3 Study design and objectives

Our aim was to train maternity providers (doctors and midwives) in vaginal PPIUC insertion in NHS Lothian and subsequently introduce and evaluate a routinely-available service. The key study objectives:

(i) To design and deliver a training package in vaginal PPIUC insertion for doctors and midwives working in the UK

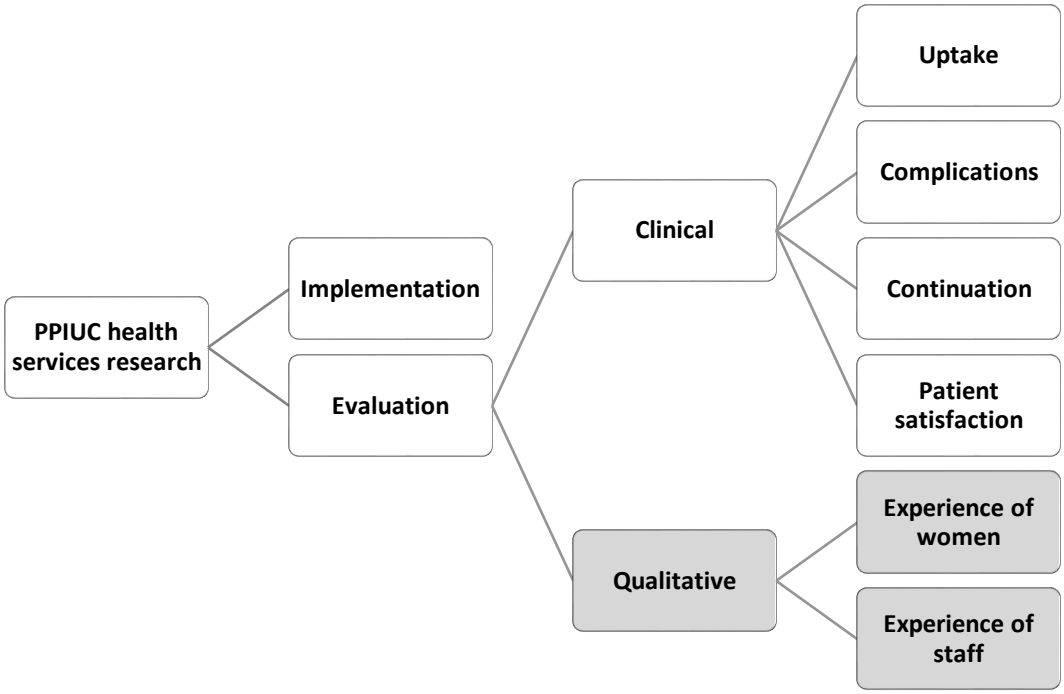
(ii) To determine the uptake, complications and continuation rate of vaginal PPIUC provision

(iii) To assess patient satisfaction with vaginal PPIUC

(iv) To identify facilitators and barriers to PPIUC service provision

The design, delivery and evaluation of the training programme will be discussed in greater detail in Chapter 4. To achieve the broad study aim, we adopted a mixed methods approach appraising both clinical and qualitative outcomes. The overall project outline is summarised in **Figure 3-1**.

Figure 3-1: Overview of PPIUC health services research evaluation project (PPIUC, postpartum intrauterine contraception)



Primary clinical outcomes of interest included uptake, complications (infection, perforation, expulsion) and satisfaction at six-weeks' postpartum, and method continuation up to 12 months. The six-week time point was chosen as most earlier studies had indicated a low rate of complications beyond this point. Also, in the event that reinsertion was required following an expulsion or removal, this could be safely achieved within current UK guidelines (where insertion after four weeks' postpartum is a UKMEC 1 i.e. unrestricted use) (Faculty of Sexual & Reproductive Healthcare, 2016).

We were also interested in the longer term outcomes after PPIUC specifically in relation to the continuation of the method. The 12-month duration was chosen as few studies had previously included data to this time point. In addition, it would allow later evaluation of the intervention as means to reducing short interpregnancy intervals, and in performing subsequent cost-effective analysis.

The acceptability and experience of PPIUC provision amongst women and maternity staff was evaluated through a concurrent qualitative study led by a team of social scientists. Results from this part of the study are published elsewhere (Boydell *et al.*, 2020). An adapted version of the peer-reviewed manuscript arising from the clinical arm of the study follows in this chapter.

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

Published in full: **Cooper M**, McGeechan K, Glasier A, Coutts S, McGuire F, Harden J, Boydell N, Cameron ST. Provision of immediate postpartum intrauterine contraception after vaginal birth within a public maternity setting: Health services research evaluation. Acta Obstetricia et Gynecologica Scandinavica. 2020 May;99(5):598-607. (Reproduced with permission)

3.4.1 Background

Unintended pregnancy in the postpartum period is common. One UK study found that at least one in 13 women attend for abortion within 12 months of childbirth (Heller et al., 2016). For women who continue a pregnancy following a gap of less than 12 months between childbirth and subsequent conception - known as a short inter-pregnancy interval - there is an increased risk of preterm labour, fetal growth restriction and stillbirth (Smith, Pell and Dobbie, 2003). Initiation of effective

contraception has been shown to reduce the incidence of unintended pregnancy and short inter-pregnancy intervals, especially when started immediately postpartum (Brunson *et al.*, 2017). As this is also a convenient and desirable option for women (Heller *et al.*, 2016), there is now an increasing requirement for maternity centres to offer a range of contraceptive services. Although both contraceptive and maternity care is 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) includes one of the largest maternity services in Scotland comprising two maternity hospitals and approximately 9000 annual births. It has also piloted a number of recent initiatives to improve access to postpartum contraception in recent years. This includes the introduction of routine antenatal contraceptive counselling (Cameron *et al.*, 2017)and the successful provision of IUC insertion at planned caesarean delivery (Heller, Johnstone and Cameron, 2017). However, most women have a vaginal birth and those intending to use IUC postpartum are still required to attend their GP or local sexual clinic several weeks after childbirth. Local data suggests that less than 50% of women attend for interval IUC insertion, even when provided with an appointment (Cameron *et al.*, 2017).

Current clinical guidelines from the UK, US and World Health Organisation all support immediate PPIUC insertion (World Health Organization, 2015; American College of Obstetricians and Gynecologists (ACOG), 2016; Faculty of Sexual & Reproductive Healthcare, 2017). This can be performed in the 10 minutes following placental delivery (post-placental insertion) and up to 48 hours after vaginal birth (Faculty of Sexual & Reproductive Healthcare, 2016). Whilst there is good evidence to support the safety of PPIUC (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015), until recently much of the clinical experience originated from low-and-middle-income settings.

Although some high-income settings such as the US 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 presents challenges.

Therefore, 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 six-weeks' postpartum, and method continuation up to 12 months. Based on previous studies we anticipated a higher expulsion rate with vaginal PPIUC insertion (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015)and therefore 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.

3.4.2 Methods

3.4.2.1 Study setting and population

The study was conducted across two NHS Lothian maternity services comprising St Johns Hospital (Hospital A; smaller regional centre) and Royal Infirmary of Edinburgh (Hospital B; large tertiary centre). PPIUC insertion at elective caesarean birth had been available to women in both hospital sites since 2015.

The vaginal PPIUC service was intentionally introduced in a phased manner, initially to Hospital A in January 2017 and nine months later to Hospital B in October 2017. The recruitment period for both hospitals continued until June 2019.

Any pregnant woman anticipating a vaginal birth in the region, interested in using IUC for postpartum contraception and without a contraindication to the method was eligible to participate. Contraindications to IUC were as defined in the 2016 UK Medical Eligibility Criteria for Contraceptive Use (Faculty of Sexual & Reproductive Healthcare, 2016) including: pelvic infection, abnormal uterine anatomy and, specific to hormonal IUC, previous or current history of breast cancer. There are also additional intrapartum conditions which may preclude the insertion of IUC in the immediate postpartum period which will be discussed later [**Section 3.3.2.4**].

Information about PPIUC and the study was provided by community midwives to all pregnant women during their routine 20-week antenatal visit. This visit is when contraception counselling is routinely offered to pregnant women as a standard component of the Lothian antenatal care pathway. This information was provided in both verbal and written format, and additional sources of information (such as the local sexual health website[3]) were signposted.

Women who were eligible and wished to receive PPIUC were provided with an information sheet and asked to complete and sign a structured self-assessment form **[Appendix 2**]. This summarised information about the available IUC methods, insertion procedure and associated risks, and the recommended follow-up pathway including consent to further contact by clinical research staff. The choice of PPIUC method included either a 52mg levonorgestrel IUS (Mirena®, Bayer) or a 380mm2 copper IUD (UT380, Durbin), both with a maximal licensed duration of five years.

A woman's PPIUC intention and chosen method were recorded in the electronic maternity record, and a designated sticky label applied to their handheld case-notes to assist in identifying them as a study participant on their admission to the birth unit[4].

[3] Available at https://www.lothiansexualhealth.scot

[4] Unless otherwise stated 'birth unit' is a holistic term used to describe both obstetric-led labour wards (n=2) and midwife-led birth centres (n=1) in the region

3.4.2.2 Staff training and education

Prior to service introduction, all obstetric doctors and a cohort of birth unit midwives were newly trained in vaginal PPIUC insertion using 33cm Kelly forceps (Roberts Surgical, UK). The literature describes a number of specific techniques to achieve PPIUC insertion including manual, ring forceps and standard plastic inserters. The use of Kelly forceps is described in detail in educational resources developed by the RCOG (Royal College of Obstetricians & Gynaecologists, 2015) and thus we chose to adopt this approach as described here. 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 then removed from its pre-packaged inserter, loaded onto the Kellys forceps and advanced into the uterine cavity. After the forceps have reached the fundus (confirmed by external palpation of the uterus with the non-dominant hand), the device is released from the forceps which are then slowly removed, and the device threads trimmed flush with the cervix. The justification for this was based on opinions of experts that leaving the threads long may predispose to expulsion due to the expected elongation of the threads during subsequent uterine involution.

Training workshops in vaginal PPIUC insertion were facilitated by clinical research staff and consisted of education about the risks and benefits of PPIUC, watching a video of the insertion technique (provided by the RCOG) and practical simulation using a postpartum uterus model (Mama-U®, Norway). Both one-to-one and small group workshops were conducted regularly throughout the study period to maximise the number of staff able to attend. Following attendance at a workshop, staff were asked to maintain a logbook of insertion procedures and expected to perform a minimum of three competent procedures under supervision prior to independent practice.

In the initial stages, both insertion and supervision were provided by clinical research team members (myself as research doctor and two trained research midwives) who were available on a 24/7 basis to facilitate PPIUC insertion. As the number of trained

inserters increased, a 'train-the-trainers' model was used to increase the pool of available supervisors. Further detailed information about the training programme is provided in Chapter 4.

In addition to training for hospital staff involved directly in insertion and supervision, educational sessions were also provided for community healthcare staff. In the UK, community midwives are the main providers of routine antenatal care and in Lothian, are the main direct source of information about contraception during pregnancy. There are ten community midwifery 'teams' covering designated geographical areas of Lothian, each consisting of between 10 and 20 midwives. Each team was visited separately by the research team and provided with information about PPIUC and the study, to enable them to counsel women about this option during their routine antenatal discussion. Additional information sessions were also held for local GPs and family nurses (responsible for young mothers under 18 years during their pregnancy and for the two years following). These sessions also included dissemination of patient resources and visual aids to support PPIUC counselling.

3.4.2.3 Insertion procedure

Women requesting PPIUC received routine antenatal and intrapartum care. Following delivery, a trained PPIUC inserter (and supervisor if required) was contacted. A second eligibility assessment was made by attending staff to identify any intrapartum exclusions to PPIUC insertion. Exclusion criteria at this stage included: 1) prolonged rupture of membranes (locally agreed as exceeding 36 hours); 2) clinical suspicion or treatment of chorioamnionitis; 3) unresolved postpartum haemorrhage (defined as blood loss greater than 1000ml). These are similar to those advised by the RCOG (Royal College of Obstetricians & Gynaecologists, 2015).

PPIUC insertion was performed in the birth unit or a designated area of the postnatal ward (if the woman had already left the birth unit at the time of insertion) anytime

within the first 48 hours after delivery. Timing of insertion depended on availability of trained staff; concomitant clinical workload; and the clinical needs and preference of the woman. This was felt to reflect a 'normal' clinical environment for a maternity centre offering PPIUC.

Insertion was performed using the technique described in section above. An ultrasound scan was not routinely performed during or immediately after insertion. All PPIUC insertion attempts were recorded by maternity staff in a designated logbook (located in birth units) and in the woman's electronic record. Information collected here included the date and time of insertion, the type of device inserted; and any immediate complications encountered. This included situations where PPIUC could not be inserted and the reason. Following insertion, women were provided with standardised written and verbal advice [**Appendix 2**]. This included information about how to recognise possible signs of expulsion and infection, what to do in the event of 'long threads' and contact information for research staff. Women were advised to avoid otherwise unprotected intercourse until they attended for a follow-up visit with the research team between four and six weeks' postpartum.

3.4.2.4 Data collection

Details of PPIUC procedures were collected from the insertion logs (date, time, location, inserting staff member). Additional information regarding the mode of delivery, analgesia and infant feeding method was obtained from maternity records along with relevant participant demographics (age, parity, postcode). All women who received PPIUC were contacted by research staff within the first postpartum week and provided with a follow-up appointment at six weeks' postpartum.

All follow-up assessments were performed by a single research doctor (myself) with the assistance of a research nurse or midwife. All follow-up visits were conducted in a clinic setting at either a central or peripheral site to facilitate women attending from

across the Lothian area. Women were asked to complete a structured survey about relevant symptoms (pain, bleeding, thread problems), infant feeding status, resumption of sexual activity and factors relating to their PPIUC experience and satisfaction (including main source of information, perceived coercion and if they would recommend PPIUC). They also underwent a clinical assessment which consisted of a speculum examination to visual and trim threads (if required), and a transvaginal pelvic ultrasound scan to determine IUC location.

The clinical outcomes of interest (infection, expulsion and uterine perforation) were determined at initial follow-up. A complete expulsion was defined as a device that had been fully expelled from the uterine cavity prior to the initial follow-up i.e. self-reported by the patient. A 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 the initial follow-up. Partially expelled devices were removed. Where no device was seen on ultrasound, an abdominal/pelvic x-ray was arranged to exclude uterine perforation. An infective complication was recorded if there was either a self-reported or documented history of receiving antibiotics (and/or device removal) for suspected intrauterine or pelvic infection at or before the initial follow-up. Women were offered reinsertion of IUC following expulsion or removal of their initial PPIUC. Where immediate reinsertion was not possible, for example due to recent unprotected sex, women were offered a further appointment and an alternative interim method.

Women were contacted again by research staff at three, six and 12 months after the initial PPIUC insertion and completed a short telephone-based survey. Data collected included self-reported complications (expulsion, removal, infection) and continued use of IUC.

3.4.2.5 Data analysis and statistics

As the aim of the study was to determine PPIUC uptake under 'normal' conditions, a convenience sample was chosen with no minimum sample size. The characteristics of the women who received PPIUC 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, insertion procedure and device type. Time to expulsion was based on the date the expulsion was first recognised (either self-reported by the woman or for partial expulsions, the date of the initial follow-up). Where the time to expulsion was unknown (complete expulsions 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.

Secondary data analysis included calculating hazard ratios of expulsion for a predefined list of patient and insertion-related variables. As any individual clinician may perform multiple insertion procedures, 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. Data analyses was performed in conjunction with a biomedical statistician and all calculations were achieved using Stata 15.1 (StataCorp).

3.4.2.6 Ethical approval

Study approval was sought from the South-East Scotland Research Ethics Service. They provided written confirmation in December 2017 that the clinical study met the

criteria for 'health services research' and as such full NHS ethical review was not required. NHS Lothian management and quality improvement team approvals were granted for all parts of the study.

3.4.3 Results

3.4.3.1 Uptake and insertion procedure

During the recruitment periods (Hospital A: 31st January 2017 to 31st May 2019; Hospital B: 1st October 2017 to 31st May 2019), 465 women requested PPIUC and were eligible at the time of delivery [**Figure 3-2**]. 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=10119). Of these 465, a total of 447 insertion procedures were completed successfully (96.1%) [**Table 3-1**].

The mean age of participants was 30 years (range 16 to 44) and most (73%) opted for the LNG-IUS (73%). The mean delivery-to-insertion interval was 6.6 hours (range 0 to 47); 28.2% (n=126) of insertions were performed within the first hour, increasing to 77.0% (n=342) within six 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 birth unit.

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

3.4.3.2 Complications, expulsion and satisfaction

Initial follow-up information was available for 379 women (84.8%) **[Table 3-2]**. Three women (0.8%) 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. Prior to the initial follow-up, 113 women (29.8%) spontaneously expelled their device. Of these expulsions, most were identified by the woman (70%; n=79), while the remainder (30%; 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 cervix. All partially expelled devices were removed. One other removal was performed at patient request. All removal procedures were performed easily within the 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.

Figure 3-2: 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

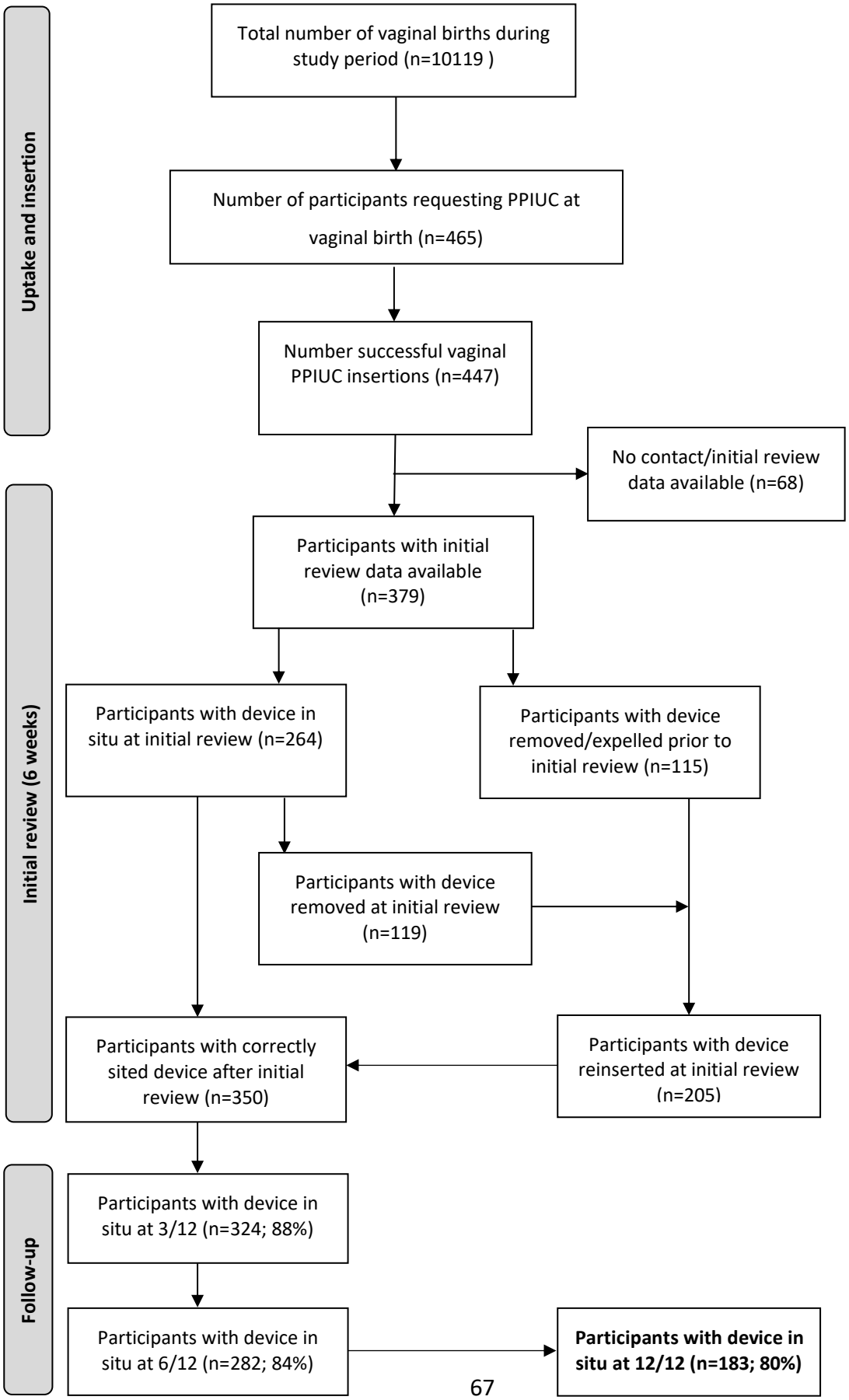


Table 3-1: Characteristics of women enrolled who had IUC successfully inserted and who have initial review data available (n=379)

Characteristic		**Number of insertions (%)**
Hospital	A	171 (45)
	B	208 (55)
Staff inserting	Doctor	139 (37)
	Midwife	240 (63)
Supervised	No	245(65)
	Yes	134 (35)
Number of previous insertions 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 or more	46 (12)
Age of woman	16 to 19	14 (4)
	20 to 24	60 (16)
	25 to 29	89 (23)
	30 to 34	118 (31)
	35 to 39	81 (21)
	40 or older	17 (4)
SIMD	1	73 (19)
	2	95 (25)
	3	79 (21)
	4	75 (20)
	5	57 (15)
Body Mass Index[a]	< 18 (underweight)	5 (1)
	18 to 24 (normal)	172 (46)
	25 to 29 (overweight)	106 (28)
	30 or more (obese)	93 (25)
Woman previously used IUC	No	295 (78)
	Yes	84 (22)

Number of previous births	0	108 (29)
	1	149 (39)
	2	122 (32)
Mode of delivery	OVD	41 (11)
	SVD	338 (89)
Analgesia used during delivery	Non-regional	320 (84)
	Regional	59 (16)
Type of IUC device inserted	Copper	101 (27)
	LNG-IUS	278 (73)
Number of hours after delivery 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)
Infant feeding mode reported at initial review	Bottle	178 (47)
	Breast	167 (44)
	Mixed	34 (9)

[a] 3 women with missing data

SIMD, Scottish Index of Multiple Deprivation; IUC, intrauterine contraception; OVD, operative vaginal delivery; SVD, spontaneous vaginal delivery; LNG-IUS, levonorgestrel intrauterine system;

Table 3-2: Summary of recorded complications and outcomes of postpartum intrauterine contraception insertion in those with initial follow-up data available (n=379)

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

IUC, intrauterine contraception

In multivariate survival models, the rate of expulsion was associated with type of staff inserting, analgesia during delivery and previous IUC use **[Table 3-3]**. Higher rates of expulsion were observed for insertions by midwives (versus doctors) and for non-regional anaesthesia ($p<0.05$). Parity did not appear to affect the expulsion rate.

Table 3-3: 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 expulsion only**	
Characteristic	Adjusted hazard ratio (95% CI)	P value	Adjusted hazard ratio (95% CI)	P value
Staff inserting		0.045		0.056
Doctor	1 (reference)		1 (reference)	
Midwife	1.46 (1.01, 2.12)		1.84 (0.99, 3.42)	
Supervised		0.77		0.159
No	1 (reference)		1 (reference)	
Yes	1.07 (0.7, 1.63)		1.64 (0.82, 3.25O	
Number of previous insertions by clinician		0.78		0.29
1 versus 0	1.05 (0.91, 1.22)		1.19 (0.91, 1.57)	
2 versus 1	1.05 (0.91, 1.20)		1.18 (0.91, 1.52)	
3 versus 2	1.04 (0.93, 1.16)		1.15 (0.93, 1.42)	
4 versus 3	1.03 (0.95, 1.11)		1.11 (0.95, 1.30)	
5 versus 4	1.01 (0.96, 1.07)		1.08 (0.97, 1.19)	
7 versus 6	1.00 (0.97, 1.03)		1.03 (0.99, 1.07)	
10 versus 9	0.99 (0.94, 1.03)		1.00 (0.94, 1.05)	
Age of woman		0.093		0.82
25 versus 20	0.88 (0.66, 1.17)		1.04 (0.67, 1.60)	
30 versus 20	0.86 (0.53, 1.40)		1.09 (0.53, 2.24)	
35 versus 20	1.04 (0.60, 1.80)		1.19 (0.56, 2.55)	
40 versus 20	1.39 (0.73, 2.65)		1.33 (0.54, 3.31)	
Body Mass Index		0.50		0.31
25 versus 20	1.10 (0.87, 1.39)		1.21 (0.86, 1.68)	
30 versus 25	1.07 (0.95, 1.21)		1.15 (0.96, 1.38)	
Woman has previously used IUC		0.28		0.034
No	1 (reference)		1 (reference)	
Yes	0.82 (0.57, 1.18)		0.57 (0.34, 0.96)	
Number of previous births		0.18		0.55
0	1 (reference)		1 (reference)	
1	0.94 (0.65, 1.36)		1.18 (0.64, 2.16)	
2 or more	0.68 (0.42, 1.1)		0.91 (0.48, 1.76)	

Mode of delivery		0.50		0.62
OVD	1 (reference)		1 (reference)	
SVD	1.21 (0.69, 2.12)		1.25 (0.52, 2.98)	
Analgesia during birth		0.033		0.034
Non-regional	1 (reference)		1 (reference)	
Regional	0.61 (0.38, 0.96)		0.43 (0.2, 0.94)	
Type of IUC inserted		0.13		0.99
Copper	1 (reference)		1 (reference)	
LNG-IUS	0.83 (0.64, 1.06)		1.00 (0.66, 1.52)	
Number of hours after delivery IUC inserted		0.19		0.30
6 versus 1	0.93 (0.64, 1.34)		1.02 (0.61, 1.68)	
12 versus 1	0.85 (0.49, 1.46)		0.96 (0.45, 2.05)	
24 versus 1	0.70 (0.42, 1.18)		0.77 (0.38, 1.56)	
48 versus 1	0.58 (0.32, 1.05)		0.59 (0.28, 1.27)	
Infant feeding mode reported at initial review		0.83		0.73
Bottle	1 (reference)		1 (reference)	
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)	

[a]3 out of 379 women had BMI missing and were not included in the above analysis

IUC, intrauterine contraception; OVD, operative vaginal delivery; SVD, spontaneous vaginal delivery; LNG-IUS, levonorgestrel intrauterine system;

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 3-4** summarises 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 a later time-point, method continuation and pregnancy status were recorded [**Figure 3-2**].

Table 3-4: 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 one week before delivery	9 (2.6)
During labour	0 (0)
Postnatal period (up to 48 hours)	29 (8.4)
Not recorded	5 (1.4)
Main source of information about PPIUC	
Community midwife	232 (67.0)
Antenatal clinic	28 (8.1)
Labour 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)
Perceived pressure or coercion towards PPIUC	
No	345 (99.7)
Yes	0 (0)
Unsure	1 (0.3)
Would recommend PPIUC to friend/family	
No	0 (0)
Yes	340 (98)
Unsure	6 (2)

[a]33 women with missing data at initial follow-up

3.4.3.3 Method 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.

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 an alternative method)

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

3.4.4 Discussion

This study demonstrates that routine vaginal PPIUC is feasible to provide in a publicly-funded maternity setting. Almost 1 in 20 women having a vaginal birth chose PPIUC, comprising women of all ages and socioeconomic backgrounds, most of whom had not used IUC before. Most PPIUC insertions were successful despite relatively low rates of regional anaesthesia, and women were satisfied with their experience. Our separate qualitative paper reports further on the high acceptability of PPIUC in this cohort (Boydell *et al.*, 2020).

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 providers, 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 low rate of participant loss.

There was a very low incidence of insertion-related complications in line with existing evidence (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). Infective complications were rare and there were no cases of uterine perforation. The overall expulsion rate observed was higher than generally reported elsewhere, although rates in the literature do vary considerably for vaginal PPIUC insertion (0-50%) (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). Direct comparisons are also difficult due to variability in

insertion techniques, follow-up and definitions of expulsion between studies. Recently published findings from a large-scale PPIUC initiative across six low and middle-income countries reported combined expulsion rates of under 4% (similar to standard IUC insertion) (Makins et al., 2018). 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 for insertion procedures performed by midwives compared to doctors. This 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 (Thiery, Van Kets and Van Der Pas, 1985). We did not observe a reduction in the expulsion rate with increasing number of insertions, perhaps due to the relatively small number of overall procedures performed by any individual. Furthermore, 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 to low and middle-income 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 (Thapa *et al.*, 2018).

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 some studies compared to early postpartum insertion (Sonalkar and Kapp, 2015). This could not be evaluated here as none of our insertions were truly 'post-placental' and only a small proportion (28%) were performed within the first hour after birth. Again, this likely reflects some of the early challenges of service introduction, including timely access to a trained inserter and supervisor.

While we did observe a reduction in the delivery-to-insertion interval as the study progressed, further improvement is needed as earlier post-partum 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 LNG-IUS compared to the CU-IUD (Turok *et al.*, 2017; Averbach *et al.*, 2020). Most women in our study received the LNG-IUS 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. Thus, 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, while 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 (Goldthwaite *et al.*, 2017). Within routine service provision, access to ultrasound is likely to be more limited unless indicated on clinical grounds e.g. non-visible threads. While some studies have included the use of immediate post-insertion ultrasound, this has not been shown to reduce subsequent expulsion (Goldthwaite 2017) and could be a barrier to providing this service.

Several lessons can be learned from this translational study. The importance of a follow-up visit is strengthened given the small number of observed pregnancies in those who did not attend, and the small number of women who did not recognise their device had expelled and could have been at-risk of pregnancy. 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 determine accurate estimates of risk. Whilst the possibility of expulsion is an important counselling 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 free-of-charge, the initial costs of PPIUC and possible re-insertion may limit the uptake and acceptability.

We have modified our service in light of the high expulsion risk including individualised performance 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 widely in use. In a recently conducted randomised-controlled trial by Blumenthal et al (Blumenthal *et al.*, 2018), the dedicated postpartum inserter was favoured 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 suggests that PPIUC addresses a key gap in provision (Ogburn, Espey and Stonehocker, 2005; Cameron *et al.*, 2017). This high continuation rate was maintained at 12 months after PPIUC, with almost 4 out of 5 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 pregnancy. Although there is 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 (Washington *et al.*, 2015). Therefore, the benefits of PPIUC are likely to persist, particularly in settings with low attendance rates for interval IUC insertion.

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 counselling, availability of appropriately trained providers and a robust follow-up pathway that includes access to ultrasound and the option for IUC 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.

~ End of published paper ~

3.5 Conclusions

The methodological approach used here allowed us to adequately achieve our study aims. As anticipated, evaluating PPIUC provision under 'normal' clinical conditions revealed challenges which may not have been evident in the more controlled environment of an RCT. Many of these challenges related to the training of maternity staff and the study findings highlighted the integral role of training in the optimal provision of PPIUC to minimise complications and increase efficacy of the intervention.

Although a brief summary of our approach to training maternity staff in PPIUC insertion was included in this paper, I will explore this in greater detail in the next chapter. This will include discussion of the broader aspects of training design and delivery, as well as how the training programme was formally evaluated.

Chapter 4 Developing and evaluating a simulation-based training programme in vaginal PPIUC insertion

4.1 Introduction

In the preceding chapters, I explained that vaginal PPIUC provision is not widely available in the UK and the technique used to achieve insertion at this time is one which most clinicians here are unfamiliar. This in itself may be a barrier to the option of PPIUC becoming more widely available and indicates a need for further training and education. Furthermore, evidence suggests that the insertion technique (and hence operator skill) may be linked to greater retention of the device, and therefore has a direct impact on the efficacy of PPIUC. As such, appropriate training of providers is integral to the success of this intervention.

In this chapter I will describe our approach to training both midwives and obstetricians across Lothian maternity services in vaginal PPIUC insertion. This will include a discussion of how the training programme was designed, delivered and evaluated.

4.2 Background literature

A previous survey of US midwives and obstetricians found that while support for PPIUC provision was high, experience and knowledge within this group was relatively low (Holland *et al.*, 2015). In a similar study of IUC providers in California, several misconceptions were noted about the timing of provision, with only 43% of clinicians agreeing that IUC could be performed at the time of delivery despite national guidelines at the time supporting this (Biggs *et al.*, 2014).

Lack of provider experience has been frequently acknowledged as a possible barrier to the provision of PPIUC (Goldthwaite *et al.*, 2018). At the time of commencing this research, there were no similar studies of UK maternity providers available. However, PPIUC was only offered as a limited service in a few centres and was not available anywhere to women immediately after vaginal birth. One of the explanations for this is a lack of provider experience with the technique itself, as it differs considerably from IUC insertion in the non-postpartum setting.

As discussed in Chapter 2, different techniques can be used to achieve vaginal IUC insertion in the postpartum uterus (manual, instrument or inserter) however the general approach itself is similar and has been described in detail in the literature (O'Hanley and Huber, 1992). The goal is to achieve fundal placement of IUC through the dilated cervix while correcting the uterocervical angle and removing the insertion tool without dislodging the device. While this technique has been used to insert PPIUC in a number of early clinical studies, the wider approach to provider training was rarely described in detail and many of these studies have trained only a small number of providers.

Over the past 20 years, numerous large-scale national PPIUC programs have been developed to increase the availability of effective contraception in LMIC settings in Africa, Asia and the Middle East. As such an increasing collection of generic and country-specific toolkits and resources have been developed to assist programme developers, trainers and providers. More recently in 2015, the RCOG produced its own training package in postpartum family planning to support the 'Leading Safe Choices' initiative. This was specifically aimed at addressing the unmet need for contraception in South Africa and Tanzania through upskilling of the current healthcare workforce, including practical training in PPIUC insertion.

Although there are regional differences in how each of these training programmes were delivered, the training itself was fairly consistent. With regards PPIUC, the training extended beyond just the insertion technique itself to include the underlying theory, and information about risks and benefits of the procedure to aid the

counselling process. As part of the drive to increase the number of trained providers in these countries and rapidly 'scale-up' PPIUC programmes, the need for an inexpensive, portable and realistic simulation aid was identified and a postpartum uterus model was developed in conjunction with Laerdal® to support this training (Jhpiego, 2012) **[Figure 4-1]**.

Figure 4-1: "Mama-U" postpartum uterus trainer (reproduced courtesy of Laerdal, Norway)

Simulation-based training is widely used in medical education and can enhance learning beyond traditional didactic techniques. It is underpinned by the educational theory of 'constructivism', whereby the learner plays an 'active' role in the learning event aided by the teacher (Piaget, 1971); and furthermore when delivered in a small-group environment, the concept of 'social constructivism' encourages additional educational gain through collaboration with others (Vygotsky, 1978).

There are several examples of multi-professional training in healthcare which utilise model simulation and small-group learning. Within maternity care, the annual mandatory course 'Practical Obstetric Multi-Professional Training (PROMPT)' in UK,

has been nationally implemented and is now delivered locally in maternity units to practise emergency skills (Crofts *et al.*, 2012). Incorporating simulation into a training programme allows participants to practice and modify techniques in a 'no risk' environment. When simulation-based training in PPIUC insertion is combined with additional theory, it has been shown to lead to an increase in both the skill and knowledge of providers. In a study of 84 midwives and obstetrics doctors in one US centre, both objectively assessed knowledge and self-reported 'comfort' with the insertion technique increased immediately after attending a training workshop (Goldthwaite *et al.*, 2016). This increase was also found to be maintained six months later. However, the literature evaluating these training methods specific to PPIUC is limited.

Given the integral nature and importance of training in establishing a new PPIUC service, it was our aim to describe in detail our approach to PPIUC training within our setting and to evaluate the training programme using a number of different methods. As our intention was to ultimately introduce vaginal PPIUC insertion within a large publicly funded maternity service, there was a need to training a significant proportion of the workforce and therefore a consistent and replicable approach to training was required. As discussed in Chapter 1, for LARC provision within maternity to be successful, trained providers need to be present in sufficient number to ensure unrestricted access. As most direct care during labour and delivery is provided by midwives in the UK, we also wanted to determine if it was feasible to train both midwives and obstetricians to perform this procedure, and to formally evaluate their experience and performance using educational principles.

4.3 Justification for methodology

The resources produced by the RCOG as part of Leading Safe Choices programme formed the basis for designing our local training package (Royal College of Obstetricians & Gynaecologists, 2015). These were selected for a number of reasons. The resources were published shortly before commencing this research and had been developed through expert groups informed by the most up to date evidence. Members of our project steering group had been involved in the development of many of these resources and had first-hand experience of their successful use in LMIC settings. In addition, as the RCOG holds a highly respected role amongst our intended audience of midwives and obstetricians in the UK, we felt this would aid acceptance in learning the new and unfamiliar skill.

The RCOG approach included a programme of theoretical knowledge, model simulation and workplace-based training (Royal College of Obstetricians & Gynaecologists, 2015). As this approach had also been used successfully elsewhere and was supported by evidence, we chose to align our training package with these resources. This would include the use of Kellys forceps as the sole means to achieving vaginal PPIUC insertion. As the training programme formed part of a wider clinical study, we did not want to introduce multiple different insertion techniques which could potentially affect the measured outcomes. Additionally, the use of one method allowed for a consistent approach to the training itself. It was recognised that some adaptations would be required to the available RCOG resources to enhance their suitability for our UK setting however, a similar over-arching structure of theory, model simulation and workplace supervision was proposed.

Our methodological approach to training will be described in detail and framed around three main phases: development, delivery and evaluation. The first stage describes the preparatory phase of how the training package and resources were developed. The second describes how the training was executed in both the pre-clinical and clinical environments. The final phase describes how the training

programme was evaluated. The aim of the evaluation was firstly to determine if it achieved the desired objectives, but secondly to collect data to inform further training and service delivery both locally and elsewhere. Our approach to evaluation was framed around Kirkpatrick's 'Four Levels of Training Evaluation'. This is the mostly widely used training evaluation model in the world and uses objective measures to assess the effectiveness of a training programme (Kirkpatrick and Kirkpatrick, 1993). **Table 4-1** demonstrates how the methods we used for evaluating PPIUC training map to each of the stages.

This approach involved mainly objective measurements of experience and performance. The advantage of using this approach is that it would allow for rapid data collection and comparison of results over time. However, the participant survey was designed using a mixed methods approach to gain further detail about learner experience, unachievable through quantitative methods alone.

In order to gain a more comprehensive understanding of staff experience, qualitative research methodology should ideally be used. This would also provide deeper understanding of the barriers and facilitators involved in the training process. As part of the wider research study, qualitative interviews and focus group discussions were conducted with maternity staff about their experience of PPIUC training and service provision. As I was not directly involved in this part of the study, the results are not included here but have been published elsewhere (Boydell et al, 2020).

Table 4-1: Summary of Kirkpatrick's training evaluation model - adapted from (Kirkpatrick and Kirkpatrick, 1993)

Level	Stage	Outcome measure	Tools used in training
1	Reaction	How learners feel about training event	Participant survey
2	Learning	How improvement of skills or knowledge is demonstrated	Observed performance on training model Multiple choice knowledge test
3	Behaviour	How learning is applied in the workplace	Observed performance in clinical setting
4	Results	Measurement of clinical or patient-related outcomes following event	Number of PPIUC insertions performed successfully

4.4 Methods

The methodological approach to training is framed under three key headings: development, delivery and evaluation; which are described in turn.

4.4.1 Development

Permission was obtained from the RCOG to adapt their PPIUC resources from the Leading Safe Choices programme for local use as part of the study. These resources were reviewed by the multi-professional project steering group to identify and reach a consensus agreement on any local modifications required. This primarily related to the minimum number of 'supervised' insertion procedures a trainee would be required to perform on a model and/or patient before allowing independent practice. The RCOG manual recommends that trainees perform five insertions on the simulator

and another five for patients under direct supervision (Royal College of Obstetricians & Gynaecologists, 2015). From a logistical perspective, due to the expected lower uptake of PPIUC among our population; the required number of trained individuals necessary for Lothian-wide provision; and the limited number of 'trainers' available at the outset; it was agreed that on balance that this number was unlikely to be achievable in the time frame. As such local agreement for three insertions each on both the model and under direct supervision was reached.

The proposed structure of the training programme consisted of background theoretical knowledge, model simulation training and a period of direct clinical supervision. While the focus of the training would be on gaining practical skills in PPIUC insertion, it was acknowledged that as this was an unfamiliar procedure in the UK, additional context and background information would be required in the theoretical component. In addition to gaining practical skills in PPIUC insertion, those performing the insertion procedure would also be required to obtain informed consent and participate in service delivery, so these were also important aspects to include in the training.

The aim was to provide this training in a small group 'workshop' format, with repeated workshops delivered over the duration of the study to gradually increase the numbers of trained providers, while ensuring adequate insertion opportunities to achieve and develop skills. Workshops were delivered by the clinical research staff involved in the study and each session was jointly facilitated by an obstetric doctor (myself) and a research midwife. Each training session was expected to last for around two hours depending on the number of participants involved. Both midwives and obstetricians were invited to attend workshops at their convenience.

During the development phase, a number of resources were created to support both the training and service delivery. The aim was to distribute these to staff during the training workshops. They were also made available on the local staff intranet and within clinical areas for further reference. Workshop participants received an

individual 'training pack' to allow familiarisation with the resources and to support their ongoing training **[Table 4-2**].

Table 4-2: Contents of PPIUC 'training packs' (included as Appendix 1)

Counselling checklist
Memory aid "It's SIMPLE" poster (*S=suitability, I=informed consent, M=materials, P=person to fit, L=leaflet, E=entry record*)
Pre- and post-insertion patient information leaflets
Standard Operating Procedure
Training logbook (including insertion guidance)

A supply of the Laerdal® postpartum uterus models and the instruments required for insertion were obtained. The model was identical to that used in the training video and the instruments were the same as those available in workplace settings. We felt this was important to maximise the educational benefit of the simulation training, and to ease the transfer of learned skills into clinical practice. Additional models were given to each of the PPIUC trainers and left in communal non-clinical areas of the birth units to allow staff to further practise the skill in their own time.

The plan was for the training programme (and the service itself) to be rolled out in a phased manner across each hospital site. At the primary site, the initial focus was on training medical staff followed by midwives. However, before progressing to the second hospital site, it was observed that a significant number of the insertion procedures were being performed by midwives. As such we altered our approach and opted subsequently to train both doctors and midwives simultaneously.

In response to the different training needs of providers, we also had to tailor our training approach to each staff group. As the study progressed, we observed that medical staff often found it difficult to attend the full training workshops due to clinical commitments and work patterns. Therefore, alongside the more formal

training workshops which continued for midwives, we offered a more flexible approach for medical staff, including a mix of 'drop in' sessions and targeted individual training. While often shorter in duration, the main elements of these training encounters were the same.

4.4.2 Delivery

4.4.2.1 Training workshops

Formal training workshops were delivered to small groups of around 6-10 participants. These were hosted in non-clinical areas at each hospital and repeated regularly during the study period. Attendees were asked to sign up in advance and there was no requisite fee for participants. Each session was jointly facilitated by at least two members of the clinical research team, including both an obstetric doctor and midwife. These were the same research team members who would later provide the on-site supervision. The overall structure and content of each workshop is summarised in **Table 4-3**. Breaks and refreshments were provided during each session.

The first half of each workshop focused on the background theory to help contextualise the role and need for PPIUC provision. This was delivered as an informal didactic session assisted by Microsoft Powerpoint® presentation software and included: evidence relating to short inter-pregnancy intervals and unintended pregnancy; the role of postpartum contraception; contraceptive method eligibility for postpartum and breastfeeding women; and the timing and role of LARC. Local data were incorporated where possible. This included results of local surveys of postpartum women about their contraceptive intentions (Heller *et al.*, 2016) and outcomes of the intra-caesarean PPIUC service which was already well-established in the region (Heller, Johnstone and Cameron, 2017). This was followed by a summary of the guidance relating to IUC insertion after vaginal birth including the benefits,

risks and international experience to date. The aim was to provide staff with adequate evidence-based information so that they would feel equipped to counsel women effectively about the procedure and obtain informed consent.

Table 4-3: Overall content and structure of vaginal PPIUC training workshops

Introductions
Session outline and learning objectives
Background and general contraceptive methods
Overview of PPIUC
Video of vaginal PPIUC insertion technique (courtesy of RCOG)
Refreshment break
Simulation-based model training
Completion of knowledge assessment
Summary of local clinical pathways and training arrangements
Completion of survey and group reflection exercise
Close of session

PPIUC = postpartum intrauterine contraception; RCOG = Royal College of Obstetricians and Gynaecologists

The second half of the workshop focussed on the practical aspects of vaginal PPIUC insertion. This began with an overview of the local training package before participants watched an eight-minute video of the insertion technique (provided courtesy of RCOG). This was followed by a further 'live' demonstration on the model by one of the facilitators. Attendees were then divided into smaller groups of two or three participants, and each group was provided with the necessary equipment to practise the insertion technique for themselves **[Table 4-4]**. Facilitators moved around each group to provide informal feedback and support as required. A minimum of three competent insertion procedures was expected to be performed by each

participant by the end of practical session, under the direct observation of a facilitator.

On completion of the simulation training, participants were asked to complete short, mandatory written assessment of their knowledge. This included eight questions in a single best answer format covering key aspects of the background theory of postpartum contraception and PPIUC [**Appendix 2**]. A minimum pass mark of 80% was required. Answers were reviewed immediately by one of the facilitators during the closing session to enable rapid feedback of the results.

Table 4-4: Equipment required for PPIUC model simulation training

Postpartum uterus model (Laerdal®)
Sims speculum
Kellys long placental forceps
Rampleys sponge-holding forceps x 2
Mayo curved scissors
Training IUD
Gauze swabs
Light source (head torch)
Step-by-step picture reference guide

PPIUC = postpartum intrauterine contraception; IUD = intrauterine device

The closing session consisted of a large group lecture detailing key components of the proposed local PPIUC clinical pathway (antenatal, intrapartum and postnatal) and the next stages of training. This covered logistical aspects of service delivery such as documentation, location of equipment, arrangements for clinical supervision and post-insertion processes. Participants were then invited to complete an evaluation

survey. The close of the session revisited the initial learning objectives and allowed time for group refection on the learning experience.

Over the study period, we introduced modifications to our training approach in light of feedback and direct observations. In addition to the alternative options for medical staff, this also included providing 'refresher' model training on request to those who had experienced a delay between attending a workshop and performing their initial insertion.

4.4.2.2 Workplace-based training

Staff who had successfully completed the training workshop were eligible to enter the next phase of training, which provided the opportunity to perform the procedure under direct supervision in their own clinical environment.

After a woman requesting vaginal PPIUC insertion had given birth, on-site maternity staff were asked to confirm eligibility and consent. In some instances, women had already been counselled for the procedure during the antenatal period and a completed consent checklist was available in the maternity record. Staff then contacted a PPIUC 'trainer' to attend from an available (and regularly updated) list and obtained the necessary insertion equipment. Trainers were contactable on a 24/7 basis. Initially an 'on call' service was provided by off-site clinical research staff until an adequate number of on-site trainers were accessible to support ongoing 'in house' supervision.

The insertion procedure was then performed by the staff member under the direct supervision of the trainer. Where necessary, 'hands on' support was provided. Post-insertion ultrasound did not form a routine part of the insertion or supervision process but could be used in select cases at the discretion of attending staff. All insertion procedures were documented in the trainee logbook, including whether the attempt was successful or not. On completion of a minimum of three independently

performed and successful insertion procedures, a local certificate was issued enabling the individual to perform the procedure unsupervised. However, the option of an extended period of supervision was available to staff if they wished. Insertion procedures were also documented in the study procedure log, including the name and designation of the inserting staff (and attending trainer).

4.4.2.3 "Train the trainers"

After completing the insertion training package, staff members were encouraged to undertake additional training to become a 'trainer'. This role was primarily aimed at senior medical (consultants, senior trainees) and midwifery staff (Band 6 or above) who had previous experience of clinical supervision. Requirements to become a trainer included: completion of the PPIUC insertion package; a minimum of five successful insertion procedures; evidence of ongoing continuing professional development relating to PPIUC and at least one observed PPIUC insertion in a supervisory role (where a current trainer would observe the individual supervising another learner). Potential trainers were also invited to attend and participate in a training workshop as a facilitator.

Trainers were contacted in the same way to provide this 'train the trainers' role as for directly supervised insertions, and with the express consent of the woman. A supervision logbook was maintained, and a local trainer certificate issued to the individual on completion of the required elements described above. Both the insertion training and 'train the trainers' programmes ran continuously throughout the study period to gradually increase the number of both trained inserters and on-site supervisors. The clinical research team continued to deliver all of the training workshops but over time, most of the workplace-based supervision was provided by on-site trainers.

4.4.3 Evaluation

Due to the multi-modal and complex nature of the training programme, a number of different tools were used to evaluate it. Each of these will be discussed as separate entities as they map to Kirkpatrick's model (outlined in **Table 4-1**), but in practice many of these were conducted either simultaneously or in a non-linear manner throughout the study period.

4.4.3.1 Stage 1: Learner experience

Firstly, those who attended formal training workshops were invited to complete an anonymous, paper-based questionnaire [**Appendix 1**] about their experience. This was distributed during the workshops and collected at the end. The questionnaire included a combination of fixed-response and open-ended questions covering the following areas: (1) previous experience of IUC insertion (2) perceived complexity of the technique (3) any challenges/barriers encountered (4) overall experience of training. Formal analysis of the combined results using a mixed methods approach was performed at the end of the overall training period [**Section 4.5**].

4.4.3.2 Stage 2: Improvement in skills and knowledge

During each training workshop, both practical skills and knowledge were assessed in different ways. Firstly, each participant was expected to perform at least three competent insertion procedures on the training model, under the indirect supervision of the workshop facilitator. Adequate time was provided during the workshop for this, but if it was not achieved by the end of the session, progression onto the next phase of training was not permitted and additional support was offered. Secondly, knowledge of the theoretical aspects of PPIUC was assessed

through a short informal written assessment. This comprised ten single-best answer questions covering the learning material contained in the workshop. Finally, in the questionnaire mentioned earlier, participants were asked to reflect on the skills and knowledge they had gained. Self-reflection is an important component of adult learning theory and was a useful adjunct to the more formal objective measurements of performance.

4.4.3.3 Stage 3: Application of learning

This aspect of the training evaluation related to the observed performance in the workplace setting. As discussed, the training package included a mandatory period of supervised clinical practice. This consisted of at least three competent insertions performed under the direct supervision of a locally recognised PPIUC trainer. Staff were encouraged to maintain a record of their insertion procedures and reflect on any challenges encountered. On completion of this period of supervised practice, inserting staff were deemed as able to perform the procedure independently.

4.4.3.4 Stage 4: Outcomes of learning

The direct outcome of how successful the learning event had been at organisational level was determined by the number of successful PPIUC insertion procedures performed in the clinical setting by maternity staff who had taken part in training. All PPIUC insertion attempts were recorded contemporaneously, along with the inserting staff and if applicable, the supervisor. Where an insertion attempt was unsuccessful, staff were also asked to document the reason for non-insertion, including any 'technical difficulty' encountered. Quantitative data relating to the number of training sessions delivered, number of staff trained and the number of 'trainers' developed was also collected and included in this part of the evaluation

4.5 Results

4.5.1 Learner experience survey (midwives)

All midwives who attended the training completed the survey (n=63) therefore the response rate was 100%. Participant characteristics are shown in **Table 4-5**. Most of those who attended training and completed the survey were senior grade midwives with little or no previous experience of IUC insertion, and most worked in labour ward.

Table 4-5: Demographics of midwives who completed training evaluation survey (n=63)

Characteristic (N = 63)	**N (%)**
Seniority grade of midwife	
Band 7	9 (14)
Band 6	51 (81)
Band 5	2 (3)
Other	1 (2)
Primary working environment	
Obstetric-led labour ward	43 (68)
Maternity ward (antenatal/postnatal)	16 (25)
Community/midwife-led birth unit	4 (6)
Previous IUC insertion experience (non-PPIUC)	
Yes	5 (8)
No	58 (92)

IUC = intrauterine contraception; PPIUC = postpartum intrauterine contraception

Participants were asked to rate the overall 'quality' of the training workshop and all rated this as 'excellent' (89%) or 'very good' (11%). When asked to rate the training in terms of 'difficulty', all rated it as 'about right' (95%) or 'easy' (5%). They were then asked to rate their level of satisfaction with each of the key individual components of the training workshop (theory, video, model simulation) on a five-point numbered Likert scale (1=very poor; 5 = excellent) and the mean score for each element was then calculated. All components of the training were rated highly, with the model simulation receiving the highest overall score (theory = 4.95/5; video 4.79/5; model simulation = 4.97/5)

In the free text questions of the survey, participants were first asked to detail any challenges (real or perceived) with the PPIUC training and 31 provided responses. The responses could be grouped into five main themes: technical aspects of the training; perceived difficulties in accessing clinical supervision; ensuring adequate clinical exposure; challenges relating to 'on the job' provision; and other more general aspects of training participation. Examples of free text responses as they align to each theme are shown in **Table 4-6**.

In the second free text question, participants were asked to provide any suggested improvements to the training programme. Eleven participants provided a response to this question and the main themes included: provision of protected time or payment for more staff to attend training (several reported attending in their own time due to difficulty attending while on shift). Several participants said that accessing some of the training digitally would be useful; some suggested that a 'real life' video of the insertion technique would be helpful; and one participant said they would have liked more time to be spent discussing alternative methods of contraception.

A final free text box was provided for any other comments about the training as a whole. Ten participants provided a response to this question and all of these were positive praise about the content and delivery of the training, and in particular the model simulation.

Table 4-6: Examples of free text comments from midwives about 'challenges' of PPIUC training

Technical aspects of the training
'Trying to get past the cervix with the forceps' *'Removing the Kellys forceps without removing the coil'* *'Not enough hands!'* *'Keeping the IUD at the fundus'* *'The insertion technique is quite fiddly until you get used to it'*
Accessing clinical supervision
'Probably (having) someone available to supervise me on shift' *'Finding enough trainers available in the workplace'* *'Availability of staff to supervise or support'* *'Achieving supervised insertions'*
Adequate clinical exposure
'Finding enough women to practice on fairly soon as lots of people have now done the training' *'Placing a successful coil requires practice – will be hard if you're not getting regular experience'*
Service delivery challenges
'Ensuring an appropriate area to insert with equipment available' *'Anticipate the challenge will be when labour ward is busy'* *'Getting experience and hands on when working'* *'Getting called, being available and having a bed available for insertion'*
Ability to attend training
'Having to do the course in my own time' *'Being allowed time/funding to attend the training'*

4.5.2 Learner experience survey (doctors)

Of the 52 doctors who attended PPIUC training, 29 completed the training survey (response rate 56%). This included consultants (n=9), associate specialist/staff grade doctors (n=2) and trainees (n=18). A total of 62% (n=18) reported experience of non-postpartum IUC insertion in the last 12 months.

Doctors rated the overall 'quality' of the training as 'excellent' (88%) or 'very good' (12%). They rated the complexity level as 'about right' (78%) or 'easy' (22%). As in the midwife survey, participants were asked to rate each individual component of the training (where applicable) with overall scores as follows: theory = 4.3/5; video 4.3/5; model simulation = 4.8/5).

Only five participants provided free text comments about the challenges of PPIUC training. These mainly related to equipment concerns (availability, familiarity) and competing clinical workload. Four participants provided free text comments regarding suggested improvements to training. All of these related to the training video, with two indicating preference for a 'real life' insertion.

4.5.3 Training outcome data

A total of twelve formal training workshops were delivered across both hospitals during the 18-month study period. The mean number of attendees per workshop was 7 (range 4-12). Sixty-three midwives completed the training programme and 17 (27%) went on to become trainers. Thirty-two doctors completed the training programme and 17 (53%) went on to become trainers.

A total of 447 vaginal PPIUC insertion procedures were performed during the study period across both hospital sites. Of these, 240 procedures were performed by midwives (53%) and 207 by doctors (47%). A further 18 procedures were attempted

but abandoned. The documented reason was 'technical difficulty' in eight of these cases. The overall successful insertion rate was 96%.

4.6 Discussion

This is the first vaginal PPIUC insertion training programme to be designed and delivered in a UK setting. In terms of achieving the overall objectives, the training programme can be considered a success. We have demonstrated that is feasible to train both midwives and doctors in vaginal PPIUC insertion, even when they have little or no previous experience of the technique, and the training was well-received by participants. By developing a structured and comprehensive training programme we were also able to deliver this at repeated intervals across multiple sites, which ensured consistency in the approach. This enabled the training to be effectively rolled out at organisational level across the region.

The main components of our training programme are similar to those used successfully in other countries. While many of these have been evaluated using either participant feedback surveys or quantitative outcome data, few have evaluated PPIUC training using a multi-model evaluation framework mapped to principles of educational theory. This approach allowed us to measure the 'success' of the training in a number of different yet complementary ways.

We had to modify our approach to training in a number of ways. With regards workplace practice, other programmes (such as RCOG Leading Safe Choices) required participants to perform a greater number of procedures under supervision (often a minimum of five) (Royal College of Obstetricians & Gynaecologists, 2015). We expected a lower rate of uptake amongst our population and so had to the balance the need for adequate clinical supervision and exposure, with the need to train a large number of providers in sufficient numbers across the organisation. We therefore made a pragmatic decision to recommend a lower minimum number of

supervised insertions, acknowledging that clinicians and trainers would modify this according to individuals' learning needs as appropriate.

While the training programme performed well and achieved the expected outcomes, some challenges were encountered. It became clear at an early stage that we would have to modify our approach to training medical staff due to difficulties with attendance. In addition, as there was sometimes a delay between staff members attending a training workshop and performing their first clinical procedure, optional 'refresher' training sessions were introduced to the overall programme. Although midwives responded favourably to the training workshops, they also expressed some concerns about the wider aspects of training and service delivery in a clinical setting. These are all important considerations for any UK region considering introducing PPIUC training and highlight that the practical training itself cannot be considered in isolation, but as part of a larger and more complex implementation process. This will be addressed in greater detail in Chapter 6.

There are some limitations of our training methods and evaluation. The approach used to train doctors was not as uniform as for midwives. It became apparent during the early stages of training that medical staff, especially Consultants, were frequently more time-pressured and often found it difficult to attend formal training workshops at fixed times. We therefore had to adapt out approach to include different training delivery methods such as condensed 'drop in' and targeted one-to-one sessions. This made both the distribution and completion of the evaluation survey more difficult and as such the response rate from medical staff was lower than for midwives, who all attended a formal training workshop. This is reflective of some of the challenges likely to be encountered with organisation-wide training in routine clinical settings. Despite these challenges, the results were generally similar for both, even though midwives had less previous experience with IUC procedures than the doctors. Furthermore, despite the slight difference in training approaches between the two staff groups, similar numbers of procedures were performed by each and the overall successful insertion rate remained very rate high (96%).

The training workshops and initial clinical supervision in our project was provided by clinical research staff external to the maternity service. This was necessary to introduce the training and service as part of the research study however it is unlikely that this would be available to other maternity services wishing to adopt it. One of the other key steps in ensuring successful initiation and sustainability of PPIUC in non-research settings is the development of trainers. Adequate and timely supervision was a particular concern expressed by midwives in the survey and is clearly central to ensuring both clinical safety and support for learners. By including a 'train the trainers' component within our training programme, we were able to rapidly accumulate the number of trainers available 'in house' to provide the clinical supervision required. To further support sustainability and dissemination, we were keen to develop a training package and resources than could be reproducible, as well as piloting these in a 'real life' clinical environment to identify some of the challenges involved.

One of the challenges of the 'real life' environment noted in survey responses, was the ability of clinical staff to be available to attend training. This was also clearly apparent for the medical staff. Some survey respondents suggested e-learning as a more easily accessible alternative to some of the theory training, which contributed to a significant amount of the total workshop time. The use of e-learning is now widespread in medical education and a tool which many healthcare professionals are familiar with. It also has the advantage of allowing wider accessibility and greater consistency in training. By combining evidence-based resources with our own experience of delivering this training, we have now developed a Scottish national online training resource in PPIUC which is freely available to all maternity providers, replacing the theory component and video elements of the training workshops. The aim is for the model simulation and clinical supervision elements to be delivered within the local clinical environment by 'in house' maternity staff, ensuring an easily accessible and sustainable approach to PPIUC training and provision.

While this training package was introduced and evaluated within a large maternity service, it may not be directly transferable in its entirety to other non-UK regions due to inherent differences in healthcare system structures. However, a similar approach has recently been used successfully to train multi-professional providers across six countries as part of a large-scale FIGO initiative (Makins *et al.*, 2018).

The most successful PPIUC initiatives have used a similar approach of developing evidence-based and country-specific resources, supplemented with expert advice and experience from centres where PPIUC has already been established, and used these to rapidly scale-up the intervention. With specific reference to the UK, by making comprehensive training resources available on a national platform; utilising digital modalities to facilitate a broader reach; and incorporating PPIUC into midwifery and obstetric curricula; it may be possible to increase both the acceptability and accessibility of PPIUC training in the UK.

4.7 Conclusions

We developed a comprehensive training programme for vaginal PPIUC insertion in the UK maternity setting, adapted from RCOG resources, which achieved the desired objectives and demonstrated that it is possible to train both midwives and obstetricians with no previous experience to perform this technique. This was the first vaginal PPIUC training programme to be successfully delivered across a large publicly funded maternity service in the UK. By adopting a similar approach, other maternity centres in the UK could feasibly increase the skills and knowledge of staff in vaginal PPIUC insertion, removing one of the potential barriers to more widespread availability of this service.

Chapter 5 Community sexual health providers' views of immediate postpartum intrauterine contraception

5.1 Introduction

In Chapter 3 I presented the findings of an observational study of a routinely available vaginal PPIUC service in Lothian, and in Chapter 4 described the approach to the training and education of maternity staff to achieve this service. This work demonstrated that it was feasible and safe to provide vaginal PPIUC within an NHS setting. However, similar to the findings from other studies, the expulsion rate was noted to be high (Lopez et al., 2015; Sonalkar and Kapp, 2015), and indeed higher than our previous experience of providing PPIUC at caesarean birth in the same region (Heller, Johnstone and Cameron, 2017).

The follow-up of women after PPIUC insertion was conducted and funded within a research setting. This formal follow-up visit at six weeks' postpartum provided the opportunity to identify an expulsion and provide IUC re-insertion if the woman wished. It is for this reason that many studies advocate the importance of a formal postpartum follow-up visit after PPIUC insertion. In our study, the opportunity to access rapid re-insertion following an identified expulsion contributed to the high rates of method continuation observed at 12 months. One of the concerns about translating this research into clinical practice, is the question of how and where a post-insertion follow-up visit would take place, and how access to ultrasound and IUC re-insertion could be facilitated if required.

In the UK, most contraceptive care is provided within general practice and community sexual health clinics. After childbirth, routine postpartum care is also provided within community settings. Therefore, it seems logical that this group of community providers could have an important role in the follow-up of women after PPIUC

insertion. Specialist sexual health clinicians also have a central role in training other healthcare professionals in LARC provision. It follows that they may also contribute to the development and delivery of PPIUC training, and this has certainly been the case in our region. Therefore, while the training of maternity providers in PPIUC insertion is integral to establishing a PPIUC service, other clinicians likely to be involved in training and aftercare are also key stakeholders in the wider development of these services in the UK.

While Chapter 4 identified some of the barriers involved in the training and education of maternity providers, engaging community sexual health providers in PPIUC service delivery may also be met with challenges. Studies have reported that lack of staff 'buy-in' and misconceptions around PPIUC can lead to apprehension to provide or support this service (Holland *et al.*, 2015; Rauh-Benoit *et al.*, 2017). While these surveys have predominantly focused on those healthcare professionals performing PPIUC insertion, it may be inferred that the same could apply to those involved in the wider aspects of service delivery such as aftercare.

In this chapter I will discuss my rationale and approach to determining the views of UK-based community sexual health providers (GPs, practice nurses and specialist sexual health clinicians) about PPIUC implementation using a semi-structured survey, along with the findings and impact in the context of wider service development. The original peer-reviewed publication arising from this work is included in the main body of this chapter.

5.2 Justification for methodology

We had first-hand experience of some of the challenges involved in providing aftercare to women following PPIUC insertion. At the time this research was conducted, PPIUC insertion was not widely available in the UK but had been available locally to women delivering by elective caesarean for approximately 18 months,

following a successful research pilot study (Heller, Johnstone and Cameron, 2017). During this study (similar to ours), women attended follow-up within a clinical research setting for a thread check and ultrasound if required. When this research reached completion and the service became established into routine care, there were ongoing discussions around when and where women would attend for postpartum follow-up. Initial discussions with community providers were met with some reluctance and posed logistical challenges in terms of training, funding and referral pathways in the event of complications such as non-visible threads or suspected expulsion.

We anticipated that other services aiming to embed PPIUC into routine service delivery could encounter similar barriers, and that the scale-up of any PPIUC intervention in the UK would require the support of community sexual health providers. It was also hypothesised that the views and challenges may vary in regions across the UK due to significant differences in the funding and delivery of sexual health and primary care services.

We therefore sought to explore the views of this group using a national survey. In an attempt to gain representative findings from a variety of healthcare professionals across the UK, the survey was distributed at leading annual national sexual health conferences. Attendees were known to predominantly include the population of interest; namely general practitioners, practice nurses and clinicians working in specialist sexual health services.

In the context of increasing access to immediate PPIUC, the aim of the research described was to determine the current views and willingness of these healthcare professionals to participate in a PPIUC service, as well as to identify potential barriers to this aspect of provision. To obtain more breadth of data, we opted for a mixed methods approach. The survey therefore included a combination of free and fixed response questions to allow participants to expand further.

It is acknowledged that surveys have limited potential as a qualitative evaluation tool. However, in the absence of previous research in this area among this group of healthcare professionals, our aim was to gather an overview of national opinion and identify any common themes that emerged rather than to explore these in depth. It was therefore felt that a mixed methods survey would allow us to reach a wider audience and address our research question adequately [**Appendix 3**]. The author team also included an experienced social scientist to support detailed analysis of the qualitative responses received.

5.3 Community sexual health providers' views on immediate postpartum provision of intrauterine contraception

Published in full: **Cooper M**, Boydell N, Heller R, Cameron S. Community sexual health providers' views on immediate postpartum provision of intrauterine contraception. BMJ Sexual & Reproductive Health. 2018 Apr 1;44(2):97-102. (*Reproduced with permission*)

5.3.1 Background

There is growing interest towards the provision of immediate postpartum intrauterine contraception (PPIUC) (Moniz *et al.*, 2017). This may help reduce the risk of unplanned pregnancy following delivery, and short inter-birth intervals which are associated with increased obstetric and neonatal morbidity (Smith, Pell and Dobbie, 2003; Bigelow and Bryant, 2015). The clinical safety and feasibility of this technique is well-documented; with no observed increase in the risk of complications such as infection or uterine perforation when compared to interval insertion (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). Although the risk of expulsion is higher, the long-term continuation rate of PPIUC suggests that this remains an excellent option for women (Sonalkar and Kapp, 2015).

At present in the UK women seeking intrauterine contraception (IUC) after childbirth would generally attend either their general practitioner (GP) or local sexual health clinic to arrange insertion in the weeks following delivery. However, the need to attend a further postpartum visit is recognised as a potential barrier for women (Ogburn, Espey and Stonehocker, 2005; Cameron *et al.*, 2017). The shift towards delivery of IUC within maternity settings can help to overcome these barriers, but it may also indirectly impact the community contraceptive provider. Following PPIUC insertion women require a thread check to confirm device location, and referral for ultrasound if IUC threads are not visible. For intra-caesarean insertion, threads may not be visible in up to 50% of women (Dewan *et al.*, 2017; Heller, Johnstone and Cameron, 2017).

Currently, PPIUC is not routinely available in the UK. The recent 'Contraception After Pregnancy' guideline published by the Faculty of Sexual of Reproductive Healthcare (FSRH) supports the insertion of IUC within the first 48 hours postpartum (Faculty of Sexual & Reproductive Healthcare, 2017). However, there is limited data around the practical implementation of PPIUC within a public health service. PPIUC is available in many low-and-middle-income countries worldwide, and despite the diversity of these settings, common themes emerge as being essential for successful implementation (Canning *et al.*, 2016; Hofler *et al.*, 2017).

Stakeholder involvement and staff engagement are consistently recognised as crucial, along with the identification of clinician 'champions' (Canning *et al.*, 2016; Hofler *et al.*, 2017). These are individuals able to actively demonstrate the benefits of providing PPIUC to clinical and managerial colleagues, policymakers and commissioners; and to encourage and support its implementation. This may involve dispelling some of the misconceptions that are known to exist amongst healthcare providers around the provision of IUC at this time (Holland *et al.*, 2015; Rauh-Benoit *et al.*, 2017).

Previous studies have focused on the views and practices of maternity providers (obstetricians, midwives) around PPIUC (Holland *et al.*, 2015; Rauh-Benoit *et al.*,

2017). However, to our knowledge, there have been no studies focused specifically on community sexual health providers. GPs and sexual health clinicians represent two major stakeholder groups for successful implementation in the UK. They are most likely to be involved in the aftercare of women following PPIUC (including thread checks and managing late complications), and it is likely that their opinions and concerns may differ from those involved in the delivery of the hospital-based service component. Having successfully established intra-caesarean PPIUC provision within our region (NHS Lothian) (Heller, Johnstone and Cameron, 2017) it is our experience that the responsibilities, referral pathways and funding for PPIUC aftercare can present a significant challenge.

The aim of our study was to determine the views of UK community-based sexual health providers (GPs, sexual health practitioners) about the implementation of PPIUC, and to identify possible facilitators and barriers to successfully achieving this.

5.3.2 Methods

A paper-based questionnaire for self-completion was distributed to all attendees at two UK sexual health conferences: FSRH Annual Scientific Meeting (April 2017) and Lothian Sexual Health Update (May 2017). This recruitment method was chosen as it provided a convenience sample of our target population. It was known from previous experience that attendees of both conferences were largely community sexual health providers. Participation was voluntary and anonymous, with general information outlining the background and aims of the study provided in advance.

Research questions focussed on three key areas: (1) overall feeling towards implementation of PPIUC in the UK; (2) perceived role in a future PPIUC service; (3) and potential challenges they anticipated. As a validated tool was not available, questions were designed based on researchers' clinical expertise in this area and were pilot tested on the target population. The survey consisted of a combination of

fixed response, rating scale and open-ended questions. Respondents were also invited to add additional comments, either to expand on a previous response or to raise issues which had not otherwise been discussed.

Results from both sites were combined and a mixed methods approach was used for analysis. The fixed responses from the surveys were coded and entered into a Microsoft Excel® database and descriptive statistics performed. Thematic analysis was used to examine free text comments surrounding reasons for feelings about PPIUC and its implementation. Responses were analysed by the second author using an inductive approach and grouped according to themes derived from the data (Braun and Clarke, 2006). The first author reviewed the coding framework and contributed to interpretation of the data.

Ethical approval was not required to conduct this study as it was considered health service evaluation. The NHS Health Research Authority provides clear guidance on this and was consulted in advance. Permission was sought from conference organisers to distribute the survey.

5.3.3 Results

A total of 240 questionnaires were distributed to attendees across both conferences. Of those returned, 156 were completed either fully or in part, representing a response rate of 65%. Data were combined for analysis and the overall demographics of respondents are shown in **Table 5-1**.

Table 5-1: Characteristics of survey respondents

Characteristic (N = 156)	N (%)
Professional role	
GP	62 (39.7)
SRH doctor	71 (45.5)
Practice nurse	2 (1.3)
SRH nurse	12 (7.7)
O&G doctor	1 (0.6)
Other	8 (5.1)
Years in current role (n=155)	
Less than 1	7 (4.5)
Between 1 and 5	26 (16.8)
Between 5 and 10	38 (24.4)
More than 10	84 (54.2)
Working location	
England	67 (42.9)
Scotland	70 (44.9)
Wales	17 (10.9)
Northern Ireland	0 (0)
Outside UK	2 (1.3)
IUC experience (n=155)	
Current holder LoC IUT and/or inserts regularly	69 (44.5)
Completed LoC IUT but does not insert regularly	6 (3.9)
Current trainer in LoC IUT	36 (23.2)
Currently in training	4 (2.6)
Not completed LoC IUT/do not insert	40 (25.8)

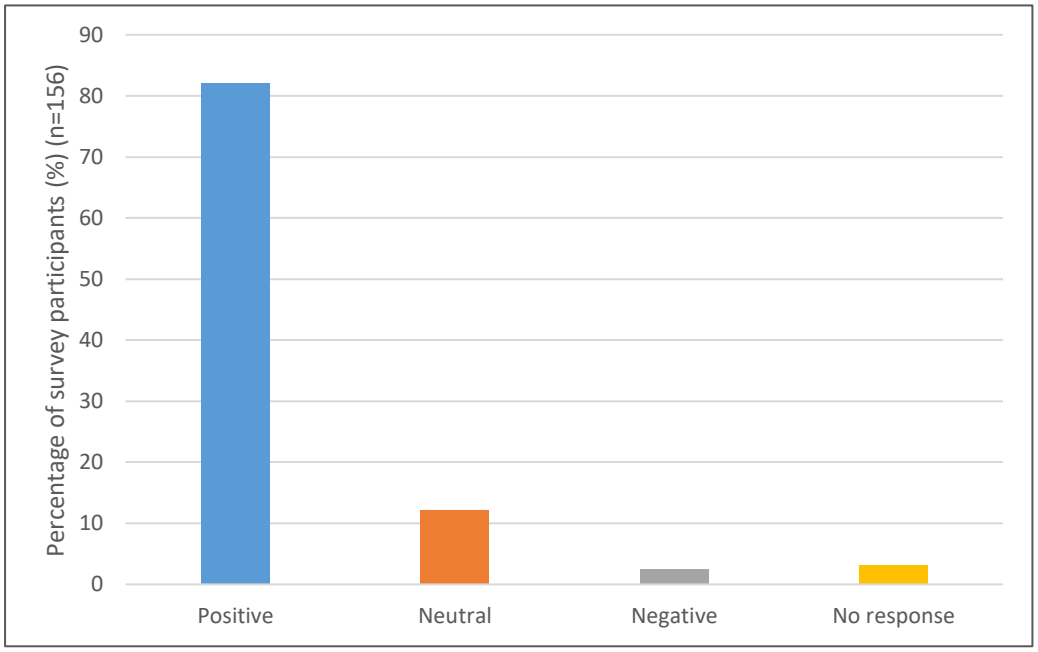
IUC = intrauterine contraception; O&G = obstetrics & gynaecology; GP = general practitioner; LoC IUT = Letter of Competence in Intrauterine Techniques[1]

[1] Recognised UK FSRH qualification for standard IUC insertion and removal

5.3.3.1 Overall feeling towards PPIUC

Respondents were asked to rate their overall feeling towards the implementation of PPIUC in the UK using fixed responses (positive, neutral, negative). Results are summarised in **Figure 5-1**.

Figure 5-1: Respondents' overall feeling towards PPIUC implementation in the UK



5.3.3.2 Perceived clinical challenges

Respondents were asked to rate their perceived importance of certain challenges in PPIUC aftercare provision from a pre-defined list (staff time, available equipment and resources, funding and reimbursement, experience of managing clinical issues, access to ultrasound for confirming IUC in situation of non-visible threads). The list was generated based on expert opinion and feedback from stakeholders within an established PPIUC service (Heller 2017). Survey respondents most frequently indicated that challenges would include staff time, inexperience of managing clinical

issues with postpartum insertion e.g. long or non-visible threads, and referral pathways for access to ultrasound in the presence of non-visible threads.

5.3.3.3 Future role in PPIUC service

Respondents were asked to indicate what their perceived role in a future PPIUC service might be. The possible answers and reported frequencies are shown in **Table 5-2**. This also includes subgroup analysis for the most highly represented staff groups (GPs and SRH clinicians). Of all respondents, 67.9% (n=106) indicated that they would be happy to promote PPIUC and to conduct postpartum thread checks.

Respondents less frequently indicated an intention to train in PPIUC insertion themselves (28.2%), to train other healthcare professionals (32.1%) or to provide a 'champion' or specialist role in a future PPIUC service (24.4%).

Table 5-2: Survey participants' anticipated role in future PPIUC service

Future role in PPIUC service (n = 156)	N (%)
Happy to promote	
All (n = 156)	106 (67.9)
GP (n = 62)	41 (66.1)
SRH clinicians (n = 83)	60 (72.3)
Happy to conduct thread checks	
All	106 (67.9)
GP	41 (66.1)
SRH clinicians	58 (69.9)
Keen to train in PPIUC insertion myself	
All	44 (28.2)
GP	11 (17.7)
SRH clinician	32 (38.6)
Keen to train other healthcare professionals in PPIUC insertion	50 (32.1)
All	11 (17.7)
GP	35 (42.2)
SRH clinician	
Keen to be a postpartum contraceptive/PPIUC 'champion'	
All	58 (37.2)
GP	15 (24.2)
SRH clinician	40 (48.2)
Keen to provide a specialist role in PPIUC	
All	38 (24.4)
GP	11 (17.7)
SRH clinician	24 (28.9)

PPIUC = postpartum intrauterine contraception; GP = general practitioner; SRH = sexual and reproductive health

5.3.3.4 Free-text responses

There were two areas of the survey where respondents were invited to provide additional free text responses: in discussing the reasons for their overall feeling towards PPIUC implementation, and to provide any additional general comments. A summary of the responses is provided below.

Reasons given for 'positive' views

Of the 128 respondents (82%) who reported feeling positive towards implementation of PPIUC, 81 supplied additional comments (extracts shown in **Table 5-3**). Three keys issues emerged: PPIUC as improving access to long-acting reversible contraception (LARC) and addressing unmet contraceptive needs; the role of PPIUC in maximising contraceptive options for women; and potential challenges in PPIUC service implementation.

PPIUC was framed as means to increase access and uptake of LARC. Respondents emphasised key benefits of PPIUC including effectiveness; reduced risk of unplanned and repeat ("back-to-back") pregnancies; high acceptability; and high continuation rates with the method. Respondents noted the potential of PPIUC in reducing the need for multiple appointments. As such, PPIUC was described as an intervention which could "save time" for both patients and services.

PPIUC was framed as an intervention to maximise contraceptive options. Respondents' highlighted the importance of increasing contraceptive options for women, providing them with choices around when and where to access services. PPIUC was described as especially important for women who were sure of IUC as their intended contraceptive method.

Table 5-3: Examples of reasons given for positive views towards PPIUC provision

PPIUC as improving access to LARC and addressing unmet needs	*"Anything that expands access to LARC for women is fantastic!"* *"Reduced pregnancies back to back"* *"Safe and effective. Good continuation rate. Less likely to have perforations. Less visits for patient to access LARC."* *"Very effective and (will) save a lot of time for the patient."* *"Feedback from the women that I have seen after PPIUC has been so positive. Even if the device is expelled, they are by and large keen to continue with IUC."* *"Choice – particularly for women at risk of further unintended pregnancies […] Practicality for everyone debatable."*
Role of PPIUC in maximising contraceptive options for women	*"Any intervention which gives women maximum choices on when and where to have their preferred method is good."* *"Always good to give women more contraceptive choices and will hopefully reduce pregnancy intervals."* *"I'm in favour of anything that improves women's contraceptive options and choices"* *"Sounds as though it is what women want and good way to ensure they have sufficient contraception in a timely fashion"*
Potential challenges to PPIUC service implementation	*"[…] limited funds locally to action this."* *"[…] valid concerns that obstetricians and midwives are too pressed with concerns around safe delivery of baby to provide the service before most women are discharged."* *"Idea of providing contraception immediately postpartum good but limitations of service make implementation difficult."* *"All for it. But the Gynae and midwife colleagues need to be on board."* *"Will take time and energy to get key stakeholders involved."* *"Good thing to offer quickly although I worry about lost threads/removal later and how difficult this will be."*

Reasons given for 'negative' or 'neutral' views

Of the 23 respondents (15%) who reported feeling either negative or neutral towards PPIUC implementation, 16 supplied additional comments (extracts shown in **Table 5-4**). Four keys issues emerged: concerns around clinical risks of PPIUC; lack of knowledge and awareness of PPIUC as an option among healthcare professionals; lack of alignment with women's priorities in the postpartum period; and practical barriers to PPIUC service implementation. Clinical concerns included the increased risk of IUC expulsion (including unnoticed expulsion), the (false) perception that there may be an increased risk of uterine perforation, and issues around the clinical management of non-visible threads.

Table 5-4: Examples of reasons given for negative or neutral views towards PPIUC provision

Concerns around clinical risks associated with PPIUC	*"I believe there are risks to insertion of IUC whilst the uterus is still 'soft' post-delivery posing increased perforation risk. […] Also is there is a risk of the coil or threads being lodged in the uterine incision scar?"* *"[I have] concerns re perforation and expulsion"*
Practical barriers to PPIUC service implementation	*"Local funding issues – having to save 6% every year."* *"It is a difficult time. Trained people are not available as freely as SRH. It may take ages to get a positive feeling."*
Lack of knowledge and awareness of PPIUC as a contraceptive option	*"Not come across this concept before. No patients have had it done to my knowledge."* *"Never worked in a service where (this) option was possible."*
Alignment with women's priorities in the postpartum period	*"For vast majority (of) postnatal women contraception does not seem like (the) immediate priority."* *"I can see the benefits, however I think this discussion about contraception should take place before admission to hospital, ideally in the community, when the women can have time to consider the risks/benefits of IUS, and possibly include in her birth plan."* *"[Women] have other priorities and less likely to be able/willing to access healthcare professional if having problems."*

Practical barriers to PPIUC service implementation included: maternity staff shortages, lack of trained staff to insert IUC in the maternity setting; time pressures within maternity services resulting in delays to providing PPIUC; concerns around funding for PPIUC provision and subsequent thread check/review services. In addition, poor staff engagement was framed as a potential challenge to service implementation, with the need for local PPIUC 'champions' to encourage 'buy-in' highlighted. Many of these potential challenges were also echoed by those with an overall 'positive' view towards implementation.

Additional issues

Access to education and training in PPIUC emerged as a key issue **[Table 5-5]**. Training was perceived as critical to increasing awareness of PPIUC and equipping staff with the necessary skills for insertion at caesarean and vaginal delivery. Nevertheless, concern about shortage of maternity staff and an inability to release available maternity staff for training in PPIUC techniques was seen as a significant challenge. Some respondents suggested that PPIUC training should be integrated into the Royal College of Obstetricians and Gynaecologists (RCOG) curriculum, and/or as part of the FSRH Letter of Competence qualification.

Table 5-5: Examples of additional challenges to PPIUC implementation

Access to education and training on PPIUC	*"Potentially high training workload for us – must develop a sustainable training model."* *"We are always short-staffed so releasing a doctor/nurse to go up to the hospital to train/fit PPIUC would be difficult."* *"Giving midwives the time to study and train."* *"Should it be mentioned in LoC IUT training? Add information about procedure to e-learning on LfH site [eLearning for Healthcare]."* *"[PPIUC] is dependent on uptake and training by O&G trainees so needs to be in RCOG curriculum."*

5.3.4 Discussion

Most community sexual health providers were enthusiastic about the implementation of PPIUC in the UK. There was recognition of the potential benefits of PPIUC in relation to increasing access to effective contraception and in reducing subsequent unintended pregnancy. As expected, community providers viewed their role predominantly in the aftercare of women following PPIUC, with most indicating that they would be happy to provide this.

However, as well as recognising many of the benefits of a PPIUC service, they also acknowledged several possible barriers and areas of concern. Many of these are consistent with the implementation challenges noted in previous studies (Hofler *et al.*, 2017). In relation to potential clinical issues, respondents felt that access to ultrasound and lack of experience in managing complications after PPIUC were of greatest importance. For PPIUC establishment, multidisciplinary staff training, funding and stakeholder co-operation were highlighted as key areas.

5.3.4.1 Training

Further education for both maternity and sexual health staff was noted as essential, both in PPIUC insertion techniques and more generally around risks and management of clinical issues. The RCOG have developed PPIUC training materials as part of their work to improve access to postpartum contraception in South Africa and Tanzania, through the Leading Safe Choices Initiative (Royal College of Obstetricians & Gynaecologists, 2015). With permission, we have adapted these locally for training maternity staff in our region. Incorporating information about PPIUC into the national training curricula for midwives and junior obstetricians may assist in achieving widespread adoption and sustainability of this service. For training community-based providers, PPIUC ‘champions’ within sexual health services are likely to play a key

role. Widespread staff education for community and hospital-based staff involved in the antenatal and postpartum care of women may assist in dispelling some of the misconceptions which currently exist, and in supporting providers in both the delivery and follow-up care of patients requesting PPIUC. Services which have successfully implemented PPIUC will prove invaluable in disseminating their experience and knowledge.

5.3.4.2 Funding/commissioning

There is evidence from the US to support the cost-effectiveness of providing PPIUC (Washington *et al.*, 2015)and its availability aligns with many of the current sexual health strategies in the UK (Welsh Assembly Government, 2010; Department of Health, 2013; Scottish Government, 2015). Demonstrating local service need and identifying key clinician 'champions' to present local data on the benefits of a PPIUC service may assist in prioritising the agenda and securing appropriate funding support. There will be more specific challenges for some regions of the UK in relation to clinical commissioning groups, particularly as a PPIUC service will naturally cross the hospital and community care boundaries.

5.3.4.3 Stakeholder involvement

As identified in survey responses, collaborative working between multiple key areas is integral to the establishment of PPIUC. In the UK, stakeholders may include hospital and service managers, maternity staff (midwives, obstetricians), theatre staff, sexual health services, primary care, radiology, pharmacists, IT specialists and patient group representatives. In our experience, a core steering group can help facilitate communication, and aid the development of antenatal and postpartum care

pathways to manage the patient journey effectively between hospital and community services.

Although the demographics of respondents in this survey closely matched that of the conference delegates, it is possible that the views of conference attendees may not reflect those of the wider group of community sexual health providers. It will be beneficial to conduct similar surveys with other key groups to canvas a wider pool of opinion and identify other unique challenges. As part of our ongoing research around PPIUC, we are conducting qualitative interviews and focus groups with maternity providers. This will further assist in identifying facilitators and barriers towards successful implementation.

Although the survey response rate was acceptable, the reasons for non-completion are unknown. Therefore, it is possible that an element of bias exists in the results. However, the mixed methods approach to analysis allowed us to achieve the study aims of identifying possible facilitators and barriers, as both were commented on in the free text responses. It is also interesting to note that individuals who reported either positive or negative views towards PPIUC, provided both positive and negative comments in the free text. Therefore, the feedback may be more balanced than initially expected. It also indicates that while the practical and health benefits of PPIUC are recognised, this does not necessarily translate into widespread adoption as there are many other factors to consider. This may explain in part why countries such as the UK have been slow to establish PPIUC.

In this regard, the development of a shared-learning culture will prove essential to achieving implementation. The experience of healthcare professionals already involved in PPIUC service delivery will be invaluable. There is no doubt that successful PPIUC establishment requires cross-specialty support, particularly from within the maternity sector who will be delivering the service. However, perceptions and opinions of the wider stakeholder group are helpful to assemble in advance so that potential barriers can be anticipated and addressed. This study reflects important stakeholders previously unreported in the literature. In conjunction with data from

other studies, we can hopefully further knowledge around the practical aspects of PPIUC implementation and move closer to achieving widespread availability of this service in the UK.

~ End of published paper ~

5.4 Conclusions

The research methodology chosen here adequately achieved the study aims of identifying potential facilitators and barriers to PPIUC amongst community providers. The findings from this survey echo those raised in other provider surveys about PPIUC (Holden *et al.*, 2018). In terms of the wider clinical impact, awareness of these factors can encourage the development of tools and strategies to support successful implementation of PPIUC. This survey also identified the need for training and education amongst non-inserting clinicians who may be involved in pre-procedure counselling or follow-up. Interestingly, many of the themes expressed in relation to challenges for PPIUC provision were similar to those identified in the training evaluation survey of maternity staff (Chapter 4).

These findings further support the view that PPIUC should not be considered as an isolated labour ward procedure. Focusing training and education interventions only on those inserting PPIUC is inadequate to achieve a safe and sustainable service. In addition, it is necessary to develop a robust clinical infrastructure both before and after PPIUC insertion, not least of all to ensure that complications such as expulsion and non-visible threads are identified and managed appropriately.

In our Lothian service, the follow-up of women after PPIUC insertion has now moved into the community with GPs and practice nurses performing thread checks as part

of a locally agreed and funded service agreement[5]. In response to some of the findings in this survey about lack of education and tools to support implementation, we have developed a number of resources specifically aimed at supporting and clarifying the aftercare for women following PPIUC insertion locally.

This has included a clear pathway to aid the management of the clinical presentations most commonly encountered in PPIUC follow-up (long threads, non-visible threads) [**Appendix 2**]. A dedicated email advice inbox has been established to provide a rapid response to clinical queries, and a supporting compilation of "Frequently Asked Questions" developed based on the most commonly encountered queries. By supporting clinicians involved in the aftercare of women following PPIUC insertion, clinical issues can be managed at an early stage and women can be reassured. This helps to ensure that the efficacy and safety observed in PPIUC research studies is preserved in routine clinical settings.

This survey was conducted in 2016 and demonstrated enthusiasm amongst UK providers towards PPIUC. However, at the time of writing in 2020, PPIUC is still not widely available in the UK. One of the challenges noted in this paper, and in other chapters of this thesis, is the translation of this enthusiasm and evidence into clinical practice, a process otherwise described as 'implementation'.

The previous two chapters have shown that staff engagement, structured training and education and clear clinical pathways are essential to the successful implementation of PPIUC. In the following chapter, I will discuss the aspects of implementing PPIUC services more broadly, utilising the knowledge gained from conducting this research project and the existing literature to propose a reproducible 'framework' for PPIUC implementation.

[5] At the time this paper was published, this was only the case for women receiving intra-caesarean insertion but following completion of the vaginal PPIUC study now applies to all women

Chapter 6 The role of implementation science in the provision of immediate postpartum intrauterine contraception

6.1 Introduction

In previous chapters, it was noted that while the evidence-base supporting the safety and efficacy of PPIUC is now considerable, the widespread provision of this service is not yet a reality. As with many new interventions, the translation of research into routine clinical practice can prove challenging.

Implementation science is defined as "*the study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice and hence, to improve the quality and effectiveness of health services*" (Eccles and Mittman, 2006). As such it focuses not just at patient level, but at provider and organisation level to guide both the introduction and sustainability of an intervention.

In this respect, centres who are among the first to introduce new interventions into complex health systems, sometimes referred to as 'early adopters', can be a useful source of knowledge and support to others wishing to replicate the process in their own environment. By utilising principles of implementation science, we sought to summarise our overall approach to establishing PPIUC services in Lothian, and to generate a strategic framework to promote its wider dissemination.

This chapter includes a short discussion of the background literature which informed this approach, before presenting an amended version of the resulting published manuscript. While the research outlined in Chapters 3 and 4 focused specifically on the clinical and training outcomes for vaginal PPIUC insertion, this chapter relates to

PPIUC implementation as a whole within the region and incorporates the preceding research and service developments which made this possible.

6.2 Justification for methodology

At the time of commencing this research, the literature around PPIUC implementation was limited however, it is now an emerging area. A more recent screen of the literature in this area (PubMed; search terms: 'postnatal' OR 'postpartum' AND 'implementation' AND 'contraception'; September 2020) generated twenty-eight relevant articles. The literature was heterogenous in nature and included a combination of descriptive methodology, qualitative or mixed methods research, review papers and implementation science models. All of the relevant literature had been published in the last five years and (excluding two published works by this author team) related to either US or LMIC experience.

While the process of implementation is often complicated, there is agreement in the literature that any implementation effort can be described through a series of discrete stages. As such, a number of generic 'frameworks' have been proposed as tools to assist those seeking to either conceptualise or replicate the implementation of a specific intervention.

One such of these is the 'Promoting Action on Research Implementation in Health Services' or 'PARIHS' framework. It was first conceived in 1998 and has been used extensively to explain how or why the successful translation of evidence into practice occurs (Helfrich *et al.*, 2010). As a conceptual framework, it was one of the first to acknowledge the complex and multi-dimensional nature of implementation. It was also used by Hofler and colleagues to align findings from a qualitative study of PPIUC providers, into a stage-based guide to support wider uptake (Hofler *et al.*, 2017). As a well-established framework, which had previously been used to inform

implementation-based research in PPIUC, we felt this would be an appropriate tool with which to encapsulate our experience.

However, the aim was also to describe our experience with a view to reproducibility, by identifying the barriers and facilitators encountered during the process. As such, we felt that incorporating a thematic approach would allow us to achieve this in a more comprehensive way. Other researchers have used a thematic-based approach to describe their own experiences of PPIUC implementation across a range of settings (Pfitzer *et al.*, 2015; De Caestecker *et al.*, 2018).

6.3 Successful implementation of immediate postpartum intrauterine contraception services in Edinburgh and framework for wider dissemination

Published in full: **Cooper M**, Cameron S. Successful implementation of immediate postpartum intrauterine contraception services in Edinburgh and framework for wider dissemination. International Journal of Gynecology & Obstetrics. 2018 Sep;143:56-61. (Reproduced with permission).

A note on timing: this paper was written and published before the study end date and as such interim data is included which may differ from the final analysis included in earlier chapters.

6.3.1 Introduction

It is estimated that at least one third of births in the UK are not intended at conception (Lakha and Glasier, 2006). Unintended pregnancy is associated with poorer maternal and neonatal outcomes (Hall *et al.*, 2017) and comes at an annual

estimated cost of £1 billion to the health service (Thomas and Cameron, 2013). Pregnancy planning allows for maternal health to be optimised before conception and can be supported by contraception (Hall *et al.*, 2017), which is available for free in the UK.

The postpartum period is recognised as a high-risk time for unintended pregnancy. Ovulation can return from as early as three to four weeks in non-breastfeeding women (Jackson and Glasier, 2011). While the lactational amenorrhoea method (exclusive breastfeeding, amenorrhoea, baby under six months) can be used for contraception, data from the England suggests that only 28.5% of mothers continue to breastfeed exclusively at six weeks' postpartum (Public Health England, 2017).

Access to effective contraception may also be difficult for women due to the demands of looking after a newborn. Early resumption of sexual intercourse (at least 50% of couples by six weeks) (McDonald and Brown, 2013) means that a considerable proportion of postnatal women are potentially at risk of further pregnancy soon after giving birth.

A UK study estimated that one in 13 women requested abortion in the 12 months after having a baby (Heller *et al.*, 2016). Additionally, amongst a population of women giving birth, 1 in 13 had conceived within 12 months of previous childbirth (Heller *et al.*, 2016). This short-interpregnancy interval (less than 12 months) is associated with an increase in the risk of obstetric complications such as preterm labour, intrauterine growth restriction and stillbirth; and an overall increase in neonatal mortality (Smith, Pell and Dobbie, 2003). Therefore, improving access to effective postpartum contraception could prevent more unintended pregnancies in the UK that end in abortion, and also help women and couples to optimise birth spacing for improved health outcomes.

6.3.2 UK maternity care

Maternity care in the UK is predominantly delivered within the publicly funded National Health Service (NHS). Women have access to a midwife throughout their pregnancy and the opportunity to attend regular antenatal visits in accordance with their specific clinical and social needs (National Maternity Review, 2016). For otherwise healthy women, care throughout pregnancy, labour and the immediate postpartum period is mostly delivered by midwifery staff. The majority of women deliver in hospital-based birth units, with most experiencing a vaginal birth (NHS Digital, 2017; NHS Scotland Information Services Division, 2017). However, the overall rate of operative delivery continues to rise, with more than one in four women in the UK delivering by caesarean section (NHS Digital, 2017; NHS Scotland Information Services Division, 2017).

Currently in the UK, midwives may discuss contraception with women before they are discharged from the maternity unit. However, studies have shown that there are many barriers to providing contraceptive advice in this setting (McCance and Cameron, 2014). For example, women may not wish to discuss contraception as they are focused on their baby (Glasier, Logan and McGlew, 1996) and having sex again may not seem an immediate priority (Wilson *et al.*, 2011). Discussion may be further impeded by a lack of privacy on postnatal wards and the presence of visitors. The current and expanding workload of hospital midwives may mean that contraception becomes a lesser priority (McCance and Cameron, 2014), with inadequate time for a full discussion.

General practitioners (GPs) may also provide contraceptive advice and supplies at a six-week postnatal visit (Glasier, Logan and McGlew, 1996; National Institute for Health & Care Excellence (NICE), 2006). However, there is some evidence that young women and those form deprived areas who may be at high risk of an unintended pregnancy may be least likely to attend (Lunniss, Cameron and Chen, 2016). For women who wish to have an LARC method fitted (CU-IUD, LNG-IUS or implant), they

may require a further visit to the GP or a specialist contraceptive service for this. The need for multiple appointments for postpartum contraception allows a margin for unintended pregnancy.

The UK Faculty of Sexual and Reproductive Healthcare (FSRH) and have recently recommended that discussion about future contraception should ideally take place during the antenatal period (Faculty of Sexual & Reproductive Healthcare, 2017), to allow women time to consider their options. It is increasingly recognised that healthcare professionals should be promoting the most effective long-acting reversible methods of contraception (LARC), which include intrauterine contraception.

The need for an additional postpartum visit for fitting is known to be a barrier for women accessing intrauterine contraception at this time (Ogburn, Espey and Stonehocker, 2005). The option of immediate insertion after childbirth provides a convenient alternative, and PPIUC provision has consistently been shown to be safe (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015).

Most clinical guidelines and public health policies now advocate earlier contraceptive discussion and enhanced provision from within maternity services (Scottish Government, 2015; Faculty of Sexual & Reproductive Healthcare, 2017). We[6] demonstrated that routine antenatal contraceptive counselling is both feasible for community midwives to deliver, acceptable to women and is associated with an increased uptake of methods after delivery (Cameron *et al.*, 2017). However, there are several barriers to effectively delivering this service, particularly in relation to IUC insertion. It mostly due to these barriers that the adoption of PPIUC in countries such as the UK and US has been relatively slow (Moniz *et al.*, 2017), despite evidence supporting the safety and efficacy of the technique (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015).

[6] Refers to the wider Lothian research group

Introducing PPIUC into clinical practice is complex for many reasons. The intervention does not exist in isolation as a delivery unit procedure, as there are pre-counselling and follow-up arrangements to consider. As such, a comprehensive PPIUC service involves aspects of antenatal, intrapartum and postnatal care; and includes both hospital and community providers. This presents challenges in relation to communication, clinical pathways and referral.

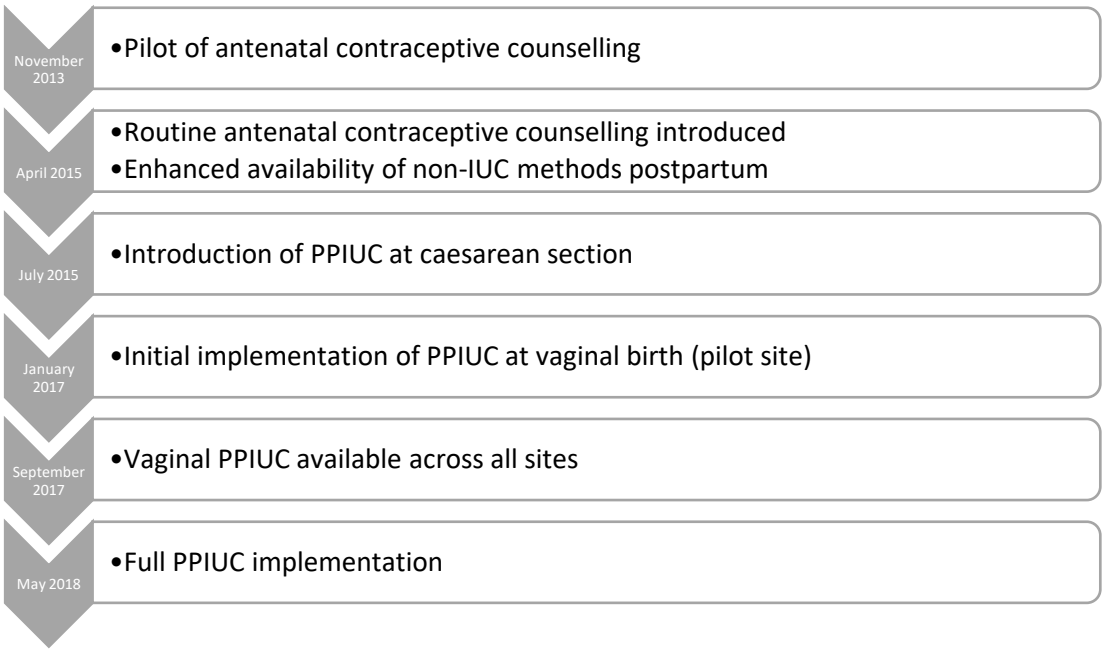
UK providers' lack of experience with the technique may also lead to misconceptions and initial reluctance (Luchowski *et al.*, 2014; Cooper *et al.*, 2018). This service would have to be incorporated into the current remit of maternity care, potentially without additional dedicated time or funding to support it. For providers, the change in role and increased training requirement may be met with some resistance. Securing funding to support this service may be challenging as although there are data to support the cost-effectiveness of PPIUC (Washington *et al.*, 2015), the financial benefits may not be immediately clear or easily demonstrable.

However, many of these potential challenges can be overcome. In this article, we discuss our experience of successfully implementing PPIUC insertion within a UK maternity service in Edinburgh, Scotland. The region contains two maternity hospitals responsible for 9250 live births in 2016, with an overall caesarean section rate of 30.3%[7] (NHS Scotland Information Services Division, 2017). PPIUC has been available to women giving birth here since 2015, initially at elective caesarean section and more recently following vaginal birth. The timeline for service development is shown in **Figure 6-1**.

In the two years prior to PPIUC service arrival, routine antenatal contraceptive counselling was introduced to the region in conjunction with increased awareness and general training in postpartum contraceptive methods for maternity staff.

[7] Combined rate for elective and emergency procedures

Figure 6-1: Timeline of postpartum intrauterine contraception (PPIUC) service implementation in Edinburgh



However more than half (58%) of those women who expressed desire for a postpartum IUD did not attend a follow-up appointment for insertion (Cameron et al., 2017), reflecting findings from other studies that the additional visits for insertion were a significant barrier to uptake (Ogburn, Espey and Stonehocker, 2005). This provided justification to introduce PPIUC within a maternity culture already geared towards enhanced contraceptive services.

A summary of our overall PPIUC implementation strategy is represented in **Figure 6-2**. This is framed around the evidence-based stages of implementation devised by the National Implementation Research Network (NIRN)[8] (Fixsen *et al.*, 2013), which has previously been used successfully to structure qualitative interview findings from healthcare providers about their PPIUC implementation experience (Hofler *et al.*, 2017).

[8] This represents a modified version of the PARIHS framework and includes the following stages: exploration, installation, initial implementation and full implementation

Figure 6-2: Key components of establishing a PPIUC service using the NIRN 'Stages of Implementation' framework (Fixsen 2003)

6.3.3 Funding, advocacy and stakeholders

The 'exploration' stage consisted of the necessary 'pre-planning' steps prior to practical delivery of PPIUC. Formative research on views of women from baseline data indicated support for the service. Of 250 postnatal women surveyed, 30% indicated that they would opt for PPIUC if this were available (Heller *et al.*, 2016). Demonstration of local unmet need along with service-user demand provided a

useful tool in gaining the funding and support necessary to introduce a PPIUC service. We established a PPIUC steering group to guide overall project direction and facilitate communication between key stakeholders. This included a senior obstetrician, lead midwife, sexual health lead, general practitioner, clinical and qualitative research teams and a patient group representative. Involving key individuals at an early stage in the process can assist in identification and resolution of potential barriers.

6.3.4 Training, education and resources

The 'installation' stage included the practical factors which needed to be in place prior to formal service introduction. Considerable time was dedicated to the training and education of obstetricians and midwives and conducted well in advance of anticipated service introduction. This was conducted in two main streams: practical training for maternity staff fitting postpartum devices (obstetricians and labour ward midwives), and more general education for those providing information to women (community midwives and GPs).

When developing the training strategy, it was recognised that the size of the maternity unit and expected uptake of PPIUC would influence the rate and availability of fully trained inserters. Training workshops were tailored to the needs of each staff group and repeated at regular intervals to maximise the number of staff able to attend.

Obstetricians were trained in intra-caesarean insertion using a locally produced video and a period of supervised practice. For vaginal PPIUC, we opted to train both obstetric and labour ward midwifery staff to ensure consistent availability of fitters. A phase-based approach was adopted where all obstetric staff entered training first, followed by groups of midwives, to ensure that adequate training opportunities and supervisors were available.

For training in PPIUC insertion at vaginal birth we modified (with permission) resources developed by the Royal College of Obstetricians and Gynaecologists (RCOG) for use in South Africa and Tanzania as part of the Leading Safe Choices initiative (Royal College of Obstetricians & Gynaecologists, 2015). This involved a combination of theoretical and simulation training using the Mama-U® (Laerdal, Stavanger, Norway) postpartum uterus model.

Following this, a period of supervised workplace-based practice continued until clinical competency with the technique was achieved. PPIUC 'trainers' were appointed to assist with training sessions and clinical supervision. These individuals were obstetricians or senior labour ward midwives identified as having relevant training and practice in contraception, enhanced knowledge and enthusiasm for PPIUC, and experience in clinical teaching. A local policy included a minimum of three insertion procedures performed under supervision until independent competency was achieved.

Education of community midwives about the availability of PPIUC took place concurrently. Gaining support from this group was considered crucial as they were already providing routine antenatal contraceptive counselling for women. Meetings were conducted with all community midwife teams in the area. This stage also involved engagement with other key personnel (hospital theatre staff, pharmacists) to ensure the service was fully prepared and stocked to provide PPIUC. Training events also allowed for patient and staff resources to be disseminated [**Figure 6-3**].

Equipment needs were also addressed at this stage. The Kellys forceps for vaginal PPIUC insertion were ordered and processed through sterile services, before being packaged into designated 'vaginal PPIUC' trays along with the other required equipment. Women could choose either the levonorgestrel-releasing intrauterine system or copper-bearing intrauterine device for PPIUC, and so stocks were ordered from pharmacy to ensure that a consistent supply was available in the both labour suites and theatres.

Figure 6-3: Resources developed to support PPIUC service delivery[9]

Pre-insertion/antenatal	• Patient information leaflet • Self-complete consent checklist • Community midwife pathway for managing PPIUC request • Posters • Local health website information • Information guide for community providers e.g. GPs
Procedural/post-delivery	• Insertion log • Training logbook • Staff posters – 'SIMPLE' mnemonic for insertion procedure (*Suitability, Informed consent, Materials, Person to fit, Leaflet, Entry record*) • Standard Operating Procedure • Supervision/insertion pathway (to access inserter/supervisor)
Post-insertion/aftercare	• Patient aftercare leaflet • Referral pathway for primary care • Quick reference guide/pathway for community providers (e.g. GPs) conducting thread checks

6.3.5 Site-level engagement and clinical pathways

We opted to introduce the intra-caesarean PPIUC service first. Women undergoing planned caesarean section were an easily identifiable group, and pre-existing visits to discuss surgery and obtain consent could be utilised for discussion about PPIUC. Obstetricians performing these surgeries constituted a small and well-defined group and therefore training could be targeted more easily.

This also allowed the service as a whole to become more familiar with PPIUC as a concept, easing the transition to later offering it at vaginal birth and emergency caesarean.

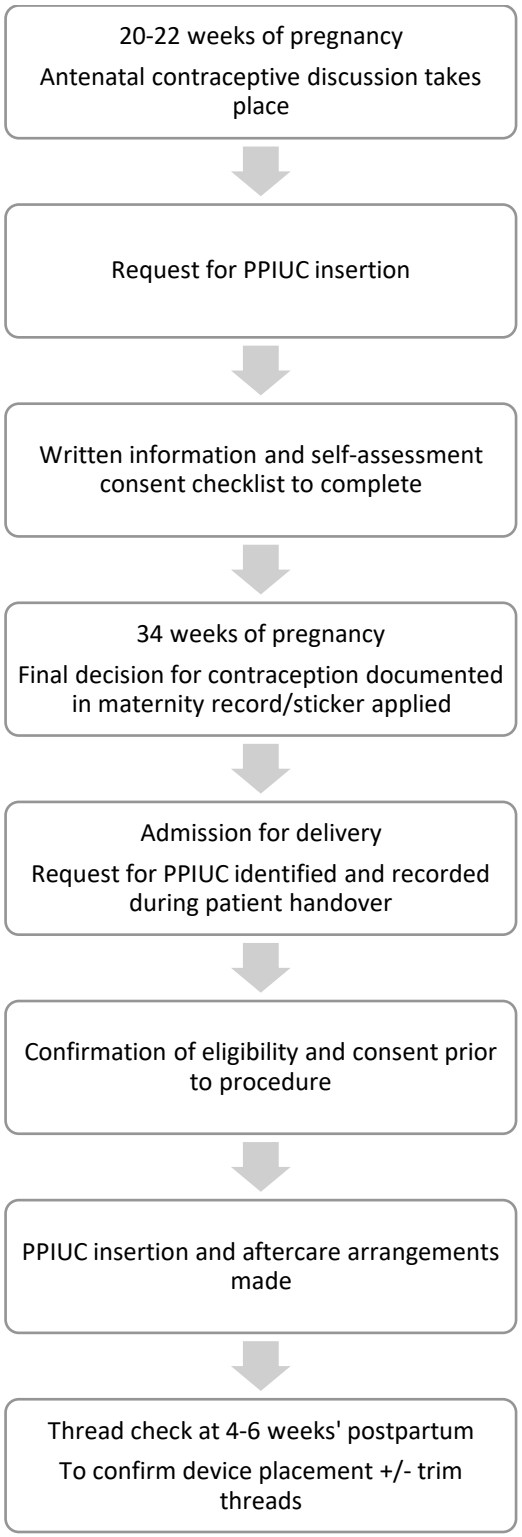
[9] Several of these resources are included in the Appendix section of this thesis

Due to the increased complexity of establishing a vaginal PPIUC service (training, equipment etc), the decision was taken to pilot this at the smaller maternity hospital first. This provided a valuable opportunity to review and modify the process before introducing this on a larger scale across the region. The arrival of PPIUC at each site was signalled by a 'launch week'. This involved on-site presence by the PPIUC research team in the outpatient antenatal clinic to directly engage with patients and staff, generating further enthusiasm and interest. Distribution of posters and leaflets in clinical areas helped to inform about service availability.

Clinical pathways were formalised and tested during this stage. An example of the patient journey for a woman requesting PPIUC in the region is shown in **Figure 6-4**. Women requesting PPIUC at delivery were identified via a visible sticker (of an IUD) on their clinical notes and information in their maternity record. After delivery, the attending doctor or midwife confirmed eligibility, ensuring that there were no contraindications (Royal College of Obstetricians & Gynaecologists, 2015) and re-confirmed consent before inserting PPIUC. At caesarean section, devices were fitted immediately after removal of the placental. After vaginal birth, a 48-hour period was available for insertion in line with current clinical guidelines (Faculty of Sexual & Reproductive Healthcare, 2017).

Following PPIUC insertion, women were recommended to attend for a thread check between four and six weeks to confirm device placement and trim long threads if required. These visits initially took place in a clinical research setting. Following full implementation of PPIUC, a local enhanced service agreement was developed enabling community-based practice nurses and GPs to perform aftercare checks and refer for ultrasound if necessary, in return for a nominal fee.

Figure 6-4: Clinical pathway for women requesting PPIUC in Lothian



6.3.6 Full service implementation

Following successful installation at the pilot site, the vaginal PPIUC service was extended to the larger hospital. The pilot experience allowed us to achieve installation more quickly and provided foresight into the potential obstacles that 'scaling-up' to a larger tertiary hospital setting may bring e.g. increased training requirements, larger patient population, higher clinical activity; and allowed for modification of some aspects of our approach. Experience and testimonies from patients and staff already involved in the PPIUC service assisted in overcoming many of the perceived barriers and in gaining wider support.

The National Implementation Research Network (NIRN) define full implementation as when more than 50% of personnel are involved in service delivery and suggest this may take between two to four years for any new service (Fixsen *et al.*, 2013). Over 100 obstetricians and midwives have attended PPIUC insertion training thus far in our service, representing more than 50% of the permanent labour ward workforce. Several midwives and obstetricians are now PPIUC 'trainers' which is essential to ensure ongoing sustainability of the service.

As the service becomes embedded, continued service promotion exercises to raise awareness among the wider public is important. For us this has included engagement with patient advocacy groups and involvement of local and national media channels. There is also ongoing evaluation work using both quantitative and qualitative means as part of a health service research co-funded by Wellbeing of Women and the Chief Scientist Office.

Since its introduction in 2015, almost 1000 women[10] have received PPIUC insertion at either caesarean section or vaginal birth. The PPIUC service at caesarean section is now fully established. Initial published outcome data (n=120) demonstrated a PPIUC uptake rate of 13.7% of all women having an elective caesarean (Heller, Johnstone

[10] Information correct at time of publication in 2018

and Cameron, 2017). There were no incidences of uterine perforation and one case of infection (0.8%). At 12 months, the cumulative expulsion rate was 8.8% and of those contactable (82.5%), 84.8% continued to use the method.

Site-wide implementation of vaginal PPIUC is now established with data collection and analysis ongoing. Early outcomes indicate a higher rate of device expulsion in line with other studies, however this is expected to decline with increasing provider experience (Cooper *et al.*, 2018).

6.3.7 Discussion

Our experience indicates that it is feasible to implement PPIUC within a publicly funded UK maternity setting. Ongoing investment in PPIUC training and education will be essential to ensuring a sustainable service. We have demonstrated clear demand from women for this service, with holistic care and convenience reported as key advantages. It is important for women to receive information about all available methods of contraception during the antenatal period, allowing them to make a considered and informed choice.

Development of a PPIUC service can allow more women to access effective contraception after childbirth. In the UK, this may help prevent more unintended pregnancies, and extend inter-pregnancy intervals to reduce complications. Through ongoing research and development of a shared-learning culture, it is possible for PPIUC to become more widely available across the UK.

~ End of published paper ~

6.4 Conclusions

Implementation science methodology can be used successfully to guide and appraise PPIUC implementation at an organisational level. By applying these principles, we were able to consolidate our approach to PPIUC service introduction and delivery, identify lessons learned and propose a generic framework to support wider dissemination. At the time of publication, implementation-science informed research in PPIUC was limited and this work was the first of its kind to be published from a UK centre. However, since then the role of implementation support in bridging the gap between evidence-based recommendations and practice change in PPIUC has been increasingly recognised (Rankin *et al.*, 2016; Hofler *et al.*, 2017; Harper *et al.*, 2020; Horvath, Bumpus and Luchowski, 2020).

Our findings in relation to the integral components of successful implementation are consistent with other studies. In particular, the role of the clinical 'champion' is a frequently recurring theme (Okoroh *et al.*, 2018; Bonawitz *et al.*, 2020; Harper *et al.*, 2020). One comparative case study of PPIUC implementation in 11 maternity centres in the US identified the role of the 'champion' as so important, that it sought to identify the key attributes of 'champions' from qualitative interviews (Bonawitz *et al.*, 2020). One attribute identified was 'the physical presence at the point of change' – a feature that was fundamental to our own success in Lothian.

In my opinion, the role of the PPIUC 'champion' can be considered in two main realms. Firstly, the 'internal' role of the champion is to build and strengthen links within the multidisciplinary team at institution level to support change and overcome challenges. At an 'external' level, the 'champion' can assist in prioritising the agenda for PPIUC within the government and public health arena by informing about existing evidence and advocating for change. An implementation-science based framework could prove a particularly useful tool in bridging the gap between research and routine clinical provision. This will also likely involve early-adopter sites sharing examples of best practice and lessons learned.

This shared-learning approach has been recognised by a number of centres in the US as crucial in supporting the scale-up of PPIUC and LARC interventions across state regions, and in helping to overcome challenges during the implementation process (Hofler *et al.*, 2017; Brown, Greenfield and Rapkin, 2020; Lacy *et al.*, 2020). Some of the challenges encountered during PPIUC service introduction are likely to be similar, whereas others may be specific to the organisation or geographical region. Therefore, a blended approach of generic implementation guidance supplemented by expert advice and local knowledge is essential. This has proved an effective strategy in the US, where for example rules regarding reimbursement for postpartum LARC can differ between states (Horvath, Bumpus and Luchowski, 2020) and as such individualised adaption of universal policy has been required to expand provision.

This may also be applicable in the UK. Although contraceptive costs to the user are not an issue within the NHS, there are unique challenges involved in introducing PPIUC into a publicly funded health service. In England for example, the responsibility and funding for contraception is primarily community-led, and at present most maternity hospitals are neither funded nor staffed to provide additional contraceptive services (Public Health England, 2013). However, as the evidence around unintended postpartum pregnancy and service-user demand continues to grow, the landscape is slowly changing. Therefore, this may be an opportune time to educate and share experience of PPIUC provision.

In the final chapter, I will seek to summarise how the research contained within this thesis may be used to inform and guide the increased availability of PPIUC in the UK, and the progress made with this to date.

Chapter 7 Final discussion, implications and future research direction

7.1 Introduction

In this final chapter I will examine the research contained within this thesis within the context of increasing access to immediate postpartum intrauterine contraception in the UK. This will include a summary of the main findings as they relate to the original research aims and background literature, the implications of this work more widely and ideas for future research direction.

7.2 Postpartum contraception: are we delivering?

In Chapter 1 I introduced the role of postpartum contraception in the prevention of unintended pregnancy. Prior UK research demonstrated that at least one in 13 women experience either an unintended pregnancy leading to abortion, or a short inter-pregnancy interval, in the 12 months after childbirth (Heller *et al.*, 2016). Short inter-pregnancy intervals are linked with negative outcomes for maternal and neonatal health (Smith, Pell and Dobbie, 2003). Managing the consequences of unintended pregnancy come at considerable cost to the NHS, as well as emotional costs to women and their families. Many of these can be mitigated by providing contraceptive care that effectively meets the needs of women during this unique time in their lives.

Traditional pathways for accessing postpartum contraception in the UK often fall short in providing convenient, comprehensive and equitable access. Previous studies with both GPs and midwives in the UK reported inadequate time for a full discussion

about contraception, especially LARC (McCance and Cameron, 2014; Lunniss, Cameron and Chen, 2016). Furthermore, when interval appointments are provided for LARC initiation, up to 50% of women do not attend (Cameron *et al.*, 2017; Thwaites *et al.*, 2018). Indeed, the need to attend multiple visits presents a barrier for new mothers trying to access contraception.

Given the early resumption of sexual activity and fertility in the weeks after childbirth (Jackson and Glasier, 2011; McDonald and Brown, 2013), the immediate postpartum period presents an optimal time to commence contraception and is a highly convenient option for women. This was recognised by the FSRH in the 2017 'Contraception after Pregnancy' guideline which explicitly states that women should be able to access their chosen method of contraception before leaving the delivery unit, following full discussion during the antenatal period (Faculty of Sexual & Reproductive Healthcare, 2017). This has also been echoed in numerous Government health policies and public health strategies in the UK.

> "NHS England, NHS Scotland, NHS Wales and Health and Social Care Northern Ireland must embed immediate post-pregnancy contraception maternity pathways and support for all women. Until 100% implementation has been achieved, clear referral pathways into general practice or sexual and reproductive healthcare clinics should be provided. All midwives and allied professions should be trained to provide this important aspect of this holistic maternity pathway and reproductive care"
>
> *Better for Women* Report, 2019 (Royal College of Obstetricians & Gynaecologists, 2019)

As a result, there is an increasing focus is on maternity services in the UK to expand provision beyond current models of care. The UKMEC supports the use of most methods of contraception after childbirth, including LARC, and these methods in particular have been shown to be superior to short-acting methods in the prevention of unintended pregnancy and short IPI. However, these guidelines and directives have not yet translated into routine access to all methods of contraception after childbirth for all women. This is especially true for PPIUC, which is a relatively under-utilised option.

In Chapter 2 I appraised the available literature in relation to immediate postpartum insertion of IUC after vaginal birth. This showed that vaginal PPIUC was safe for both breastfeeding and non-breastfeeding women; with low rates of complications such as infection, uterine perforation and bleeding problems (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). It is a highly acceptable option for women, providing both convenience and possibly less insertion-related pain (Braniff, Gomez and Muller, 2015). While the expulsion rate of vaginal PPIUC appears higher than for non-postpartum insertion, women who opt for immediate insertion are more likely to actually initiate and continue the method (Lopez *et al.*, 2015; Sonalkar and Kapp, 2015). Therefore, in public health terms it remains a valuable option for reducing unintended pregnancy and short interpregnancy intervals.

But in spite of these numerous advantages, PPIUC provision is not common practice in the UK. In Chapters 1 and 2, I introduced some of the potential barriers for this including provider myths and misconceptions; lack of appropriate education and training; and at the time of study, a relative absence of implementation-based research supporting the introduction of these services into complex health systems. Of the research which now exists in this area, most has originated from LMIC settings and the US, and is not directly applicable a publicly funded healthcare setting such as the UK.

7.3 What this research adds

The over-arching aim of this research was to introduce and evaluate PPIUC after vaginal birth in a UK maternity setting using a health services research model. The intention was to determine both clinical and qualitative outcomes across a number of different aspects of the implementation process.

Chapter 3 reported the feasibility and clinical outcomes of an observational study of routine provision of vaginal PPIUC. A total of 465 women having a vaginal birth (5% uptake) opted to receive immediate postpartum insertion (within 48 hours) of either the CU-IUD or 52mg LNG-IUS. This was provided by newly trained midwives and obstetricians within the context of routine maternity service delivery. The 447 women who received vaginal PPIUC were followed-up in person at six weeks and by telephone at three, six and 12 months. The overall complication rate was less than 1% and the complete expulsion rate was 29%. Most insertion procedures were provided by midwives, and secondary analysis of hazard ratios for expulsion found that this outcome was more likely for insertions performed by midwives compared to doctors. No difference was demonstrated by device type. Despite the high overall rate of expulsion, most women chose to have further IUC inserted at the follow-up visit such that at 12 months overall method continuation was 80%. Patient satisfaction was high with 98% of women stating they would recommend PPIUC to others.

This work demonstrated that it is safe, feasible and acceptable to provide PPIUC in a UK setting. However, it highlighted a number of the challenges which may be encountered during the early introduction of these services, including the need to rapidly train a multi-professional workforce in adequate number to achieve universal provision. This can lead to delays in insertion timing (which some studies suggest are linked to higher expulsion) and a longer time frame for individual providers to develop mastery of the skill. Given the role of inserter experience in optimising

clinical outcomes, it is clear that the service delivery of PPIUC and efficacy of this intervention are inextricably linked.

In this study, we found that the vast majority of women who expelled their device opted for re-insertion at the initial follow-up visit. This suggests that the experience of expulsion does not diminish women's enthusiasm for the method. It also highlights the important role of PPIUC aftercare; both in terms of identifying an expulsion or other issues (such as long threads), but also in providing an opportunity for further insertion if desired. The structure and delivery of PPIUC aftercare is therefore an essential component of service development.

In the context of a introducing a new and unfamiliar service to the UK, the inclusion of a robust follow-up pathway will also help to provide quality assurance amongst women and providers. Therefore, ensuring 'buy-in' from those involved in PPIUC aftercare is as essential as from those directly involved in PPIUC provision. This is of particular relevance in UK setting as those involved in aftercare are likely to be a different group of staff (GPs, practice nurses and sexual health clinicians) from those performing the insertion procedures (midwives and obstetricians).

In Chapter 5, I explored the acceptance and views of community sexual providers by means of a national mixed methods survey. Of the 156 who completed the survey (response rate 65%), 82% reported feeling 'positive' towards PPIUC provision in the UK, and most (68%) said they would be happy to support the aftercare of women following PPIUC insertion. Perceived challenges among participants included competing clinical workload; difficulties accessing to ultrasound if required and a lack of awareness and experience of managing clinical issues unique to PPIUC. Arguably one of the most important aspects of PPIUC service delivery is the training and education of healthcare providers. This is especially true in the UK where providers have limited or no experience of the procedure.

In Chapter 4 I discussed in detail our approach to successfully training previously inexperienced midwives and obstetricians in vaginal PPIUC insertion through a

combination of theory, simulation and direct clinical supervision. This blended learning approach, and its accompanying resources, was shown to be a feasible model for training maternity providers in large number across an NHS organisation. Incorporating a 'train the trainers' arm within the programme was key to ensuring the ongoing sustainability of the training, which has since continued in the region.

As part of the training evaluation process, a survey was conducted among the midwives and doctors who took part. All participants rated the quality of training as either 'very good' or 'excellent', and the level of complexity as 'about right' or 'easy'. The survey also sought to identify perceived challenges which included ensuring adequate supervision and time to perform the procedure within the busy clinical environment of labour ward. These are not unique challenges and are likely to present themselves within any clinical environment aiming to establish PPIUC services. In addition to ensuring patient safety and efficacy, training and education has the additional role of overcoming misconceptions and increasing acceptance amongst providers. These are known to be common in relation to PPIUC and may present a barrier to the wider uptake of this intervention. By gaining a better understanding of the facilitators and barriers involved in establishing and providing PPIUC, we can better support the dissemination of this intervention across the UK in a more rapid and streamlined way.

Understanding and overcoming the challenges involved in introducing new services into complex health systems describes in part the role of implementation science methodology. More recently, for the reasons indicated above, this has become an increasing focus of the literature around PPIUC provision and the experiences of early adopters of these services are fundamental to this.

In Chapter 6, I sought to consolidate the knowledge and understanding gained from the investigative studies contained within this thesis into a conceptual 'framework', by utilising key principles of implementation science. The aim was to propose a generalised systematic approach to PPIUC implementation, with a view to supporting replication of this work in other regions of the UK. The approach was framed around

four stages as devised by the National Implementation Research Network (NIRN): exploration, installation, initial implementation and full implementation; with consideration of the key components involved at each stage. Full implementation is defined by the NIRN as when at least 50% of personnel are involved in service delivery (Fixsen *et al.*, 2013), which was achieved by the end of this study.

This chapter also described some of the barriers and facilitators encountered in service implementation. For example, the important role of the clinician 'champion' in gaining support, driving change and overcoming difficulties. This concept has since featured in several other studies seeking to further define the approach to PPIUC implementation. In addition to supporting replication and scale-up of PPIUC services in the UK, the aim is that by sharing knowledge in a structured and evidence-based way, a consistent approach to training and service delivery may be achieved.

7.4 Strengths and limitations

At the outset of this project, there were no previous studies of vaginal PPIUC in the UK and few more widely which sought to evaluate this intervention under 'normal' clinical conditions. The strength of this approach lies in the ability to investigate the outcomes of PPIUC beyond solely clinical parameters, and to help bridge the gap between research and clinical practice. This is recognised as one of the principal barriers to the widespread provision of PPIUC (Rankin *et al.*, 2016; Harper *et al.*, 2020), and is particular challenge in the UK given the lack of familiarity with the technique.

However, there were also several limitations. As the service was introduced and evaluated simultaneously, the outcomes may not be reflective of a more established service. This is particularly true in relation to the expulsion rate, which was found to be higher than in previous studies. As the service was established as part of a research study, some of the challenges which may be experienced in relation to funding

support were less of an issue. However, the data and evidence used to gain research funding support will likely be similar to that used to inform PPIUC business cases within local health boards.

While this research was able to demonstrate that vaginal PPIUC provision is safe, effective and acceptable to both women and a range of providers; it does not include an evaluation of cost-effectiveness. I recognise that this is a central component of implementation research and an important consideration for hospital managers and policymakers. In addition to time constraints for this project, the research included in Chapter 3 did not include a comparison group by design. As such there were inherent difficulties in comparing the cost effectiveness of PPIUC in this setting compared to standard practice within our population.

Finally, the qualitative research contained within this thesis is limited to survey-based methods which may not wholly reflect the broader views and experiences of the groups in question. As indicated in Chapter 3, our wider study included a qualitative arm which sought to explore the views and experiences of both women and healthcare providers through focus group discussions and one-to-one interviews. Work published so far indicates that women opted to receive PPIUC due to perceived convenience and most were satisfied with their experience, in particular the aftercare provided to them following insertion (Boydell *et al.*, 2020). However, some reported service delivery issues including delays in receiving PPIUC and occasional lack of communication from staff during busy periods. This again highlights the value of conducting this research in a 'real life' clinical environment, so that we can learn from and adapt our approach and share valuable lessons learned with others seeking to establish these services.

7.5 Impact of this work to date

The work contained within this thesis has already informed a number of important developments in expanding access to PPIUC provision in the UK. Recognising the challenges involved in ensuring a consistent and easily accessible approach to training, I have since led the development of a national e-learning resource commissioned by the Scottish Government. This launched in September 2019 and is available to all NHS staff in Scotland via the LearnPro® NHS platform, with some health boards including it as a mandatory module for those working in maternity services. It includes evidence-based information about the role and provision of postpartum contraception, as well as the theoretical component of PPIUC insertion training. In conjunction with on-the-job practical training supported by in-house trainers, the aim is to reduce barriers to accessing PPIUC training while ensuring a consistent approach between regions.

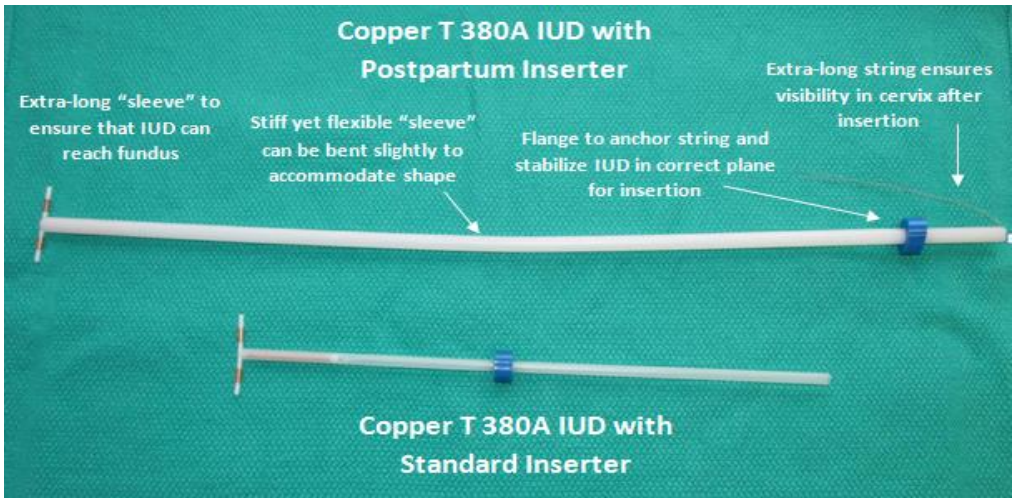
Several of the PPIUC clinical resources that were we developed to support this project are now available on the FSRH website (for members). More recently, a successful application has been made to the RCOG to host a comprehensive PPIUC 'toolkit' on their e-learning platform. The aim is to incorporate not just practical training information but to incorporate some of broader knowledge of PPIUC implementation gained from our experience. This may help to further promote acceptance and enthusiasm for PPIUC with a view to increasing access to this service in the UK.

7.6 Further research

Despite growing enthusiasm for PPIUC, the expulsion rate associated with vaginal PPIUC insertion is often reported as a 'limitation' of the intervention. Provided women are appropriately informed and measures are in place to detect and manage expulsion, it should not outweigh the many advantages offered by PPIUC. Nonetheless, minimising the risk of expulsion is an important quality assurance consideration. There remains limited evidence about the factors associated with expulsion and gaining further understanding could prove useful. While it is recognised that insertion technique may play a role, there is little evidence about how this can be optimised beyond 'inserter experience' i.e. increasing the number of procedures performed. As mentioned in earlier chapters, there are now dedicated postpartum inserters available in some countries (for both LNG-IUS and CU-IUD) which more closely resemble a standard IUC inserter **[Figure 7-1]**.

While these have not been shown to be superior to forceps insertion in clinical trials (Blumenthal *et al.*, 2018), they have not been tested in a UK setting. Given the challenges reported by some midwives in our study regarding use of the forceps to achieve insertion, the dedicated inserter may present a more acceptable option, particularly for those approaching PPIUC insertion with greater hesitancy.

Figure 7-1: Image of dedicated postpartum IUD inserter (courtesy of Pregna International Ltd)



As noted in Chapter 2 the incidence of non-visible threads is common following PPIUC insertion. Although from our data this is a less frequent occurrence when PPIUC devices inserted vaginally compared to during caesarean section (19% versus 50%) (Heller, Johnstone and Cameron, 2017). A recurring concern amongst providers is the perceived difficulty associated with removal of devices in the absence of visible threads. While subjective reports suggest this is not a significant issue, there is no formal published data investigating removal outcomes following PPIUC insertion as primary outcome. This is in part due to the lack of longer-term data (beyond 12 months) of PPIUC in the literature, which presents another potential area for further study. It would also require robust long-term follow-up pathways and centralised outcome reporting, which are often absent from many of the larger PPIUC studies in LMIC settings. However, these data would be useful to ensure women are effectively counselled regarding the potential long-term consequences of PPIUC insertion, and to better inform clinicians with reliable evidence.

At present, cost-benefit analysis for PPIUC is limited to the US setting. These studies have confirmed the cost-effectiveness of PPIUC, even in the presence of expulsion rates beyond those reported more widely in literature (Washington *et al.*, 2015). General LARC provision is well recognised as a cost-effective intervention in the UK (National Institute for Health & Care Excellence (NICE), 2005) and given the similarities in study populations, it likely that inferences drawn from US data for PPIUC are accurate, but at present no specific published data exists around PPIUC provision in the UK. While this is not surprising given the limited availability of this service, it is an important focus for further study and a valuable tool for garnering further support to expand these services.

Although the research contained in this thesis primarily relates to intrauterine contraception, it is important that this not viewed in isolation. It is my belief that PPIUC should be provided as part of a comprehensive postpartum contraceptive package, including the opportunity for women to receive antenatal contraceptive counselling and immediate postpartum access to the full range of methods. This will

help to ensure we support women's informed choice and reduce the potential for LARC coercion (Wale and Rowlands, 2020). While postpartum contraception should be readily accessible to all, in order to achieve equitable access, further research is needed about how to engage harder to reach groups such as younger women and those from black and minority ethnic backgrounds, who may experience even greater difficulty accessing mainstream sexual health services.

Beyond the scope of postpartum contraception, there is a need to explore contraceptive access in other post-pregnancy situations such as following a miscarriage, ectopic pregnancy or stillbirth; where research suggests current provision is even more limited (FSRH 2017).

7.7 Conclusions

By harnessing the available evidence which supports the safety and efficacy of PPIUC with the experience of providing this service within the NHS, it is hoped that this research will go some way to bridging the translation gap in PPIUC implementation. By doing so it may be possible to increase access to this service in the UK and to simplify and expand contraceptive choice for women after childbirth.

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Appendix 1 PPIUC training resources developed as part of this research

1) Training logbook
2) Memory aid poster “It’s SIMPLE”
3) Participant knowledge test (single best answer)
4) Learner experience survey

NHS Lothian

Vaginal PPIUC Insertion Record

Name:

Insertion Checklist

1. Check notes to ensure self-assessment checklist completed and ensure no contraindications to immediate PPIUD insertion such as
   a. **Prolonged rupture of membranes > 36 hours**
   b. **Signs of intra/post-partum sepsis**
   c. **Unresolved PPH**
2. Device should be fitted as close to time of delivery as possible, but there is a window of **up to 48 hours** for insertion
3. Confirm correct equipment available
   a. 'PPIUC Tray' containing Kellys forceps, Rampleys, scissors, swabs
   b. Also required - Gallipot, cleaning solution, IUD of choice (UT380 or Mirena IUS)
4. Perform hand hygiene and wear sterile gloves
5. Position woman on bed and inspect perineum – you may choose to repair any lacerations first, especially if these are bleeding
6. Visualise cervix by inserting Sims speculum to depress the posterior vaginal wall, and clean using antiseptic solution
7. Gently grasp anterior lip of cervix with ring forceps up to first lock only
8. Grasp IUD in the sterile pack using a no-touch technique
9. Apply gentle traction on the anterior lip of cervix and insert IUD into lower uterine cavity, avoiding contact with the walls of the vagina
10. Once placental forceps are in lower uterine cavity, lower the ring forceps holding cervix and move left hand to woman's abdomen to push entire uterus superiorly upwards to straighten the canal
11. Move the placental forceps towards the fundus following the curve of the uterus. Keep the instrument closed so as not to drop the IUD and take care not to apply excessive force.
12. Confirm that the end of the placental forceps has reached the fundus, and tilt the forceps slightly inwards before opening them to release the IUD
13. Sweep the placental forceps to the right side-wall of the uterus (maternal left) and stabilise the uterus with your hand to help prevent the IUD being drawn downwards
14. Slowly remove the placental forceps, taking care not to dislodge the IUD and maintain stabilising pressure until forceps are completely removed
15. Examine to cervix to ensure that IUD is not seen protruding through. If this is the case, remove and reinsert. Do not attempt to push the IUD back up using forceps. If the threads appear very long, the device has not been placed at the fundus and should be removed (using the same forceps) and reinserted.

Counselling and Contraindications

Possible side effects

- Perforation: 1-2 per 1000 insertions
- Expulsion: 1 in 20 with interval insertion, up to 1 in 7 with immediate postpartum insertion
- Infection: 1 in 100 over first few weeks, thereafter not increased
- Failure: Less than 1 in 1000
- Ectopic pregnancy: not increased compared with using no contraception
- Bleeding patterns: Irregular bleeding common for first 6 weeks with IUS, mostly settle with time. Periods may be heavier with copper IUD

When can an IUD <u>not</u> be inserted immediately postpartum?

- Ruptured membranes > 36 hours
- Unresolved postpartum haemorrhage
- Presence of sepsis

Which women should <u>not</u> use an IUD in general?

- Abnormal uterine anatomy e.g. large fibroids
- Unexplained abnormal vaginal bleeding
- Active/current PID or pelvic TB

Vaginal PPIUC Insertion Log **Name:**

No.	Date	Patient ID	Supervised by*	Immediate problems or complications	Comments
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

COIL AT DELIVERY
LOTHIAN PPIUC

NHS Lothian

THE UNIVERSITY of EDINBURGH
MRC Centre for Reproductive Health

PPIUC: It's "SIMPLE"

Suitability	No sepsis? No PPROM >36hrs? → **GO** No ongoing PPH?
Informed consent	Self-assessment checklist completed?
Materials	'Vaginal PPIUC' Tray Located: _____ *(+ coil, cleaning solution, Gallipot, gloves)*
Person to fit	Contact on-call medical staff +/- supervisor (AA/YC/MC)
Leaflet	'Post-insertion advice' green leaflet to woman
Entry record	Enter details on TRAK and Labour Suite register (PPIUC Folder – behind main desk)

PPIUC Knowledge Test: Single Best Answer **Name:**

1) **What is the estimated risk of expulsion with immediate vaginal post-placental IUD insertion?**
   A. 1 in 20
   B. 1 in 7
   C. 1 in 10
   D. 1 in 5 **ANSWER:**

2) **Which of the following methods of contraception can <u>NOT</u> be initiated immediately following delivery in postpartum women?**
   A. Copper IUD
   B. Implant
   C. Combined Oral Contraceptive
   D. Progestogen-only Injectable **ANSWER:**

3) **Which of the following methods of contraceptive methods is least effective?**
   A. Progestogen-only Pill
   B. Copper IUD
   C. Implant
   D. Mirena IUS **ANSWER:**

4) **Which of the following is <u>NOT</u> a routine step in the recommended procedure for post-placental IUD insertion?**
   A. Visualise the cervix
   B. Correct the uterine angle
   C. Release the IUD at the fundus
   D. Measure uterine length with a sound **ANSWER:**

5) **Which of the following would exclude a woman from receiving PPIUD?**
   A. Operative vaginal delivery
   B. No regional anaesthesia
   C. Prolonged rupture of membranes >36 hours
   D. Intention to breastfeed **ANSWER**:

6) **Which of the following factors is associated with an increased expulsion rate of an IUD inserted immediately after delivery?**
   A. Appropriately trained inserter
   B. Non-fundal placement of the device
   C. Use of syntocinon
   D. Breastfeeding **ANSWER:**

7) **Which of the following does <u>NOT</u> feature in the aftercare advice provided to women following PPPIUD insertion?**
   A. Condoms until device location is confirmed
   B. How to recognise expulsion
   C. Follow-up check required at 4-6 weeks
   D. Regular self-checking of threads **ANSWER:**

8) **Which of the following is <u>NOT</u> an appropriate time to insert an IUD following birth?**
   A. Within 10 minutes of placental delivery
   B. 12 hours following delivery
   C. 3 weeks following delivery
   D. 6 weeks following delivery **ANSWER:**

PPIUC Post-Training Survey (Midwives – SJH/RIE)

About This Survey

The aim of this survey is to gather feedback about your personal experience of PPIUC (postpartum intrauterine contraception) in Lothian. It should take around 5-10 minutes to complete and your responses are anonymous. We thank you for taking the time to complete this survey.

Background Information

1) What is your current grade and base? (*please tick one*)

	√
Band 7+ Midwife	
Band 6 Midwife	
Band 5 Midwife	
Other (*specify*):	

2) Main place of work (at time of training)? (*please tick one*)

Labour Ward Maternity Ward Community

Other (specify):

3) Approximate number of intrauterine device (IUD) insertions in the **non-postpartum setting** during the last 12 months? (*please tick one*)

	√
None	
Less than 10	
Between 10 and 30	
More than 30	

4) Are you a current holder of any of the following? (*please tick all that apply*)

Local "Contraceptive Champion" certification

Full Diploma of Faculty of Sexual & Reproductive Health (nDFSRH)

FSRH Letter of Competence in Intrauterine Techniques (LoC IUT)

Training Experience

5) Please rate the **overall quality** of the PPIUC training you received (*please tick one*)

Excellent Very Good Average Poor Very Poor

Please turn to next page

1) How **useful** did you find each aspect of the PPIUC training package? (*please tick one per row*) ([Scale: 1 = Not At All, 5 = Extremely]

	1	**2**	**3**	**4**	**5**
Theory/background information					
Video of insertion technique					
Model simulation training					
Supervised clinical practice (*if applicable*)					

2) How would you rate the PPIUC training in terms of **difficulty**? (*please tick one*)

	√
Too Hard	
Hard	
About Right	
Easy	
Too Easy	

3) What are the **main challenges** (if any) you have encountered or anticipate during the PPIUC training? (*free text box*)

4) What **one** aspect of the PPIUC training would you improve? (free text box)

5) Would you be interested in becoming a PPIUC **trainer** within your workplace?

Yes No

6) If you have any further comments or suggestions in relation to PPIUC training in Lothian please use the space below:

Thank you for taking the time to complete this survey

If you have any further questions or comments, or wish to raise any concerns please contact
Dr Michelle Cooper

1

Appendix 2 PPIUC clinical resources developed as part of this research

1) Patient information leaflets
2) Self-assessment consent checklist
3) Standard operating procedure
4) Clinic room poster
5) Aftercare pathway

Intrauterine contraception, commonly known as a 'coil', is one of the most effective ways of preventing or delaying a further pregnancy. It is now possible to have this fitted shortly after your baby is born.

Why might this be good?

- Provides contraception straight away
- Quick procedure – only takes a few minutes
- Convenient – one less visit/examination at a later date
- May be less painful due to pain relief used during labour
- Safe to use while breastfeeding
- Either the hormone coil (Mirena®) or hormone-free copper coil can be fitted at this time

What else do I need to know?

- You will still need to have check-up at around 4 weeks after insertion to make sure the threads can be seen and to trim them if needed
- There may be a slightly higher chance of the coil becoming expelled as your womb returns to its non-pregnant size
- Most women will be aware if this happens - we will be able to check this for you at your appointment and fit another coil for you if needed

NHS Lothian Sexual Health Webpage:

www.lothiansexualhealth.scot.nhs.uk

What happens after the coil is fitted?

You will need to have a check-up at between 4 and 6 weeks after insertion to make sure the coil threads can be seen, and to trim them if needed. This can be done at a time that suits you and you can bring your baby with you if you wish. If the threads can not be seen you will need an ultrasound scan to check that the coil is still inside the womb. This is usual after any coil insertion and can usually be done at the same visit.

We would recommend that you use an additional form of contraception e.g. condoms, until you have been seen to check that the coil is in the correct place.

I'm keen to have this – what should I do next?

You should let your midwife or obstetrician know. There is a quick checklist for you to complete to make sure you understand the method and insertion procedure. A trained doctor or midwife will then fit this for you shortly after your baby is born.

If for any reason you can't have your coil fitted at this time, we can arrange an appointment for you to have this done a few weeks later.

I'm not sure – where can I find out more about it?

You can have a look at Lothian Sexual Health website where you will find more information about all types of contraception, and the different types of coil available.

If you have any further questions you can also speak to your midwife or obstetrician, or contact the dedicated team from Chalmers Centre using the details on the back of this leaflet.

For more information you can speak to your midwife or obstetrician, or contact the dedicated team from Chalmers Centre below who will be happy to help.

Contact Information

PPIUC Team Mobile
XXXXXXXXXX

Available Monday to Friday during daytime hours. A message can be left if there is no answer.

This leaflet should only be used by women giving birth in Lothian.

Guide to IUC at Vaginal Birth. Oct 2018 v3.0 (MC)

NHS
Lothian

Intrauterine Contraception or 'coil' insertion at the time of vaginal birth

A guide for women

What will happen now?

In the first 24 hours after a coil fitting you might experience mild, cramping abdominal pain. Simple painkillers can help with this if needed.

During the first few weeks, there is a slightly higher risk of infection developing inside the womb. Signs to look out for include: pain that does not go away, fever or feeling generally unwell, heavy bleeding or a vaginal discharge which may have a smell.

If you are worried or develop any of these symptoms you should contact your doctor or the dedicated team at Chalmers Centre (contact details on back of this leaflet).

When should I have my first check-up?

It is important that you are seen at around 4 to 6 weeks to have your coil checked. At this visit, we will be able to confirm that the coil is in the correct position and trim the threads if needed.

You should use condoms until this check-up visit as there is a small chance the coil may not be in the correct position.

What will happen to my bleeding?

- **If you have had a Mirena/IUS fitted:**
  - The normal bleeding you experience after having probably be lighter than normal and may stop earlier
  - After that it is normal to experience irregular bleeding or spotting for up to 6 months
  - This usually settles and in time your periods will become lighter or may stop altogether
- **If you have had a copper IUD fitted:**
  - When your periods return they may be a day or two longer than they used to be and can be a bit heavier, although this is not the case for everyone

Is it OK to use tampons?

We recommend that you avoid using tampons in the first few weeks after your coil fitting because of the slightly higher risk of infection. It is fine to use tampons after this although do take care as occasionally the threads of coil may be long at the start and can become entangled.

I think I can feel my threads – is that normal?

Often when a coil is fitted at the time of vaginal birth the threads are left long and come down into the vagina as your womb returns to normal size. We can check this for you at your check-up appointment and trim the threads if necessary. However, if you feel or see the threads before then you should contact us sooner to have them trimmed. Try to avoid pulling on the threads yourself as the coil may be removed by accident.

I think my coil might have fallen out – what should I do?

Although uncommon, sometimes the coil can become expelled from the womb. If you suspect this might have happened it is important that you contact us as soon as you can and avoid any unprotected sex until this has been checked.

Can I start having sex again?

You can start having sex again whenever you feel ready although the timing of this will vary for each woman. Both types of coil are very good at preventing pregnancy and will start working straight away if the coil is in the right place. We will be able to confirm this for you at your first check-up.

However, if you do have sex before your first check-up, we would recommend that you use condoms (or alternative contraception) until we can make sure that the coil is in the correct position.

If you have any questions or concerns, please contact the dedicated team from Chalmers Centre using the details below.

In case of an emergency, or if you feel unwell, you should contact your GP or NHS 24.

Contact information:

PPIUC Team Mobile
XXXXXXXXXXX

Available Monday to Friday during daytime hours. A message can be left if there is no answer.

This leaflet is intended for use by women who have had a coil inserted at the time of vaginal birth in Lothian.

Advice after IUC at Vaginal Birth. Oct 2018, v5.0 (MC)

NHS Lothian

Advice for women following coil fitting at the time of vaginal birth

You have been fitted with a:

Date of insertion:

Date for change/removal:

Follow-up appointment:

PREPARING FOR INSERTION OF AN INTRAUTERINE DEVICE (COPPER IUD OR IUS/MIRENA®) AT THE TIME OF VAGINAL BIRTH

We will aim to insert an IUD/IUS for you shortly after your baby is born if you wish. It is important that you have read the following information beforehand and are suitable to have it fitted at this time. You can speak to your doctor or midwife if you have any questions.

Please bring this completed form with you when you attend your next antenatal appointment.

Please tick the boxes to confirm that you have **understood and agreed** to the following:

- ❑ I have read the leaflet ***or*** viewed the website information ***or*** I have already had an IUD/IUS and am familiar with the method.
- ❑ I understand that no method is 100% effective but that the IUD/IUS has a very low risk of failure (less than 1 pregnancy per 100 women over 1 year).
- ❑ I understand that there might be up to a 2 in 1000 chance of injury to the womb (perforation) at the time of insertion of the device.
- ❑ I understand that there is approximately a 1 in 7 chance of the device coming out/being expelled from the womb after insertion – slightly higher than if it were inserted a few weeks later (1 in 20).
- ❑ I understand that the IUD/IUS will not protect against sexually transmitted infections and condoms are recommended in addition if, for example, I have a new partner.
- ❑ I understand that there is a small risk of infection (1 in 100) in the first few weeks following insertion of the device – this is not any higher when inserted shortly after childbirth.
- ❑ I know that a copper IUD can make my periods slightly heavier, longer and more painful.
- ❑ I know that an IUS (*Mirena*®) will make my periods much lighter but can cause some erratic bleeding or spotting in the first few months of use.
- ❑ I understand that I will need to attend a check-up at around 4 to 6 weeks as the coil threads might need to be trimmed. If threads are not seen at this time, I will need an ultrasound scan to confirm that the IUD/IUS is still in place.
- ❑ I understand that in rare circumstances it may not be possible to fit the device immediately after childbirth, and in this situation it would be postponed for at least 4 weeks.

Print Name (patient): _____ Date: _____

Signature (patient): _____

Completed form should be checked and filed in handheld maternity notes

Pre-insertion checklist, July 2017 v2.0 (MC)

NHS Lothian

Standard Operating Procedure (SOP)

INSERTION OF POST-PLACENTAL INTRAUTERINE CONTRACEPTION FOLLOWING VAGINAL DELIVERY

Current Version /Date	**v1.2 16/06/2018**	**Author(s)**	MC/STC
Previous Version/Date	v1.1 16/01/2017	**Approved by**	Lothian PPIUC Steering Group
Next Review Date	01/06/2019	**Approval Date**	20/01/2017

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1. Background

This guidance has been produced to standardise the insertion procedure for routine insertion of an intrauterine device following vaginal birth.

It should only be carried out by a healthcare professional following completion of an accepted local training programme.

2. Scope

This SOP covers the insertion of an intrauterine device (levonorgestrel-system or copper IUD) in the immediate postpartum period. This is defined as within 48 hours following a spontaneous or assisted vaginal delivery. Insertion may take place in a labour room, maternity theatre or other suitable clinical setting.

This SOP does not cover intrauterine device insertion beyond the first 48 hours following birth, at the time of early pregnancy loss or termination, or during a caesarean section.

3. Responsibilities

It is the responsibility of the person performing the procedure to ensure they have received the appropriate training and supervision to proceed.

It is the final responsibility of the person performing the procedure to confirm that the woman is suitable to have the method fitted, and has had sufficient time to consider appropriate written and verbal information prior to insertion.

4. Procedure

4.1 Assessment and Eligibility

An assessment should be carried out prior to insertion to ensure suitability for the method and procedure.

The procedure should **NOT** be performed in the presence of the following:

- Suspected or confirmed sepsis
- Prolonged rupture of membranes > 36 hours*
- Unresolved post-partum haemorrhage
- Any contraindication to an intrauterine method of contraception e.g. abnormal uterine anatomy, active pelvic infection

*RCOG states > 24 hours but locally agreed policy for > 36 hours

4.2 Timing

Post-placental insertion can take place at any suitable time within the first 48 hours following vaginal birth. However, this should ideally occur as soon after delivery of the placenta as possible.

Any insertion request which can not be completed within the first 48 hours should be delayed until after 4 weeks, in accordance with currently accepted national guidance.

4.3 Consent

Verbal consent is adequate to proceed. The inserter should be satisfied that the woman understands the procedure and risks involved, and has appropriate capacity to give consent on a voluntary basis.

4.4 Equipment

The procedure may be performed in a labour room, maternity theatre or other suitable location provided the necessary equipment is available.

The basic equipment list is as follows:

- Long placental forceps (Kellys) x 1
- Sponge holding forceps (Rampleys) x 1-2
- Intrauterine device (IUS or copper IUD) x 1
- Cleaning solution
- Detectable swabs (counted)
- Sterile gloves
- Adequate light source

The intrauterine device should not be inserted using the standard inserter, as it may be associated with a higher risk of expulsion (due to inadequate fundal placement) or uterine perforation in the immediate post-partum setting.

4.5 Preparation for procedure

The woman should be positioned in lithotomy for the duration of the procedure. It is considered best practice to have a suitable chaperone/assistant present.

If the woman has vaginal or perineal lacerations, generally these should be repaired after the device is inserted unless in the presence of significant bleeding. However, clinical judgement should be employed as there may be a risk of dislodging the device during repair.

4.6 Analgesia

Routine analgesia is not recommended specifically for the procedure.

If a regional block is already in situ this can be maintained. Inhalational nitrous oxide (Entonox) may be provided if the women wishes.

Cervical infiltration with local anaesthesia is not recommended as the cervix is already dilated, and injection may precipitate bleeding.

4.7 Insertion technique

Insertion should be carried out in accordance with the RCOG-approved technique and training.

This technique is summarised below with a more detailed guide provided in Appendix 1.

4.8 Post procedure care

Following completion of the procedure, the woman can receive routine postnatal care and breastfeed normally.

Additional written and verbal advice should be provided, including when and how to seek help following discharge from hospital. This should specifically include the duration of the device, signs of possible expulsion and management of 'long threads'.

Self-checking of threads should not be routinely advised in this setting due to the risk of accidently removing the device.

All women are recommended to attend for clinical review after 4 to 6 weeks, at which time device placement will be confirmed. Alternative contraception is recommended until this has taken place.

4.9 Documentation

The procedure should be clearly documented in the patient's paper and/or electronic health record (TRAK).

Documentation should include the insertion technique used, analgesia (if required), type and duration of device inserted, batch number and expiry date.

5. References

Royal College of Obstetricians and Gynaecologists. Leading Safe Choices: Training Manual in Postpartum Family Planning. RCOG. Version SA-01. Dec 2015.

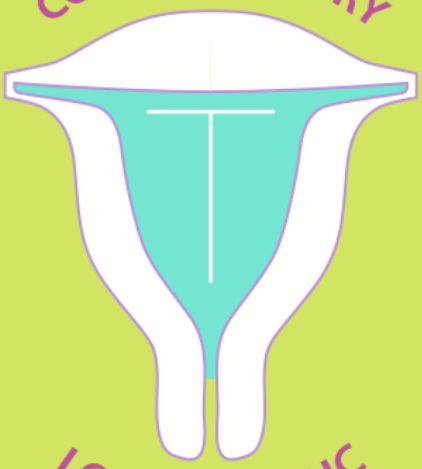
Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit. UK Medical Eligibility for Contraceptive Use (UKMEC 2016). 2016. Available at: https://www.fsrh.org/standards-and-guidance/external/ukmec-2016-digital-version.

This document has been reviewed and approved for use by the NHS Lothian PPIUC Steering Committee.

Pregnant?

Thinking about future contraception?

COIL AT DELIVERY



LOTHIAN PPIUC

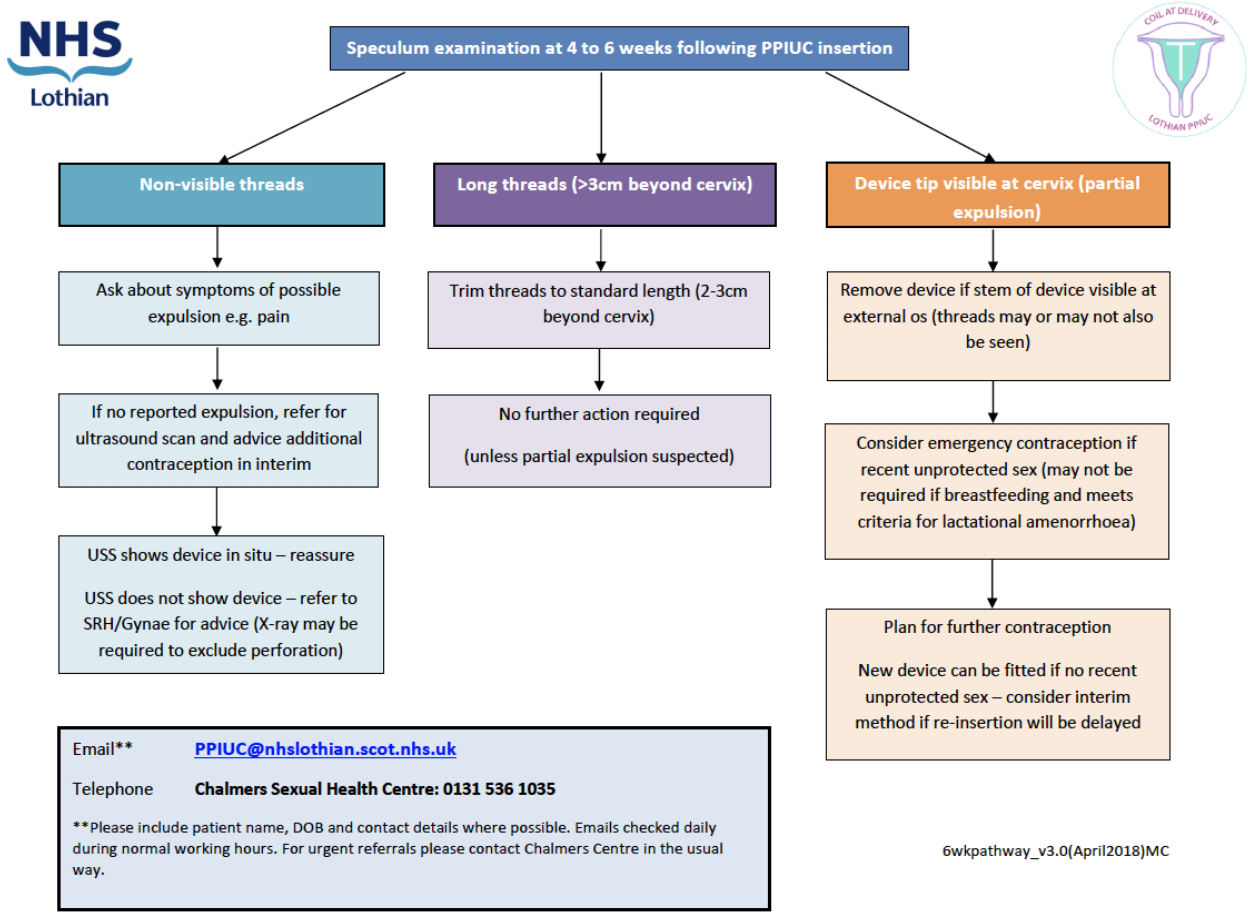
A coil is one of the most effective methods of contraception – and you can now have this fitted at the time your baby is born'

For more information pick up a leaflet or speak to your midwife/obstetrician today.

THE UNIVERSITY of EDINBURGH

MRC Centre for Reproductive Health

NHS Lothian


NHS Lothian
Speculum examination at 4 to 6 weeks following PPIUC insertion
Non-visible threads
Long threads (>3cm beyond cervix)
Device tip visible at cervix (partial expulsion)
Ask about symptoms of possible expulsion e.g. pain
If no reported expulsion, refer for ultrasound scan and advice additional contraception in interim
USS shows device in situ – reassure
USS does not show device – refer to SRH/Gynae for advice (X-ray may be required to exclude perforation)
Trim threads to standard length (2-3cm beyond cervix)
No further action required
(unless partial expulsion suspected)
Remove device if stem of device visible at external os (threads may or may not also be seen)
Consider emergency contraception if recent unprotected sex (may not be required if breastfeeding and meets criteria for lactational amenorrhoea)
Plan for further contraception
New device can be fitted if no recent unprotected sex – consider interim method if re-insertion will be delayed
Email** PPIUC@nhslothian.scot.nhs.uk
Telephone Chalmers Sexual Health Centre: 0131 536 1035
**Please include patient name, DOB and contact details where possible. Emails checked daily during normal working hours. For urgent referrals please contact Chalmers Centre in the usual way.
6wkpathway_v3.0(April2018)MC

Appendix 3 Survey used in Chapter 5

ASM Survey v4.0 (April 2017 - Cardiff) *Study No:*

The provision of post-placental intrauterine contraception or '**PPIUC**' is defined as immediate insertion of an intrauterine device from 10 minutes after placental delivery to within 48 hours following childbirth. It features as a recommendation in FSRH guidance and national sexual health strategies but is currently only available in a few centres in the UK. We are keen to understand the attitudes of healthcare professionals towards the development of a PPIUC service and their future role.

1 What is your primary role? *(please tick one)*

GP ☐ SRH Doctor ☐ Practice Nurse ☐

SRH Nurse ☐ O&G Doctor ☐

Other (specify):

2 How long have you been in your current role? *(please tick one)*

< 1 year ☐ 2-5 years ☐ 5-10 years ☐ >10 years ☐

3 Where are you currently based? *(please tick one)*

England ☐ Scotland ☐ Wales ☐

N.Ireland ☐ Outwith UK ☐

4 What is your current level of experience with intrauterine device insertion? *(please tick one)*
[NB/. LoC IUT = FSRH Letter of Competence in Intrauterine Techniques – or equivalent]

Currently hold LoC IUT and/or insert regularly ☐

Completed LoC IUT but do not insert regularly ☐

Current trainer in LoC IUT and insert regularly ☐

Currently in training ☐

Not completed LoC IUT/do not insert ☐

5 Based on your previous knowledge and information received during this conference, what is your overall feeling towards PPIUC in the UK?

Positive ☐ Negative ☐ Neutral ☐

Please expand on your reason for this answer:

6 **It is recommended that women receive a thread check and review at 4-6 weeks following PPIUC insertion. What do you think are the most important factors to consider providing this service within the community e.g. GP or SRH services?**
(Please indicate 1 to 3 in the relevant boxes to identify your top three selections where 1=most important)

Factor	Importance
GP/SRH staff time	
Access to appropriate equipment for thread check/review (speculum, scissors etc)	
Reimbursement for thread check/review service	
Experience of managing clinical issues e.g. long threads	
Referral pathway for access to ultrasound when threads are missing	

7 **What would you want your role to be in a future PPIUC service?** *(please tick ALL that apply)*

- ☐ I would be happy to promote immediate IUD insertion to women antenatally
- ☐ I would be happy to promote immediate IUD insertion to women antenatally following further information/training
- ☐ I would be happy to conduct postnatal thread checks
- ☐ I would be happy to conduct thread checks following further information/training
- ☐ I am keen to be trained in PPIUC insertion myself
- ☐ I am keen to train other healthcare professionals in PPIUC insertion e.g. obstetric staff, midwives
- ☐ I would like to be a postnatal contraceptive 'champion'
- ☐ I would like to provide a specialist role in PPIUC

8 **Do you have any additional comments in relation to immediate post-placental intrauterine contraception?**

Many thanks for taking the time to complete this survey