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Third Stage of Labour Management Approaches in Midwife-led Units

(Part One)

Karen Baker

This thesis is submitted to the University of Huddersfield in
partial fulfilment of the requirements for the degree of
Doctor of Midwifery

School of Human and Health Sciences
University of Huddersfield
January 2020

Resubmitted 22nd September 2020-major amendments

Abstract

Practices during the third stage of labour are likely to be influenced by a range of factors, not just findings from studies. Also, little is known regarding the incidence of and treatment for postpartum haemorrhage (PPH) in women giving birth solely in midwife-led units or what factors midwives feel influence their use of third stage management approaches in this birth setting. Therefore, a research project (using a multi-method research design) exploring third stage of labour management approaches and incidents of PPH, as well as the acceptability and practicability of third stage approaches for women, giving birth in midwife-led units was conducted. This consisted of a quantitative and qualitative study.

Findings from the studies revealed a statistically significant increase in the incidence of PPH (defined as blood loss 500 mL or over) with expectant compared to active management. There was also a statistically non-significant incidence in the relationship between third stage management approaches and incidence of severe PPH (defined as blood loss of more than 1000 mL). Also, although more women who initially received expectant management needed treatment for excessive bleeding, once these women received this first-line treatment their need for further treatment, to manage continual bleeding was slightly reduced. This is compared to women who initially received active management and experienced a PPH.

Additionally, from interviews with midwives four themes were developed capturing midwives' understanding of the factors they felt influenced their use of third stage management approaches in midwife-led units. It was evident that tensions were present within and between these themes and midwives need to balance these tensions when trying to provide woman-centred care. The themes generated from these interviews need to be addressed to facilitate third stage of labour management approaches. This is because this research project, with support from other studies, found that expectant management was a reasonable option for women at low risk of PPH, who wanted to labour and birth with minimal intervention in a midwife-led unit.

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Acknowledgements

I would like to thank the following individuals for their help and support throughout my Doctorate journey. Without their help and support this thesis would not have been possible.

My academic research supervisors:

- With special thanks to John Stephenson for his continuing support both on an academic and pastoral level, without which I would not have continued this journey.
- Dawn Leeming for her continuing support and practical approach
- Hora Soltani for her support and input
- Rob Burton for his support and guidance
- Mara Philips for her support and guidance in the early stages of this Doctorate study

The disability advisor at Huddersfield University Sue Jones for her support and encouragement and my proof readers Rachel Balen and Sue Daley-Yates for proof reading my work, sometimes at very short notice

The NHS Trust for allowing me to conduct this study within their organisation, the midwives I interviewed for allowing me to gain an insight into their experiences and to the maternity service where I work as a practicing midwife, for supporting me in my studies.

On a personal level I would like to thank my family especially my husband Peter and sons William and Daniel for their continuing support and the time they gave me to complete this thesis. I would also like to acknowledge the support given by other family members, who I have lost on the way to completing this thesis. I know they would be proud. My Dad Stanley, Father-in-law Tom and a very close friend I regarded as my grandma, Lillian.

I would like to acknowledge my previous supervisor of midwives Ann Hill for her encouragement at the beginning of my midwifery career. Ann sadly passed away whilst I was writing these amendments.

Without all this support this Doctorate study would not have been possible.

Presentation of Thesis

This thesis consists of a series of chapters, which comprise of different sections:

Chapter 1: Introduction: This chapter outlines briefly what this thesis aims to achieve and why this is an important area to research

Chapter 2: A General Literature Review: This chapter gives background information and explains and expands on key concepts referred to in this thesis. It briefly outlines the stages of labour, the physiology of the third stage of labour and blood loss during this period. It then examines the third stage of labour in more detail, focusing on the care provided and research studies that have informed practice regarding third stage management approaches. Place of birth is then considered and how it affects the women's birth outcomes and third stage management. Different models of care and the medicalisation of childbirth are briefly discussed and the implications these may have on care provided, during the third stage of labour, are also highlighted. A conclusion is then presented.

Chapter 3 Structured Literature Reviews: This chapter consists of two separate structured literature reviews. Structured Literature Review One identifies the state of knowledge regarding active and expectant management approaches and blood loss, during the third stage of labour or shortly after, in women giving birth in midwife-led units. Structured Literature Review Two identifies the state of knowledge concerning midwives' perspectives regarding factors they feel shape, facilitate or constrain their use of third stage management approaches. Gaps in knowledge were identified through the structured literature reviews. This helped to inform the conduct of two studies in order to address these gaps.

Chapter 4 Methodology: This chapter outlines and justifies the methodology for this research project. It highlights the different research

paradigms, drawing reference to the research project's overall research paradigm and the research paradigms of the component studies. The overall research design is also discussed and the research project's ethical issues are highlighted.

Chapter 5 Study One: This chapter outlines Study One's aim, objectives and ethical and approval processes. It discusses the study's quality assurance issues, outlines the study's setting and discusses the study's exploratory phase and its main study. The study's data collection method, analysis and results will also be highlighted, discussed and presented. A summary of the results is then given.

Chapter 6 Study Two: This chapter outlines Study Two's aim, objectives, ethical and approval processes and how ethical issues were dealt with. The study's data collection method, analysis and findings are also highlighted, discussed and presented. A summary of the findings is then given

Chapter 7 Discussion of the findings from Study One and Two: This chapter presents a summary of how this research project contributes to addressing the gap in knowledge. It discusses how each study helps to answer the overall research question and adds to the already existing evidence, regarding third stage of labour care. The limitations of Study One and Two are then outlined. Implications for practice and further research are also discussed. Finally, any conflict of interest is stated.

Note

This thesis consists of a research project comprising of two research studies. Study One is a quantitative study whilst Study Two is a qualitative study. In line with common writing conventions for the presentation of quantitative and qualitative research studies, the following sections of this thesis are written using the passive voice: Chapter 1 Introduction to the thesis; Chapter 2 A general literature review of the current understanding of the nature and context of third stage of labour care; Chapter 3 Structured literature reviews; Chapter 4

Methodology (when discussing Study One's research methodology); Chapter 5 Research Study Two; and Chapter 7 Discussion (when referring to study One).

The following sections are written using the first person: Acknowledgements; Chapter 4 Methodology (when discussing Study Two's research methodology and the ethics of my dual role as clinician and researcher); Chapter 5 Study One; and Chapter 7 Discussion (when referring to Study Two and when discussing the implications of Study One's and Two's findings on practice).

In this thesis numbers are written as figures at all times except when quoting numbers which are less than 10, but don't have units. Percentages are always written as a number and a % sign. To simplify terminology the terms birth centres and midwifery-led units are all referred to in this thesis as midwife-led units.

Table 1 Definition of Terms

Terminology	Definition
Active management	This third stage of labour management approach aims to accelerate delivery of the placenta to reduce blood loss. A prophylactic uterotonic drug (exogenous oxytocin) is given to accelerate the contractility of the uterus, to cause the placenta to separate from the uterus wall more quickly and, in turn, reduce bleeding. Other components of active management include delayed cord clamping, cutting of the cord and controlled cord traction (NICE, 2017; RCOG, 2016).
Caesarean section	This is a surgical procedure used to deliver a baby through incisions in the abdomen and uterus.
Continuity of carer	This is where a midwife provides all the care for a group of women from early pregnancy to six weeks postnatal, liaising and referring to other healthcare professionals if needed.
Controlled Cord Clamping (CCT)	Once the umbilical cord has been clamped and cut the practitioner, after signs of placental separation, then applies controlled cord traction (CCT) (NICE, 2017). Controlled cord traction enables the placenta to be delivered quickly by the practitioner, once the uterotonic drug has been administered, to prevent the placenta from being retained (Begley et al., 2019. CCT consists elevating the uterus suprapubically while maintaining steady traction on the cord, once there is clinical evidence of placental separation and the uterus is contracted (Hofmeyr, Mshweshwe, Gülmezoglu, 2015).
Episiotomies	A surgical incision by the healthcare practitioner at the opening of the vagina during childbirth, to aid a difficult delivery and or to prevent extensive damage of the tissues of the perineum.

First stage of labour	Consists of the woman giving birth experiencing regular, painful contractions, with progressive cervical dilation from 4 cm until fully dilated at 10 cm (NICE, 2017)
High risk PPH	The woman has known identified risks for postpartum haemorrhage
Labour	Labour is traditionally divided into three artificial divisions (stages).
Low risk of PPH	The woman has no known identified risk for postpartum haemorrhage
Midwife-led units are also known as midwifery-led units and birth centres. They are all categorised as alternative institutional birth settings.	They promote normal labour and birth and women are cared for by midwives. These midwives are sometimes supported by maternity support staff. There is no routine input by obstetric staff, as women who birth in midwife-led units are ideally classified as at low risk of obstetric complications. If complications occur during childbirth or shortly afterwards the woman will need to be transferred to an obstetric-led unit.
Mixed management is also referred to as the 'piecemeal approach'.	It consists of a combination of the components of both expectant and active management, but without completely containing all the components of either (Begley et al., 2019).
Normal physiological birth	Labour occurs spontaneously and the woman is at low risk of obstetric complications at the start of labour and remains low risk throughout labour and birth. The baby is born spontaneously and in the head-down position between 37 and 42 completed weeks of pregnancy. After birth, woman and baby are in good condition WHO (1997), meaning that there are no concerns regarding the woman's or the baby's physiological wellbeing after the birth.

Obstetric-led units	These units are ideally for women or babies who have an increased risk of obstetric or medical complications during or shortly after labour. NICE (2017) comments that care for these women and babies on an obstetric-led unit would be expected to reduce this risk. The emphasis of care in this environment is more likely to be on the detection/management of risk and routine use of intervention, rather than promoting physiological birth (Hodnett et al., 2012).
Operative vaginal delivery or also referred to as assisted vaginal delivery	The use of vacuum and forceps applied to the baby's head when the woman is fully dilated, to shorten the second stage of labour, to help the woman birth their baby, mimicking a spontaneous vaginal birth (RCOG, 2020).
Oxytocin	ormone that causes the woman's uterus to contract and reduce in size (Buckley, 2009; 2015; Uvnaas & Moberg, 2011).
Postpartum haemorrhage (PPH)	Defined as blood loss of 500 mL or more from the vaginal tract after the birth of the baby (WHO, 2012).
Primary postpartum haemorrhage (PPH)	Traditionally, a primary PPH is defined as bleeding from the genital tract of 500 mL or more within 24 hours after giving birth, occurring after 20 weeks gestation (WHO, 2012).
Second stage of labour	This stages is from when the woman's cervix is fully dilated until the birth of the baby (NICE, 2017)
Third stage of labour	The period of time between the birth of the baby and the birth of the placenta and membranes (NICE, 2017).

Uterotonic drugs	A prophylactic uterotonic drug (exogenous oxytocin) is given to accelerate the contractility of the uterus. This aims to cause the placenta to separate from the uterus wall more quickly and, in turn, reduce bleeding. Prophylactic uterotonic drugs are a key component in this reduction of PPH (RCOG, 2016).
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**Table 2: Study One and Two Operational
Definitions**

Term	Definition
Acceptability (Examined in Study One)	Refers to the use of active and expectant third stage of labour management approaches
Outcome (Examined in Study One)	Refers to the physical outcome of blood loss (incidence of PPH) after the birth of the baby or shortly afterwards.
PPH	Defined as blood loss of 500 mL or over after the birth of the baby or shortly afterwards
Practicability (Explored in Study Two)	Refers to my interpretation of the midwives' understanding, regarding the factors they felt shape, facilitate or constrain their use of third stage management approaches in midwife-led units.
Severe PPH	Defined as blood loss of 1000 mL or more after the birth of the baby or shortly afterwards

Chapter 1

Introduction

This section outlines briefly what this thesis aims to achieve and why this is an important area to research.

1. What the thesis aims to achieve

Labour is traditionally divided into three artificial divisions (stages). The third stage is the period of time between the birth of the baby and the birth of the placenta and membranes National Institute of Clinical Excellence [NICE] (NICE, 2017). There is always some blood loss during the third stage of labour. Care during this period aims to reduce excessive blood loss and is managed in clinical practice by two distinct clinical approaches active and expectant management (Begley et al., 2019). At present, active management of the third stage of labour is routinely used by most practitioners in the UK and Ireland, as in most high-income countries (Begley et al., 2019). This is as a result of the reduction in and treatment for postpartum haemorrhage (PPH) found in research studies with active management compared with expectant management. PPH is defined as blood loss of 500 mL or more from the vaginal tract after the birth of the baby (WHO, 2012).

However, expectant management is sometimes used by practitioners in the UK and Ireland, mainly those practising in midwife-led units or home birth settings (Begley, Devane & Clarke 2009; Blackburn, 2008; Dencker, Begley, Smith & McCann 2017; Fry, 2007; Kanikosma, 2007). Midwife-led units are also known as midwifery-led units and birth centres are categorised as alternative institutional birth settings. Midwives who work in these settings and women, who choose to birth there, are more likely to value minimal intervention (Shallows, 2003; Walsh, 2012). Women who choose to birth in midwife-led units are also more likely to be at low risk of PPH; hence the use of expectant management may be more suitable for them.

After critically reviewing the evidence that informs third stage of labour practice guidelines it is apparent that these research studies are not robust, particularly

for women at low risk of PPH who choose not to give birth in hospital obstetric-led units. Thus the generalisability of these research studies, and the third stage of labour guidelines and recommendations they inform, to women at low risk of PPH who choose to birth in midwife-led units or home birth setting is questionable.

Research studies have also found that in different birth settings and between healthcare professionals, management during the third stage of labour differs. This suggests that practices regarding third stage management are likely to be influenced by a range of factors, not just physical findings from research studies and/or third stage of labour guidelines and recommendations. Therefore, this thesis intends to answer the research question: What are the outcomes, acceptability and practicability of active and expectant third stage of labour management approaches for women giving birth in midwife-led units?

Outcome in this research project refers to the physical outcome of blood loss. Acceptability refers to the use of active and expectant third stage of labour management approaches. Practicability refers to my interpretation of midwives' understanding of the factors they felt shaped, facilitated or constrained their use of third stage management approaches in midwife-led units?

The relationship between active and expectant management approaches for women at low risk of PPH birthing in midwife-led units and the incidence of PPH is examined in Study One, the quantitative study. The acceptability of third stage management approaches is also investigated in Study One. The practicability of third stage management approaches is explored in Study Two, the qualitative study.

1.1. Why this is an important area to research

It is important to investigate third stage of labour physical outcomes, the use of expectant and active management and the factors interpreted by midwives as influencing their use of these third stage management approaches. This is because finds from these investigations, and other research studies, will help to

inform practice and assist in any change in practice The aim of any change in third stage management is to improve the woman's care.

Chapter 2

A general literature review: The current understanding of the nature and context of third stage of labour care and place of birth

This section gives background information and explains and expands upon key concepts referred to in this professional doctorate thesis. It briefly outlines the stages of labour, the physiology of the third stage of labour and blood loss during the third stage. It then examines the third stage of labour in more detail, focusing on the care provided during this period and research studies that have informed practice regarding third stage management approaches. Place of birth is then considered and how it affects women's birth outcomes and the third stage management. Different models of care and the medicalisation of childbirth are briefly discussed and the implications these may have on care provided during the third stage of labour are also highlighted. A conclusion is then presented.

2. Stages of labour

As stated previously in the thesis, labour is traditionally divided into three artificial divisions (stages). Edwards and Wickham (2018) comment that dividing labour in this way makes it easier to understand. The first stage of labour consists of the woman giving birth experiencing regular, painful contractions, with progressive cervical dilation from 4 cm until fully dilated at 10 cm. The second stage continues from when the woman's cervix is fully dilated until the birth of the baby. The third stage is the period of time between the birth of the baby and the birth of the placenta and membranes (NICE, 2017). It is a special time when the woman meets her baby. It involves emotional, physiological, bacteriological, hormonal and spiritual exchanges between mother and baby (Mercer & Erickson-Owens, 2010).

2.1 Physiology of the third stage of labour

During a normal labour and birth the woman's body produces a hormone called oxytocin. This hormone causes the woman's uterus, which is made up of a

unique interlacing network of muscle fibres known as the 'myometrium', to contract and reduce in size (Buckley, 2009; 2015; Uvnaas & Moberg, 2011). This brings about the birth of the baby. Following the birth of the baby the woman's body then releases a surge of oxytocin. This causes the placental bed to continue to contract and reduce in size, causing the woman's placenta to separate from the uterus wall and be birthed by maternal effort in expectant management of the third stage of labour, or by applying controlled cord traction in an actively managed third stage of labour (Mousa et al., 2014).

The contraction of the myometrium also reduces the blood flow to the placental bed; this helps to limit bleeding when the placental bed becomes detached from the uterus wall (Mousa et al., 2014). This haemostatic mechanism is known as 'physiological sutures' or 'living ligatures' (Baskett, 2000). The myometrial contraction is the main driving force for placental separation and haemostasis of the blood vessels that supply the placental bed (Mousa et al., 2014).

2.2. Blood loss during the third stage of labour

There is always some blood loss during the third stage of labour as the placenta separates from the uterus wall and is birthed. What is considered a normal amount of blood loss during the third stage of labour is subject to debate (Gyte, 1992). Mousa et al. (2014) define a blood loss of up to 500 mL as part of a normal physiological process. It is thought that a normal blood loss of less than 500 mL will not change a woman's clinical observations. However, they may be changed by a blood loss of 500 mL or more. Although the impact of this blood loss during the third stage of labour or shortly after will vary for every woman, it will depend on the volume of blood lost, her general state of health, the speed of the loss, her haemoglobin levels at the time and her coagulation system (Begley et al., 2019). Furthermore, in women with lower body mass (e.g. less than 60 kg) a lower level of blood loss may be clinically significant (Knight & Paterson-Brown, 2017).

However, it has been commented that well-nourished, healthy women are able to compensate for a blood loss of up to 1000 mL (Blackburn, 2008; Cunningham & Williams, 2001; Oishi, Tamura & Yamamoto, 2017). As a result,

a blood loss of up to 1000 mL may be considered physiological in a woman dependent on the woman's physiological response to that loss (World Health Organisation [WHO], 1996). This is because the total blood volume during pregnancy can potentially increase by between 1400 mL and 2000 mL (Bloomfield & Gordon, 1990; Cunningham & Williams, 2001). A cohort study by Oishi et al., (2017) found that a number of women at low risk of PPH who had a normal birth (including a physiological third stage with expectant management) in a midwife-led unit, experienced blood loss during the third stage and up to two hours postpartum of more than 500 mL. They commented that this blood loss may have been as much as 1000 mL but none of these women experienced any adverse physiological effects as a result.

2.2.1. Assessing blood loss

The amount of blood loss during childbirth is most commonly assessed through visual estimation from the healthcare practitioner (Diaz, Abalos & Carroli, 2018). Blood loss can also be assessed by collecting all blood lost during the third stage of labour in a disposable, funnelled, plastic collector bag (WHO, 2012). The bag can be weighed or calibrated, allowing for a direct measurement (Ambardekar et al., 2014). However, it is widely acknowledged that blood loss during the third stage of labour or shortly after birth is difficult to assess accurately and is frequently under-or over-estimated by practitioners (Razv, Chua, Arulkumaran & Ratnam, 2008; Schorn, 2010). This is because the blood lost after the birth maybe mixed with amniotic fluid and soaked into sheets and pads. A more precise measurement of blood loss is the assessment of haemoglobin concentration (Hb) in venous blood sampling and spectrophotometry (Diaz, Abalos & Carroli, 2018). However, these are both invasive techniques.

2.2.2. Primary postpartum haemorrhage (PPH)

Due to the risk of excessive bleeding the third stage of labour has often been described as the most dangerous part of childbirth for the woman (Mousa et al., 2014). This is because if the uterus does not contract strongly enough after the birth of the baby, a primary PPH can occur (Mousa et al., 2014). Traditionally, a primary PPH is defined as bleeding from the genital tract of 500 mL or more

within 24 hours after giving birth, occurring after 20 weeks gestation (WHO, 2012). This may also be accompanied by one or more clinical signs and symptoms of shock, for example hypotension, tachycardia, weakness, faintness and thirst; depending on the amount of blood loss, the speed of the loss and the ability of the woman's body to cope with this loss (Begley et al., 2019; Mousa et al., 2014).

The most common cause of primary PPH is failure of the uterus to contract adequately (atonic uterus) after the birth (Mousa et al., 2014; WHO, 2012). Other causes of primary PPH include trauma to the genital tract, bleeding due to retention of the placental tissue and failure of the coagulation system (Carroli, Cuesta, Abalos & Gulmezoglu, 2008; Cocker & Oliver, 2012). Fullerton, Danielian and Bhattacharya (2013) identified a primary PPH rate of 10% in women's first and second pregnancies. A primary PPH is the most common single cause of maternal death worldwide (Say et al., 2014; WHO, 2012) and the vast majority of these deaths from primary PPH happen in the developing world (Begley et al., 2019). Primary PPH is now an uncommon cause of maternal death in the UK (Knight & Paterson-Brown, 2014). However, significant maternal morbidity does occur from major bleeding due to an atonic uterus (Begley et al., 2019).

2.3. Care during the third stage of labour

In the UK midwives are the main providers of care for women during labour and childbirth. If any deviations from the normal occur, midwives refer women to the obstetric team and work with them to meet the woman's needs. Care during the third stage of labour consists of two distinct clinical approaches: active and expectant management (Begley et al., 2019). In practice, however, a mixed management approach can also occur (Harrison, 2006; Winters, et al., 2007).

2.3.1. Active management

Active management aims to accelerate delivery of the placenta to reduce blood loss. Active management does not rely solely on the woman's body to produce oxytocin and birth her placenta. Instead, a prophylactic uterotonic drug (exogenous oxytocin) is given to accelerate the contractility of the uterus. This

aims to cause the placenta to separate from the uterus wall more quickly and, in turn, reduce bleeding. Prophylactic uterotonic drugs are a key component in this reduction of PPH (Royal College of Obstetrics and Gynaecology [RCOG], 2016). Other components of active management include delayed cord clamping and cutting of the cord and controlled cord traction (NICE, 2017; RCOG, 2016).

Until very recently early cord clamping was part of active management. This involved clamping and cutting the cord within 1 minute after birth. However, it was realised that early cord clamping was potentially harmful for the baby. Therefore, delayed cord clamping was recommended if there were no concerns about the baby's heart rate or concerns about the integrity of the cord (NICE, 2014; WHO, 2014). Delayed cord clamping consists of the practitioner delaying cord clamping for at least one minute (WHO, 2014; 2018) or between 1 and 5 minutes (NICE, 2017) after the birth of the baby. Delaying cord clamping between 1 and 3 minutes after birth can have positive effects on the baby such as higher birth weight, early haemoglobin concentration and increased iron reserves up to 6 months after birth (McDonald, Middleton, Dowswell & Morris, 2013).

Once the umbilical cord has been clamped and cut the practitioner, after signs of placental separation, applies controlled cord traction (NICE, 2017). Controlled cord traction enables the placenta to be delivered quickly by the practitioner, once the uterotonic drug has been administered, to prevent the placenta from being retained (Begley et al., 2019). When controlled cord traction is used as part of active management a small reduction of blood loss and a reduced risk of manual removal of the placenta may occur (Hofmeyr, Mshweshwe, Gulmezoglu, 2015).

2.3.2. Expectant management

Expectant management is also known as physiological, passive or conservative management. The main principle of expectant management is to support the woman during labour and birth so her body can produce optimal levels of endogenous oxytocin. This is achieved by providing a warm and calm environment during labour and birth, encouraging the woman to have skin-to-

skin contact with her baby and only intervening in labour and birth when necessary (Buckley, 2009, 2015; Odent, 2002, 2004). With expectant management the practitioner also watches and waits for signs of placental separation, after which the placenta is birthed spontaneously or with the aid of gravity and maternal pushing (NICE, 2017).

Variations within expectant management include waiting for the placenta to be birthed before clamping and cutting the cord, or waiting until the cord has finished pulsating before it is clamped and cut. Breastfeeding or nipple stimulation is sometimes used to stimulate the physiological release of oxytocin (Bullough, 1989). Anything that interferes with this oxytocin release by the woman's body will reduce the effectiveness of a physiological third stage of labour (Buckley, 2004; Fry, 2007; Inch, 1985). Hence, expectant management would not be appropriate. Consequently, expectant management of the third stage of labour is only appropriate for women who have had a normal physiological birth. A normal physiological birth is defined by WHO (1997) as, where labour occurs spontaneously and the woman is at low risk of obstetric complications at the start of labour and remains low risk throughout labour and birth. The baby is born spontaneously and in the head-down position between 37 and 42 completed weeks of pregnancy. After birth, woman and baby are in good condition, meaning that there are no concerns regarding the woman's or the baby's physiological wellbeing after the birth. NICE (2017) also adopts the WHO (1997) definition of a normal physiological birth.

Expectant management is common practice in many northern European countries and in New Zealand (Begley, et al. 2019). In the UK and Ireland it is practised mainly by midwives (Farrar, Tuffnell, Airey & Duley, 2010), mostly those practising in midwife-led units and home birth settings (Begley et al., 2009; Blackburn, 2008; Fry, 2007; Kanikosma, 2007) or providing continuity of carer (Homer, Leap, Edwards, Sandall, 2017; Sandall, Soltani, Gates, Shennan & Devane, 2016). In low-income countries expectant management is commonly practised when women birth at home or in the community (Begley et al., 2019).

2.3.3. A change from expectant to active management

NICE (2017) advise changing from expectant management to active management if excessive bleeding occurs during the third stage of labour, or if the placenta is not delivered within 1 hour of the birth of the baby. Additionally, if the woman wants to shorten the third stage of labour, they should be offered a change from active management to expectant management (NICE, 2017).

2.3.4. Mixed management:

Mixed management is also referred to as the 'piecemeal approach'. It consists of a combination of the components of both expectant and active management, but without completely containing all the components of either (Begley et al., 2019). Different clinical situations might result in the woman having a mixed management approach. For example, the woman may choose to have active management, the midwife gives the prophylactic uterotonic drug and cuts and clamps the cord, but before the midwife can conduct controlled cord traction the woman births her placenta independently.

2.3.5. Treatment for PPH

NICE (2017) recommend that if a woman has a PPH the practitioner needs to call for help and give immediate clinical treatment consisting of: emptying of the bladder; massaging the uterus and administering uterotonic drugs and intravenous fluids. Controlled cord traction should also be applied if the placenta has not been delivered. The practitioner must also continuously assess blood loss and the woman's condition, identify the source of bleeding, give supplementary oxygen and arrange for transfer of the woman to obstetric-led care. The uterotonic drug treatment recommended consists of a first-line uterotonic drug treatment and if needed a second-line uterotonic drug treatment for PPH, and adjuvant options for managing significant continuing PPH (NICE 2017).

2.4. Contemporary third stage practice

At present, active management of the third stage of labour is routinely used by most practitioners in the UK, as in most high-income countries for management of the third stage of labour. This is as a result of the widespread introduction of

a prophylactic uterotonic drug in the 1960s (RCOG, 2009) and the reduction in PPH and treatment for this excessive blood loss found in the research studies with active management compared with expectant management (Begley et al., 2010; Begley, Gyte, Devane, McGuire, Weeks, 2011a; 2015; Begley et al., 2019; Prendiville, Elbourne, & McDonald, 2000; Rogers et al., 1998; Prendiville, Harding, Elbourne, & Stirrat, 1988; Thilaganathan, Cutner, Latimer & Beard, 1993). As a result of the findings from research studies international and national practice guidelines and practice recommendations all recommend active management of the third stage of labour (Royal College of Obstetricians and Gynaecologists [RCOG], 2016; WHO, 2007; 2012; 2018; NICE, 2014; 2017, the International Confederation of Midwives [ICM] and the International Federation of Gynaecology and Obstetrics [FIGO] [ICM-FIGO] 2006; 2003; Royal College of Midwives [RCM], 2018). International and national practice guidelines and practice recommendations are important as they subsequently inform local healthcare provision's guidelines.

However, intervention by the healthcare practitioner during the third stage of labour occurred before research studies were conducted (Edwards & Wickham, 2018). For example, immediately clamping and cutting the cord after the birth of the baby became common practice before any research studies were conducted into the third stage of labour. Immediate clamping and cutting the cord enabled the baby to be removed from the mother instantly, so the birth attendants could concentrate on caring for the woman unhindered by the presence of the baby (Inch, 1985). Downey and Bewley (2012) commented that Charles White, an English physician and surgeon who made significant contributions in obstetrics, wrote in 1773 that the "common method of tying and cutting the navel string in the instant the child is born... has nothing to plead in its favour but custom" (pp.325-326).

A study by Farrah et al. (2010) in the UK found that active management was reported to be always or usually used by 93% of obstetricians and 73% of midwives. Additionally 6% of obstetricians and 22% of midwives also reported sometimes using active management; whilst less than 1% of obstetricians and 5% of midwives reported rarely or never using active management (less than

1% of obstetricians did not respond to this question). This was compared to 2% of obstetricians and 9% of midwives who reported always or usually using expectant management and 13% of obstetricians and 47% of midwives also reported sometimes using expectant management; whereas, 85% of obstetricians and 44% of midwives reported rarely or never using expectant management.

Although active management is routinely used by most practitioners in the UK and Ireland, as in most high-income countries, research studies have shown that when women are offered expectant management as a reasonable option, they will choose it (Begley et al., 2011b; Davies et al., 2012, Dixon et al., 2009; 2013; Fahy, et al., 2010; Gottvall, Waldenström, Tingstig & Grunewald, 2011, Grigg, 2017 ; Kataoka, Masuzawa, Kato, Chiho & Eto, 2018; Laws, Xu, Welsh, Tracy & Sullivan, 2014; Monk, Tracy, Foureur, & Tracy, 2014; Rogers et al., 1998). Furthermore, the National Collaborating Centre for Women and Children's Health (2017) also acknowledges that some women may want to experience a birth with minimal intervention and request a physiological third stage of labour, resulting in them having expectant management. Consequently NICE (2017) recommend that women who want an expectant third stage management approach should be supported with their choice. The last four systematic reviews by the Cochrane Collaboration (Begley et al., 2010; 2011a; 2015; 2019) and practice guidance by the RCM (2018) also recommend that women should be given information on the benefits and harm of both active and expectant management, to support them making an informed choice.

2.4.1. Research studies that have informed current practice

The studies that have informed current third stage of labour practice guidelines and recommendations, regarding management of the third stage of labour for all women expecting to have a normal vaginal birth (RCM, 2018; RCOG, 2016; WHO, 2012; 2018) and for women at low risk of PPH (NICE, 2017) include Cochrane systematic reviews (Begley et al., 2011a; 2015) and other research studies (de Groot, van Roosmalen, van Dongen & Borm, 1996; Prendiville et al., 1988; Rogers et al., 1998; Thilganathan et al., 1993). The studies by Prendiville et al. (1988); Rogers et al. (1998) and Thilganathan et al. (1993) are

also included in the Cochrane systematic reviews (Begley et al., 2011a; 2015) that have informed these third stage of labour practice guidelines and recommendations.

The first version of the Cochrane review, which compared active versus expectant management of the third stage of labour, was produced by Prendiville et al. (2000). This review influenced previous practice guidelines and recommendations by RCOG (2009) regarding the prevention and management of PPH. Prendiville et al. (2000) recommended active management of the third stage of labour for all women, irrespective of their risk of PPH. This Cochrane review was subsequently updated and replaced by Begley et al. (2010; 2011a; 2015). The Begley et al. (2015) Cochrane review has recently been updated and replaced again by Begley et al. (2019).

The main results of the first Cochrane review that compared active versus expectant management (Prendiville et al., 2000), were that compared to expectant management active management reduced maternal blood loss after birth and the incidence of PPH (estimated blood loss of 500 mL or more but less than 1000 mL) or “severe PPH” (estimated blood loss of 1000 mL or more). Active management also reduced the treatment needed for this excessive blood loss, leading to a reduction in the use of therapeutic oxytocic drugs, anaemia and blood transfusion. The duration of the third stage of labour was also found to be shorter with active management. These beneficial effects of active management compared to expectant management were found in women who gave birth in hospitals obstetric-led units in high income countries, irrespective of their risk of bleeding.

However, Prendiville’s review also found that active management was associated with an increased risk of maternal nausea, vomiting and raised blood pressure when ergometrine (a prophylactic uterotonic drug) or an ergometrine-based drug (syntometrine) was used. As a result of these increased risks from using ergometrine, NICE (2017), RCM (2018) and WHO (2017; 2018) now recommend using oxytocin as the prophylactic uterotonic drug in active management. Oxytocin is associated with fewer side effects than

ergometrine or syntometrine (Westhoff, Cotter & Tolosa, 2013). At the time Prendiville's review was undertaken, no advantages or disadvantages from active management of the third stage of labour were apparent for the baby. The recommendation of the Prendiville et al. (2000) review was that active management should be the routine management of choice for every woman having a vaginal birth, regardless of their risk of PPH or place of birth.

The Cochrane reviews by Begley et al. (2010, 2011a, 2015, 2019) were the same as Prendiville et al.'s (2000) review's findings for women irrespective of their risk of bleeding. However, for women identified only as at low risk of PPH, the Begley et al. reviews did not identify any statistically significant difference for severe PPH (estimated blood loss of 1000 mL or more) or incidences of anaemia. Furthermore, the Cochrane reviews by Begley (2010, 2011a, 2015, 2019) also found that, compared with expectant management active management of the third stage of labour showed a statistically significant increase in the need for postnatal analgesia. They also found an increase in women returning to hospital as an outpatient, because of bleeding and a decrease in the baby's birth weight. This reduction in birth weight was possibly caused by the practitioner clamping the umbilical cord early, therefore reducing the volume of placental blood transfusion. In term infants this may reduce the baby's blood volume at birth by about 20% (Werner, 2005). Cutting the cord before it stops pulsating has also been found to increase the risk of iron deficiency anaemia in term infants (Anderson, Hellstrom-Westas, Andersson & Domellöf, 2011; Chararro et al., 2006). As a result of these adverse effects NICE (2017), RCM (2018) and the WHO (2012; 2018) recommend not clamping and cutting the cord for at least 1 minute after the birth in an actively managed third stage. NICE (2017) refers to this practice as "deferred" cord clamping whilst the WHO (2012; 2018) refers to this practice as "delayed" cord clamping.

The findings from the Cochrane review by Begley et al. (2011a) informed the RCOG (2016) and WHO (2012; 2018) third stage of labour guidelines and recommendations and the updated Cochrane review (Begley et al., 2015), informed the RCM (2018) third stage of labour practice recommendations.

2.4.2. Critique of the Cochrane reviews

The Cochrane reviews and the RCT included in them, comparing active versus expectant management, were critically reviewed using one of the Critical Appraisal Skills Programme [CASP] tools (CASP, 2018a, b) (See appendix 1 and 2). Critically appraising a paper enables the assessment of whether a paper is of high enough quality to contribute to an area of investigation (Aveyard, 2014).

The Cochrane review by Prendiville et al. (2000) included five randomised controlled trials (RCTs) (Begley, 1990; Khan, John, Wani, Doherty & Sibai, 1997, Prendiville et al., 1988, Rogers et al., 1998, Thilaganathan et al., 1993). These RCTs assessed women at mixed risk of PPH (comprising of high and low risk of PPH). Four of these studies also assessed women identified as at low risk of PPH (Begley, 1990; Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993). The Prendiville et al. (1988) RCT consisted of a secondary analysis involving women whose first and second stages of labour were defined as at low risk of PPH.

The women at high risk of PPH in the RCTs by Khan et al. (1997) and Prendiville et al. (1988) should not have been included in studies comparing active versus expectant management. As stated previously in this thesis, expectant management is only appropriate for women who are at low risk of PPH and have had a normal physiological birth (see definitions of terms). Furthermore, many of the women identified as at low risk of PPH included in the Begley (1990), Prendiville et al. (1988) and Rogers et al. (1998) RCTs were, in fact, at an increased risk of PPH. Therefore, these women should also not have been included in studies comparing active with expectant management. For example, the study by Begley (1990) included 27% of women in both active and expectant management groups who had their labour induced, accelerated, or augmented using synthetic oxytocin. Consequently, these women did not have a physiological birth. The use of oxytocin in labour can also interfere with the woman's own physiological production of oxytocin (Buckley, 2009; 2015; Uvnaas & Moberg, 2011). As stated previously in this thesis, a surge of oxytocin after the birth of the baby causes the placental bed to continue to

contract and reduce in size. This causes the woman's placenta to separate from the uterus wall and be birthed by maternal effort in expectant management of the third stage of labour (Mousa et al., 2014). Anything that interferes with the normal physiological birthing process will reduce the effectiveness of a physiological third stage of labour (Buckley, 2004; Fry, 2007; Inch, 1985). NICE (2017) also state that the use of oxytocin in labour is among the risk factors for PPH, and as such, women who receive these interventions should receive active management of the third stage of labour.

The RCTs by Begley et al. (1990), Prendiville et al. (1988) and Rogers et al. (1998) also consisted of women who had episiotomies (See definition of terms). Again episiotomies are identified as a risk factor for PPH (NICE, 2017), meaning these women should not have received expectant management. In Begley (1990), Rogers et al.'s (1998) and Prendiville et al.'s (1988) RCTs there also appeared to be many variations in active and expectant third stage of labour management approaches. Consequently, it was evident that many of the women in these three RCTs received a mixed management approach rather than active or expectant management. Additionally, more women in these three studies who were intending to have expectant management received mixed management. As previously stated in this thesis, mixed management of the third stage of labour has been found to increase the risk of PPH. Therefore, the results of Begley (1990), Rogers et al.'s (1998) and Prendiville et al.'s (1988) RCTs are biased in favour of active management. Also, the RCT by Khan et al. (1997) did not compare active with expectant management. Women in the expectant management group received mixed management. Therefore like the three previous RCTs the RCT by Khan et al. (2017) is biased in favour of active management. The many variations in third stage management approaches in Begley's (1990), Rogers et al.'s (1998) and Prendiville et al.'s (1988) RCTs also reduce the internal reliability and validity of these RCT's findings. The Begley (1990) RCT also used intravenous ergometrine as the uterotonic drug for women having active management. This drug is no longer used in current practice, which calls into question the generalisability of the Begley (1990) study.

An RCT was also carried out by Thilaganathan et al. (1993). This was a smaller scale study compared to the Begley (1990), Rogers et al. (1998) and Prendiville et al. (1988) RCTs. It did, however, only include women at low risk of PPH. However, the research paper by Thilaganathan et al. (1993) did not give enough information to enable the study to be appraised thoroughly. For example it was not clear how many women were initially randomised, when this randomisation took place and how many women were withdrawn following randomisation, due to caesarean section or operative delivery. Therefore, the RCT was more likely to be bias due to incomplete data. The Thilaganathan et al. (1993) RCT also had selected reporting bias, as PPH rates were not presented and mean blood loss figures were rounded; an issue which was also highlighted by Begley et al. (2010). Furthermore, no power calculation was conducted for Thilaganathan et al. (1993) study. Therefore, as well as the study having reduced rigour, reliability and validity, reducing its generalisability, the results of this RCT (no significant differences in estimate blood loss and haemoglobin drop in active compared with expectant management) could have occurred by chance.

The subsequent Cochrane reviews (Begley et al., 2010, 2011a, 2015, 2019) did not find any additional studies, comparing active with expectant management for women at mixed or low risk of PPH that met their inclusion criteria, to those identified in the Prendiville review (2000). These reviews did, however, include the Khan et al. (1997) RCT in the category of "active compared with mixed management". Therefore Khan et al. (1997) RCT was not included in the main analysis, comparing active with expectant management for women at mixed risk of PPH. Additionally, the Prendiville et al. (1988) RCT secondary analysis involving women whose first and second stages of labour were defined as at low risk of PPH was not included in the subsequent Cochrane reviews analysis, comparing active with expectant management for women at low risk of PPH. This was because the women in Prendiville et al. (1988) secondary were not considered to fit the criteria of low risk of PPH.

The subsequent Cochrane reviews (Begley et al., 2010, 2011a, 2015, 2019) also assessed the risk of bias in the identified RCTs more thoroughly than in

the Prendiville et al. (2000) Cochrane Review. In addition these subsequent Cochrane reviews used a random-effects model for analysis. This was due to variations in the specific forms of active and expectant management used in included RCTs. However, many of the criticisms regarding the reliability, validity and generalisability of the RCTS included in the Prendiville et al. review (2010), assessing women at mixed and low risk of PPH are still applicable to the updated versions of this Cochrane review (Begley et al., 2010, 2011a, 2015, 2019). The findings of the Cochrane reviews are important as they are used to inform international and national third stage of labour guidelines and recommendations, which in turn influence local maternity guidelines.

2.4.3. NICE third stage of labour guidelines for women at low risk

NICE (2017) guidelines regarding active versus expectant management approaches during the third stage of labour for women at low risk of obstetric complications were based on the evidence from four RCTs (de Groot et al., 1996; Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993). These studies were identified from a literature review conducted by the National Collaborating Centre for Women's and Children's Health (2014) and their findings were that active management of the third stage of labour was associated with a reduced risk of PPH (defined as 500 mL or more and 1000 mL or more) blood transfusion and anaemia. A reduction in the need for therapeutic uterotonic drugs following active management was also found. However, side effects consisting of nausea, vomiting and hypertension were more common in women receiving active management. The review also noted that most of these RCTs used a combination of oxytocin and ergometrine as the therapeutic uterotonic drug in active management. As noted previously in the thesis, ergometrine is associated with a higher incidence of side effects. Consequently oxytocin is now recommended as the therapeutic uterotonic drug in active management (NICE, 2017; RCOG, 2016; WHO, 2012, 2018). Babies born also had a lower birth weight with active management. As stated previously in this thesis, this was possibly caused by the practitioner clamping the umbilical cord before it had stopped pulsating.

2.4.3.1. Critique of the research studies informing NICE guidelines

The RCTs by de Groot et al. (1996), Prendiville et al. (1988), Rogers et al. (1998) and Thilaganathan et al. (1993) were critically reviewed using a CASP (2018b) tool (See appendix 2). Three of these four studies (Prendiville, et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993) are also included in the Cochrane reviews (Prendiville et al., 2000; Begley et al., 2010; 2011a; 2015; 2019) comparing active versus expectant management. Concerns regarding Prendiville et al.'s (1988), Rogers et al.'s (1998) and Thilaganathan et al.'s (1993) RCTs have been discussed previously in this thesis.

The RCT by de Groot et al. (1996) did not compare active with expectant third stage of labour management. This study compared intramuscular oxytocin or a placebo. No other component of active or expectant management was reported. The National Collaborating Centre for Women's and Children's Health (2014) commented that the placebo arm of this RCT was comparable to women receiving expectant management. However, expectant management consists of more than just the absence of giving oxytocin. As stated previously in this thesis, expectant management also consists of supporting the woman during labour and birth, so her body can produce optimal levels of endogenous oxytocin, so she can birth her placenta physiologically, with the help of gravity or maternal effort. Also an active third stage of labour approach consists of other components (delayed cord clamping and controlled cord traction) and not just the administration of an uterotonic drug. This questions the validity of de Groot et al.'s (1996) findings when examining active versus expectant management of the third stage of labour. As a result, de Groot et al.'s (1996) RCT should not have been used by the National Collaborating Centre for Women's and Children's Health (2014) to inform NICE's (2017) third stage of labour practice guidelines. This is because it does not compare active versus expectant management. Both third stage approaches are mixed management approaches.

2.4.4 Quality of evidence

.After critically appraising the above research studies underlying the third stage of labour practice guidelines and recommendations (see appendix 1 and 2), it

is not surprising that the National Collaborating Centre for Women's and Children's Health (2014) graded the quality of evidence, supporting NICE's (2017) guidelines, regarding active compared with expectant management and incidence of PPH (blood loss of 500mL or over) as low (de Groot et al., 1996, Prendiville et al.,1988; Rogers et al., 1998) and severe PPH (blood loss of 1000 mL or over) as very low (de Groot et al.,1996; Prendiville et al., 1988; Rogers et al., 1998). This was as a result of the risk of bias, inconsistencies and indirectness in the studies.

In addition the latest Cochrane review (Begley et al., 2019) comparing active versus expectant management for women at low risk of PPH, graded the quality of evidence examining the incidence of PPH (blood loss of 500 mL or more) as low quality (Begley, 1990, Rogers et al., 1998) and severe PPH blood loss over 1000 mL) (Begley, 1990, Rogers et al., 1998) and haemoglobin less than 9 at 24 hours (Thilaganathan et al.,1993) as very low-quality evidence. The quality of evidence regarding mean maternal blood loss (mL) (Begley, 1990, Rogers et al., 1998; Thilaganathan et al., 1993) and maternal blood transfusions was also graded as low quality (Begley, 1990, Rogers et al., 1998). However, the quality of evidence examining the use of therapeutic uterotonic during the third stage and/or within the first 24 hours was graded as moderate (Begley, 1990, Rogers, et al., 1998; Thilaganathan et al., 1993). This puts into question the reliability,, validity and generalisability of these research studies' findings, and their suitability to inform third stage of labour practice guidelines and practice recommendations by NICE (2017); RCM (2018); RCOG (2016) and WHO (2012; 2018).

2.4.5. Areas for further research

Regarding the potential harms found in research studies regarding active management (Begely et al. 1990; Prendiville et al, 1988; Rogers, et al., 1998), Begley et al. (2019) commented that these harms were more concerning in women at low risk of PPH. This was because for these women, there was no statistically significant evidence that severe PPH (blood loss of over 1000 mL) was reduced by active management compared to expectant management and, as stated previously in this thesis, well-nourished, healthy women are able to

compensate for a blood loss of up to 1000 mL (Blackburn, 2008; Cunningham & Williams, 2001; Oishi, Tamura & Yamamoto, 2017). This suggests that if active management is unlikely to reduce severe PPH in women at low risk of PPH, then it is maybe of limited value to this group of women. Begley et al. (2019) commented that further studies comparing active with expectant management in women at low risk of PPH would be needed to confirm if there was a difference in severe bleeding.

2.4.6. Place of birth and midwife's experience regarding third stage outcomes

The Cochrane reviews and other studies discussed above that have informed current international (WHO, 2012; 2018) and national (NICE, 2017; RCM, 2018; RCOG, 2016) third stage of labour practice guidelines and recommendations all consisted of women, who gave birth in hospital obstetric-led units. Edwards and Wickham (2018) comment that hospital obstetric-led units may not provide the necessary conditions favourable to the flow of birth hormones needed to physiologically birth the placenta. Consequently expectant management may not be appropriate for women, who give birth in hospital obstetric-led units. Therefore, these reviews and studies, as well as the third stage of labour guidelines and recommendations they inform, probably cannot be generalised to midwife-led units or home birth settings.

Additionally, in these reviews and studies active management of the third stage of labour was routine. As a result, midwives were more experienced in conducting active as opposed to expectant management. The experience of healthcare professionals in conducting third stage management approaches is important in reducing blood loss during the third stage of labour or shortly after. This is evident in the RCTs by Begley (1990) and Rodgers et al. (1998). These studies found that midwives who did not routinely use expectant management needed time to become familiar with it. Once midwives in these studies were familiar with expectant management, the blood loss during the third stage of labour reduced. In Begley's (1990) RCT the PPH rate in the expectant management group dropped during the trial from 21% in the pilot study to 12% in the first 4 months and to 7% in the last six months of the main study.

2.4.7. Conclusion regarding the evidence informing current practice

What is evident, after reviewing these Cochrane reviews and other studies that have informed third stage of labour practice guidelines and recommendations, is that they do not present robust evidence regarding whether active or expectant management reduces PPH during the third stage of labour or shortly after birth in women at low risk of PPH, particularly for women who birth in midwife-led units and at home. Consequently, these practice guidelines and recommendations by NICE (2017); RCM (2018); RCOG (2016) and WHO (2012; 2018) probably cannot be generalised to women at low risk of PPH, giving birth in a midwife-led unit or at home.

2.5. Place of birth

In England since 1993, maternity care policy has promoted women's choice regarding place of birth (Cumberlege, 1993). Also in 2004 maternity care policy stated that women should be able to choose where to give birth and the healthcare professional providing their care (DH, 2004). Additionally, the International Confederation of Midwives (ICM, 2014) highlighted choosing the place of birth and receiving care during labour and birth from a qualified midwife as women's basic rights. A woman's choice of place of birth became the national choice guarantee (DH, 2007) with three options hospital obstetric-led units, midwife-led units or birth at home.

Midwife-led units can be 'alongside' and 'freestanding'. Alongside midwife-led units are situated within a hospital which has an obstetric-led unit. If a woman chooses to give birth in an alongside midwife-led unit and if complications occur during childbirth or shortly afterwards, the woman will need to be transferred to an obstetric-led unit. This transfer will happen via a wheelchair or bed, or she may walk (McCourt et al., 2014). By contrast, freestanding midwife-led units are geographically separate from a hospital obstetric-led unit. If a woman chooses to give birth in a freestanding midwife-led unit and complications occur during childbirth or shortly afterwards, the woman must be transferred to the obstetric-led unit via ambulance (Christensen & Overgaard 2017).

In England during the period 2010 to 2016, the number of 'alongside' midwife-led units has nearly doubled from 53 to 97. The number of 'freestanding' midwife-led units also rose from 58 to 61, whilst the number of hospital obstetric-led units reduced by 10% from 177 to 159 (Walsh et al., 2018). A woman's right to choose a midwife-led unit for her place of birth care has been reinforced by the Government's five year forward view for maternity (DH, 2016) and NICE (2017). Many other national maternity systems also promote midwife-led units as a woman's place of birth, depending on the woman's preference and her obstetric need (Walsh et al., 2018).

Place of birth is important, as research studies have shown that healthy women at low risk of obstetric complications experience fewer interventions when planning to give birth in midwife-led units (Alliman & Phillippi, 2016; Brocklehurst, et al., 2011; Christensen & Overgaard, 2017; Hodnett, Downe & Walsh, 2012; Hollowell et al., 2011 Walsh & Downe, 2004) and at home (Hollowell et al., 2011; Olsen & Clausen, 2012) compared to women planning to birth in hospital obstetric-led units. These studies have also shown that women who birth in midwife-led units and at home also experience higher levels of satisfaction with their birthing experience, than women birthing in hospital obstetric-led units, without increasing risks to mothers.

Outcomes for the baby are similar for women who have given birth previously and plan to birth at home, in a midwife-led unit or hospital obstetric-led unit. Although there is a small increase in the risk of an adverse outcome for the baby of women, who have not given birth before and plan to birth at home, compared with those planning to birth in an obstetric-led unit (NICE, 2017). However, for women who have not given birth before and plan to birth in a midwife-led unit, the outcome for the baby is no different compared with planning to birth in an hospital obstetric-led unit (NICE, 2017). Yet despite the advantages of midwife-led units, the vast majority of women continue to give birth in obstetric-led units (Walsh, et al., 2018).

2.5.1. Midwife-led units

Midwife-led units, also known as birth centres and midwifery-led units are considered to be alternative institutional birth settings. Midwife-led units were established as a result of concerns about how the physical environment of an obstetric-led unit can affect the development of complications during childbirth and how it can also influence women's satisfaction with care (Hodnett, et al., 2012). Midwife-led units promote active labour and birth and women are cared for by midwives. These midwives are sometimes supported by maternity support staff. There is no routine input by obstetric staff, as women who birth in midwife-led units are ideally classified as at low risk of obstetric complications.

Women who have given birth in midwife-led units have expressed high levels of satisfaction with their birth experience and midwives who work in them have expressed a sense of well-being and autonomy (Bernitz, Øian, Sandvik & Blix, 2016; McCourt, et al., 2016). Studies also suggest that midwife-led units are also more cost-effective (Bernitz, Aas, & Øian, 2012; Schroeder et al., 2012, Kenny, et al., 2015). As stated above midwife-led units are ideal for women at low risk of obstetric complications and for women who prefer little or no intervention in the birthing process, aiming to have a physiological birth (birth without medical intervention) (Hodnett et al., 2012). This is also reflected in the third stage of labour care these women receive, as research studies have shown that a physiological third stage of labour and, as a result, expectant management, is more prevalent in midwife-led units than in hospital obstetric-led units (Begley et al., 2011b; Davis, et al., 2012; Dencker, et al., 2017; Dixon, et al., 2009; 2013; Fayh et al., 2010; Grigg et al., 2017; Kataoka, et al., 2018; Laws, et al., 2014; Monk, et al., 2014).

Shallows (2003) comments that the term 'birth centre' or 'midwife-led unit' represents a set of values and beliefs about birth and these are reflected by the midwives who work in them. The philosophy in midwife-led units is centred on the concept of a social model of care rather than a medical model of care. A social model of childbirth is based on the belief that pregnancy and birth are 'normal' life events for the majority of women, who need little or no medical intervention (Walsh, 2012). These women would be classified by NICE (2017)

as at low risk of obstetric complications. Furthermore, a belief held by the social model of childbirth is that by protecting and promoting this normal physiological process, the woman's body can give birth safely (Walsh & Newburn, 2013a; 2013b).

Expectant management of the third stage of labour is situated in the social model of care. Midwives who adopt a social model of care and work in an environment that facilitates this model are increasingly likely to support women, so that the woman's body produces optimal levels of endogenous oxytocin, which will enable them to safely birth their placenta physiologically (Walsh & Newburn, 2013a, 2013b). These midwives are likely to be more knowledgeable and experienced in physiological birth, which includes a physiological third stage of labour and, as a result, expectant management, than midwives working in hospital obstetric-led units.

2.5.2. Hospital obstetric-led units

Midwives working in hospital obstetric-led units are increasingly likely to provide care for women or babies where there is an increased risk of obstetric or medical complications for the woman or baby during or shortly after labour. NICE (2017) comments that care for these women and babies on an obstetric-led unit would be expected to reduce this risk. The emphasis of care in this environment is more likely to be on the detection/management of risk and routine use of intervention, rather than promoting physiological birth (Hodnett et al., 2012). The main aim of care in hospital obstetric-led units is to reduce the risk for the woman or baby (Hodnett et al., 2012), reflecting a medical model of childbirth, rather than supporting physiological birth.

The medical model of childbirth is based on the belief that childbirth is risky and requires medical control in order to ensure safety, through monitoring. This will enable intervention at the earliest sign of pathology (Hodnett et al., 2012). Active management of the third stage of labour is situated within the medical model of childbirth. Midwives who adopt the medical model are increasingly likely to intervene during the third stage of labour to prevent the possible risk of excessive blood loss, even if it may not be necessary.

However, active management of the third stage of labour may be increasingly needed for women who give birth in an obstetric-led unit as they are more likely to be at an increased risk of PPH. This is due to pre-existing maternal risk factors for PPH, the possible iatrogenic effect of labour interventions such as induction of labour or because, as highlighted previously, the obstetric-led unit does not provide the necessary conditions to promote a physiological third stage of labour. These factors may reduce a woman's ability to produce endogenous oxytocin to safely birth her placenta physiologically. Therefore, active management of the third stage of labour would be needed for these women so their placenta could be delivered safely. Consequently, midwives working in a hospital obstetric-led unit may be less experienced and knowledgeable in facilitating physiological birth of the placenta and expectant management. They may also be more knowledgeable and experienced in active management of the third stage of labour.

2.6. The concept of risk in maternity care

Dahlen (2010, 2015) comments that at present we live in a culture that amplifies risk, placing emphasis on possible adverse outcomes. This is reflected in maternity care, where women are classified as at low or high risk of obstetric complications. Based on their risk classification women are then treated accordingly in the belief that these risks can be controlled or prevented. The concept of risk, and the belief that it can be controlled and prevented, is a fundamental tenet of the medical model of childbirth. As childbirth becomes increasingly more medicalised the concept of risk and the need to control risk may be exposing women to more intervention than is necessary (Dahlen, 2010; 2015; Healy, Humphreys, & Kennedy, 2016).

If a woman has a risk factor for PPH, having expectant management will not guarantee more bleeding than usual. It means the chance of this happening might be higher than if that risk factor was not present. Interestingly, the WHO (2012) comments that most incidences of PPH occur in women with no known risk factors for PPH. Consequently, healthcare professionals need to critique the evidence on which their practice is based to ensure their practice is based

on the best available evidence and not the maternity care system's heightened perception of risk.

2.7. A change in the model of childbirth

Over time a process of social change has occurred, from a social model of childbirth to a more medical model of childbirth. This process of social change is referred to as the medicalisation of childbirth (Van Teijlingen, 2004) and it is a central feature of childbirth in Western societies (Johanson, Newburn, & Macfarlane, 2002). It has resulted in an increase in routine medical interventions during pregnancy and childbirth and, since the middle of the 20th century, the majority of women living in high and middle income countries are now giving birth in hospitals rather than at home (Olsen & Clausen, 2012). In the UK the movement of birth from home to hospital occurred at the same time as the reduction in perinatal and maternal mortality (Walsh, 2012). However, it has been commented that to link the two would be an error (Walsh, 2012). This reduction in perinatal and maternal mortality is thought to be a result of the dramatic improvements in women's health and living conditions that also occurred at this time (Walsh, 2012).

The relationship between hospitalisation, childbirth and intervention is an important issue because of concerns regarding the iatrogenic effects of medical intervention in women who do not have a clinical need for it. However, Davis-Floyd (2009) comments that, in the medical model, the possible iatrogenic effect of labour interventions is given little attention, as they are seen as necessary to control labour and childbirth and reduce risk. Edwards and Wickham (2018) comment that, in many hospital obstetric-led units the level of intervention is so high that active management of the third stage is needed. This is because of the interference in the physiology of labour and birth, which can reduce a woman's body's ability to secrete oxytocin, which is needed to birth the placenta safely in a physiological third stage. Consequently, expectant management would not be appropriate for these women.

2.8. Summary

The third stage of labour is an important time for both the woman and her baby. It can also be a potentially hazardous time for the woman due to the risk of excessive bleeding and the morbidity and mortality associated with this. In the UK care during pregnancy and childbirth, as well as postnatal care is mainly conducted by midwives, who are the experts in normality. If any deviations from the normal occur the woman is then referred by the midwife to the obstetric team and the midwife will work with them to meet the needs of the woman and her baby. Care provided during the third stage of labour aims to reduce any excessive bleeding and protect this special time for the woman and her baby.

After using the appropriate CASP tool (2018a, b) to review the research studies, informing third stage of labour practice guidelines and recommendations, it is evident (for the reasons given in the preceding sections of this chapter) that the reliability and validity of some of the research studies are debatable. Identified omissions and errors included: inconsistencies in definition of management style (de Groot et al., 1996; Khan et al., 1996); variations in the components of active and expectant management (Begely (1990); Rogers et al.'s (1998); Prendiville et al.'s) ; to lack of information regarding the study's procedure (Thilaganathan et al., 1993); inclusion of confounding factors such as women who had their labour induced, accelerated or augmented using oxytocin and use of episiotomies (Begely, 1990; Prendiville et al., 1988; Rogers et al., 1998), and the inclusion of outdated procedures (Begley et al., 1990). Additionally, all the research studies informing third stage practice guidelines and practice recommendations were conducted in hospital obstetric-led units. Therefore, the generalisability of these practice guidelines to midwife-led units is also questionable.

Midwife-led units represent a different set of values and beliefs regarding birth, than those held by hospital obstetric-led units. Furthermore, women at low risk of obstetric complications are increasingly choosing to birth in midwife-led units. In these settings the philosophy is centred on the concept of a social model of care, rather than the medical model of care that is reflected in obstetric-led units. A social model of childbirth is based on the belief that pregnancy and

birth are 'normal' life events for the majority of women, who need little or no medical intervention. By contrast, a medical model of childbirth is centred on the idea that childbirth requires medical control in order to ensure safety (Hodnett et al., 2012).

Midwives who work in midwife-led units, as opposed to obstetric-led units, are increasingly more likely to hold values and beliefs that reflect a social model of childbirth. These midwives are likely to be more knowledgeable and experienced in physiological birth, which includes a physiological third stage of labour and, as a result, expectant management, than midwives working in hospital obstetric-led units. Therefore, midwives who work in midwife-led units are more likely to support women to enable them to safely birth their placenta physiologically. Also women birthing in midwife-led units are more likely to be at low risk of PPH and less likely to need medical interventions. Therefore they do not necessarily need active management. These women are also more likely to want a physiological birth, which includes a physiological third stage and subsequent expectant management, than women birthing in an obstetric-led unit.

2.9. Conclusion

The reliability and validity of some of the research studies informing third stage of labour practice guidelines and recommendations are questionable.

Furthermore, these research studies and third stage of labour guidelines and recommendations probably cannot be generalised to midwife-led units.

Consequently, further exploration of evidence regarding the relationships between active and expectant third stage management approaches and subsequent blood loss in women giving birth in midwife-led units is required.

Additionally, it is evident that within different birth settings and between different healthcare professionals, third stage management practices differ. These practices are likely to be influenced by a range of factors, not just findings from research studies and third stage of labour practice guidelines. Furthermore, because midwives are the main carers for women during pregnancy, childbirth and the postnatal period, it would be beneficial to explore evidence

investigating midwives' interpretation regarding factors they feel affect their use of these third stage management approaches in midwife-led units. To explore these issues further, Chapter Three consists of two separate structured literature reviews.

Chapter 3

Structured Literature Reviews

This chapter consists of two separate structured literature reviews. Structured Literature Review One identifies the state of knowledge regarding active and expectant management approaches and blood loss, during the third stage of labour or shortly after in women giving birth in midwife-led units. Structured Literature Review Two identifies the state of knowledge concerning midwives' understanding regarding factors they feel shape, facilitate or constrain their use of third stage management approaches.

3. Overview

These structured literature reviews identify any gaps in knowledge and help to inform the conduct of two research studies to address these gaps in knowledge. Structured Literature Review One identifies quantitative research papers that link to Study One. Structured Literature Review Two identifies study papers that link to Study Two.

3.1. Structured Literature Review One

Evidence informing practice guidelines regarding management during the third stage of labour and related excessive blood loss during this period or shortly after, does not include any studies conducted in midwife-led units. Therefore, Structure Literature Review One searched systematically for studies focusing on midwife-led units. It aimed to identify and evaluate any studies that investigated active versus expectant management of the third stage of labour and any related blood loss, during this period or shortly after. These studies only included women, who had a normal physiological birth and gave birth or intended to give birth in a midwife-led unit.

3.1.1. Data Sources

The search strategy to identify primary quantitative research comprised of:

- Searching electronic databases EMBASE (Excerpta Medica Database), Psych Info (Psychology and allied fields), AMED (Allied and Complementary Medicine), HBE (Health Business Elite), PubMed, BNI

(British Nursing Index), HMIC (Health Management Information Consortium), CINAHL (Cumulative Index to Nursing and Allied Health Literature) and Medline.

- Looking at reference lists from relevant studies
- Hand searching the most frequently cited journals and key midwifery and medical journals: British Journal of Midwifery; Midwifery; Journal of Advanced Nursing; Birth, Women and Birth.
- Searching relevant Internet resources: NICE; Cochrane Library; World Health Organisation (WHO); Royal College of Obstetrics and Gynaecology (RCOG)

3.1.2. Study Selection

Advanced searches were conducted on the most relevant electronic databases used for medical and midwifery research. The electronic database search was focused around the PICOS model. Table 3.1.2(a) outlines the PICOS model used to guide the electronic database search and the search/ MeSH terms used.

Table 3.1.2(a): The electronic database search

PICOS Elements	Search Terms
P - Population: women receiving midwifery- led care/giving birth in alternative institutional settings	midwifery-led care midwife-led care alternative birth setting alternative institutional birth setting birth centres birth centre midwifery-led unit midwife-led unit midwifery unit
I - Intervention	third stage after birth active management expectant management physiological management
C - Comparison	None identified at this stage
O - Outcome	blood loss postpartum haemorrhage postpartum hemorrhage
S - Study Design	Study Trials studies RCTs

Study selection from electronic database results was then conducted in two stages, as identified by the Centre for Reviews and Dissemination (CRD, 2009). This process aimed to increase the transparency of the study selection process (CRD, 2009).

Stage 1: An initial screening of titles and, where possible, abstracts was conducted against pre-determined inclusion criteria. Table 3.1.2 (b) outlines the structured review's inclusion and exclusion criteria.

Table 3 .1.2(b): Pre-determined inclusion and exclusion criteria

PICOS Elements	Inclusion	Exclusion	Justification for exclusion
P- Population	Studies which define pregnant women as being at low risk of PPH birthing in midwife-led units. Studies where the data on outcomes was presented separately for the different places of birth, so that the outcome for midwife-led units compared to other settings was evident.	Studies which identify pregnant women as being at high risk of PPH. Women in low-income countries who did not give birth midwife-led units (birth centres or midwifery led units). Women not birthing or planning to birth in midwife-led units.	These women have factors which increase their risk of PPH. If studies containing these women were included it would bias the results and reduce the generalisability of the findings to low risk women in high-income countries. Place of birth has been shown to influence birth outcomes.
I - Intervention	Studies which define active management and expectant management of third stage of labour as outlined in the glossary of terms.	Studies which do not use oxytocin or syntometrine, as the routine prophylactic uterotonic drugs, but use another pharmacologic agent.	Oxytocin or syntometrine are the pharmacologic agents currently used in high income countries for active management of the third stage of labour
C - Comparison	Studies which compare active versus expectant management of the third stage of labour.	Any interaction which does not compare active versus expectant management of the third stage of labour.	This systematic review aims to compare active versus expectant management of the third stage of labour and blood loss during the 3 rd stage of labour or immediately following the birth of the placenta and membranes and not any other management of the third stage of labour approaches.
O - Outcome	Studies which report PPH and blood loss after birth as estimated by practitioner by visual estimation or weighed. Studies that report treatment received for excessive blood loss.	Studies that do not measure blood loss.	PPH or excessive bleeding at or after childbirth is potentially a life-threatening complication and one of the major contributors to maternal mortality and morbidity worldwide.
S - Study Design	Primary published quantitative research studies-reviews, RCT and observational studies (cohort and case control studies) No date restrictions were applied. Research articles written in the English language.	Unpublished research studies. Qualitative studies	Obtaining unpublished research studies can be time-consuming and the original data may no longer be available. As a result of these practical difficulties it was unachievable in the timescales available for this review.

Studies that were rejected at the first stage of the study selection process fell into two main groups, as outlined by CRD (2009). These consisted of studies that were not primary studies and did not address the topic. They also

consisted of studies that were primary studies and addressed the topic but did not meet one or more of the criteria outlined.

Stage 2: The second stage of the study selection process consisted of obtaining in full all the research study papers that appeared to meet the study selection criteria or those that were ambiguous and screening them in full against the inclusion criteria (see Appendix 3).

Research studies were also identified by looking at reference lists from relevant studies, hand searching the most frequently cited journals and key midwifery and medical journals and searching relevant Internet resources. They were then assessed for inclusion in the review against the pre-determined criteria, which was identified in Stage 1 of the CRD (2009) and the Stage 2 electronic database results study selection process.

3.1.3. Results

A narrative approach to data synthesis was used to summarise the findings of Structured Literature Review One. The total number of research study papers that were identified through the literature search was 686. After duplicates were removed 451 papers were left, from screening the title and abstract 59 papers remained. After reading the full text, nine papers appeared to meet the inclusion criteria (see Appendix 4, PRISMA diagram). These papers were critically reviewed using a CASP (2018b, c) tool and were judged to be of high enough quality to be included in this review (see appendix, 5). After critically appraising these papers some were judged to provide a higher level of evidence than others.

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3.1.3.1. Included studies

Nine studies (Begley et al., 2011b; Davis et al., 2012; Dixon et al., 2009; 2013; Fahy, et al., 2010; Grigg et al., 2017; Kataoka, et al., 2018; Laws, et al., 2014; Monk, et al., 2014) compared directly or indirectly active versus expectant third stage management approaches, for women at low risk of PPH giving birth in midwife-led units, and blood loss during the third stage of labour and shortly after. The Davis et al. (2012), Dixon et al. (2009 ; 2013), Fahy et al. (2010),

Kataoka et al. (2018) and Laws et al. (2014) studies were all retrospective cohort studies; whilst Grigg et al. (2017) and Monk et al.'s (2014) were prospective cohort studies and Begley et al. (2011b) was an RCT.

3.1.3.2. Outline and critique of identified papers

The Davis et al.'s (2012) large, national study took place in New Zealand, where midwives are the lead maternity caregivers for the majority of women. In New Zealand, midwives support women to birth in a variety of birth settings: home, primary level units, which are midwife-led units, and secondary and tertiary-level hospitals, which are obstetric-led units. Midwives, as the lead maternity caregivers, provide continuity of care for a caseload of women from early pregnancy to six weeks postnatal, liaising and referring to other healthcare professionals if needed. Consequently, the midwife who provides care for a woman during labour and birth will be known to her. The study investigated the effect of planned place of birth on the risk of severe PPH (defined as blood loss of more than 1000 mL) and active and expectant management of the third stage of labour.

The study analysed data collected from the New Zealand College of Midwives' research database for women giving birth in 2006 and 2007 who were classified as at low risk of PPH when labour commenced. The New Zealand College of Midwives' research database holds data for approximately 32% of all the births in New Zealand. Data was obtained for 39,677 births, of which 16,453 (41.5%) births met the study criteria. Outcomes of the study were attributed to the planned place of birth at the onset of labour.

The study found that the proportion of women who had a severe PPH was higher in the women who received active management, compared to, those who received expectant management in all birth settings, which included the primary units (midwife-led units). This difference was statistically significant (RR: 2.14, 95% CI: 1.42–3.22). Additionally, in the primary level units women who received active management were more than twice as likely to have a severe PPH, as women who received expectant management (1.7%, 23 women versus 0.6%, 9 women). However, twice as many women in the

expectant management group went on to have further (uterotonic) treatment for excessive blood loss compared with those in the active management group (14.0% vs 7.3%).

The study by Dixon et al. (2009) also analysed data collected from the New Zealand College of Midwives' research database. It compared active and expectant management of the third stage of labour for all normal physiological births from 2004 to 2008. During this time period 33,752 women met the study inclusion criteria. The study found that primary level units (midwife-led units) experienced a reduction in the occurrence of PPH, despite an increase in the use of expectant management (expectant management rate 57.8%) compared to active management (active management rate 42.2%). This was in comparison to the secondary and tertiary level units (obstetric-led units) which had an increased proportion of active management (63.7% and 65.5% respectively) compared to expectant management (36.3% and 34.1 respectively). The proportion of blood loss of 501-1000 mL was 4.1% and 0.99% for a blood loss greater than 1000 mL at the primary level units (midwife-led units). At the secondary and tertiary level units (obstetric-led units) the proportions of blood loss of 501-1000 mL were 4.2% and 5.2% respectively. For a blood loss greater than 1000 mL they were 1.2% and 1.5% respectively.

Dixon et al. (2013) also wrote a research paper analysing further the data from their 2009 study (Dixon et al., 2009). They also found women who had expectant management compared with active management received more treatment for excessive blood loss, consisting of the use of an uterotonic drug, after birth. The relative risk of having treatment for excessive blood loss if a woman was in the expectant management group was 70% higher than if she was in the active group (Relative risk 1.7, 95% CI: 1.6–1.8). However, once the women had the uterotonic drug to treat excessive blood loss, those in the expectant management group were less at risk of a PPH compared with the active management group (RR: 0.54, 95%CI: 0.5–0.6). Amongst women in the expectant management group, 3.7% had a blood loss of more than 500mL, compared to 6.9% in the active management group.

The small study of Grigg et al. (2017) was also carried out in New Zealand. It compared clinical outcomes for women, intending to give birth in a freestanding midwife-led unit or a tertiary level unit (obstetric-led unit). The study consisted of 407 women who intended to give birth in a midwife-led unit and 285 women who intended to give birth in a hospital obstetric-led unit in 2010–2011. All of the women planning to birth in the obstetric-led unit were identified as at low risk of obstetric interventions. Of the women planning to birth in the midwife-led unit 29 were identified as high risk of obstetric interventions, consequently, they would also be at high risk of PPH. Grigg et al. (2017) found that expectant management was higher in the women who intended to birth in the midwife-led unit compared with the obstetric-led unit (41.8 % versus 19.3%). Despite this increase in expectant management in the midwife-led compared with the obstetric-led unit, both groups of women had similar overall rates of PPH. At the midwife-led unit 23.3% of women had a PPH (17.4% of women had a blood loss of 500-999 mL and 5.9% had a blood loss of 1000 mL or over), compared with 24.7% of women in the obstetric-led unit who had a PPH (20.1% had a blood loss of 500-999 mL and 4.6% had a blood loss of 1000 mL or over).

Fahy et al.'s (2010) study was conducted in New South Wales, Australia. It collected and analysed data on all women classified as low risk of PPH who gave birth at a freestanding midwife-led unit from July 2005 to June 2008 and at a tertiary level maternity unit (obstetric-led unit). The tertiary level maternity unit consisted of an obstetric-led unit as well as an alongside midwife-led unit. Data for the tertiary level maternity unit was collected from January 2006 to June 2008. The total number of women who gave birth at the tertiary unit during the study was 9,313, of which 67% (6,240) were excluded due to identified risk factors for PPH. The total number of women who birthed at the freestanding midwife-led unit was 431 of which 16.2% (70) were excluded for risk factors for PPH. Therefore, the total number of women who met the study criteria was 3,436, consisting of 3,073 at the tertiary level unit and 361 at the freestanding midwife-led unit.

At the freestanding midwife-led unit the midwives worked with a modified caseload model of care; consequently, the women would have known the

midwife providing care for them during labour and birth. The tertiary level's obstetric-led unit was a major obstetric and neonatal referral centre for the region. At the tertiary maternity unit active management of labour was the policy and almost universal practice. Expectant management was mainly practised at the freestanding midwife-led unit and midwives who worked there received extra training in this management approach.

The study's intention-to-treat analysis found an overall PPH rate of 8.6%, defined as blood loss of 500 mL to 1000 mL, and 1.8%, defined as blood loss more than 1000 mL. It also found a PPH (defined as blood loss of 500 mL or more) rate of 11.2% (344 of 3075 women) for active management, which was the intended third stage management approach at the tertiary level unit. This is compared with a PPH rate of 2.8% (10 of 361 women) for expectant management, which was the intended third stage management approach at the freestanding midwife-led unit. This increased incidence of PPH with active management versus expectant management was statistically significant (OR 4.4, 95% CI: 2.3 to 8.4).

At the freestanding midwife-led unit, treatment-received analysis found an increased PPH (defined as blood loss of 500 mL or more) rate with active management (12.5%; 6 of 48 women) compared to expectant management (1.3%; 4 of 313 women). There was also a lower blood loss and incidence of PPH (defined as blood loss of 500 mL or more) associated with expectant management compared with active management in women at low risk of PPH in all birth settings. Additionally, this blood loss and incidence of PPH were lower at the freestanding midwife-led unit regardless of third stage management approach.

However, the number of women included in the study who birthed at the freestanding midwife-led unit was small (361) compared to women who birthed at the tertiary unit (3075). Also, at the freestanding midwife-led unit the number of women who received active management compared to expectant management was over six times smaller (48 versus 313); whilst on the tertiary unit the number of women who received expectant management compared to

active management was over 27 times smaller (107 versus 2968). Despite the high numbers of women in this study who received active management, the low numbers of women who received expectant management limit the precision of estimates and power of this study.

Another study conducted in New South Wales, Australia, by Laws et al. (2014) consisted of a large scale matched pairs cohort study. This study consisted of women defined as at low risk of PPH. The maternal outcomes for these women, who intended to birth at New South Wales birth centres (midwife-led units), were matched with women who intended to give birth at alongside hospital's obstetric-led units. Data was collected from the computerised maternity notes of 15,742 women, between 2001 and 2009, who intended to birth at the midwife-led units and met the study criteria. Data was also collected from the computerised maternity notes of 66,190 women who intended to give birth in the alongside hospital's obstetric-led units during the same period. Maternal outcomes examined in the study included PPH (defined as blood loss more than 500 mL). The PPH rate at the obstetric-led units was 10.6% compared with 8.6% at the birth centres. This lower rate of PPH at the midwife-led units versus hospitals obstetric-led units was significantly lower (OR 0.79, 95% CI: 0.74 to 0.85), despite a much higher rate in expectant management of the third stage at the midwife-led units (24.4 vs 2.0%).

A study by Monk et al. (2014) was also conducted in New South Wales, Australia. This study investigated specified maternal and neonatal outcomes in women at low risk of obstetric complications. It compared women giving birth in one of two freestanding midwife-led units in regional and urban areas, with women intending to give birth in one of two tertiary level units (obstetric-led units). The tertiary level units were the referral hospitals for the freestanding midwife-led units. Midwives at the midwife-led units worked in small groups and provided twenty-four hour on-call midwifery care. Data was collected from the computerised maternity notes of women, who met the study criteria and booked to give birth at the freestanding midwife-led units and the tertiary-level units, from 2010 over a 17- month period. The number of eligible women was 3,651, of whom 494 planned to birth on the freestanding midwife-led units and 3,157

planned to birth the tertiary–level units. Analysis of data was by intention-to-treat with outcomes attributed to planned place of birth at the time of booking.

The prevalence of PPH (defined as blood loss of 500 mL to 1000 mL) on the free standing midwife-led units was 9.7% compared to 15.4% on the tertiary level units, which was statistically significant ($p=0.031$), whilst the prevalence of severe PPH (defined as blood loss of 1000 mL or more) was 3.4% the free standing midwife-led units compared to 3.6% the tertiary level units, which was not statistically significant ($p=0.618$). This likely reduction in PPH for women booked for the freestanding midwife-led unit was despite a higher incidence of expectant management of the third stage of labour for these women, compared with women booked on the tertiary-level units (37.4% compared with 2.9%).

An RCT conducted by Begley et al. (2011b) compared midwife-led care versus consultant-led care (obstetric-led care) for women at low risk of childbirth complications in Ireland. The study involved 1653 women who were randomised to midwife-led care or consultant-led care. If they were randomised to midwife-led care they were expected to birth at the midwife-led unit. If they were randomised to consultant–led care they were expected to birth at the obstetric-led unit. 1,101 women were randomised to midwife-led care and 552 were randomised to consultant-led care.

The study found that despite an increase in expectant management at the midwife-led unit compared to the obstetric-led unit (12.4%, 137 of 1101 versus 0.2%, 1 of 552; RR 68.69) there was no statistically significant difference in estimated mean blood loss during the third stage of labour or shortly after (323 mL (SD 317 mL) vs 324 mL (SD 401 mL); MD 6.17, 95% CI 32.12, 44.46) and incidence of PPH (13.1%, 144 of 1101 versus 13.6%, 75 of 552; RR 0.96, 95% CI 0.74, 1.25). However, a large scale study by Kataoka et al. (2018) found that the number of women who had a blood loss defined as either over 500 mL, or over 1000 mL was higher on the birth centres (midwife-led units) where the women received expectant management, compared to the hospital obstetric-led units, where women received active management. This difference was statistically significant for a blood loss defined to be more than 500 mL; 22.1%

compared with 18.4% (OR 1.47, 95% CI: 1.31 to 1.64, $P < 0.001$); and for a blood loss of over 1000 mL, 3.6% compared with 2.4% (OR 1.77, 95% CI: 1.35 to 2.33, $P < 0.001$).

Kataoka et al.'s (2018) study was conducted in Tokyo, Japan. The study consisted of 9,588 women who were defined as at low risk of obstetric complications (including PPH), who had a spontaneous vaginal birth in one of 19 birth centres (midwife-led units) or in one of two hospital obstetric-led units. Data was collected from maternity computerised records for women who birthed in the midwife-led units from 2001 to 2006; for women who birthed in one of the hospital's obstetric-led unit from 2004 to 2006; and for women who birthed in the other hospital's obstetric-led unit over a twelve month period from 2008 to 2009. The midwife-led units were staffed by 43 independent midwives and women who birthed there received expectant management, whilst the women who birthed in the hospital obstetric-led units received active management of the third stage of labour.

The study compared numerous maternal and neonatal outcomes in the midwife-led and hospital obstetric-led units, including blood loss during the third stage of labour or shortly after birth. These outcomes were analysed according to actual place of birth. Logistic regression analysis was also used to compare outcomes in the midwife-led units with outcomes in the obstetric-led units, adjusting for age, parity, mode of delivery, and number of gestational weeks. During the study 5379 women birthed in the midwife-led units and 4209 women birthed in the hospital obstetric-led units.

However, women identified in the study as being at low risk of PPH had risk factors for PPH and received expectant management in the midwife-led units. This was because the midwives working in the midwife-led units during this time were not allowed to conduct active management. These risk factors included maternal age 40 years and over, parity 4 or more, baby's birth weight 4kg or more, all of which are identified as risk factors for PPH by NICE (2017). It is not known how many of these women identified as being at increased risk of PPH experienced a PPH in the study. Therefore, not analysing potential confounders

for PPH reduces the reliability and validity of the study and the generalisability of the study's findings, to women at low risk of PPH. This is because expectant management is only appropriate for women at low risk of PPH. Furthermore; the midwives in this study were not able to convert to active management if the woman experienced excessive blood loss, as they would have done in the UK. Kataoka et al.'s (2018) study also comments, because midwives practicing at the midwife-led units were unable to conduct active management the risk of expectant management and PPH on midwife-led units should not be overestimated. Since this study was conducted midwives, practising at midwife-led units in Japan, are now able to conduct active management if women develop risk factors for PPH or experience excessive blood loss, during the third stage of labour or shortly after.

The cohort studies by Davis et al. (2012), Dixon et al. (2009; 2013), Fahy et al. (2010), Kataoka et al. (2018) and Laws et al. (2014) did not conduct power calculations. Therefore, any non-statistically significant finding in these studies could have been a chance finding and might have been due to the study being underpowered, and as a result, unable to find a statistically significant difference. However, the large size of the study samples and use of multiple sites in some of the studies (Davis, et al., 2012; Dixon, et al., 2009; 2013; Kataoka et al., 2018) are likely to lead to highly powered studies and precise estimates of effect, as reflected by the quoted confidence intervals in some of these studies, resulting in a good level of generalisability.

Begley et al. (2011b), Dixon et al. (2009), Grigg et al. (2017), Laws et al. (2014) and Monk et al. (2014) studies did not directly analyse the effect of third stage of labour management style on PPH for women giving birth on a midwife-led unit. They analysed place of birth (midwife-led unit or obstetric-led unit) and the incidence of PPH and place of birth and the type of third stage management approach. However, it can be inferred from the results of these studies whether third stage of labour management type leads to a higher rate of PPH, for women giving birth in midwife-led units. This is because there is a link between type of birth setting (midwife-led or obstetric-led unit) and the likely management style experienced by a woman, birthing in that setting (with higher

proportions of women at midwife-led units having expectant management). Therefore, despite the lack of direct comparison of outcomes in the two management styles, the higher rates of PPH observed in obstetric-led units leads to the inference of lower rates of PPH in women, having expectant management in the midwife-led units.

While most of these studies (Begley et al., 2011b; Dixon et al., 2009; Grigg et al., 2017; Kataoka et al., 2018; Laws et al., 2014) identified in Structured Literature Review One compared management styles, in obstetric-led units with management styles in a midwife-led unit, it may be expected that findings may be different when comparing management styles just in a midwife-led unit.

3.1.4. Summary

Structured Literature Review One has identified nine studies that directly or indirectly analysed active compared with expectant management approaches and blood loss, during the third stage of labour and shortly after birth. Most women in these studies were identified as at low risk of PPH and gave birth in a variety of birth settings, including midwife-led and obstetric-led units.

Davis et al (2012) and Fahy et al.'s (2010) studies found a higher incidence of PPH with active management compared with expectant management in all birth settings. Additionally, in midwife-led units women who received active management were more likely to have a PPH compared to women who received expectant management. Although twice as many women in the expectant management group went on to have further (uterotonic drug) treatment for excessive blood loss, compared with those in the active management group (Davis et al., 2012), Dixon's study also found that women who received expectant management and had treatment for excessive blood loss (use of an uterotonic drug) after birth were then less at risk of, having a PPH compared with women who received active management.

The studies by Dixon et al. (2009), Grigg et al. (2017), Laws et al. (2014) and Monk et al. (2014) found that a lower incidence of PPH in midwife-led units, despite an increased rate of expectant management and a reduced rate of

active management, in comparison to the obstetric-led units. Begley et al. (2011b) also found that despite an increase in expectant management, in a midwife-led unit compared to obstetric units, there was no statistically significant difference in estimated mean blood loss during the third stage of labour or shortly after, or in the incidence of PPH. Therefore, it can be inferred that, in these studies, expectant management did not lead to a higher rate of PPH. In fact it led to a reduced rate of PPH. However, Kataoka et al. (2018) found a higher incidence of PPH in women, who birthed in midwife-led units, where the women received expectant management, compared to the hospital obstetric-led units where the women received active management. This higher incidence of PPH in midwife-led units was statistically significant. However, women who had risk factors for PPH were included in the study and received expectant management in the midwife-led unit. The effect of these risk factors on the incidence of PPH in the midwife-led and obstetric-led units was not known. Consequently, not analysing potential confounders for PPH reduces the validity of the study and the generalisability of the study's findings to women without these risk factors for PPH. Also, being unable to convert to active management, if excessive bleeding was observed during the third stage of labour, again reduces the validity and generalisability of the findings of this study to the UK setting.

3.1.5. Conclusion from Structured Literature Review One

None of the studies identified in Structured Literature Review One were conducted in the UK. There is also a lack of studies that directly compare the incidence of and treatment of PPH and active versus expectant management, in women at low risk of PPH giving birth in midwife-led units. Structured Literature Review One only identified two studies that directly examined the incidence of PPH and active versus expectant management in women at low risk of PPH, giving birth in midwife-led units (Davis et al., 2012; Fahy et al., 2010). One of these studies, consisting of a large national study, only examined the incidence of severe PPH (defined as blood loss of more than 1000 mL) (Davis et al., 2012). The other study was a small study with low numbers of women, who received active management at the midwife-led unit compared to expectant management, limiting the reliability, validity and generalisability of the

study's findings (Fahy et al., 2010). Structured Literature Review One did not identify any studies that examined treatment for PPH and the relationship between active and expectant management in women at low risk of PPH, giving birth in midwife-led units. The research study papers identified in Structured Literature Review One were also of varying quality and their generalisability to women at low risk of PPH, who have a physiological normal birth, and give birth in midwife-led units in the UK is limited.

The studies identified in Structured Literature Review One were not stated as evidence by international (WHO, 2012; 2018) and national third stage of labour practice guidelines (NICE, 2017; RMC, 2018; RCOG, 2016) or included in the Cochrane Reviews (Begley et al., 2010; 2011a; 2015; 2019; Prendiville, et al., 2000) that compared active versus expectant management. Eight of the studies identified in Structured Literature Review One were not included as evidence in the Cochrane Reviews because they were observational studies. Cochrane reviews only consist of randomised control trials, or quasi-randomised control trials. RCTs are generally regarded as the most appropriate research method, when the intention is to compare one intervention with another (CRD, 2009). RCTs are held as the gold standard for evaluating the effectiveness of interventions (Schulz, Douglas & Moher, 2010; Torgerson & Torgerson, 2008).

However, cohort studies reflect more accurately what is happening in practice, as the researcher does not intervene in practice but observes it (Hackshaw, 2015). Although, cohort studies can also be more susceptible to confounding bias, as participants are not assigned randomly to intervention groups and, as a result, their outcomes may differ. These differences are not due to the intervention, but because the participants or their circumstances may be inherently different from the start (Greenhalgh, 2019). Additionally, researchers in retrospective cohort studies can only use data that has already been collected, so there is a greater potential for missing data (Greenhalgh, 2019). These issues may reduce the validity and reliability and increase bias in these types of studies (Greenhalgh, 2019).

However, it has been questioned whether an RCT is appropriate to investigate an expectant third stage of labour management approach and any associated blood loss (Fahy et al., 2009). This is because for a woman to participate in an RCT, investigating an expectant third stage of labour management approach and associated blood loss, she should be randomised after the birth of the baby. At this point it will be known if she has had a spontaneous vaginal birth and is at low risk of PPH. This is essential, as stated previously in this thesis, expectant management is only appropriate for women who have had a normal physiological birth and are at low risk of PPH. However, Fahy et al. (2009) comments that to randomise women after the birth of the baby would be unethical due to difficulties regarding obtaining informed consent. It has also been commented that asking women to think about taking part in a study and give their informed consent during this stage of labour, might be an intervention that disturbs their hormones and impacts on the birthing process, including the birth of the placenta and membranes (Edwards & Wickham, 2018). Consequently, to conduct an RCT to investigate an expectant third stage of labour management approach and any associated blood loss, during the third stage or shortly after might not be appropriate.

The RCT by Begley et al. (2011b) identified in Structured Literature Review One was not included in the Cochrane reviews, as it did not directly analyse management style and PPH. It compared midwifery care (where women were expected to birth at a midwife-led unit) versus consultant care (where women were expected to birth at an obstetric-led unit) and nine key neonatal and maternal outcomes. These outcomes included incidence of PPH and third stage of labour management approaches.

Structured Literature Review One did not identify any RCTs that directly analysed active versus expectant management approaches and the incidence of PPH, in women giving birth in midwife-led units. However, eight cohort studies were identified that did directly or indirectly investigate these variables. Findings from eight of these studies (Begley et al., 2011b; Davis et al., 2012; Dixon et al., 2013; 2009; Fahy et al., 2010; Grigg, et al., 2017; Laws, et al., 2014; Monk, et al., 2014). are in contrast to the findings of the evidence

informing international and national third stage of labour practice guidelines and recommendations, and the findings from the latest Cochrane review (Begley et al., 2019). However, the study by Kataoka et al. (2018) did support this evidence.

3.1.6. Overall conclusion

.None of these studies identified in Structured Literature Review One were conducted in the UK. There is also a lack of studies that directly compare the incidence of and treatment of PPH and active versus expectant management in women at low risk of PPH, giving birth in midwife-led units. Only two studies were identified in Structured Literature Review One that examined the incidence of PPH and active versus expectant management in women at low risk of PPH, giving birth in midwife-led units (Davis et al., 2012; Fahy et al., 2010). One of the studies only examined the incidence of severe PPH (defined as blood loss of more than 1000 mL) (Davis et al., 2012), whilst the generalisability of the other study's findings to women at low risk of PPH who birth at midwife-led units is limited (Fahy et al., 2010).

Also, the evidence that third stage of labour practice guidelines and recommendations are based on is of low quality and does not provide robust evidence regarding, third stage management approaches. Additionally, these research studies informing third stage of labour practice guidelines and recommendations were conducted in hospital obstetric-led units. This therefore, calls into question the generalisability of these practice guidelines to midwife-led units.

Birth settings are becoming increasingly more important. This is because of the beneficial outcomes reported in research studies for healthy women at low risk of obstetric complications, who plan to give birth away from hospital obstetric-led units. Consequently, further exploration of evidence regarding the relationships between active and expectant third stage management approaches and incidences of PPH in women, giving birth in midwife-led units is required. Therefore, Study One was conducted, aiming to answer the research questions:

What is the relationship between active and expectant third stage of labour management approaches and the incidence of PPH, during the third stage of labour or shortly after, in women at low risk of PPH who give birth in midwife-led units?

What is the acceptability of active and expectant management approaches for these women in midwife-led units? (See Chapter 4, Study One)

3.2. Structured Literature Review Two

The general literature review in Chapter One and the findings of Structured Literature Review One also suggest that third stage management practices differ in different birth settings and between healthcare professionals, providing third stage of labour care. This indicates that practices during the third stage of labour are likely to be influenced by a range of factors, not just anticipated physical outcomes from research studies, that have provided evidence for third stage of labour international and national guidelines and practice recommendations (NICE, 2017; RCOG, 2016; RCM, 2018, WHO, 2012; 2018).

Additionally, midwives are the main carers for women classified as at low risk of obstetric complications during the pregnancy and birth continuum (DH, 2016) Midwives also work with the obstetric team in providing care for women defined to be at high risk of obstetric complications. Thus midwives might have a useful understanding of the factors that are likely to influence their use of third stage of labour management approaches. Consequently, their perspective would be valuable to explore, particularly midwives working in midwife-led units. This is because, as stated previously in this thesis, women are increasingly choosing to birth in midwife-led units. This increase can be attributed to the beneficial effects of midwife-led units for women and babies found in research studies (Alliman & Phillippi, 2016; Brocklehurst, et al., 2011; Christensen & Overgaard, 2017; Hodnett, Downe & Walsh, 2012; Hollowell et al., 2011 Walsh & Downe, 2004). Findings from research studies regarding place of birth have subsequently influenced NICE (2017) intrapartum care guideline and, consequently, local maternity care provision guidelines, recommending

midwife-led units as the place of birth for women identified as at low risk of obstetric complications.

Furthermore, practice guidelines and recommendations regarding the third stage do not draw on any research that has explored midwives' perspectives, regarding third stage of labour. National and international third stage of labour practice guidelines and recommendations are based solely on physical outcomes regarding the third stage of labour management approaches (NICE, 2017; RCM, 2018; RCOG, 2016; WHO, 2012; 2018). Therefore a second structured literature review was needed to identify any research studies that have explored midwives' views and experiences regarding factors that they feel influence their use of third stage management approaches.

3.2.1. Data Sources

Databases were searched using a combination of words: "midwives views", "midwives experience", "third stage of labour", "third stage of labour", "study" and "studies".

The search strategy to identify primary research studies comprised of:

- Searching electronic databases EMBASE (Excerpta Medica Database), Psych Info (Psychology and allied fields), AMED (Allied and Complementary Medicine), HBE (Health Business Elite), PubMed, BNI (British Nursing Index), HMIC (Health Management Information Consortium), CINAHL (Cumulative Index to Nursing and Allied Health Literature) and Medline.
- Looking at reference lists from relevant studies:
- Hand searching the most frequently cited journals and key midwifery and medical
Journals: British Journal of Midwifery; Midwifery; Journal of Advanced Nursing; Birth, Women and Birth.
- Searching relevant Internet resources: NICE; Cochrane library

3.2.2. Study Selection

The identification of studies for Structured Literature review Two followed the same study selection process identified in Structured Literature Review One.

3.2.3. Pre-determined inclusion criteria

Studies that explored midwives' first-hand accounts of their experiences and views regarding their use of active and expectant third stage of labour management approaches. All studies had to be primary published research studies conducted in high income countries. Initially no date parameter was set.

3.2.4. Results

A narrative approach to data synthesis was used to summarise the findings of Structured Literature Review Two. The total number of research study papers identified through the literature search was 329. After duplicates were removed 231 articles remained. After stage 1 of the selection process 25 papers remained and after stage 2, of the study selection process, only five papers that identified studies that met the inclusion and exclusion criteria remained (see Appendix 6 and 7). Again as in Structured Literature Review One, papers identified were critically reviewed using a CASP (2018d) appraisal tool and also (Greenhalgh, 2019) appraisal tool. These five papers were considered to be of sufficient quality to be included in Structured literature review Two (see Appendix 8). However, after the critical appraisal process certain studies were considered to be of higher quality than others.

3.2.4.1. Included studies

Structured Literature Review Two identified five research studies that explored midwives' views and experiences, regarding factors influencing their use of third stage management approaches. Qualitative studies were conducted by Begley, Guilliland, Dixon, Reilly and Keegan, (2012); Jangsten, Hellstrom and Berg (2010), Noseworthy, Phibbs and Benn (2013) and Schorn, Minnick and Donaghey (2015). Additionally, a short questionnaire study was conducted by Harding, Elbourne and Prendiville (1989). This was the only UK study identified.

3.2.4.2. Summary and critique of identified studies

Begley et al.'s (2012) study explored the views and experiences of midwives in Ireland and New Zealand regarding why they used expectant management of the third stage of labour. It also explored the skills they used to facilitate this third stage approach. The Irish midwives worked on midwife-led units whilst the

New Zealand midwives were self-employed or publicly-funded midwives and worked in a variety of birth settings (hospital obstetric-led units, midwife-led units and home birth settings). All midwives had experience of and were skilled in conducting expectant management of the third stage of labour. Therefore, their views and experiences regarding this third stage of labour approach are valuable to explore.

Data was collected from 27 midwives: 18 midwives in New Zealand and nine in Ireland. Semi-structured individual interviews were conducted with 18 midwives, one semi-structured interview was conducted with two midwives and one focus group was conducted with seven midwives. Data was analysed using a constant comparative method. The four themes identified were helpful in illuminating key aspects regarding, what experienced midwives felt assisted their use of expectant management. The four themes identified were 'Going with the flow', 'Knowing it's separated', 'Coping with the abnormal' and 'Letting it come'.

'Going with the flow' comprised of midwives' views and beliefs on normal birth. Midwives discussed how they viewed expectant management as, being a part of this normal birthing process and supporting the woman's body to birth her placenta. 'Knowing it's separated' consisted of midwives discussing how they observed the woman during the third stage for signs or symptoms that the placenta had separated. 'Coping with the abnormal' consisted of midwives discussing how they would assess the woman for risk factors for PPH before labour and during and after birth. If any risk factors were present before birth, the midwives discussed how they would inform the woman of this risk. They would also inform them why active management might be more appropriate for them. If risk factors developed during labour or birth midwives discussed how they were ready to intervene if necessary. 'Letting it come' consisted of midwives' discussions regarding the activities they used during expectant management, to aid the birth of the placenta. These identified themes illustrate how midwives must balance supporting the normal birthing processes and intervening, when deviations from the normal occur.

The midwives in Begley et al.'s (2012) study also identified several factors that they felt influenced their third stage of labour approaches. Midwives in both countries discussed the pressures they felt from other healthcare professionals to conduct active management, of the third stage of labour. However, these midwives also believed that if the woman had a normal physiological labour and birth then no intervention, during the third stage of labour was necessary. Midwives in both countries talked about intervening during the third stage if the woman's blood loss was excessive or her wellbeing was compromised. The importance of ensuring an environment that supports third stage physiology was also discussed. Some of the midwives, in both countries, spoke about how feeling nervous when they initially started to conduct expectant management led to them overestimating blood loss and intervening by giving an uterotonic drug. However, once they gained experience in expectant management they were less worried about blood loss and intervened less often.

All of the midwives discussed how if the woman had risk factors for PPH they would advise active management. They would, however, support the woman if she wanted to have an expectant management approach but were prepared to intervene quickly if needed. The New Zealand midwives discussed how they felt autonomous in the care they provided to women. This autonomy meant that these midwives did not feel judged regarding their midwifery practice, whilst the Irish midwives felt their third stage of labour care took place within guidelines with little autonomy.

The data collection and analysis was explained in detail in Begley et al.'s (2012) research paper, increasing the transparency of the research process. The paper also outlines activities that were undertaken to increase the confirmability and credibility of their study's findings. An example to increase confirmability, the data was analysed by more than one researcher and their findings were discussed. An example to increase credibility, draft results were returned to participants to ensure that they were in agreement with the researchers' interpretations. These activities, as well as other activities outlined in the research paper, increased the trustworthiness of Begley et al.'s (2012) study.

However, the Begley et al. (2012) study only explored the midwives' views regarding expectant management. The midwives' views regarding active management were not explored. Also, the Irish midwives in the study worked at the only two midwife-led units in Ireland; these midwife-led units were established in 2004 and the study was conducted in 2010. Therefore, the provision of midwife-led units was a relatively new concept in Ireland at the time of the study. Consequently, the views of the Irish midwives in the study may be different than the views of midwives working at midwife-led units where this provision of care is more established. The New Zealand midwives in the Begley et al. (2012) study provided care for a caseload of women, during their pregnancy, birth and the postnatal period. The midwives provided this care in a variety of settings. Therefore, their views and experiences regarding expectant management may be different from the views of midwives not providing care for a caseload of women and who work solely in one birth setting.

Jangsten et al.'s (2010) study explored midwives' experiences of management of the third stage of labour, consisting of both active and expectant management. The study was conducted in Sweden and consisted of six focus groups with 32 midwives, who worked on six obstetric-led hospital units. The midwives had extensive experience of assisting women in labour. Data was analysed using content analysis and three categories were generated: 'Bring the process under control'; 'Protect normality and women's birthing experiences' and 'Maintain midwives' autonomy'. These categories also comprised of subcategories.

The category 'Bring the process under control' consisted of midwives' discussions regarding, how they assessed for progress during the third stage of labour and what actions they felt they needed to conduct, to ensure the successful management of the third stage. The category 'Protect normality and women's birthing experiences' consisted of midwives' discussions concerning how, if labour was progressing normally, then they would not intervene by conducting active management. Midwives commented that they would facilitate the woman to birth the placenta physiologically. However, the midwives also

voiced how it was difficult to assess if the placenta was retained and when to intervene.

The category 'Maintain midwives' autonomy' consisted of midwives' discussions regarding the importance of their knowledge, relating to physiological birth and applying this knowledge in their clinical discussions, rather than just following recommendations from hospital guidelines that advocated active management. The midwives in the study also discussed how if the woman had risk factors for PPH they would advise active management. They would, however, support the woman if she wanted to have an expectant management approach but were prepared to intervene quickly if needed.

Reviewing the categories generated from Jangsten et al.'s (2010) study highlighted several factors influencing midwives approach to the third stage of labour management. All the midwives, like all the midwives in Begley et al.'s (2012) study, discussed the importance of assessing for the presence of risk factors for PPH, as well as, assessing for any deviations from the normal. They could then intervene if needed. Midwives in Jangsten et al.'s (2010) study, like the Irish midwives in the Begley et al. (2012) study, felt hospital guidelines influenced their third stage of labour management approach. In the Jangsten et al. (2010) study midwives discussed how most of them conducted active management of the third stage of labour for all women, because this was the hospital guideline. However, several midwives in the study also discussed basing their third stage of labour management approach on the individual woman's needs rather than the hospital guideline. All the midwives in Jangsten et al.'s (2010) study, again like all the midwives in Begley et al.'s (2012) study, also regarded childbirth as a natural and normal process not needing routine intervention, and this included the third stage of labour. Some of the midwives in the Jangsten et al. (2010) study also discussed being reluctant to conduct active management as a prophylactic management approach for women, who had a normal birth with no risk factors for PPH. The study also used focus groups to collect data. Although focus groups have many advantages, it may be that midwives in these focus groups were reluctant to discuss sensitive issues around practice in front of others.

While, the Jangsten et al. (2010) research paper outlines how data was collected and analysed, linking the categories generated to the participant's transcripts, the data collection and analysis process was not as transparent as it could have been. Furthermore the researchers were not reflexive within the research study. This lack of transparency and reflexivity reduces the dependability and credibility of the study's findings and the trustworthiness of the study. The midwives in the study also only practised in obstetric-led units. Furthermore, at the time of the study active management of third stage of labour did not consist of all the components of active management, as it does in the UK. Active management in the study only consisted of giving an uterotonic drug. Therefore, the transferability of Jangsten et al.'s (2010) study findings to midwives practising in other birth settings (midwife-led units or home birth settings) and where all the components of active management are instigated may be reduced.

The Noseworthy et al. (2013) study was conducted in a large region in New Zealand with eight woman-midwife pairs, in 2009 and 2010. Prenatal and postnatal interviews with woman-midwife pairs were conducted to explore issues around decision-making within childbirth in general and the third stage of labour in particular. Data was analysed using Braun and Clarke's (2006) six-phase guide to performing thematic analysis. Themes identified within these interviews, which centred upon relational influences, were subsequently analysed using the ideas of embeddedness and post-structural understandings of identity. Findings from the study were that a range of relational, social and political factors were identified by midwives and women as influencing their decision-making within childbirth and during the third stage in particular.

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From reviewing the findings of this study it was evident that all midwives perceived their third stage of labour management as being influenced by their practice philosophy and the woman's beliefs regarding birth. These factors also influenced how information was discussed, and determined for the midwife how she offered choice to the woman and how she practised as a midwife, whilst providing care for that woman. All the midwives discussed how a woman's choice was also dependent upon circumstances and the woman's choice might

alter with any change in these circumstances. Midwives also discussed how women did not make choices regarding the birth in isolation, but were influenced by partners or family.

Noseworthy et al.'s (2013) research paper outlines activities that were undertaken to increase the trustworthiness of the study, for example the data was analysed by more than one researcher, increasing the confirmability of data analysis. However, the paper did not, like the Jangsten et al. (2010) paper, consider how the views of the researchers involved in the study might influence the study's findings. Not being reflexive reduces the dependability and credibility of the study's findings and reduces the trustworthiness of the study.

Additionally, like the New Zealand midwives in the Begley et al. (2012) study, the midwives in Noseworthy et al.'s (2013) study provided care for a caseload of women in a variety of birth settings. Therefore, like the midwives in the Begley et al. (2012) study, these midwives' views regarding care during the third stage of labour might have been different to the views of midwives, who did not provide care for a caseload of women and who worked solely in one birth setting. Also, the Noseworthy et al. (2013) study consisted of woman-midwife paired interviews. For this reason, there may have been issues around practice that the midwives might not have revealed with the woman present. Therefore, the study may have under-emphasised the institutions' effects on practice. These issues reduce the transferability of the study's findings to midwives practising in other birth settings (midwife-led units or home birth settings). They also reduce the dependability and credibility of the research findings and the trustworthiness of the study.

The study by Schorn et al. (2015) was conducted in the USA to obtain preliminary data for the development of a national study of interventions used by US birth attendants, during the third stage of labour. This study aimed to identify certified nurse-midwives', certified professional midwives', obstetricians' and family practice physicians' assessments and interventions used during the third stage of labour. It also aimed to examine which management steps or

interventions these practitioners believed should always be used during the third stage of labour.

The study found that midwives and physicians identified factors such as maternal medical and obstetric history, pregnancy and the current labour as affecting their management of the third stage of labour. The midwives identified that patient preferences would also impact on their management of the third stage. From reviewing the findings of this study it was evident that midwives felt the woman's medical and obstetric history, her pregnancy and her process in labour as well as the woman's choice were factors, which influenced their third stage of labour management approach. Like Begley et al. (2012) and Jangsten et al.'s (2010) study findings, if the woman had any risk factors for PPH they would be ready to intervene.

Schorn et al. (2015) paper outlines activities that were undertaken to increase the confirmability of their study's findings, for example the data was analysed by more than one researcher. However, like the previous two papers discussed, Schorn et al (2015) did not consider how the views of the researchers involved in the study might influence the study's findings. Schorn et al. (2015), like Jangsten et al. (2010), also used focus groups involving other health care professionals, as their data collection method. The disadvantages of using this data collection tool have been highlighted previously in this thesis. These issues reduce the credibility of Schorn et al.'s (2015) findings. The study was conducted in the USA and also all participants provided care during labour and childbirth in hospital obstetric-led units, except the certified professional midwives. One of the certified professional midwives provided care during labour and birth in a midwife-led unit, seven worked in a home birth setting and two worked in group practices. The provision of healthcare during the pregnancy and birth continuum is very different in the USA compared to the UK. The former having more medicalised models whilst the later has less medicalised models. Therefore, the transferability of the research findings to midwives, who practise in the UK, and in particular midwives in the UK who practice in midwife-led units may be reduced.

A short questionnaire study by Harding et al. (1989) assessed the views of mothers and midwives who participated in an RCT conducted by Prendiville et al. (1988). This RCT examined active versus expectant management of the third stage of labour and has been discussed previously in this thesis. Participants in Harding et al.'s (1989) study consisted of midwives who practised in a UK hospital obstetric-led unit and women who laboured and gave birth in this setting at the time of the Prendiville et al.'s (1988) RCT. Data for the study was collected via two different short questionnaire, consisting mainly of multiple-choice questions, although open-ended comments were also invited. One of the questionnaires was completed by 191 mothers (11% of the total number of women randomised in the RCT) and the other questionnaire was completed by 49 midwives. The study found that both mothers and midwives commented negatively on the length of time expectant management of the third stage of labour took. This would suggest that the time a physiological third stage of labour takes is a factor that might affect a midwife's use of and a woman's request for expectant management.

Findings from the questionnaire showed, which management approach women wanted was important to the midwives and this would influence the third stage management approach used. Additionally, the majority of midwives thought women preferred an active management approach. Also, assessing the woman for any risk factors for PPH and any deviation from the normal during labour was important to the midwife. If any risk factors for PPH were present or any deviation from the normal occurred, during labour, the midwife thought active management would be appropriate.

Although Harding et al.'s (1989) study was the only one conducted in the UK its findings may have limited generalisability to midwives practising in midwife-led units or home birth settings. This is because all midwives in the study only practised in hospital obstetric-led units. Harding et al.'s (1989) study did not explore the views of participants; it just highlighted their limited responses to questions asked in the short questionnaire, which mainly consisted of multiple choice questions. The study was also conducted in 1989 and views regarding childbirth, including the third stage of labour, have changed. In the 1990s and

2000s, as a result of the rising rates of medical intervention during labour and birth, there has been an increasing international interest in promoting normal birth and working towards less medicalised models of birth (Prosser, Barnett & Miller, 2018). These issues reduce the validity of the Harding et al. (1989) study's finding regarding its ability to explore the views of midwives and women, regarding their third stage of labour management and its generalisability to midwives in contemporary practice, particularly midwives practising in midwife-led units.

3.2.5. Summary of key findings

The critical appraisal tools used (CASP, 2018d, Greenhalgh, 2019) helped to make sense of Structured Literature Review Twos' identified studies' findings, as well as, assessing the quality of the research papers. From using these critical appraisal tools it was evident that some of the research papers provide higher quality evidence than others. Furthermore, only three studies involved midwives practising in midwife-led units (Begley et al., 2012; Noseworthy et al., 2013; Schorn et al., 2015) and only one was conducted in the UK (Harding et al., 1989). However, all of the studies identified in the papers highlighted important issues that explore midwives' views and experiences, regarding factors that they feel influence their use of third stage management approaches. The importance of the woman's choice in influencing midwives' use of third stage management approach was highlighted in all the studies. However, the Irish midwives in the Begley et al. (2012) study and the midwives in the Jangsten et al. (2010) study also discussed the pressures they felt from other healthcare professionals and hospital third stage of labour guidelines to conduct active management of the third stage of labour. These midwives provided care in a hospital obstetric-led unit. However, the New Zealand midwives in Begley et al.'s (2012) study, who provided continuity of care to the women, did not feel confined by hospital guidelines. They felt more able to base their third stage management approach on what the woman wanted and the woman's clinical need.

The midwives in the Begley et al. (2012) and Jangsten, et al. (2010) studies also believed that, if the woman had a normal physiological labour and birth, no

intervention during the third stage of labour was necessary. Midwives in these two studies and midwives in Schorn, et al.'s (2015) and Harding et al.'s (1989) studies also discussed the importance of continually assessing for any deviations from the normal and risk factors for PPH and advising active management, if any these were present or occurred. By contrast, midwives in the Noseworthy et al. (2013) study discussed how their practice philosophy and the woman's beliefs regarding birth were strong factors that influenced the care they provided during childbirth. These midwives also discussed how their practice philosophy and the woman's beliefs regarding birth also influenced how they discussed information, regarding the third stage management, with the women and offered them choice. Although, as noted previously in this thesis, midwives were saying this in paired interviews with mothers present and this may have influenced the midwives responses.

On the other hand, midwives in Harding et al.'s (1989) study discussed their preference for active management, feeling that women disliked expectant management due to the longer length of time it took. However, this study took place over thirty years ago and the implications of this have already been discussed in this thesis, regarding the changing views regarding towards pregnancy childbirth and the effect of this on maternity care provision and practice. Midwives in Noseworthy et al.'s (2013) study were also aware that women were influenced by their partners or family, regarding third stage management and that a woman's choice regarding third stage management might change during labour and childbirth..

3.2.6. Conclusion

Structured Literature Review Two identified limited research of varying quality regarding perspectives from midwives, who practice in midwife-led units, on factors they feel influence their third stage of labour management approach. Place of birth and healthcare practitioners providing care during labour and birth are important, as discussed in Chapter One and in Structured Literature Review One; third stage of labour practices are not just based on evidence from research studies, practice guidelines and recommendations. Third stage practices are likely to be influenced by different healthcare practitioners, by the

context in which healthcare practitioners work and by the expectations of others and it would be useful to understand these. Therefore, there is value in a UK-based study that involves midwives experienced in both third stage of labour management approaches and working in midwife-led units. Thus, in order to fully answer this overarching question, a second research question and a second study were needed.

The second research question and study explored the practicability of active and expectant third stage of labour management approaches for women giving birth in midwife-led units. This was achieved by investigating midwives', experienced in active and expectant third stage management and working in midwife-led units, understanding of the factors they feel shape, facilitate or constrain their use of third stage of labour management approaches, to try to understand what the situation meant to the midwives and what was important in their decision making. This was explored in Study Two and is presented in Chapter Six of this thesis.

Chapter 4

Methodology

This chapter justifies the methodology for this research project. It highlights the different research paradigms, drawing reference to the research project and the research paradigms of the component studies. The overall research design is discussed. The research projects' ethical issues are highlighted and a conclusion is then drawn.

4. The doctorate project research paradigm

The most frequently used research paradigms in healthcare are positivism, interpretivism and pragmatism (Harvey & Land, 2017). Within pragmatism there is an acceptance that researchers can move between positivist and interpretivist according to their research questions. This doctorate project's research paradigm was based on pragmatism., incorporating both post-positivist and interpretivist perspectives to answer the research project's overarching research question:

What are the outcomes, acceptability and practicability of active and expectant third stage of labour management approaches for women giving birth in midwife-led units?

4.1. Research paradigms

A research paradigm is a school of thought, an overarching opinion, a set of beliefs that guides how the researcher conducts the study. These thoughts, opinions and beliefs are often referred to as ontological, epistemological and methodological beliefs and these differ dependent on the different paradigms (Clough & Nutbrown, 2012; Harvey & Land, 2017).

4.1.1. Pragmatism

The ontological beliefs of pragmatism are that there are different perspectives about reality. Therefore, reality can be singular or multiple, and its epistemological beliefs are that knowledge can be obtained objectively and subjectively. Its methodological beliefs are that the most appropriate research

method and design should be adopted to answer the research questions, rather than being governed by the researcher's theoretical perspectives (Clough & Nutbrown, 2012; Harvey & Land, 2017; Robinson, 2015).

4.1.2. Positivism

The ontological belief of positivism is that there is one single reality, which is fixed and objective. As a result of this belief, it also adopts a realist ontological position (Braun & Clarke, 2012; Harvey & Land, 2017; Robinson, 2015). Its epistemological belief is that valid knowledge is obtained through scientific methods that control variables and remove contamination and bias. It is concerned with objective knowledge gained from direct experience or observation (Harvey & Land, 2017; Robson, 2015).

4.1.2.1 Post-positivism

A less pure form of positivism is post-positivism, which has ontological and epistemological beliefs similar to those of positivism (Harvey & Land, 2017; Byman, 2017). However, it believes that research is always flawed and questionable and although measures should be instigated to remain objective, the researcher will, to some extent, influence the research findings (Harvey & Land, 2017; Robson, 2015). Furthermore, in research involving people it is not always possible to predict outcomes in the same way as research in the natural sciences. Additionally, rather than establishing cause and effect, post-positivists aim to identify correlations or relationships (Harvey & Land, 2017; Ormston, Spencer, Barnard & Snape, 2014). The methodological beliefs of positivism or post-positivism are that research studies should use fixed design and measure and quantify outcomes, establishing cause and effect or identify correlations or relationships by manipulating events or people. Research methods include randomised control trials, cohort studies and case studies (Harvey & Land, 2017; Robson, 2015).

4.1.3. Interpretivism and constructionism

Interpretivist, sometimes known as naturalist or constructivist (Harvey & Land, 2017; Ormston, et al., 2014), and constructionist research paradigms reject the ontological, epistemological and methodological beliefs of positivism. The

ontological beliefs of Interpretivists and constructionists are that there are multiple realities, which are subjective as individuals construct their own understanding of reality. Their epistemological beliefs are that knowledge regarding the understanding of the social world is obtained through interpretation and observation and produced by shared understanding between individuals. Additionally, that the researcher's beliefs are thought to influence the research being conducted (Bryman, 2017; Harvey & Land, 2017; Ormston, et al. 2014). Therefore, in order to understand clinical practice, an interpretivist paradigm would assume it is important to understand how key practitioners interpret the situation and the meaning for them of the care they offer.

Constructionists also believe knowledge is constructed by individuals rather than being passively received by them (Bryman, 2017; Ormston, et al., 2014). The methodological beliefs of Interpretivists and constructionists are that research studies should be comprised of flexible designs that highlight detail and provide narrative information. It does not involve measurements to control or manipulate events or people (Harvey & Land, 2017; Ormston, et al., 2014).

4.2 Adoption of pragmatic paradigm

The use of a pragmatic paradigm for this research project enabled the investigation of the physical outcomes and practicability of active and expectant management approaches in midwife-led units. In doing so, the overarching research project question was able to be answered effectively. Harvey and Land (2017) comment that pragmatism allows the researcher to investigate a complex issue using the most appropriate research approach. This therefore makes pragmatism particularly suitable for nursing and midwifery research, as it often investigates complex issues.

4.2.1 Research Study One

Study One contributed to answering the research project's overarching research question by examining outcomes and acceptability of active and expectant third stage of labour management approaches for women giving birth in midwife-led units. This was achieved by examining the relationship between active and expectant third stage management approaches and the incidence of

PPH in women, who had a normal birth in midwife-led units; and the acceptability of active and expectant management approaches.

Study One utilised a post-positivist paradigm, as it reflected the ontological, epistemological and methodological beliefs of this research paradigm. It aimed to measure the effect of an exposure on an outcome; the effect being third stage of labour management approach and the outcome being blood loss and treatment for this loss. It applied a retrospective cohort design, which is a type of observational study. An observational study was used, as research evidence is limited comparing third stage management approaches and the effect of any blood loss and treatment of this blood loss, for women choosing to give birth in midwife-led units. Furthermore, as discussed previously in this thesis, the evidence that informs third stage of practice guidelines and recommendations may not be generalisable to women giving birth in midwife-led units. This evidence is also of low quality. Hackhaw (2015) comments that observational studies are commonly used to examine issues that have not been examined before, to validate or refute previous evidence, or to examine a subject on which previous evidence has had limitations or seen has scientifically flawed (Hackhaw, 2015). Therefore an observational study design was an appropriate design to use for Study One.

The researcher also wanted to observe what was actually happening in practice, regarding third stage of labour management approaches and the effect of these approaches on maternal blood loss and treatment for this blood loss, without intervening. Consequently an experimental design would not have been appropriate for this study. However, by not intervening the researcher was aware that Study One would be more susceptible to confounding bias as researchers have no control over the interventions. This in itself may reduce the validity of Study One's findings. Therefore the researcher introduced measures to increase validity and decrease the confounding bias in Study One.

In Study One to minimise the risk of confounding or other forms of bias, baseline characteristics were summarised by management group. Variables on which a substantive baseline imbalance existed could have implications for

confounding bias. Hence Study One's research design included provision for applying statistical control of any such variables to the main analysis. It was not expected that the sample characteristics would show any systematic departures from the characteristics of the wider population, due to the nature of the midwife-led unit from which data was collected, and the large size of the data set. However, the inspection of sample characteristics also allowed the confirmation of representativeness of the sample, further limiting the potential for bias.

Cohort studies are also higher in the traditional hierarchy of evidence than other observational studies (Greenhalgh, 2019) and if their findings are credible, they are considered to provide better evidence than studies lower in the hierarchy. In the current investigation, a retrospective cohort study was seen as an appropriate observational study design to contribute to answering the overall research question, given the available resources and time period for this doctorate study. The researcher was aware that retrospective cohort studies are particularly susceptible to missing data, which may bias the results of a study. Therefore Study One conducted a statistical test for missingness to analyse the extent of this issue, the possible affect it may have on the results of the study and to assess if a retrospective cohort study was the most appropriate observational research design to answer part of the research project's question. Strategies were put in place to combat the effects of any missing data, including data imputation, complete case analysis and changes to the study design (for example, to a case-control study). However, such changes were subsequently found to be unnecessary.

4.2.2. Research Study Two

As stated previously in this thesis, Study Two contributed to answering the research project's overarching research question by exploring key midwives' understanding of and experience regarding, factors they felt shaped, facilitated or constrained their use of third stage management approaches in midwife-led units; to try to understand what the situation meant to these midwives and what was important in their decision making.

This is an important area to address as the midwives understanding of what is happening in their clinical situation will influence their third stage management approach, as stated previously in this thesis, third stage practices are likely to be influenced by different healthcare practitioners, by the context in which they work and by the expectations of others. I was however aware that my role as a researcher and as a practising midwife, with my own beliefs regarding third stage management approaches, may influence the research being conducted. Therefore I undertook measures to minimise this, to increase the credibility of the study's findings (see study 2).

Data for Study Two was collected using semi-structured interviews with experienced midwives. This data collection method would allow me to explore these midwives understanding, as I expected that what these participants said in these interviews would reveal to me their interpretation and understanding of their third stage of labour practice and how they thought the context in which they worked influenced their third stage practice. What participants said during these interviews reflected their understanding of events and I undertook measures to ensure that midwives were able to disclose their views freely, without being influenced by their environment or by myself in the role as the researcher, increasing the credibility of Study Two's findings (see Chapter, Study 2). Thematic analysis was then used to analyse the participants' narratives from these interviews. I also undertook measures to assess if the study participants felt my translation of their interviews was a fair reflection of their understanding and that a shared understanding was being presented (see Study 2). These measures aimed to increase the trustworthiness of Study Two and increase the credibility of its research findings. It was also in keeping with an interpretivist based study.

The results of Study One and Study Two are brought together at the discussion stage of this thesis to answer the research project's overarching research question.

4.3. Overall research design

This research project's design was in line with what Morse (2003) refers to as a multi-method research design. Each study in a multi-method research design maintains its own research paradigm, its subsequent ontological, epistemological and methodological beliefs, and is a complete study. The results of each study are brought together at the discussion stage to answer the research project's overarching research question (Creswell. 2015; Morse, 2003). A multi-method research design could also consist of two or more quantitative or qualitative research studies within one research project (Creswell. 2015; Morse, 2003). A research project using a multi-methods design is different from a single study using a mixed methods design. The latter consists of the use of both quantitative and qualitative research approaches within a single study, with the less dominant research approach not having to be a complete study in its own right (Creswell. 2015; Morse, 2003).

4.4. Conflict between the different paradigms

It has been commented that there is an inherent difference between the research paradigms underlying qualitative and quantitative research and as a result of this difference these two research methods cannot be mixed (Bryman, 2017; Robinson, 2015). However, by combining quantitative and qualitative research approaches the researcher is able to offset each method's weaknesses by drawing upon each method's strengths (Bryman, 2017; Robinson, 2015). They are also able to answer particular types of research questions more thoroughly than if just one approach was used. For example, by using a quantitative research approach I was able to investigate the physical outcomes of the incidence of PPH and any relationships between active and expectant third stage of labour management approaches in women at low risk, giving birth in midwife-led units. This was achieved by measuring variables and analysing these variables to establish any relationships between them. By using a qualitative approach and adopting an interpretivist perspective, I was able to explore how midwives viewed and made sense of the two third stage management approaches and how they used them in their practice. As stated previously in this thesis, this is important because midwives

understanding of what is happening in their clinical situation will influence their decision making.

4.5. Background information regarding the studies

In this research project equal priority was given to Study One and Study Two. Study One was primarily used to assess the significance of third stage of labour management approach in the context of a generalisable analysis; and Study Two, being important in answering the overall research questions more thoroughly.

Both Study One and Two took place in the same NHS Foundation Trust in the North East of England over a period of 18 months. The studies were conducted by a part-time postgraduate researcher, who was also a practising midwife in the NHS Trust where the studies were conducted. Whilst working as a researcher in the Trust the researcher's midwifery colleagues at the midwife-led unit were informed that they would not become involved in providing clinical midwifery care. All data for the studies was collected, analysed and interpreted by the postgraduate researcher with support from their research supervisors.

4.5.1. Ethical issues

High quality research is essential as healthcare needs to be based on the best available evidence, to improve the general health and wellbeing of people. However, it has been argued that all research can be potentially harmful to participants and researchers (Beauchamp & Childress, 2013). An ethical framework presented by Beauchamp and Childress (2013) outlines four ethical principles: respect for autonomy, beneficence, non-maleficence and justice. In this framework four ethical rules that give more precise ethical guidance for research involving people are also outlined. These rules are veracity, privacy, confidentiality and fidelity. Therefore, researchers need to address these ethical principles and rules to ensure that their research is ethically designed and conducted. In conducting these studies I encountered many ethical issues that were addressed to ensure that ethical considerations were a fundamental part of this research project.

4.6. Conclusion

The methods and findings from the two studies conducted as part of this research project are now presented separately. Study One is presented in Chapter 5 and Study Two is presented in Chapter 6. Each of these chapters outlines the study's ethical approval process; how ethical issues were addressed before and during each study. The results of Study One and Study Two are brought together in Chapter 7 at the discussion stage of this thesis to answer the research project's overarching research question.

Chapter 5

Study One

This chapter outlines Study One's aim, objectives and ethical and approval processes. It discusses the study's quality assurance issues, outlines the study's setting and discusses the study's exploratory phase and the main study. The study's data collection method, analysis and results will also be highlighted, discussed and presented. A summary of the results is then given. A discussion of the study's findings with regard to how they contribute to answering the overall research question and how they add to the body of evidence regarding third stage of labour care is discussed, with the findings from Study Two in Chapter 7.

5. Aim

Study One consisted of a quantitative research approach, involving an exploratory phase and a main study. It aimed to examine the relationship between active and expectant third stage management approaches and the incidence of PPH in women, who had a normal birth in a midwife-led unit . It also aimed to examine the acceptability of third stage management approaches in these settings.

5.1. Primary research objective

The primary objective of Study One was to examine the relationship between active and expectant management of the third stage of labour and the incidence of PPH (defined as blood loss of 500 mL or over) or severe PPH (defined as blood loss of 1000 mL or more) in women who had a normal birth in two midwife-led units. These relationships were assessed using unadjusted and adjusted analyses.

Adjusted analyses considered potential confounding variables of maternal BMI (categorised as BMI of 35 kg /m² or above and BMI up to 35 kg/m²); maternal age (categorised as aged over 40 years and aged up to 40 years) and baby's birthweight (categorised as over 4.0 kg and 4.0 kg or under) in women who had a normal birth in two midwife-led units. Maternal BMI and baby's birthweight,

classified as above, were selected as possible confounding variables as they were identified as risk factors for PPH by NICE (2017) and RCOG (2016). They were also identified as risk factors for PPH in the NHS hospital Trust's guidelines for the prevention and treatment of PPH.

Maternal age over 40 years was identified as a possible confounding variable as this was also identified in the NHS hospital Trust's third stage of labour and PPH practice guidelines as a risk factor for PPH. Maternal age over 40 years was also identified in the RCOG first edition of the PPH guideline (RCOG, 2009), although, in its updated version of the guideline (RCOG, 2016) maternal age was not identified as a risk factor for PPH. NICE (2017) identified maternal age of 35 years or older as a risk factor for PPH. However, maternal age was not categorised in this way as a potential confounding variable for Study One, as it was considered that the evidence it was based on (Jolly, Harris, Robinson, & Regan 2000; Ohkuchi, et al., 2003) was not generalisable to women who had a normal physiological labour and birth in a midwife-led unit.

5.2. Secondary research objectives:

Secondary research objective 1: To examine the relationship between active management and the group of women who intended to have expectant management but were converted to active management, due to maternal request or clinical need, and the incidence of and treatment for PPH (blood loss of 500 mL or over), in women who had a normal birth in two midwife-led units.

Secondary research objective 2: To investigate any rationale documented by midwives for not conducting expectant management, if that was the woman's initial third stage management choice.

A power calculation, also known as sample size calculation, was not conducted for this observational study. Power calculations are often conducted before experimental or observational studies, involving patient recruitment, are commenced. This is because if a study is organised to test the effectiveness of a particular treatment and people agree to take part then only as many participants as are needed should be recruited, to avoid wasting resources and

researcher and participant time. Conversely, if too fewer people are recruited for the study then the study may be underpowered. This again wastes time and money and is also unethical, as people's time would be spent in participation of a study with a low probability of reaching a definitive conclusion, regarding the effectiveness of the treatment under consideration. However, Study One was a retrospective cohort study involving collecting data from women's maternity notes, so it was considered that there were no ethical disbenefits in recruiting too many or too few participants to the study (notwithstanding the difficulties in determining an appropriate sample size as discussed below). To minimise the probability of the study being underpowered, the data collection strategy involved collecting the maximum extent of available data within the allocated resource.

Power calculations for uncontrolled studies with dichotomous outcomes, requires estimation of data variability and the anticipated magnitude of the treatment effect (Hackshaw, 2015). This can be accomplished by referring to previous studies in the literature; however, Literature Review One did not find any suitable studies from which these parameters could be estimated. Peduzzi, Concato, Kemper, .Alvan, Feinstein, (1996) suggested an approach based on maintaining a minimum events-per-variable (EPV) ratio of approximately 10 for dichotomous events, as is the case for all outcomes in the current investigation. This minimum ratio is easily exceeded in the current study for all analyses with even highly conservative estimates of event rates. The conservative approach to data collection adopted appeared justified. The large size of the study sample is likely to lead to a highly powered study leading to precise estimates of effect, facilitated by the construction of confidence intervals around estimates.

5.3. Ethical Approval

Approval for the study was given by the University of Huddersfield's School Research Ethics Panel (SREP) on the 28th November 2016 (see appendix, 9). Once approved by the SREP, the Research and Development Department of the NHS Trust where the study was to take place was sent the study's research proposal. A meeting was then arranged with the Trust's Research Co-ordinator

to discuss the research proposal further. The Trust's Research and Development Department confirmed that study One did not need HRA Approval or Confidential Advisory Group (CAG) authorisation, as raw data to be used in the study had already been collected as part of a service evaluation by the researcher in her role as employee at the Trust, as a result, the information needed for Study One could be de-identified before being used by the researcher in Study One.

Once permission to conduct the study was given by the NHS Trust's Research and Development Department and the Trust's clinical governance lead, the Head of Midwifery was contacted. A meeting was arranged and she was sent the study proposal. Approval by the Head of Midwifery was obtained on 1st December 2016 (see appendix, 10). The Trust's Caldicott Guardian was made aware of the study protocol and that the necessary approval had been given.

5.4. Quality assurance issues

The study aimed to be generalisable to the wider population of women giving birth in midwife-led units. The cohort characteristics were assessed in detail to ensure that the sample of women the data was based on was a fair representation of the wider population. There was no evidence that the sample of women included in the study differed systematically from the wider population.

Confounding bias is a well-recognised common source of systematic bias. The adjusted analyses allowed for the control of potential confounding bias, by applying statistical control to the selected controlling variables (maternal age, maternal BMI, baby's birthweight). The effect of possible confounders on inferences relating to the key variable (management approach) was facilitated via a comparison with the parallel unadjusted analyses.

All key measures in this study (PPH, severe PPH, third stage of labour management approaches, potential confounding variables) could be measured objectively and reliably, promoting the study's internal validity and reliability.

5.5. Study setting

The study was conducted within a NHS Foundation Trust in North-West England. The Trust provided maternity care for women at high and low risk of complications during pregnancy, birth and the postnatal period. The Trust's maternity service consisted of community and hospital-based services. Hospital based services included two antenatal and one postnatal unit, two antenatal day units, a maternity assessment centre, an obstetric-led unit and two midwife-led units. The trust's birth centres (midwife-led units) consisted of an alongside and a freestanding midwife-led unit (The different types of midwife-led units have been discussed previously in this thesis). The alongside midwife-led unit was established in 2003 and the freestanding midwife-led unit was established in 2008. The number of women, who gave birth at the Trust during the last 12 months the data was collected for the study (1st January 2015 to 30th December 2016) was 4278, of which 2177 women birthed on the obstetric-led unit, 1195 women birthed in theatre, 43 women birthed before arrival at the hospital, 45 women gave birth at home (these were planned home births) and 818 women birthed at the midwife-led unit.

Women defined as at low risk of obstetric complications received antenatal and postnatal care from their community midwife. If the woman was defined to be at high risk of obstetric complications, she received shared care by midwives and the obstetric team. Women at high risk of obstetric complications were advised to birth at the hospital's obstetric-led unit and women at low risk of obstetric complications were given the option to birth at the obstetric-led unit, midwife-led units or at home. Occasionally, women at high risk of obstetric complications chose to birth at one of the midwife-led units or at home. Although the Trust advised women at high risk of obstetric complications to birth at the hospital obstetric-led unit, if the woman made an informed choice to birth at one of the midwife-led units or at home, the Trust supported her choice.

Ideally, as well as being at low risk of obstetric complications (including at low risk of PPH) women who chose to labour and birth at the midwife-led units should also have valued minimum intervention during labour and childbirth. Women who laboured and birthed on the midwife-led units received care in

labour and during the birth by a midwife. If any complications occurred during labour or postnatally, the woman was then transferred to the obstetric-led unit for assessment and further treatment by the obstetric staff and the rest of the maternity care team. The midwives who provided care for the women on the midwife-led units were not known to the women before labour started. During the time period, data was collected for the study care was provided by 24 midwives, who worked on both midwife-led units.

5.6. Exploratory phase before the main study was conducted

Before the retrospective cohort study took place it was necessary to assess the rate of active and expectant management approaches in the midwife-led units during the time period data would be collected for the main study. This would help to assess whether midwives working in midwife-led units at this time had been exposed to both third stage of labour management approaches. This was important because research has found that if midwives are regularly exposed to both active and expectant management approaches it increases their confidence in conducting both approaches (Begley et al., 2012; Harding et al., 1989). It was also essential to assess whether the midwives who provided care during the time period data would be collected for the main study, were experienced in working in the midwife-led units and felt confident in active and expectant third stage management approaches. Again, this was important as previous studies have shown that if midwives were experienced and felt confident in conducting both third stage of labour management approaches, midwives estimation of blood loss during the third stage of labour or shortly after was reduced (Begley, 1990; Begley et al., 2012; Fahy et al., 2012; Rogers et al., 1998). Although, some of these studies are dated (Begley, 1990; Rogers et al., 1998) they have been identified as evidence in all the Cochrane Reviews, comparing active versus expectant management of the third stage of labour, (Prendiville et al., 2000; Begley et al., 2010; 2011; 2015; 2019); therefore their findings are still seen as generalisable.

5.6.1. Data collection- (midwife demographics, experiences and practices)

Data collected for this exploratory phase was based on data previously collected by the research as part of the service evaluation. Data was collected

from the Trust's computer-based maternity data set. The maternity computer notes of 1324 women who had a normal physiological vaginal birth at the Trust's midwife-led units between 1st July 2015 and 30th December 2016 were reviewed to obtain information to assess the frequency of active and expectant management approaches in this birth setting. This time period comprised the dates over which the main study (i.e. the retrospective cohort study) was to be conducted.

The midwives who provided care for the women during the dates the main study was to be conducted and who still worked at the Trust were sent a study invitation and information sheet via email as part of the service evaluation. A study questionnaire was attached to the email (see Appendix 11). The questionnaire aimed to gain information regarding the midwives' demographic details and to assess if these midwives were experienced in working in the midwife-led units and felt confident in active and expectant third stage management approaches.

If midwives wanted to participate in the service evaluation, they were asked to print out the questionnaire and complete it within 14 days of receiving the invitation email. The midwives were instructed to put the completed questionnaire in a sealed envelope addressed to the researcher and leave the envelope at one of the midwife-led units for the researcher to collect. The questionnaire was anonymous and tested on three midwives, who worked on the midwife-led units but did not provide care for the women during the time period the service evaluation was being conducted. Before the questionnaire was sent out changes were made to it to ensure it was simpler for the midwives to complete. Out of the 24 midwives who worked at the midwife-led units and provided care for the women during time period the service evaluation was conducted, 22 still worked at the Trust, and all of these 22 midwives completed and returned the questionnaire. The information gained from these questionnaires was examined in the exploratory phase of Study One.

5.6.2. Results of exploratory phase

Descriptive statistics were used to summarise data collected from this exploratory phase. Between 1st July 2015 and 30th December 2016, 57.7% of women (765) who birthed at the midwife-led units intended to have active management, compared with 38.4% (508) of women who intended to have expectant management. Table 5.6.2(a) summarises the frequency and proportion of active and expectant management approaches, between 1st July 2015 and 31st December 2016 at the two midwife-led units.

Table 5.6.2(a): Frequency and proportion of management approach (ITT)

Third stage of labour management approach (ITT)	Count (Valid %)
Active management approach	765 (57.7%)
Expectant management approach	508 (38.4%)
Missing data	51 (3.86%)
Total	1324

The results of the questionnaire sent to midwives who provided care for the women between 1st July 2015 and 30th December 2016 are presented in Tables 5.6.2 (b), (c) and (d). Out of 24 midwives, 22 midwives completed and returned the questionnaire. The 22 midwives' characteristics are summarised in Table 5.6.2(b).

Table 5.6.2(b): Midwives' characteristics

Characteristic	Range
Age	23-53 years
Time since qualification as midwife	2-28 years
Time worked as a midwife	2-28 years
Time worked at midwife-led unit (n=22)	15 months -10 years
Time worked in community (n=18)	6 months - 20 years
Time worked at the obstetric-led unit/ labour ward (n=22)	6 months -10 years
Time worked in antenatal ward (n=4)	6 months - 4 years
Time worked in postnatal ward (n=5)	6 months - 5 years

The 22 midwives' views regarding their experience and confidence in providing care for women at the midwife-led units and in conducting active and expectant third stage management approaches are presented in Table 5.6.2(c).

Table 5.6.2(c): Midwives' views regarding their experience and confidence

Midwives' views regarding how they felt about each statement	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Total
I feel experienced in supporting women who want to birth at the midwife-led unit and want to have a normal birth.	18	4	0	0	0	22
I feel confident in conducting expectant management	12	10	0	0	0	22
I feel confident in conducting active management	20	2	0	0	0	22

All 22 participating midwives correctly identified all the components of active and expectant management approaches. Midwives' opinions as to what comprised the components of active and expectant management approaches are outlined in Table 5.6.2 (d).

Table 5.6.2(d): Components of management approaches identified by midwives

Management approach	Components of active and expectant management approaches identified by all participating midwives
Active	Routine use of uterotonic drug Deferred clamping and cutting of the cord Controlled cord traction after signs of separation of the placenta.
Expectant	Supporting the woman's body to physiologically birth her placenta No routine use of uterotonic drug No clamping of the cord until pulsation has stopped Delivery of the placenta by maternal effort

5.6.3. Discussion of the results of the exploratory phase

Although active management of the third stage of labour is recommended for all women by international (WHO, 2012; 2018) and national (NICE, 2017) third stage of labour guidelines, as well as the Trust's local third stage of labour guidelines, it was evident that expectant management of the third stage of labour was also widely used at the midwife-led units during the proposed dates over which Study One's main study (i.e. the retrospective cohort study) was

conducted. Consequently midwives practising at the midwife-led units during the cohort study would have been exposed to both third stages of labour management approaches. This is important as a study Farrar et al. (2010) found that 73% of midwives always or usually always used active management of the third stage of labour for vaginal births.

The same components of what active and expectant management consisted of were identified by all midwives. All midwives reported that they felt confident in conducting both third stage of labour management approaches and providing care for women during birth at the midwife-led units. However, more midwives reported feeling more confident about conducting active management compared to expectant management. After this exploratory phase was conducted, Study One's main study was then commenced.

5.7. Main Study

This consisted of a retrospective cohort study. Data for this study was collected from the same time period as the exploratory phase. Data was obtained from the maternity computer records between 1st July 2015 and 30th December 2016 to obtain information to analyse and answer the research objectives. Initially it was undecided whether a case-control study or cohort study would be conducted to answer the research objectives. However, after speaking to the Trust's Research and Development Department it became evident that the information needed to conduct a retrospective cohort study could be relatively easily obtained from the service evaluation data, previously collected by the researcher from the Trust computerised maternity notes in her role as an employee in the Trust. Furthermore, as discussed previously in chapter 5; this type of observational study would provide stronger evidence than a case-control study (Greenhalgh, 2019). Therefore, a retrospective cohort study was conducted.

5.7.1. The computer-based maternity data set

The computer-based maternity data set consisted of a record of all the care given by the Trust's maternity healthcare team to every woman. Every interaction with a woman by the healthcare team should have been

documented in her maternity computer records. These entries consisted of answers to pre-determined questions and/or free text entries. During labour, birth and the postnatal period midwives continually entered information regarding care given, the woman's progress in labour and the wellbeing of the woman and baby. These entries also included the woman's intended third stage management approach, identified by the midwife providing her care. Each midwife identified on the computer records the third stage of labour management approach they initially intended to use (intention to treat) and the third stage management approach they actually used (treatment received). They also documented which third stage components they used.

If the third stage management approach conducted was different to what the midwives initially intended to conduct, the rationale for this should also have been documented by the midwives in the woman's computerised maternity notes. The midwife also documented in the woman's computer notes the woman's blood loss volume during the third stage of labour and shortly after and any treatment received due to excessive blood loss during this period. Blood loss was assessed by midwives providing care for the woman by weighing any blood-stained sheets and pads and by visual estimation, as per Trust guidelines, described in more detail below. At the Trust, care given by healthcare professionals should be in accordance with Trust guidelines. If there was any deviation from the Trust's guidelines a clear rationale should have been documented in the woman's maternity computer records.

5.7.2. Third stage of labour management

Care provided by midwives during the third stage of labour was based on the Trust's third stage of labour guideline. This guideline was in line with national and international guidelines (NICE, 2014; WHO, 2012) at the time the study was conducted. These guidelines recommended active management of labour for all women. The Trust guideline, in line with the NICE (2014) guideline, also considered that some women might want to labour and birth with minimal intervention. Consequently, the Trust, like NICE (2014) recommended that midwives should give women information regarding both the third stage of labour approaches, to enable them to make an informed choice. The Trust's

definition of active, expectant and converted management of the third stage of labour was in line with the NICE (2014) guidelines definition.

The Trust's guideline defined active management of the third stage of labour as administering an uterotonic drug with the anterior shoulder or as soon as possible after the birth of the baby and before the cord was clamped and cut. The uterotonic drug consisted of syntometrine given by intramuscular injection. However, if the woman had raised blood pressure or the midwife was unable to monitor the woman's blood pressure, oxytocin by intramuscular injection should be administered. After administering the uterotonic drug the cord should be clamped and cut. The cord should not be clamped and cut earlier than 1 minute after the birth of the baby, unless there were concerns about the integrity of the cord, or the baby's heart rate was below 60 beats per minute and not getting faster. Ideally, the cord should be clamped and cut within five minutes of the birth of the baby. However, if the woman wanted the cord to be clamped and cut later than 5 minutes, she should be supported in her choice. Controlled cord traction, to deliver the placenta, should be carried out after signs of placental separation (NICE, 2014).

Expectant management was defined in the Trust's guideline as no routine use of uterotonic drugs, no clamping of the cord until pulsation has stopped and delivery of the placenta by maternal effort. In addition, women should be advised to convert to active management if their third stage blood loss becomes excessive, the placenta is not birthed within 60 minutes, or if there are concerns about the baby or the integrity of the umbilical cord or maternal request (NICE, 2014).

Converted management of the third stage of labour was defined in the Trust's guideline, as a woman initially having expectant management but being converted during the third stage of labour, due to clinical need or maternal request, to active management (NICE, 2014).

Regardless of management approach, the Trust guidelines commented that once the placenta has been delivered, it should, along with any blood loss from

the third stage of labour, be collected in a receiver. If there are any pads or sheets underneath the woman that are blood-stained, they should be removed and replaced. Any blood loss during the third stage of labour, including blood-stained sheets and pads, should be weighed, to give an estimated blood loss. Weighing this blood loss is not always possible; for example, if the woman has a pool birth, then the blood loss in the pool has to be estimated by the midwife.

5.7.3. Inclusion & exclusion criteria

All women who had normal vaginal birth at the midwife-led units between 1st July 2015 and 31st December 2016 inclusive were included in the study. A normal vaginal birth was defined in the study as an unassisted vaginal birth following a spontaneous labour and birth at term (between 37 and 42 weeks gestation) with a cephalic presentation of a single live baby. At the analysis stage adjusted analyses were conducted to assess the effect of potentially confounding variables considered to be of clinical importance: maternal BMI and age and baby's birth weight (categorised as previously documented).

5.7.4. Data collection

The data collection tool for the cohort study consisted of a specially designed data extraction sheet devised before the study was conducted. Data collection for the study took place between 2nd January 2017 and 30th August 2017. The data used in Study One, as stated previously in this thesis, was already de-identified by the researcher prior to commencing the study. The original data had been collected by the researcher as part of a service evaluation. It was agreed by the hospital Trust's Research and Development Department that this data could be used by the researcher if de-identified by them first.

Data for the service evaluation was collected from the computer-based maternity data set on one of the Trust's computers, which was password protected. The NHS numbers of all included women were retrieved from the computer-based maternity data set and stored on a password-protected, encrypted memory stick. The women's NHS numbers were entered into the maternity database. The women's notes were accessed and the relevant sections in the women's electronic notes were reviewed; information needed

from the service evaluation was identified and this information was documented on the data extraction tool. A code was used to replace each woman's NHS number. This code was entered onto the data extraction sheet next to the woman's data, so the data was de-identified on the data extraction sheets. This de-identified data was then used for Study One. The key to the de-identified data was entered into a database on the encrypted memory stick and kept by the research and development team at the Trust.

5.7.5. Data storage

The data from the Study One, which was de-identified, was stored as recommended by the University of Huddersfield's Code of Practice for Research (2019), in line with the Data Protection Act (1998; 2018). The raw data from the service evaluation, which Study One's findings were based on, was stored on an encrypted memory stick that was stored at the NHS Trust's Research and Development Department, in a locked cabinet. The password for the encrypted memory stick was also stored at the NHS Trust's Research and Development Department, in a separate locked cabinet to that containing the encrypted memory stick. The completed questionnaires were also stored in the locked cupboard with the password for the encrypted memory stick. Only the researcher and development lead at the hospital had access to these locked cabinets. If the researcher had any queries about the de-identified information provided for Study One they could have contacted the Trust's research and development lead and they would assist with their query.

5.7.6. Study One data analysis

After all the data for the cohort of women was extracted and entered on the data extraction sheet, it was then inputted into an Excel spreadsheet. Specific data from the Excel spreadsheet was then extracted and inputted into SPSS statistical software to conduct statistical analysis to answer the research objectives. Cohort study data for Study One's main study was analysed on an intention-to-treat (ITT) and treatment-received basis.

It is standard practice to analyse the results of comparative studies on an intention-to-treat basis (Greenhalgh, 2019), as not including everyone who

failed to have their initial third stage of labour management approach might have biased the results of the study in favour of that approach. This is because for an intervention to work not only has it to be effective, it has to be acceptable to the woman and the woman's clinical needs. Therefore the woman not continuing with the management approach or the clinical need to have to change to another approach should count as a failure of the intervention. With regards to third stage of labour management approaches once active management is commenced there is no way to change to expectant management. However, if a woman initially received expectant management they can be converted to active management due to maternal choice or clinical need. If this happens data from this group should be analysed with data from the expectant management group, as it should be seen as a failure of the expectant management approach.

Descriptive statistics were utilised to characterise the sample and measure the strength of the association between the exposure factors (third stage of labour management approaches and, in the case of the controlled analyses, possible confounding variables) and the outcomes of interest (incidence of PPH and severe PPH). Descriptive statistics were also used to summarise data for secondary research objective 2; the rationale given by midwives for not conducting the woman's initial third stage of labour management approach. Inferential statistical tests were conducted to make inferences about the populations from which the sample was drawn.

Initially, for primary research objective 1 bivariate associations were tested, using unadjusted analysis methods. These assessed the effect of management approach on PPH and severe PPH, without taking into account additional identified risk factors for PPH (possible confounding variables). These unadjusted analyses were conducted to gain an initial insight into the nature of relationships between third stage of labour management approaches and incidence of PPH in women who had a normal physiological birth.

Inferential statistical tests for the unadjusted (uncontrolled) analyses consisted of chi-squared (χ^2) tests of association to test for association between the key

predictor variable (management approach) and incidence of PPH and severe PPH. These tests assess the strength of the evidence for an association between categorical factors, such as management approach during the third stage of labour and incidence of PPH. Significance levels (p-values) and effect sizes (as measured by the phi (Φ) statistic) were reported for all bivariate tests. Both odds and relative risks (risk ratios, RR) and associated 95% confidence intervals (CI) for third stage management approach were also generated.

Following completion of these initial analyses, adjusted analyses were subsequently conducted. Corresponding adjusted (controlled) logistic regression methods were used to assess the effect of management approach on PPH and severe PPH, controlling for possible confounding variables, as identified previously in this thesis. Key predictor variables (active and expectant third stage management approaches) and potentially confounding variables were included in a forced entry main effects analysis. Parallel analyses were conducted, using both PPH and severe PPH. P-values, odds ratios and associated 95% confidence intervals were reported for all controlled analyses. The calculated odds ratios closely approximate risk (incidence) ratios (relative risks), as odds approximate risk when the event of interest is relatively uncommon, as was the case in these analyses.

Not all variables were recorded for all women. However, the amount of missing data was very low and could be shown to be completely missing at random, using Little's test for missingness. Hence complete case analysis was utilised for data analyses. The number of valid cases utilised in the adjusted analyses (938) was lower than for the unadjusted analyses. This was because only cases with a complete set of valid data for all included variables could be included. Therefore, the numbers of valid cases was higher for the unadjusted analyses, which make fewer demands on the cases.

5.7.7. Study One Results

5.7.7.1. Baseline Data

A summary of the characteristics of the women and of risk factors for PPH partitioned by management approach are presented in Table 5.7.7.1. The

controlling variables to be included in the adjusted analysis are highlighted in Tables 5.7.7.1(a), (b).

Table 5.7.7.1(a): Summary of the cohort's characteristics and risk factors for PPH partitioned by management style (ITT)

Maternal antenatal characteristics	Count (Valid %)		
	Active management	Expectant management	Total
Antenatal			
***Previous retained placenta	1 (0.13%)	0 (0)	1
***Previous PPH due to hypotonic uterus	1 (0.13%)	0 (0)	1
***Previous caesarean section	1 (0.13%)	0 (0)	1
***Existing uterine abnormalities	2 (0.26%)	0 (0)	2
***Body mass index (BMI) ≥ 35 kg/m²	14 (1.8%)	8 (1.6%)	24 (1.9%)
Body mass index (BMI) < 35 kg/m ²	761 (98.2%)	495 (98.4%)	1256 (98.3%)
Maternal Age (years)			
<20	21 (2.7%)	8 (1.6%)	29 (2.3%)
20-29	340 (43.9%)	221 (43.9%)	561 (43.9%)
30-34	268 (34.7%)	182 (36.2%)	450 (35.2%)
***35-39	122 (15.7%)	76 (15.1%)	198 (15.5%)
***≥ 40	24 (3.1%)	16 (3.2%)	40 (3.1%)
***>40 and not *multiparous	0	0	0
Total	775	503	1278
Missing data			46
Count (Valid %)			
**Parity	Active management	Expectant management	Total (1324)
0	248 (32.4%)	187 (36.9%)	435 (34.2%)
0-3	503 (65.8%)	320 (63.1%)	823 (64.7%)
***4	14 (1.8%)	0 (0)	14 (1.1%)
***>4	0	0	0
Total	765	507	1272
Missing data			52

*Multiparous indicates a woman who has given birth to a baby previously

**Parity indicates the number of pregnancies the woman has previously had which reached viable gestational age (24-weeks), including live births and stillbirths.

*** identified risk factors for PPH

Table 5.7.7.1(b): Summary of the cohort's characteristics and risk factors for PPH partitioned by management style (ITT)

Maternal antenatal characteristics	Count (Valid %)		
	Mean (SD)		
	Active management	Expectant management	All women
Maternal age (years)	29.8 (5.2)	29.9(5.24)	29.8(5.23)
Maternal intrapartum characteristics			
****Duration of 1 st stage of labour(minutes)	153.0 (142)	142 (140)	148 (141)
Duration of 2 nd stage of labour(minutes)	25.1 (32.5)	19.7(19.7)	23.0 (29.30)
Duration of 3rd stage of labour(minutes)	21.4 (34.6)	35.1 (35.0)	26.8(35.3)
Count (Valid %)			
Baby's birth weight	Active management	Expectant management	Total
Birth weight of baby (grams)	3478 (440)	3501 (392)	3487 (423)
***Baby's birth weight ≥4kg	162 (20.9%)	137(27.0%)	299 (23.3%)
Baby's birth weight <4kg	603 (79.1%)	370 (73.0%)	973 (77.3%)
Missing data			
***Episiotomy	1 (0.79%)	0	1 (0.79%)
Count (Valid %)			
Birth Trauma	Active management	Expectant management	Total
No birth trauma	320 (41.5%)	216 (42.7%)	536 (41.9%)
1 st degree tear	175 (22.7%)	116 (22.9%)	291 (22.8)
2 nd degree tear	251 (32.5%)	167 (33.0%)	418 (32.7%)
***3 rd degree tear	23 (3.0%)	9 (1.8%)	32 (2.5%)
Total	770	508	1278
Missing data			46

*** identified risk factors for PPH

****Note that the distribution of the duration of the first stage of labour was very skewed; with many women taking less than 30 minutes; but others taking over 1000 minutes

5.7.7.2. Primary Research Objective; 1 Unadjusted analysis (ITT)

5.7.7.2.1. PPH blood loss of 500 mL or over

These unadjusted intention-to-treat analyses, conducted to meet Primary Research Objective 1 compared women intending to have active management and those intending to have expectant management in an assessment of the relationship between management approaches and PPH (blood loss of 500 mL or over) occurrence. Table 5.7.7.2.1 indicates the frequencies and portions of

outcomes in each group and the corresponding odds ratio and effect size for PPH.

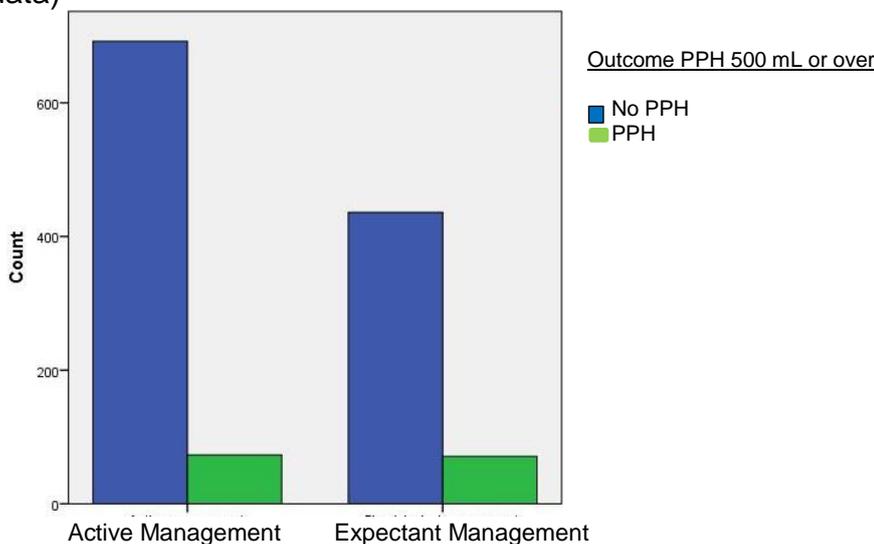
Table 5.7.7.2.1: Summary of outcomes by management approach (ITT data)

Count (Valid %)			
Management approach	No PPH ¹	PPH ¹	Total
Expectant	437 (86.0%)	71 (14.0%)	508
Active	692 (90.5%)	73 (9.5%)	765
Total	1128	144	1273
Missing data			51(3.9%)
Effect sizes			Value
Odds Ratio (expectant management : active management)			1.54
Φ statistic			0.069

¹Defined as 500mL or over

Hence the proportion of women with PPH in the expectant management group was 14.0%; the corresponding proportion in the active group was 9.5%. A χ^2 test for association conducted on this data revealed evidence of a significant association between management approach and incidence of PPH at the 5% significance level ($\chi^2_{(1)}=6.046, p=0.014$). This effect was revealed to be of small magnitude ($\phi=0.069$).

The odds ratio for PPH of 1.54 (95% CI 1.09 to 2.19); indicated that the odds of PPH in the expectant management group were 1.54 times the odds of PPH in the active management group; i.e. the odds of PPH were 54.4% higher in the expectant management group. Figure 5.7.7.2.1(a) also illustrates the frequency of women with PPH in either the active or expectant management groups. **Figure 5.7.7.2.1(a): Frequency of outcomes by management approach** (ITT data)



5.7.7.2.2. Severe PPH (blood loss of 1000 mL or more)

These unadjusted intention-to-treat analyses compared women intending to have active management and those intending to have expectant management in an assessment of the relationship between management approaches and severe PPH (blood loss of 1000 mL or more) occurrence. Table 5.7.7.2.2 below indicates the frequencies proportion of PPH in each group and the corresponding odds ratio and effect size for PPH.

Table 5.7.7.2.2: Summary of outcomes by management approach (ITT data)

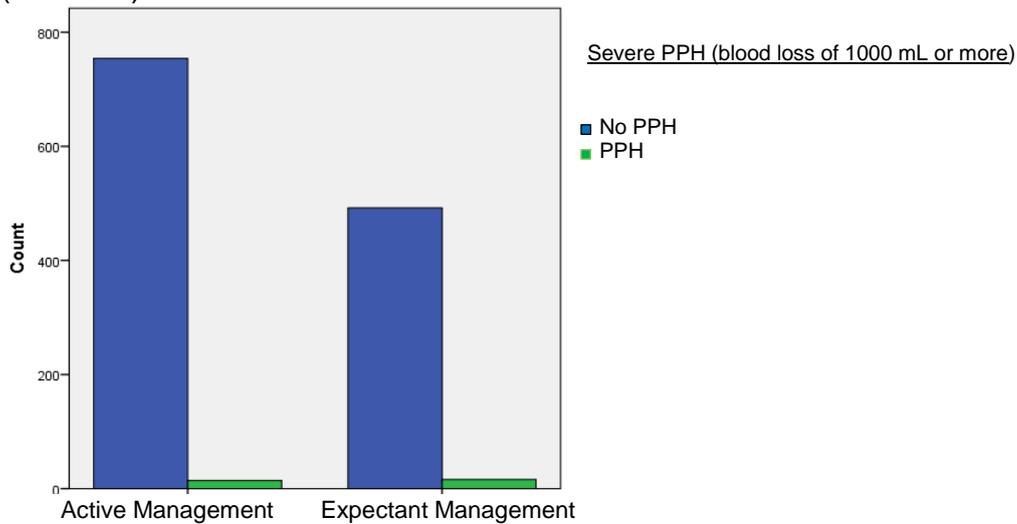
Count (Valid %)			
Management approach	No severe PPH ¹	Severe PPH ¹	Total
Expectant	492 (96.9%)	16 (3.1%)	508
Active	751 (98.2%)	14 (1.8%)	765
Total	1246	30	1273
Missing data			51 (3.9%)
Effect sizes			Value
Odds Ratio (expectant management : active management)			1.75
Φ statistic			0.043

¹Defined as blood loss 1000mL or more

Hence the proportion of women with severe PPH in the expectant management group was 3.1%; the corresponding proportion in the active group was 1.8%. A χ^2 test for association conducted on this data revealed evidence for no association between management approach and incidence of PPH (>1000 mL) at the 5% significance level ($\chi^2_{(1)}=2.344, p=0.126$). This effect was revealed to be of small magnitude ($\phi=0.043$).

The odds ratio for PPH (1000 mL or more) of 1.75 (95% CI 0.847 to 3.62); indicated that the odds of PPH in the expectant management group were 1.75 times the odds of PPH in the active management group; i.e. the odds of PPH were 75% higher in the expectant management group at best estimate. However, this result should be interpreted in the context of a non-significant finding. Figure 5.7.7.2.2(a) also illustrates the frequency of women with severe PPH in either active or expectant management groups.

Figure 5.7.7.2.2(a): Frequency of outcomes by management approach (ITT data)



5.7.7.3. Adjusted analyses

These adjusted intention-to-treat analysis compared expectant versus active management. They are presented using multiple logistic regression, including possible confounding variables: maternal age and BMI and birth weight of baby (as previously categorised in this thesis) in an assessment of the relationship between management approach and outcome occurrence.

5.7.7.3.1. PPH (defined as blood loss of 500 mL or over)

These analyses revealed that management approach was significantly associated with PPH ($p=0.015$). The odds ratio of 1.543 (95% CI 1.089 to 2.186) indicated that the odds of PPH in the expectant management group was about 54% higher than the odds of PPH in the active management group. None of the confounding variables were significantly associated with PPH ($p=0.746$ for maternal BMI; $p=0.907$ for birthweight of baby over 4.0 kg; $p=0.462$ for maternal age 40 years and over). Hence the inclusion of these potential confounding variables for PPH had minimal effect on the calculated odds ratio. Table 5.7.7.3.1 summarises the p-values, odds ratios and associated 95% CI for this analysis.

Table 5.7.7.3.1: Model parameters: adjusted analysis (ITT data)

	<i>p-value</i>	<i>Odds ratio</i>	<i>95% CI for odds ratio</i>	
			<i>Lower</i>	<i>Upper</i>
Management approach (reference category = Active)	0.015	1.543	1.089	2.19
Maternal BMI over 35 kg/m ²	0.746	0.785	0.181	3.41
Maternal age 40 years and over	0.462	0.639	0.194	2.11
Baby's birthweight over 4 kg	0.907	0.968	0.557	1.68

The odds ratio for management approach in the adjusted model was very similar to the corresponding odds ratio in the unadjusted model (unadjusted odds ratio for PPH 500 mL or over of 1.544 (95% CI 1.09 to 2.19). Hence the extra factors of maternal BMI and age and baby's birthweight made almost no difference to the effect of management approach on PPH. This is likely to be because the two groups were well balanced with respect to the confounding variables within the women who were included in these analyses.

This lack of systematic differences between the two groups other than third stage management approach strengthens the internal validity of the study. Furthermore, there were in fact very few cases of BMI over 35 kg/m² (24 cases, 1.8%); or of women over 40 years (40 women; 3.0%) or babies over 4kg (151; 11.4%).

5.7.7.3.2. Severe PPH (defined as blood loss 1000 mL or more)

These analyses revealed that management approach was not significantly associated with severe PPH ($p=0.134$). The odds ratio of 1.744 (95% CI 0.843 to 3.609) indicated that the odds of severe PPH in the expectant management group were 74.4% higher than the odds of severe PPH in the active management group at best estimate. None of the confounding variables were significantly associated with severe PPH ($p=0.441$ for maternal BMI over 35; $p=0.400$ for baby's birthweight over 4.0 kg; $p=0.244$ for maternal age 40 years or over). Table 5.7.7.3.2 summarises the p -values, odds ratios and associated 95% confidence intervals for this analysis.

**Table 5.7.7.3.2: Model parameters: adjusted analysis
(ITT data)**

		p-value	Odds ratio	95% C.I. for odds ratio	
				Lower	Upper
	Management approach (reference – Active)	0.134	1.744	0.843	3.609
	BMI over 35 kg/m ²	0.441	2.237	0.288	17.354
	Mother aged 40 years and over	0.244	2.405	0.549	10.533
	Birthweight over 4 kg	0.400	0.537	0.126	2.286

The odds ratio for management approach in the adjusted model was very similar to the corresponding odds ratio in the unadjusted model, (unadjusted odds ratio 1.751 (95% CI 0.847 to 3.62). Hence again the inclusion of the additional confounding variables had minimal effect on severe PPH, as in the analyses based on severe PPH of 500 mL or over, and for the same reasons. Again the extra factors of maternal BMI and age and baby’s birthweight made almost no difference to the effect of management style on severe PPH; with very few cases of BMI over 35 kg/m² (24 cases, 1.8%); or of women over 40 years (40 women; 3.0%) or babies over 4kg (151; 11.4%) recorded.

5.7.7.4. Secondary research objectives

5.7.7.4.1. Secondary research objective 1

To compare the relationship between active management and the group of women who intended to have expectant management but were converted to active management, due to maternal request or clinical need, and the incidence of and treatment for PPH (defined as blood loss of 500 mL or over). Table 5.7.7.4.1.summarises the third stage of labour management approach, incidence and treatment for PPH

Table: 5.7.7.4.1: Management approach, incidence and treatment for PPH (ITT data)

Count (Valid %)			
	Active (765) Management- (consisting of the administration of prophylactic uterotonic drug to prevent PPH)	Expectant (508) management	Total (1273)
PPH [†]	73 (9.5%) (32 no TMT)	71 (14%) (18+53) (18 no TMT)	144 (11.3%)
No PPH	692 (90.5%)	437 (86.0%)	1129 (88.7%)
Treatment for PPH	41 (5.36%)	53 (10.4%)	94 (7.38%)
Converted to active management or if placenta already birthed by expectant management just given 1 st line uterotonic drug treatment as treatment for PPH.	N/A	53 (10.4%)	53
Additional uterotonic drugs to manage continuing excessive blood loss			
2 nd line uterotonic drug treatment	41 (5.36%)	18 (3.54%)	59 (4.64%)
Adjuvant options for managing significant continuing PPH.	8 (1.05%)	5 (0.98%)	13 (1.02%)

[†]Defined as 500mL or over

These analyses reveal that the proportion of the women with PPH (defined as blood loss of 500mL or more) in the active management group was 9.5%; the corresponding proportion in the expectant management group was 14%. The proportion of the women with PPH in the active management group who received treatment of PPH was 5.36%; the corresponding proportion in the expectant management group was 10.4%.

The proportion of the women with PPH in the active management group, who needed additional uterotonic drugs to manage continuing excessive blood loss, was higher compared to the women in the expectant management group. The proportion of the women with PPH in the active management group who received second-line uterotonic drug treatment for PPH was 5.36%; the corresponding proportion in the expectant management group was 3.54%. Additionally, the proportion of the women with PPH in the active management group who received adjuvant options for managing significant continuing PPH was 1.05%; the corresponding proportion in the expectant management group was 0.98%.

A higher proportion of women in the expectant management group, who experienced a PPH needed treatment for this excessive bleeding, compared with the women in the active management group who experienced a PPH. However, once these women were converted to active management or just given the first-line uterotonic drug treatment if the placenta had already been birthed they were less likely to need additional treatment for managing continuing PPH, compared with the active management group who experience a PPH.

5.7.7.4.2. Secondary Research Objective 2

A summary of the extent of and rationale for midwives converting to active management

Outcome: Descriptive statistics on the converted management group revealed that out of the 508 women who initially intended to have expectant management 34.2% (174 women) were converted to active management. The reasons why midwives converted to active management are documented in Table 5.7.7.4.2.

Table 5.7.7.4.2: Reasons midwives converted to active management

Reasons for conversion to active management documented by midwives	Number Valid %
Prolonged 3 rd stage of labour (≥ 60 minutes)	41 (23.6%)
Excessive blood loss (not necessarily over 500 mL)	66 (37.9%)
Maternal choice	58 (33.3%)
Reason not documented	9 (5.2%)
Total number of women who received converted management	174

The main reason why midwives documented that they converted to active management was for excessive blood loss during the third stage of labour or shortly after (37.9%). However, a high proportion of women were also converted due to maternal choice (33.3%) and prolonged third stage (23.6%).

5.8. Study One Summary

Study One intention-to-treat analysis found that the incidence of PPH defined as blood loss of 500 mL or over was higher in the expectant management group compared with the active management group. This difference was statistically significant, although it was of small magnitude, indicating that the strength of the association between the management approach and PPH was small. The odds of a PPH in the expectant management group were also about 50% higher than in the active management group. Whilst this represents a large increased relative risk, it is based on a low baseline, and in absolute terms the raised risk is low.

Although, the incidence of severe PPH (blood loss of 1000 mL or more) was higher in the expectant management group compared with the active management group it was not statistically significant and again of small magnitude. This result may have not been statistically significant due to the inadequacy of the sample size or rarity of the event for these women. Hence the results of the analysis for the outcome of severe PPH could have been a chance finding and may be due to the study being underpowered to find a statistically significant difference for an infrequent outcome. However, as stated previously in the thesis a power calculation for Study One was not possible or deemed necessary. Although, due to Study One's large study sample it is likely

to lead to a highly powered study leading to precise estimates of effect, as reflected by the quoted confidence intervals, resulting in a good level of generalisability.

The results of unadjusted and adjusted analyses revealed that the confounding variables of maternal BMI over 35 kg/m² and age 40 years and over and babies over 4 kg had very little effect on the incidence of management approach on PPH or severe PPH and were not significantly associated with PPH or severe PPH in this study.

Study One found that a higher proportion of women in the expectant management group who experience a PPH (blood loss of 500 mL or over) needed treatment for this excessive bleeding compared with the women in the active management group who experienced a PPH. However, once these women were converted to active management or just given the first-line uterotonic drug treatment if the placental had already been birthed, they were less likely to need further treatment for managing significant continuing PPH, compared with the active management group who experience a PPH.

Study One also found that over a third of women (34.3%) who initially chose to have expectant management were converted to active management due to clinical need (excessive blood loss, 37.9% and prolonged third stage of labour 23.6%) or maternal choice (33.3%).

Chapter 6

Study Two

This chapter outlines Study Two's aim, objectives, ethical and approval processes and how ethical issues were dealt with. The study's data collection method, analysis and findings are also highlighted, discussed and presented. A summary of the findings is then given. A discussion of the study's findings with regard to how they contribute to answering the overall research question and how they add to the body of evidence regarding third stage of labour care is discussed with the findings from Study One in Chapter 7.

6. Aim

The use of a pragmatic paradigm in this research project enabled me to use an interpretivist approach to conduct this qualitative study. The study aimed to explore the practicability of midwives conducting active and expectant management approaches in the midwife-led units where the first study was conducted. Practicability refers to my interpretations of midwives' understanding of the factors they felt shaped, facilitated or constrained their use of third stage management approaches in midwife-led units ; to try to understand what the situation meant to these midwives and what was important in their decision making.

6.1. Objectives

1. To explore factors that midwives interpret as affecting their use of third stage of labour management approaches.
2. To explore how midwives feel working at a midwife-led unit affects their use of third stage management approaches

.Study Two consisted of two-stage, semi-structured interviews with six midwives experienced in practising at the midwife-led units, in the same NHS Trust where Study One was conducted.

6.2. Study method

6.2.1. Study sample

The six midwives interviewed for Study Two were experienced and skilful in active and expectant third stage management approaches and working within a midwife-led unit. Additionally, I considered they would be able to articulate their perspectives in an interview situation. I purposively chose a small number of midwives as my aim, to explore the understandings of experts in some depth, was more easily achieved with a smaller number. If after data familiarisation of the participant's initial interview I felt data saturation in that interview had not been reached, provision had been made to conduct follow-up interviews, with participants to explore their understandings further.

6.2.1.1. Demographic and background details of participants

The six participants were all white British females, with an age range of 28 to 53 years (mean age 42.8 years). They had from 3 to 29 years of experience as midwives, including 2 to 12 years' experience at working as a midwife at the two midwife-led units. Their highest level of education was a BSc (Hons) in Midwifery, which all six midwives achieved. The midwives working hours ranged from 11 ½ to 37 hours a week.

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6.2.2. Data collection

6.2.2.1 Data Collection tool

Individual semi-structured interviews were used as the data collection method for the qualitative study. They are the most commonly used data collection method for qualitative research (Bryan, 2017; King & Horrocks, 2010). They allowed me to ensure key areas I thought I wanted to explore were covered, as well as, probe answers and follow unexpected trains of thought. A conversational approach is more effective for encouraging relaxed exploration of nuances of meaning and encouraging asides that inform us about someone's views (King & Horrocks, 2010), and by doing so, increased the dependability and credibility of the study's findings and the trustworthiness of the study.

If I used unstructured interviews or diary studies although it would have assisted me to explore the participants' views it would have been difficult to

ensure a focus on the issues I thought I wanted to explore further. Additionally, the use of diary studies would have placed a great deal of responsibility on the respondents, as well as making it more time-consuming for them (Robson, 2015).

6.2.2.2. Structure of interviews

The semi-structured interviews were loose and flexible, allowing a dialogue between the interviewer and participant. The order of questions was changeable to allow easy movement between each question, the questions were designed to generate responses from participants that were spontaneous and in-depth (Baumbusch, 2010; Dearnley, 2005). This loose and flexible approach to interviewing enabled me to explore openly with the participants' their individual thoughts and ideas that emerged in the interviews, regarding third stage of labour care and what factors shaped and influenced these. The value of openness is in keeping with an interpretivist study (King & Horrocks, 2010).

Key interview questions were developed after I conducted a literature review and identified gaps in knowledge or issues that I thought I wanted to explore further. I also used my own personal experience as a midwife providing care for women during childbirth, at midwife-led and obstetric-led units, to help develop key interview questions. After the key questions were developed an initial interview guide was then outlined (see appendix, 12). The participants' responses in the semi-structured interviews would influence any follow-up questions and probes. Therefore, follow-up questions were difficult to present in advance. The interview guide was also pilot tested using two of the three techniques suggested by Kallio et al. (2016), to test, confirm coverage and content and to make any changes if necessary (Chenail, 2011). These two techniques consisted of evaluating the guide with my research supervisor, and testing the interview guide with potential study participants (Kallio et al., 2016). In keeping with an interpretivist based study, if during the interviews I thought my original research questions were unlikely to generate new or useful insights I would change my original questions (King & Horrocks, 2010).

The interviews consisted of collecting demographic data from each participant. It also consisted of asking them open-ended and closed-ended questions, comprising of key interview questions, follow-up questions and probes. Some interviews had to be rearranged, because of the activity on the midwife-led unit, and the manager not being able to provide cover for the participants to take part in the interview. Therefore semi-structured interviews were conducted over a longer time period than originally anticipated.

6.2.3. Data collection process

The semi-structured interviews were audio digitally recorded, using a digital recorder that was password protected. Prior to conducting the interviews I allocated each participant an identification number, which was confidential. I made a record of this number on the interview recording before conducting their interview. When I began recording the interviews participants' names were not used. The initial interviews lasted between 32 and 43 minutes and the follow-up interviews lasted between 12 and 18 minutes. All interviews were conducted during the participant's working day. Cover was arranged by the midwife-led unit's manager to allow participants to be interviewed on NHS premises, in a private room away from the immediate clinical area.

Participants were informed both in the study information and invitation sheet and at the beginning of the interviews that they were equal colleagues to the researcher and it was their understandings that I wanted to explore. These measures aimed to assist participants to feel more relaxed and reassured that what they disclosed was not being overheard and their understanding was valuable. This increased the likelihood of the participants disclosing their true thoughts, helping to increase dependability and credibility of the research findings and the trustworthiness of the study.

6.2.4. After conducting the initial interviews

Once the six initial interviews were conducted, I then familiarised myself with each interview by listening to every individual audio recording several times, using earphones. This data familiarisation process occurred in a private setting at Huddersfield University. This initial data familiarisation process was

conducted between 19th December 2016 and 16th January 2017. After the data familiarisation process I realised that the initial interviews raised some key issues that I wanted to explore further with the participants. Many of these issues raised were because as well as being a postgraduate researcher I was also a midwife, who was known to the participants professionally and had a working relationship with them. This relationship with the participants meant that we had a shared language and norms. This resulted in me having a greater understanding of the views and concepts these participants' discussed in their initial interviews. It also helped me to gain participant's trust, allowing me to explore openly with them their individual thoughts and ideas that emerged in the interviews, regarding third stage of labour care and what factors shaped and influenced these. The researcher's personal insights, knowledge, and experiences of the participant's social context are essential to present a fair interpretation of the the phenomenon of interest from the midwives' perspective (King & Horrocks, 2010).

However, on data familiarisation of the initial interviews I realised I did not always question participant's ideas or concepts and that I made assumptions as to what they meant. Consequently, I then arranged follow-up interviews with participants, as I realised data saturation in the participant's initial interview had not been reached. King and Horrocks (2010) comment that the researcher must also be fully aware of their personal biases and preconceptions, and not let these interfere with their ability to present a fair interpretation of the phenomenon.

6.2.4.1. Follow-up interviews

For the follow-up interviews, I made notes regarding the issues I wanted to explore further with each participant. From these notes I developed individual follow-up semi-structured interview questions (see appendix 13).

6.3. Ethical Issues

6.3.1. Approval for qualitative study

Ethical approval for the qualitative study was given by the University School Research and Ethics Panel (SREP) (see appendix, 14). Once approval was

obtained, the Integrated Research Application System (IRAS), consisting of online filter questions, was completed, to seek Health Research Authority (HRA) Approval. HRA Approval combines the NHS Research Ethics Committee (REC) review, if needed, with the legal and governance checks that NHS organisations used to conduct. Once HRA Approval was gained (25th May 2016, see Appendix, 15) I liaised with the NHS Trust's Research and Development Department and the midwifery management team regarding their permission for the study (see Appendix, 16). Once permission was given by the Trust's Research and Development Department and the midwifery management team the initial semi-structured interviews were conducted. They were conducted between 7th November 2016 and 12th December 2016 which was within twelve months of HRA Approval.

6.3.1.1. Approval for follow-up interviews

I applied for and obtained approval from the university's SREP (approval gained 19th November 2017), HRA Approve (Notification of non-substantial / minor amendments 1st August 2017 approval gained 2nd August 2017), the NHS Trust's Research and Development Department (approval gained 8th August 2017) and the midwifery management team (approval gained 11th September 2017) for the follow-up interviews (see Appendix 17 and 18). The follow-up interviews were conducted between 5th March 2018 and 16th April 2018. Prior to conducting the follow-up interviews, because of the time period between the initial interviews and the follow-up interviews, participants were asked if they would like to hear the recording of their initial interview before we commenced the follow-up interview. Four of the midwives requested this.

6.3.2. Confidentiality and protection of identity

Ensuring participant's confidentiality and protecting their identity can be more difficult in qualitative research. This is because of the small sample size of these studies, their biographical details being presented in the study or the study only being conducted on one site, causing participants to be identified (Harvelly & Land, 2017). Therefore to minimise the risk of participants being identified in this thesis I used participant codes instead of names. I removed all names identified by participants in the interviews and replaced them with a

pseudonym and I carefully chose verbatim extracts from the interviews. Furthermore the study site will not be identified in publications and presentations. Dearnley (2005) commented that using participant codes, non-identification of the study site and careful use of verbatim quotes in publications and presentations will reduce the risk of accidentally disclosing the identity of participants.

6.3.3. Informed choice

To enable the prospective participants to make an informed choice regarding their participation, they were sent a study invitation email and information sheet, which was attached to the email (see Appendix, 19). The study invitation and information sheets enabled the midwives to become familiar with the aim of the study, their role within it and an overview of what the interviews entailed, as well as allowing time for them to consider whether they wanted to participate. A study information sheet was also sent to the head of midwifery and the manager of the midwife-led unit (see Appendix 20).

In the study's information and invitation sheet midwives were also made aware that participation was voluntary and they did not have to answer every question in the interview. Additionally, they were also informed that although I was working in the role of a researcher, if any unsafe practice was disclosed I had a professional duty to report this to the appropriate authority. I also reiterated these factors to participants at the beginning of each interview. If the midwives felt they needed more information about the study a contact email address was highlighted in the study's information and invitation sheet.

Sending the midwives a study information and invitation sheet showed respect for their autonomy, acknowledging that the midwives were self-governing and able to decide if they wanted to participate in the study. Respecting a person's autonomy is central to supporting human rights within the healthcare context (Convention on Human Rights and Biomedicine, 1997). Studies conducted within the maternity healthcare setting tend to interlink the concept of autonomy with informed consent (Scott, 2013; Harvey & Land, 2017). This is because

respect for an individual's autonomy reinforces the need to obtain informed consent.

Before I conducted the semi-structured interviews participants were asked to read and sign a consent form, which, like the invitation and information sheet, complied with the guidance outlined by the HRA (HRA, 2018a) (see Appendix 21). All six midwives agreed to participate in the interviews.

6.3.4. Storage of data

The data from the study was stored as recommended by the University of Huddersfield's Code of Practice for Research (2019), in line with the Data Protection Act (2018). The audio digital recorder used to record the semi-structured interviews was password protected. Any electronic data for example interview transcripts were stored on a password-protected, encrypted memory stick. This audio digital recorder and memory stick were stored in a locked cabinet in the NHS Trust's Research and Development department. The audio digital recorder was stored in this cabinet after each interview and collected prior to the next interview. Identifying data about the participants (i.e. consent forms and computer passwords) were also stored at the NHS Trust's Research and Development department in a separate locked cabinet. I was the only person to have access to these cabinets. The study's raw data were accessed by me and my research supervisors. The study's raw data are now securely stored on a password-protected University drive for ten years, after which they will be destroyed.

6.4. Method of analysis

The purpose of data analysis is to bring out meaning from the data and to provide an account of that meaning for others (Robson, 2017). Thematic analysis is the most frequently used method to analyse qualitative data (Robson, 2017). Braun and Clarke (2006) present a six phase guide to performing thematic analysis in a way that is theoretically and methodologically rigorous.

Study Two took a broadly interpretivist approach, using thematic analysis to explore midwives' understandings, by investigating the midwives' views, what these views meant and gaining a shared understanding of this meaning. The use of thematic analysis in this study enabled the generation of a rich description of themes from the semi-structured interviews, by focusing on what the participants said and capturing their views and interpreting their meaning of these views. I identified themes within the data using an inductive (bottom-up) approach, though with analytical questions to guide the coding progress. Analytical questions consisted of constantly asking myself: What does this data tell me regarding midwives understanding of the different third stage management approaches? What are the factors that midwives perceive affect their use of active versus expectant management approaches? How do they see the context of the midwife-led units influencing their use of third stage management approaches?

Thematic analysis proved to be a lengthy process. It involved each stage being repeated and revisited until I felt that analysis of the data had been completed. Data analysis was also conducted in a private setting at Huddersfield University.

6.4.1.Phase 1: Familiarisation with the data

Once all the data from the initial and follow-up interviews were collected I again immersed myself in the data by listening to each audio digital recording several times before transcribing it into written form. A verbatim record of initial and follow-up interviews was conducted and an orthographic (secretarial/ playscript) transcription was produced. Each participant was handed a copy of their interview transcript, asked to read it and comment on whether they thought it was an accurate account of their interviews and their views, expressed in their interviews. If they had any comments regarding their interview transcript they were asked to contact me and I would arrange to meet them to discuss these concerns. Two of the participants made comments regarding their interview transcripts. These comments were incorporated into their interview transcripts and sent back to these midwives to review.

Once all the participants were satisfied that their transcripts were an accurate account of their interviews and reflected their understandings, I then read and re-read the transcripts, removed any identifiable information still present from the transcripts and then generated a list of ideas about what was interesting in the transcripts, in relation to my research aim and objectives.

6.4.2. Phase 2: generating initial codes

I conducted coding on a Microsoft Word document. Initial codes were generated from each transcript by identifying a feature in the data I found interesting, that explored the participant’s views regarding third stage of labour care and factors that influenced it. I highlighted these features on the Microsoft Word document and wrote a note on this feature of the text being analysed. An example is given in Table 6.4.2(a).

Table 6.4.2(a): Initial codes generated from transcript 1, Follow-up Interview

Transcript 1	Initial codes
<p>Interviewer: <i>You said in you initial interview you felt experienced and skilful conducting active and expectant management approaches. How did you gain this experience and skill in the different third stage management approaches?</i></p> <p>Participant 1: <i>'When I trained as a student active management was the routine. That is what we did, so from very early days in my training that is what we always did, so that experience and skill comes from seeing that it works. I suppose. Also I did not have any negative experiences with women having active management. So it was something that I was happy to do, if that's what the woman chose.'</i></p>	<ul style="list-style-type: none"> -When I trained active management routine. -Active management usual care. -Active management what we always did -Confident it worked with good results -Seeing it works Woman choice

Once all the interesting features, regarding the participants’ views, in the data had been coded I then collated all data together within each code. This involved copying extracts of data from individual transcripts that were given the same code and putting these extracts of data together within that code on a Microsoft Word document. For example: Table 6.4.2(b) shows an initial code I generated from the transcripts and the data from individual transcripts to support this code.

Table 6.4.2(b): Initial Code and data from transcripts

	Data from transcripts to support the initial code ‘Usual Care patterns’
Participant 1	“Active management was the routine” “Active management was what we did” “Active management was what all the other midwives did when I was training”
Participant 2	“Active management what we did when I was training” “Active management is what everyone did” “when I trained active management was routine”
Participant 3	“Active management was what I was used to” “Active management was the norm” “Active management was usual practise”
Participant 4	“usual care” “Active management was normal practice” “If not sure I would always do expectant management“
Participant 5	“Active management was what I was familiar with” “Active management was what I knew” “If no risk factors for bleeding I would start with expectant management”
Participant 6	“Active management was what we did” “Active management was what we were trained to do” “Comes down to routine mainly“

During phase 2 there was no limit to the codes I generated from the data. This ensured that as many potential patterns as possible were identified. A list of the different codes across the entire data set was then identified.

6.4.3. Phase 3: searching for themes

This consisted of clustering the list of the different codes across the entire data set with regard to how they could combine to form overarching themes for that coding frame. This involved writing on a separate piece of paper each code generated from the data, placing these pieces of paper on the floor, reviewing these codes, beginning to look for patterns in these codes and starting to combine them into potential main themes.

The data was also reviewed whilst sorting the different codes into potential themes for that code. This involved going back to the Microsoft Word documents produced in phase 2, identifying the initial codes which were now under a potential theme in phase 3 and identifying the data that the code was generated from. The data to support the codes was then reviewed, to ensure

the data had a strong link to the potential main theme and also to check the participant's apparent meaning. If there was a strong link between the data and the potential main theme the data was put with its code and kept under that theme. If the data did not have a strong link with the potential main theme it was put with its code and both the data and code were taken out of that main theme. The data and codes that were removed from the potential themes were then reviewed and analysed to decide whether they had a strong link to another potential theme identified.

The relationship between the codes, themes and different levels of themes were then examined and eventually a collection of candidate themes and sub-themes, with all their relevant data abstracts that had been coded to these themes and sub-themes were identified. Table 6.4.3(a) identifies one of the candidate themes, its sub-themes and some data that was coded to a sub-theme.

Table 6.4.3(a): Candidate theme and its sub-themes

Candidate theme	Midwives Practice
Sub-themes	1.Usual practice
	2.Confidence of practitioner
	3.Information giving by midwife

Table 6.4.3(b): Candidate theme, sub-theme and data coded to it

Midwives Practice	
Sub-themes	Data coded to a subtheme
1.Usual practice	Participant 5- "If no risk factors for bleeding I would start with expectant management"
2.Confidence of practitioners	Participant 1- "lack of confidence in expectant management then midwife will give active management"
3.Information giving by midwife	Participant 4- "if midwives not confident in expectant management will influence how they discuss management approaches with women"

6.4.4. Phase 4: Refining Themes

These candidate themes were then refined. This involved repeating some of the activities carried out in phase 3, such as:

- reviewing the coded data extracts to ensure the data had a strong link to the potential main theme
- reviewing the entire data set to ensure that the themes had enough data to support them
- ensuring that the data that supported the themes was not too varied
- reviewing whether any of the themes could be merged with another theme.

Themes were also reviewed to check they focused on meaning and captured the midwives' understandings. Themes were omitted where they did not have enough data to support them, or where the data was too varied, where one theme merged with another or if they did not capture the midwives understanding.

6.4.5. Level 5: Defining and naming themes

After analysing the data four themes were identified that I interpreted midwives felt affected their use of active and expectant management of the third stage of labour approaches in midwife-led units.

6.4.6. Level 6: writing the report

This involved telling the story of the data through exploring the four identified themes and providing evidence to support each identified theme., to gain an insight regarding midwives' understanding of the factors they felt shaped facilitated or constrained their use of third stage of management approaches in midwife-led units. After I had defined and named the themes and written the report, I sent a copy of this report to the participants. I asked for their comments regarding whether they thought the report produced was a fair interpretation of their thoughts regarding this aspect of care. Participants felt that the report had explored their thoughts regarding this issue and the feedback from them was very positive. This feedback from the participants increased the dependability and credibility of the research findings and the trustworthiness of Study Two.

6.5. Reflexivity

. Since Study Two was conducted within an interpretivist paradigm it was essential that I was reflexive as a researcher when undertaking this study. This is because, although my personal insights, knowledge, and experiences of the participant's social context was essential in helping to explore and interpret their understanding, I needed to be aware of my personal biases and preconceptions and not let these interfere with my ability to present a shared fair interpretation of the participants' understanding. This would increase the dependability and credibility of the study's findings and the trustworthiness of the study (Korstjens & Moser, 2018; Offrey & Vickers, 2010).

To enable me to become reflexive I wrote a reflective account of my thoughts, experience and knowledge about why I wanted to explore this aspect of maternity care (see Appendix 22). I shared this initial reflective account with my research supervisor. We discussed the possible impact of these thoughts and my presence as the researcher designing the study, conducting the interviews and analysing the data. We then discussed how to minimise this influential effect, to enable me to explore fully participants' understandings, especially ones that were different to mine. For example we discussed the study sample and the recruitment of midwives for the semi-structured interviews, to ensure I recruited midwives who were not only experienced in working in the midwife-led units and knowledgeable and skilful in third stage of labour care, but who were increasingly like to hold different views regarding the third stage of labour and would be articulate in expressing these views. It was also important that I recruit midwives, whose relationship with me was more on a professional level rather on more of a close personal level; knowing the participants on a close personal level would mean they would be increasingly likely to be more open with me during the interviews, however, there is more of a risk of me becoming over involved in the interviews and consequently influencing the participants' responses. Also we might hold assumptions about one another that might prejudice data obtained from the interview.

Being reflexive involved me constantly monitoring the possible impact of my preconceived thoughts and how my role as a researcher could influence the

research process. As part of this reflective process, I also discussed with my research supervisor the steps I used to construct the interview guide, to reduce my preconceived opinions and presence as the interviewer influencing participants' ideas. As stated previously, the interview guide was flexible, allowing participants' ideas that emerged within interviews to be explored.

Additionally as part of this reflexive process, during the data analysis process I initially coded the transcripts, after which my research supervisor conducted some coding on small sections of three of the transcripts. We then discussed our different interpretations in order to help me to reflect on what I was bringing to the interpretative process and to help me to try to focus, as far as is possible, on the participants' meanings. As stated previously in this thesis, I also sent the midwives who participated in the interviews a copy of their transcripts, to ensure they felt they were a true representation of their interviews before I began data analysis.

I also kept a reflective journal when conducting the study, highlighting my thoughts regarding the interviews and analysis process, as well as any issues I encountered in conducting Study Two. For example, because I worked with the participants as a practitioner in the clinical setting and my research was relevant to their practice, I felt that they regarded me as an equal and were therefore willing to disclose their thoughts. However, these pre-existing relationships with the participants also proved to be problematic. As I was known to the participants as a work colleague, I found that they would often presume I knew what they were referring in their discussions in the interviews. For example, participants would often say as part of their response to a question or in their discussions 'you know what I mean'. When this happened, I would acknowledge what they said with a nod, but then refocus the question back on their views by asking them if they could explain what they meant, because it sounded really relevant to the research. Participants also occasionally reflected the question back to me, by saying at the end of their response to a question or after discussing an issue 'what do you think?' and look at me for a reply. In response to this I would nod, maintain eye contact, pause and encourage participants to talk more about their views by saying

something like “it’s your views that I am really interested in and you have raised some really good points, can you tell me anything more?”

Reflecting on how I conducted the interviews in my reflective journal enabled me to be more competent in the interview process, to stay open to exploring others’ perspectives and prevent my own views or presence as the interviewer from influencing participants’ responses. Additionally as part of the reflective process I also met or emailed my research supervisor regularly to discuss my thoughts regarding the data collection and analysis process. This reflexive process aimed to increase the trustworthiness of the study.

6.6. Thematic findings

After analysing the data, I identified four themes that I felt captured the key features of the midwives’ understanding of factors that influence their use of active and expectant management of the third stage of labour approaches, for women they provided care for: ‘The woman’; ‘The Midwife’; ‘Working within an organisation’; and ‘Recent changes in childbirth’. These themes suggested that they saw their third stage of labour practice as shaped by varied and sometimes contradictory considerations and influenced by both their interactions with the women they cared for, whether the woman had any risk factors for PPH, the midwives themselves, their colleagues and also the wider organisational and ideological context.

6.6.1. Theme 1: ‘The woman’

The importance of ‘The woman’ regarding what affects midwives’ use of active or expectant third stage of labour management approaches was a crucial theme within all interviews. All participants spoke about their practice as being woman-centred, placing a strong emphasis on considering what the woman wanted and enabling her to make an informed choice. Theme 1 incorporated two sub-themes. ‘What the woman wanted ’and ‘Informed choice’

6.6.1.1. ‘What the woman wanted’

All the midwives spoke passionately about discussing with the woman their third stage of labour management options and about listening to what the

woman wanted. This was a central governing factor that affected whether midwives used an active or expectant third stage of labour management approach.

When I first meet the woman I read her birth plan, if she's made one. I'll then discuss her preferences. If she's any, that is. I'll discuss them with her and try to unpick her rationale for them. I'll say why I think one [third stage] approach might be more suited to her I'd also discuss the other one [third stage approach] If she does not have any preferences I'd discuss both third stage of labour approaches, informing her of the advantages and disadvantages of both and why one might be more suitable for her I'd listen to the woman though, at the end of the day it's what she wants. (Interviewee 3, personal communication, Initial interview, November 17, 2016, p8)

I ask the woman does she have any thoughts regarding her labour and birth. I then discuss these with her. In this discussion we'd talk about the third stage of labour and management approaches. I would discuss with her what I thought she should have and why, but after discussing with her I would be more than happy to go with what her choice is, even if it wasn't what I thought she should have. (Interviewee 4, personal communication, Initial Interview, November 23, 2016, p9)

From analysing the transcripts, I was given the impression that during the participants' discussion with the woman they were not expecting the woman to make an explicit choice between active or expectant third stage of labour management approaches.. All participants appeared to be trying to assess what the woman's general views were regarding labour and childbirth and how she wanted her labour and the birth to unfold. This assessment would affect what third stage of labour management the midwife would recommend for the woman.

Some women want the birth to be natural with minimal intervention. If they have a normal birth and no risk factors for PPH then I'd discuss why

I thought a physiological third stage with expectant management would be more suitable for them. (Interviewee 6, personal communication, Initial Interview, December 12, 2016, p8)

When the woman did voice a preference regarding her third stage of labour management all participants spoke of how they thought this preference was influenced by how the woman saw birth. If she viewed birth as a process that needed intervention she would opt for active management. If she saw birth as a natural event that did not need any intervention, all midwives felt the woman would opt for expectant third stage management, as they felt these women saw the third stage of labour as an extension of the birthing process. "Labour and childbirth for some women is seen as a process, a beginning to an end, to get it all over and done with, so they want active management. They want it over with" (Interviewee 1, personal communication, Initial interview, November 7, 2016, p10). "For some they want the birth to be natural without intervention and are seeing the third stage as an extension of the birthing process, so are opting for expectant management" (Interviewee 2, personal communication, Initial Interview, November 14, 2016, p10).

All participants discussed the importance of the woman's hormones during labour and birth, how the woman wanting skin-to-skin contact with her baby and to breastfeed would maximise her production of hormones and that this increased production of hormones would help her to birth her placenta physiologically. Consequently, if the woman wanted skin-to-skin contact with her baby and to breastfeed and had no risk factors for PPH, five of the six midwives said they would suggest a physiological third stage with an expectant third stage approach, or support the woman's choice to have expectant management. However, if the woman was not focused on her baby after birth, all of the midwives said they would advise active management, although they would support the woman's choice if they requested expectant management.

If the woman is on their phone straight away after the baby's born and they're just not interested in birthing the placenta, they are not focused I kind of think: what are we doing here? I would advise active

management. (Interviewee 1, personal communication, Initial Interview, November 7, 2016, p10)

After the birth if the woman asks me to give baby to partner or put baby in the cot because she is tired and uncomfortable and just needs to rest I would advise active management, but it would be her choice.

(Interviewee 3, personal communication, Initial Interview, November 17, 2016, p13)

Although what the woman wanted was obviously very important to all the participants, four of the participants felt that most of the women they provided care for were not really concerned with what third stage management approach they received. They felt that women were more concerned about their labour and birth. Additionally, they discussed how they felt the majority of women they provided care for did not give as much thought to what they wanted regarding the third stage of labour. These participants felt, that the third stage of labour was not as important to the women.

I don't think women are bothered really, regarding the third stage of labour and which management approach to have. The vast majority do not give it a lot of thought. They have not really thought about it too much (Interviewee 6, personal communication, Initial Interview, December 12, 2016, p9).

I don't really think the majority of women value the third stage of labour. Once the baby is born most women just want to focus on the babe in arms. Most women just think get it out [the placenta] as quickly as possible, so want active management. They want it all finished and tidying up so they can turn their attention to their baby. (Interviewee 3, personal communication, Initial Interview, November 17, 2016, p9)

All participants felt that where the woman chose to give birth influenced her views regarding birth and how she wanted her birth to be. For an increasing number of women, these views also affected their third stage of labour

management. All participants spoke about how most women who chose to birth at the midwife-led units valued minimal intervention and tended to want to do things more naturally than women, who were also low risk, and chose to birth at the obstetric-led unit. They described women who birthed at the midwife-led units as increasingly likely to want or consider a physiological third stage with an expectant third stage of labour management approach. The following quote was typical of participants' responses in the interviews, when asked by myself as the interviewer, if they felt where the woman chooses to birth influences her choice regarding her third stage of labour management approach?

Most of the women who want to birth on the birth centre have a different approach to their labour and birth than the women who want to birth on the labour ward. Women tend to want to do things more naturally, and that is why they have chosen to birth on the birth centre. For those women who want to do things more naturally expectant management is usually the desired option for them. (Interviewee 2, personal communication, Initial Interview, November 14, 2016, p14)

However, three of the participants also acknowledged that for those women who wanted to do things more naturally and initially chose expectant third stage management, once labour progressed or the baby was born their priorities might change. They commented that these women might then request active management as they wanted the placenta to be delivered more quickly, so they could concentrate on their baby. Consequently, how a woman views the third stage of labour and her choices regarding third stage of labour management approaches are dependent on her circumstances. These views and circumstances may change as labour and childbirth progress.

I do find that women who might initially plan to have a physiological third stage and choose expectant management, once the baby is born then a lot of them just want; they change their mind. They just want the placenta out. They want it over and done with, to get on with enjoying their baby. (Interviewee 4, personal communication, Initial Interview, November 23, 2016, p11)

All participants acknowledged that the increased length of time a physiological third stage of labour could take was a major factor influencing whether a woman would choose expectant management. Also, if the woman opted for an expectant management approach and she felt the placenta was taking too long to birth physiologically, she would ask the midwife to convert to active management. Again, midwives in the interviews acknowledged that a woman's views regarding her third stage of labour management might change over time. These changes in views might influence her choice of management approach. "If after the birth the woman feels the placenta is taking a long time to come she will often say, give me the injection especially if they have had active management before" (Interviewee 6, personal communication, Initial Interview, December 12, 2016, p7).

6.6.1.2. 'Informed choice'

Although what the woman wanted was central to which third stage of labour management approach midwives used, all participants also felt that it was vital that the women they cared for were fully informed about the third stage of labour. This included what the third stage consisted of, how it was managed, the advantages and disadvantages of each approach and why one approach might be more suitable for them. Participants felt that giving the woman this information allowed them to make an informed choice regarding which third stage of labour approach they wanted. It was obvious from these interviews that the participants felt that they had a role in ensuring the woman made an informed choice.

As a midwife caring for a woman in labour I'd discuss the third stage of labour with the woman, what care during this period consists of, the advantages and possible disadvantages of each approach, why one approach maybe more suitable for them. I'd then support the woman's choice, but I need to ensure she has made an informed choice. You know it's very important to me; I need to know she has made an informed choice. (Interviewee 2, personal communication, Initial Interview, November 14, 2016, p7)

Despite emphasising the importance of what the woman wanted and the woman making an informed choice regarding her third stage of labour approach, all participants acknowledged that for most part, what the woman decided was influenced by what and how they provided information and what they advised.

When looking after a woman in labour you have to provide them with the facts regarding the advantages and disadvantages of each third stage approach. It's all to do with the information you give them and how you phrase it. This will influence a woman's third stage of labour management choice. If you tell them active management will be quicker and it will stop you from bleeding too much after the birth, then you tell them expectant management will take longer and you will bleed more after the birth, then of course they will have active management. I do find though that a lot of women will just have whatever you advise. They have not thought about delivering the placenta too much. After labour! After though! (Interviewee 5, personal communication, Initial Interview, December 6, 2016, p10)

Since many of the women cared for by participants asked for their opinion and the majority of women would agree with what they suggested, all participants commented that they would ensure the information they provided to the women was current, based on research evidence and specific to each woman. If the woman had any risk factors for PPH then all participants spoke of discussing these risk factors with the woman and explaining why active management might be more appropriate for her. Alternatively, if the woman did not have any risk factors for PPH, three of the participants spoke of discussing why expectant management might be more suitable for her. After this discussion the participants felt the woman could then make an informed choice regarding an active or expectant management approach.

When providing care for a woman I discuss third stage management with the woman, discussing the evidence, local and national guidelines with her and the rationale for each. I'd discuss why she might not be suitable

for a physiological third stage and expectant management; I think it's important to make them aware of the benefits of physiological third stage and expectant management if they have no risk factors for PPH. Why should they not have expectant management? I give the woman information to make an informed choice. (Participant 6, Interviewee 6, personal communication, Initial Interview, December 12, 2016, p12)

Reflecting on theme 1, 'The Woman', it is evident that a woman's third stage management approach is not just based on her risk status regarding PPH. A woman's third stage of labour management approach is about how a woman wants to experience their birth, though they might not be explicit about this initially. In midwives trying to find out what a woman's choice was, regarding her third stage management approach, midwives were trying to understand how the woman wanted to experience her birth. To become aware of the woman's choice it is evident that midwives sometimes looked for subtle clues about the woman's preferences and they also tried to establish explicit choice where they could. This implies that midwives think that they have a responsibility to play a role within women's decision-making. They seemed to want this to be a collaborative discussion, whilst acknowledging that it might not be one.

Furthermore, although initially many women seem not to have much of a preference or to have thought about third state of labour, the midwives recognised that the woman's third stage of labour management approach may start to matter more to them once they birth their baby.

6.6.2. Theme 2: 'The Midwife'

Despite arguing strongly for supporting women's choices, the participants acknowledged that there were factors that might constrain their choices. For example, midwives were more likely to recommend either active or expectant third stage of labour management to women, depending on the woman's needs and request, if they were confident in conducting both approaches. Also, if midwives strongly believed in and valued normal birth they were more likely to promote a physiological birth and an expectant third stage of labour

management approach. Consequently, this theme had 2 subthemes 'Confidence of the midwife' and 'Midwives ideology regarding birth'.

6.6.2.1. Confidence of the midwife

All participants regarded midwives' confidence in active and expectant management approaches as a major factor affecting midwives' recommendation of and use of active or expectant third stage of labour management approaches. Participants felt that if midwives felt confident in conducting both third stage of labour approaches, then they would recommend what they felt was the most appropriate approach to a woman, based on the woman's needs. However, if midwives were more confident in one of these approaches they felt the midwife would recommend the use of this approach to the woman, rather than base the third stage approach on the woman's needs.

If midwives are confident in both third stage approaches then they will recommend both approaches to the women, depending on her needs, because they are competent and comfortable to carry out both approaches. If midwives aren't confident in both of them, how can they give women unbiased information to make an informed choice? If midwives lack confidence in expectant management then they will advise active management. It's about confidence of the midwife. (Interviewee 3, personal communication, Follow-up Interview, March 13, 2018, p5)

All participants commented that their confidence came from understanding how both approaches worked and by seeing and practising both approaches on a regular basis in practice. It was also evident in the interviews that confidence was also about awareness of risk in relation to the woman and the third stage of labour management approaches. "Confidence of the midwives comes from understanding and experiencing both third stage approaches regularly, seeing active and expectant management, doing them and understanding how they work. You know this is vital! It helps you believe they work" (Interviewee 3, personal communication, Follow-up Interview, March 13, 2018, p8).

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It was apparent in the interviews that all participants felt that the majority of midwives were less confident with expectant management, as they thought midwives were less exposed to it during their training. They also discussed how midwives, who worked on an obstetric-led unit were also less exposed to expectant management. Therefore, less confident with expectant management and more likely to recommend and practice active management.

During my training to be a midwife I was only exposed to active management; that is what we did. Even when I qualified that was what we did. It was the norm. I was aware of expectant management but no one really did it, not on the labour ward anyway. Looking back I suppose I didn't really know how it worked, I was not familiar with it, the Trust didn't promote it and I was, if I am honest maybe scared of it, shying away from it. (Interviewee 6, personal communication, Follow-up Interview, April 16, 2018, p7)

If you work in a high risk setting and labour ward is a high risk setting. Even if women aren't initially high risk they tend to get treated like that or become high risk anyway. If all you have ever seen is active management you are not going to be comfortable promoting and conducting a physiological third stage and expectant management. (Interviewee 6, personal communication, Follow-up Interview, April 16, 2018, p9)

All participants commented that although all midwives are aware of expectant management and in theory know how to conduct this third stage of labour approach, it was not until they started to work as qualified midwives, attending women during home births and caring for women at the midwife-led units, that they were regularly exposed to expectant management. In these birth settings, participants said expectant management of the third stage of labour was practised on a regular basis by the midwives already working there. Consequently, it was evident that this change in place of work resulted in a change in midwives' normal ways of working and their views regarding third stage of labour and management approaches.

Also all the participants felt they gained experience, knowledge and confidence in expectant management of the third stage of labour by working alongside their peers and being supported by them. They also discussed how they gained experience, knowledge and confidence in expectant management by working away from the obstetric-led unit and in an environment that supported a physiological third stage and expectant management.

It was not until I started working in the community, attending home births and working on the birth centre that I became confident with expectant management. It wasn't something I recommended until then. But working away from the labour ward with women who wanted to do things more naturally and were more likely to want a physiological third stage, with other midwives who were confident with expectant management I felt supported and that suppose increased my confidence with it.

(Interviewee 4, personal communication, Follow-up Interview, March 13, 2018, p4)

I was supported by other midwives you know, working on the birth centre or at a home birth. I watched them; they talked to me about it. I went away and I suppose it's what you do with everything you're not familiar with, you do some reading about it so you understand it more. Once I felt confident in expectant management I then began to promote it to women who were suitable. My confidence increased by seeing it worked and practising it just as I had seen active management work and had practiced that. (Interviewee 4, personal communication, Follow-up Interview, March 8, 2018, p6)

Consequently, it was apparent from the interviews that midwives' confidence in active and expectant management approaches came from understanding how both approaches worked and seeing and practising them on a regular basis.

6.6.2.2. Midwives' ideology of normal birth'

All participants discussed how viewing pregnancy and birth as normal events increased their confidence in conducting and recommending a physiological

third stage of labour and expectant management. They all felt that having a philosophy that supports normal birth was essential to working in a midwife-led unit or home birth setting.

Having a strong philosophy of normal birth has helped me with expectant management. You know, you need to believe in normal birth that woman can grow and birth her baby and for the majority of women pregnancy and birth is a normal event. So if they have no risk factors and are suitable then a physiological third stage with expectant management is the final piece of the jigsaw. To work in a birth centre you need to believe in normal birth and a physiological third stage is part of normal birth. It's about trusting in the woman's body and believing it will work.

(Interviewee 3, personal communication, Follow-up Interview, March 13, 2018, p6)

All participants discussed the fundamental role of the woman's hormones in achieving a normal birth. It was apparent that all participants felt their role as a midwife at a midwife-led unit was to support the woman to enable her body to produce optimal levels of hormones to birth her baby safely. "Midwives who believe in normal birth and the importance of the woman's hormones will support her during third stage regardless of management approach. Her hormones still come into play with active" (Interviewee 3, personal communication, Initial Interview, November 17, 2016, p14).

It's important as midwives working on a birth centre that we believe that a woman can birth her baby physiologically and we support her with this. We support her body to produce optimal levels of hormones to birth and this includes the third stage. We're meant to be the experts in normality after all, aren't we? (Interviewee 4, personal communication, Initial Interview, November 23, 2016, p8)

Participants discussed how believing in normal birth and the vital role a woman's hormones have in birth influences their practice. They commented that they engaged in activities to protect this sensitive period and maximise the

woman's production of these birthing hormones. This supports the woman's body to labour and birth physiologically. Protecting the woman's birth also included protecting the woman's third stage, regardless of her third stage of labour management approach.

I believe in normal birth, where a woman can birth her baby and placenta with minimal if any interventions. It's what we are designed to do. When I provide care for a woman during labour and birth I talk to the woman and partner about how they want their birth to be, including the third stage. I then discuss with them about the importance of hormones and what we can do to promote these hormones. I make sure the room is dimly lit, with minimal noise; the woman is warm, comfortable and feels safe. This will maximise her hormones for labour and birth. Third stage is just as important regardless of management. It's a special time for the woman and baby and we need to protect this time, as well as, minimise any blood loss. (Interviewee 2, personal communication, Initial Interview, November 14, 2016 p14)

All the participants also discussed how, if the midwife does not believe in normal birth, she will not be confident in recommending and supporting a physiological third stage of labour and practising expectant management.

"If midwives do not believe in normal birth and that includes a physiological third stage, then they shy away from expectant management. They are frightened by it. They do not trust them to deliver their placenta" (Interviewee 6, personal communication, Follow-up Interview, April 16, 2018, p8). Confidence of the midwives in recommending and conducting a physiological third stage of labour and expectative management has been discussed previously in the sub-theme 'Confidence of the midwife'.

Participants also discussed how their views regarding pregnancy and birth were influenced by the people around them and the area they practised and this led to a change in their ideology of pregnancy and birth. The midwives' working environment and the role it plays regarding third stage management is also discussed in the sub-theme 'Confidence of the midwife'.

Working on the birth centre enables us to promote normal birth. You see that women can birth their babies without intervention. We work alongside peers who also believe in normal birth. We see normal birth, have experience in promoting it and believe in it, and this includes a physiological third stage. (Interviewee 2, personal communication, Initial Interview, November, 17, 2016, p8)

If you work on labour ward all you see is intervention during pregnancy and birth. How can you believe in normal pregnancy and birth? How can you believe in a woman's body to birth her placenta physiologically? How can you promote a physiological third stage with expectant management for the women you provide care for? (Interviewee 6, personal communication, Initial Interview, December 12, 2016, p14)

6.6.3. Theme 3: 'Working within an organisation'

As well as the central role of the woman and the influencing role of the midwife as factors that midwives felt facilitated, shaped and constrained their use of third stage of labour management approaches, participants all recognised the influence of the organisation on their third stage of labour care. From analysing the interviews it was apparent that working within an organisation influenced midwives' use of third stage management approaches in two particular ways; these formed two sub-themes 'Trust guidelines' and 'Expectations of others'.

6.6.3.1. 'Trust guidelines'

It was apparent in the interviews that all participants were aware that they were working within an organisation with guidelines regarding third stage of labour care. These guidelines were a major factor that influenced their promotion and use of third stage approaches. All midwives spoke about pressures they felt to follow the Trust's guidelines. Midwives talked about feeling more pressure when what the woman wanted was different to what the midwife thought she should have or what was recommended in the Trust guidelines.

As midwives working within a Trust with Trust guidelines you feel under pressure to follow these guidelines. It's what is expected of you. If you

don't follow them for any reason you need to document this and escalate it to your manager or who's in charge, because if anything negative happens you will be scrutinised. Our guidelines recommend active management so you need to document why the woman has not had this. As long as you follow the guidelines or document why you have not followed the guideline. (Interviewee 1, personal communication, Initial Interview, December 12, 2016, p14)

You are aware you are working within an organisation where national and local guidelines are in place. You sometimes feel unnerved because you are not doing what the guideline recommends. Our guideline recommends active management of all women. If you conduct expectant management because that's what the woman wanted, as long as she has made an informed choice and you document your rationale then that's appropriate for that woman. Your loyalty is to the woman, but it can be unnerved at the time. (Interviewee, 3, personal communication, Initial Interview, November 17, 2016, p18)

However, all participants felt that these organisational guidelines also assisted them in providing care for a woman by providing them with up-to-date information and guidance regarding care. All participants said they would refer to these guidelines, regarding third stage of labour care, when assessing if a woman was at low risk of PPH, to assess her suitability for active or expectant management..

I refer to Trust guidelines to assess whether the woman is good to have a physiological third stage and expectant management. You know making sure she has no risk factors. If she does have risk factors for PPH then I would advise active management, but discuss both approaches. It would be her choice, as long as she has made an informed choice. I would just document what she wanted. If she wanted expectant management I would be ready to convert to active if I needed, and I would have had that discussion with her. (Interviewee 1, personal communication, Initial Interview, November, 7, 2016, p17)

All the participants talked about discussing the Trust's third stage of labour guidelines with the woman, to enable her to make an informed choice. Although all midwives commented that it was not just the risk factors for PPH stated in the guidelines that they would refer to when assessing if the woman was suitable for expectant management. The participants talked about discussing with the woman what her birth preferences were and assessing the woman's behaviour during labour, birth and after, as well as her physical and social environment.

When assessing if a woman is suitable for a physiological third stage and expectant management. It's not just about guidelines and risk factors documented in the guideline. It's also how the woman is, the support around her, how the atmosphere is in the room and if she is going to breast feed. If she is with baby! I think everything comes into play. It's about supporting her so her body can release optimal levels of hormones so she can birth her placenta safely. (Interviewee 1, personal communication, Initial Interview, November, 7, 2016, p18)

Birth preferences and the effect on her third stage management approach were discussed under a previous sub-heading 'What the woman wants'.

Throughout the interviews all participants consistently commented that if the woman had any risk factors for PPH they would advocate active management to the woman, but it would be the woman's choice. "If the woman has any risk factors for PPH I advise active management" (Interviewee 3, personal communication, Initial interview, November 17, 2016, p16). They also constantly stressed the importance of the woman making an informed choice. "Everything has to be normal, within the normal range, if any concerns I will advise active, but it's the woman's choice. You know, she has to make an informed choice" (Interviewee 6, personal communication, Initial Interview, December 12, 2016, p16).

If the woman did not have any risk factors for PPH all participants said they would discuss both third stage of labour approaches with the woman, and explain why a physiological third stage and expectant management might be more suitable for her. However, if the woman wanted an actively managed third stage approach they would support her choice. “If low risk they’re [the women] given the option of both active and expectant management approaches, but I would discuss why expectant management might be more suitable for her’ (Interviewee 5, personal communication, Initial interview, December 6, 2016, p7). “If low risk support physiological third stage and expectant management or active management depends on what the woman wants” (Interviewee 6,, personal communication, Initial Interview, December 12, 2016, p8). What the woman wanted and informed choice have also been discussed previously under Theme 1 ‘The woman’.

6.6.3.2. ‘Expectations of others in the organisation’

All participants spoke of how the expectations of people around them influenced which third stage of labour management approach they recommended to the woman and what approach they used. It was evident that these expectations shaped the participants’ practice and this practice over time, grounded in others’ expectations, became their normal practice. “When I was training active management is what everyone did. It was very much this is what you do and this is how you do it” (Interviewee 2, personal communication, Initial Interview, November 14, 2016, p15).

When I worked on the labour ward, before working on the birth centre, active management is what I did. It was what everyone did. I suppose it was what was expected of you. But then again most of the women had intervention, so were at high risk of PPH (Interview 4, personal communication, Initial Interview, November 23, 2016, p16)

Two participants spoke about how the expectations of people working within their Trust could be problematic. They commented that Trust guidelines recommend active management for all women, so they felt that the managers and midwives not working on the midwife-led units expected this. Yet, they also

felt that working on midwife-led units that promoted normal birth, for women at low risk of PPH, they should be recommending a physiological third stage with expectant management for.

As midwives in our Trust we are encouraged to advocate active management. The Trust third stage of labour guideline recommends it for all women, but working on the birth centre we promote normal birth because that is what we believe in. Normal birth includes a physiological third stage. So if woman's suitable I feel we should recommend physiological. It can be difficult at times and you sometimes feel in two minds. (Interviewee 3, personal communication, Initial Interview, November 23, 2016, p9)

Four of the midwives spoke about feeling judged by other midwives, regarding recommending a physiological third stage with expectant management to women. This made them feel vulnerable; sometimes feeling they needed to explain why they used this third stage approach.

If you're supporting a woman to have a physiological third stage of labour and expectant management on the birth centre you're classified by some midwives, who work on the labour ward as radical and out there. You sometimes feel you need to justify it to some of your colleagues. It depends who you are working with (Interviewee 1, personal communication, Initial Interview, November, 7, 2016, p12)

If we recommend a physiological third stage and expectant management some midwives, who do not work on the birth centre, will just look at you a certain way and you know they're judging you. They make you feel you need to defend why you have advocated it to the woman. (Interviewee 3, personal communication, Initial Interview, November, 17, 2016, p16)

The expectations of others and how it influences midwives practice was also discussed in Theme 2's sub-theme 'Confidence of the midwife'.

6.6.4. Theme 4: 'Changes in childbirth'

It was also evident that changes in how women and midwives viewed childbirth, and changes in practices, were also seen by midwives as facilitating, shaping and constraining their use of third stage management approaches. This theme had two sub-themes: 'Changes in practice' and 'Changes in how we view pregnancy and birth'.

6.6.4.1. Changes in practice'

All participants talked about changes in practice and who these changes influenced third stage of labour care. For example, participants talked about delayed cord clamping and the effect this has had on third stage care. What delayed cord clamping consists of, and the effect that this has on third stage of labour care and baby were discussed in Chapter 1 of this thesis. "More and more women are opting for a physiological third stage and expectant management because they have heard about delayed cord clamping" (Interviewee 1, personal communication, Initial Interview, November 7, 2016, p16). "Women are more aware of the importance of the third stage due to delayed cord clamping and opting for expectant management or having expectant management by default" (Interviewee 2, personal communication, Initial Interview, November, 14, 2016, p16).

Although, as discussed previously, participants thought the majority of women wanted to deliver their placenta quickly, or were not really too concerned about how their placenta was delivered. All participants also discussed how an increasing number of women now wanted to labour and birth more naturally, because of benefits to themselves and their baby. They commented that these women were increasingly likely to want a physiological third stage with expectant management.

If they [women] have done a lot of research into pregnancy and birth and they are aware of the benefits and they are very usually very pro-normal. You will find then they want a physiological third stage and expectant management. (Interviewee 4, personal communication, Initial Interview, November, 23, 2016, p17)

It was apparent that the changes in how a woman is able to give birth have influenced midwives' use of third stage of labour management approaches. Four of the participants discussed how women increasingly wanted to labour and birth in water and the affect this has had on third stage of labour management, if they had a water birth. Midwives discussed how if a woman birthed in the birthing pool they were more likely to have an expectant third stage management approach. This was because, although the woman might have intended to have active management, she would often birth her placenta physiologically in the pool before the midwife was able to conduct active management. Participants talked about being extra vigilant regarding monitoring the woman's blood loss and wellbeing, if she gave birth in the pool and intervening quickly if needed.

If the woman has her baby in the pool she often doesn't want to leave the pool straight after the birth. She'll stay in the pool in skin-to-skin contact with baby. You just need to observe the woman and the colour of the water for blood loss and intervene if needed. Sometimes you'll find she will just push the placenta out in the pool or when she stands up to get out.'(Interviewee 1, personal communication, Initial Interview, November 7, 2016, p18)

During a pool birth if the woman stays in the pool she often pushes the placenta out before you can conduct active management, but you've to be ready to get her out of the pool and give the injection, if needed.' (Interviewee 3, personal communication, Initial Interview, November 17, 2016, p14)

Participants all discussed how women are increasingly opting to birth in midwife-led units rather than in obstetric-led units, because of the benefits found in research studies. They spoke about how this has affected third stage of labour practices.

Women at low risk of PPH are increasingly having a physiological third stage and expectant management because they're increasingly choosing

to birth away from the labour ward. A birth centre setting promotes physiological birth and this includes third stage. Labour ward has nothing to promote a physiological third stage. (Interviewee 1, personal communication, Initial Interview, November 7, 2016, p19)

On labour ward the environment is not relaxed, it's institutionalised. Midwives on a labour ward are not used to a physiological birth and conducting expectant management. They're worried by it. Whilst midwives who practise on the birth centres are used to physiological birth and used to promoting it. They are not fazed by it. It's part of our practice. (Interviewee 3, personal communication, Initial Interview, November 7, 2016, p9)

All participants also spoke about how they felt midwives working on midwife-led units were more able to promote normal birth, as they understood the importance of a woman's hormones during labour and birth and they aimed to promote a calm environment to support these hormones. They also spoke about how they felt that midwives working in a midwife-led unit were more experienced and confident with a physiological third stage of labour and expectant management.

Hormones have a massive impact on a woman's birth and birth setting will maximise these hormones. Birth centres support a relaxing environment. You're not rushed with everything. If you have a calm environment, that has a positive effect on the woman's birthing body. She's able to produce the optimal level of hormones to birth normally. It's easier then, to facilitate a physiological third stage with expectant management. (Interviewee 1, personal communication, Initial Interview, November 7, 2016, p16)

A physiological third stage is going to be more successful in birth centres than on a labour ward, because midwives are more comfortable and experienced with physiological labour and birth and understand how to

promote it. (Interviewee 2, personal communication, Initial Interview, November 14, 2016, p17)

6.6.4.2. 'Changes in how we as a society view pregnancy and birth'

It was evident that all participants felt that the change in how society views pregnancy and birth has resulted in a change in how the third stage of labour is viewed and managed. Participants commented that pregnancy and birth are increasingly being seen by practitioners and women as normal, for the majority of women, rather than a medical event. They commented that seeing pregnancy and birth in this way increases midwives' confidence in recommending a physiological third stage with expectant management for women at low risk of PPH, as they see expectant management as part of a normal birth.

NICE guidelines support normal birth for women who have had a normal pregnancy. It also says we should provide them with information to make an informed choice regarding third stage approaches. If women birth at the birth centre and have a normal birth and are not at risk of PPH why shouldn't they have a physiological third stage? It's part of normal birth. (Interviewee 2, personal communication, Initial Interview, November 14, 2016, p9)

It's only recently though we have been encouraging women at low risk of PPH to have a physiological third stage with expectant management because of the changes in how people see pregnancy and birth and because of the advantages of delayed cord clamping. (Interviewee 4, personal communication, Initial Interviews, November 23, 2016, p17)

"Women are more aware of the benefits of normal birth and want to do things more naturally and that includes a physiological third stage with expectant management" (Interviewee 1, personal communication, Initial Interviews, November 7, 2016, p17).

Changes in how we view pregnancy and birth' was a strong sub-theme in the interviews. All midwives indicated the importance of the broader ideological context of birth and the importance to their practice of understanding how this might be shaping the views of some women in their care, as well as shaping their own and other practitioners' views regarding pregnancy and birth. Changes in how society sees birth and the effect of this are also discussed in Theme 1 sub-theme 2 and Theme 2 sub-theme 2.

6.7. Summary

I used Braun and Clarke's (2006) six phase guide to performing thematic analysis to analyse the semi-structured interviews with midwives, based on an interpretivist research approach. These midwives were experienced in caring for women during labour and birth in the midwife-led units. They were also experienced and felt confident in both active and expectant third stage of labour management approaches. I developed four themes, each with two sub-themes, from analysing these interviews. These themes captured key features of the midwives' understanding of the factors they felt shaped, facilitated or constrained their use of active and expectant third stage of labour management approaches; to try to understand what the situation meant to the midwives and what was important in their decision making. I developed these themes to help answer part of the overall research question: 'What is the practicability of third stage labour management approaches in midwife-led units?'

Chapter 7

Discussion of findings from Studies One and Two

This chapter presents a summary of how this research project contributes to addressing the gap in knowledge. It discusses how each study helps to answer the overall research question and adds to the already existing evidence regarding third stage of labour care. The limitations of Study One and Two are then outlined. Implications for practice and further research are also discussed. Finally any conflict of interest is stated.

7. Summary of how this research project contributes to addressing the gap in knowledge

As discussed previously in this thesis, active management of the third stage of labour is advised by international and national third stage of labour practice guidelines and recommendations (NICE, 2017; RCM, 2018; RCOG, 2016; WHO, 2012; 2018) as a result of the evidence provided by research studies. This prior research found a reduction in blood loss and treatment of this excessive blood loss after the birth of the baby with active management compared to expectant management (Begley et al. 2010; 2011a; 2015; de Groot et al., 1996; Prendiville et al., 2000; Prendiville et al., 1988; Rogers et al., 1998; Thilaganathan et al., 1993).

However, after critiquing these studies and the Cochrane reviews informing third stage of labour practice guidelines and recommendations, using the appropriate critical appraisal tool, it was evident that many of these studies were of low methodological quality. The National Collaborating Centre for Women's and Children's Health (2014) also graded the quality of evidence supporting NICE's (2017) third stage of labour guidelines for women at low risk of obstetric complications as very low or low quality (de Groot et al., 1996; Prendiville et al., 1988; Rogers et al., 1998) because they were methodologically flawed (the studies being biased, inconsistent and indirect). The latest Cochrane review (Begley et al., 2019) considered one of the three RCTs that examined active versus expectant management of the third stage of labour for women at low risk of bleeding to have high risk of bias, in terms of

incomplete outcome data and selective reporting bias (Thilaganathan et al., 1993). However, they considered the other two studies to be of high methodological quality (Begley 1990; Rogers, et al., 1998). All the studies informing international and national third stage of labour practice guidelines and practice recommendations were also conducted in obstetric-led units. Hence, these previous studies' findings and the third stage of labour guidelines and practice recommendations they inform probably cannot be generalised to midwife-led units or home birth settings.

Additionally, as stated previously in this thesis, there is also a lack of studies that compare directly the incidence of and treatment for PPH and active versus expectant management in women at low risk of PPH giving birth in midwife-led units. Structured Literature Review One only identified two studies that examined the incidence of PPH and active versus expectant management in women at low risk of PPH giving birth in midwife-led units (Davis et al., 2012; Fahy et al., 2010). One of the studies, which was a large national study, only examined the incidence of severe PPH (defined as blood loss of more than 1000 mL) (Davis et al., 2012), whilst the other study, was a small study with low numbers of women who received active management at the midwife-led unit compared to expectant management, limiting the validity and generalisability of this study's findings (Fahy et al., 2010). Structured Literature Review One did not identify any studies that examined treatment for PPH and the relationship between active and expectant management in women at low risk of PPH giving birth solely in midwife-led units.

Furthermore, although active management is routinely used by the majority of practitioners in the UK and Ireland (Begley et al., 2019) expectant management is still used by some practitioners and is used more frequently in some birth settings. Therefore, it is important that we examine both third stage of labour management approaches. In addition, the studies informing international and national third stage of labour practice guidelines and recommendations only examined the physical outcomes of the third stage of labour (the relationship between third stage of labour management approaches and blood loss and treatment for this loss, as well as other maternal and neonatal physical

outcomes). They did not explore the factors that influence the use of third stage of labour management approaches. Structured Literature Review Two did not identify any UK studies exploring midwives' interpretations of factors they feel affect their use of these third stage management approaches within midwife-led units.

This research project was conducted to address these identified gaps in the knowledge. It used a multi-method research design, consisting of a quantitative study (Study One) and a qualitative study (Study Two) to explore the outcomes, acceptability and practicability of third stage of labour management approaches for women giving birth in midwife-led units. Study One examined the outcomes and acceptability of active and expectant third stage of labour management approaches for women, giving birth in midwife-led units; whilst Study Two explored the practicability of third stage of labour management approaches for women giving birth in midwife-led units.

7.1. Study one

Study One consisted of a quantitative research approach, involving an exploratory phase and a main study. The main phase consisted of a retrospective cohort study, examining the relationship between active and expectant management of the third stage of labour and the incidence of and treatment of PPH (defined as blood loss of 500 mL or over) or severe PPH (defined as blood loss of 1000 mL or more) in women, who had a normal birth on one of two midwife-led units.

7.1.1. Findings from Study One in relation to previous study findings and advancing research evidence

The blood loss volumes identified by the midwives in Study One indicated that overall the prevalence of PPH (defined as blood loss of 500 mL or over) during the third stage of labour or shortly after was 11.3%, and 2.36% for severe PPH (defined as blood loss of 1000 mL or more). In comparison, an overall prevalence of PPH during the third stage of labour or shortly after ranged from 2.8% to 22.1% and from 0.9% to 3.6% for severe PPH, in previous studies

conducted in midwife-led units outside of the UK investigating the relationship between third stage management approaches and the blood loss (Begley, et al., 2011b; Davis et al. 2012; Fahy et al., 2010; Kataoka et al., 2018; Laws et al., 2017; Monk et al., 2014).

Clearly, reducing the incidence of PPH during the third stage of labour or shortly after is an important issue that needs to be addressed in order to improve the wellbeing of the woman. This is essential as significant maternal morbidity and mortality can occur as a result of excessive bleeding during the third stage of labour or shortly after, from the uterus not contracting strongly enough after the birth of the baby.

The blood loss volumes that the midwives identified in Study One suggested that the decision to assign women at low risk of PPH who had a normal physiological birth in a midwife-led unit to either an expectant or active third stage management approach had a bearing on the probability of experiencing a PPH (blood loss of 500 mL or over). This was a statistically significant finding, set at the 5% significance level ($\chi^2_{(1)}=6.046$, $p=0.014$). The effect was found to be of small magnitude ($\phi=0.069$), signifying strong evidence for a weak association, with a higher incidence of PPH in the expectant management group compared with the active management group. This suggests there is less than 5% chance that the probability of these findings was due to random variation under a null hypothesis of no effect. However, the evidence regarding the association between an expectant management approach and the incidence of PPH is weak, suggesting a finding of possible limited clinical importance. As identified previously in this thesis, significant maternal morbidity and mortality can occur as a result of excessive bleeding during the third stage of labour or shortly after, from the uterus not contracting strongly enough after the birth of the baby. Therefore, any evidence suggesting an association between third stage management approach and the incidence of PPH will be of clinical importance. This significant finding in Study One, regarding incidence of PPH, was in agreement with the findings from Cochrane Systematic Reviews (Begley et al., 2010; 2011; 2015; 2019) and a cohort study by Kataoka et al.

(2018). The findings from these Cochrane Reviews and the Kataoka et al. (2018) study have been discussed in detail previously in this thesis.

Study One's findings regarding PPH differed to those of Fahy et al. (2010), Laws et al. (2014) and Monk et al. (2014) who also investigated women at low risk of PPH, who gave birth in midwife-led and obstetric-led units. Again, these studies have been discussed previously in this thesis. Fahy et al.'s study (2010) found a higher prevalence of PPH in active management conducted at a tertiary unit, consisting of an obstetric-led unit and an alongside midwife-led unit, compared with expectant management conducted at a freestanding midwife-led unit. This finding was statistically significant. The studies of Laws et al. (2017) and Monk et al. (2014) found a higher prevalence of PPH in the obstetric-led units compared with midwife-led units despite an increased use of active management in the obstetric-led units, compared to an increased use of expectant management in the midwife-led units.

Although Study One found a statistically significant increased risk of PPH for expectant management, it did not find a statistically significant increased risk for severe PPH (blood loss of 1000 mL or more) with expectant management set at the 5% significance level ($\chi^2_{(1)}=2.344, p=0.126$). Study One's findings regarding the incidence of severe PPH are again in line with the findings from the Cochrane Systematic Reviews (Begley et al., 2010; 2011; 2015; 2019). Monk et al.'s (2014) study also did not find a statistically significant finding regarding the incidence of severe PPH in midwife-led units compared to the obstetric-led units. As commented previously, this was despite an increased use of expectant management in the midwife-led units compared with the increased use of active management in the obstetric-led units.

In Study One, however, there was a trend towards a higher incidence of severe PPH in the expectant management group, whilst in the Monk et al. (2014) study there was a trend towards a higher incidence of severe PPH in the obstetric-led units, which had an increased use of active management compared to an increased use of expectant management in the midwife-led units.

In comparison, Kataoka et al.'s (2018) cohort study did find a statistically significant higher incidence of severe PPH with expectant management compared to active management. Conversely, studies by Davis et al. (2012) and Fahy et al. (2010) found that women who had active management had an increased incidence of severe PPH compared with women who received expectant management. These findings were statistically significant in both studies.

In Study One the confounding variables of maternal BMI over 35 kg/m², maternal age 40 years and over, and birthweight over 4 kg had very little effect on the incidence of management approach on PPH or severe PPH and were not significantly associated with them. However, the statistically non-significant finding from Study One and the studies discussed above, regarding severe PPH, may have been due to the inadequacy of the study's small sample size to examine this outcome and/or the rarity of the event. This may particularly be the case in Study One's adjusted analyses where management approach is tested in conjunction with confounding variables, leading to analyses with low events-per-variable ratios. Therefore, a statistically non-significant result in Study One does not necessarily imply that a factor is not important, but merely that there were not enough women in the severe PPH category to draw a conclusion on whether certain factors have an effect on the women or not. The data, however, illustrates the clinical rarity of a severe PPH in women at low risk of PPH who birth at a midwife-led unit.

Furthermore, whilst Study One and the other research studies discussed above have shown there was a statistically significant increase in the incidence of PPH with one third stage of labour management approach compared to the other, these findings are based on a low baseline, and in absolute terms the raised risk of PPH and severe PPH in one third stage of labour approach compared to the other is low. Also, as discussed previously in this thesis, it has been commented that well-nourished, healthy women are able to compensate for a blood loss of up to 1000 mL (Blackburn, 2008; Cunningham & Williams, 2001; Oishi, Tamura & Yamamoto, 2017). As a result, a blood loss up to 1000 mL may be considered physiological in a woman depending on the woman's

physiological response to that loss (World Health Organisation [WHO], 1996). Therefore, the prevalence of PPH up to 1000 mL in women at low risk of PPH with no clinical symptoms of excessive blood loss may be of limited clinical importance. What may be of more clinical importance is the relationship between excessive blood loss, third stage of labour management approach and any treatment needed for this excessive blood loss during the third stage of labour or shortly after birth?

7.1.2. Acceptability of expectant management

As stated previously in the thesis, if, during the third stage of labour, the woman experiences excessive blood loss, the midwife must instigate treatment to reduce this loss. A component of this treatment for excessive blood loss is administration of uterotonic drugs.

Study One found that a higher proportion of women in the expectant management group who experienced a PPH (defined as blood loss of 500 mL or over) needed treatment for this excessive bleeding compared with the women in the active management group who experienced a PPH. This was also a finding in cohort studies by Davis et al. (2012) and Dixon et al. (2013), as well as the Cochrane systematic reviews (Prendiville et al., 2000; Begley et al., 2010; 2011a; 2015; 2019). However, once these women in Study One were converted to active management, or just given the first-line uterotonic drug treatment if the placenta had already been birthed, they were slightly less likely to need further uterotonic drugs to reduce excessive blood loss. This was in comparison to women who initially had an active third stage management and had a PPH. This was also a finding in studies by Davis et al. (2012) and Dixon et al. (2013). However, no inferential statistics were conducted for this outcome in Study One or in the studies of Davis et al. (2012) and Dixon et al. (2013) therefore generalising the results of these studies to a wider population is problematic. However, findings from Study One and the studies by Davis et al. (2012) and Dixon et al. (2013) may suggest that the uterotonic drug may be slightly more effective or equally effective at reducing blood loss if given as a treatment for excessive blood loss rather than to preventive excessive blood loss. (In active management the administration of a prophylactic uterotonic drug

is given to accelerate the contractility of the uterus and to prevent excessive blood loss.)

Study One also found that just over a third of women who had expectant third stage of labour management were converted to active management. This may suggest a lack of satisfaction with expectant management, questioning the acceptability of this third stage approach. However, a finding of Study One was that 38.4% of women chose to have expectant third stage of labour management rather than active management, suggesting that this approach seemed acceptable for them. Numerous other studies have also shown that when women are offered expectant management as a reasonable option, they will choose it (Begley et al., 2011b; Davis et al., 2012; de Jonge et al, 2015; Dixon et al., 2009; 2013; Fahy et al., 2010; Gottvall et al., 2011; Grigg et al., 2017; Kataoka et al., 2018; Laws et al., 2017; Monk et al, 2014; Rogers et al., 1998).

Additionally, Study Two found that midwives thought that for some women, an expectant third stage of labour management approach seemed preferable for them, as these women wanted their birth to be more natural and expectant management facilitated this. Furthermore, a study by conducted Farrah et al. (2010) in the UK found that 2% of obstetricians and 9% of midwives reported that they always or usually used expectant management and 13% of obstetricians and 47% of midwives also reported sometimes using expectant management. Therefore, expectant management is seen as a reasonable option for some practitioners and women.

7.2. Study Two

Study Two, a qualitative study using an interpretivist approach, consisted of six individual semi-structured interviews and follow-up interviews with six midwives. Participants were experienced in active and expectant third stage of labour management approaches and providing care for women during labour and birth at midwife-led units.

7.2.1. Study Two's findings

From the data collected for Study Two I developed four themes, each with two sub-themes, that captured key features of the interviewed midwives' understanding of what they felt shaped, facilitated or constrained their use of active and expectant third stage of labour management approaches; to try to understand what providing third stage management of labour care meant to these midwives. I also tried to understand what was important to them in their decision making, regarding third stage of labour management. Some of these themes and their sub-themes were also evident in other studies exploring midwives' views regarding third stage of labour care. These other studies were identified and discussed in Structured Literature Review Two (Begley et al., 2012; Harding et al., 1989; Jangsten et al., 2010; Noseworthy et al., 2013; Schorn et al., 2015). It was also evident that there were tensions within and between the themes identified in Study Two, as there were in some of the themes generated in the studies identified in Structured Literature Review Two. Therefore, it seems midwives in general may share many similar views regarding what they feel shapes, facilitates or constrains their use of active and expectant third stage of labour management approaches, which they need to consider and balance when providing care for a woman.

7.2.2. How Study Two's findings support other research, as well as advancing research evidence

7.2.2.1. Theme One: 'The Woman', incorporating the sub-themes 'What the woman wanted' and 'Informed choice'

In Study Two midwives regarded the woman, what she wanted and her making an informed choice, as governing factors that affected whether they used an active or expectant third stage of labour management approach. Midwives in qualitative studies by Begley et al. (2012), Jangsten et al. (2010), Noseworthy et al. (2013) and Schorn et al. (2015) and a short questionnaire study conducted by Harding et al. (1989) also identified a woman's preferences as a major factor that influenced their third stage management approach. These studies have been discussed previously in this thesis.

In addition, Study Two also found that the midwives interviewed also felt that, as well as discussing with the woman her third stage of labour management options, it was important to listen to what the woman wanted with regard to her labour and birth. This general discussion regarding her birth was particularly important to these midwives, as they felt that how a woman wanted her labour to unfold would help them to assess what third stage management approach the woman might prefer, if she had not already stated a preference. For example, if the woman was at low risk of PPH and it was felt by the midwife, from her discussion with her or from her behaviour during their interaction that she wanted to labour and birth with minimal intervention, the midwife would recommend an expectant third stage of labour management approach. The midwives felt that this third stage of labour management approach would complement the woman's more natural approach to childbirth. However, if the midwife felt the woman was not interested in birthing her placenta or did not want to birth with minimal intervention, the midwife would recommend an active third stage of labour management approach, as the midwives felt this management approach would reflect the woman's more medical approach to childbirth.

In Study Two it was evident that what the woman wanted and her making an informed choice, regarding her third stage of labour management approach, was central to the midwives' decision making regarding third stage care. However, if the woman had any risk factors for PPH this was also a governing factor, determining how the midwife offered choice to the woman and how she practised as a midwife. Therefore, although participants did not explicitly say so in the interviews, it was implied that if the woman had risk factors for PPH then, although ideally she had a choice regarding her third stage of labour management approach, in reality participants felt that this choice was limited to active management.

Furthermore, midwives in the Study Two were also aware that what a woman wanted regarding third stage of labour management could change at any time. This change would depend on the woman's circumstances and how the woman felt. Midwives in the Noseworthy et al. study (2013) also believed that a

woman's choice regarding third stage management approaches was dependent upon her circumstances and might change with any change in these circumstances.

Some of the midwives interviewed in Study Two also felt that the increased length of time a physiological third stage of labour could take was a major factor influencing women choosing expectant third stage management or continuing with this approach. Midwives in Harding et al.'s (1989) study also thought that the time a physiological third stage of labour takes may be a factor affecting a midwife's use of and a woman's request for expectant management.

Findings from the development of Theme One and its sub-themes add to previous research findings, as they also show the central role of the woman in influencing practice regarding third stage of labour management. However, Study Two also found that understanding 'what the woman wanted' was not just a matter of straightforwardly asking her about what third stage management approach she would prefer. Midwives were carefully monitoring how the woman they cared for responded to discussions about what type of birth she wanted. They would also observe the woman's behaviour in labour and once the baby was born, to assess how interested she was in wanting to labour and birth with minimal intervention. Depending on this assessment, the midwife would then recommend what she thought was the most appropriate third stage of labour approach for the woman. This also seemed to be how the participants in Study Two were managing the tension where women did not express a preference, or were not too concerned regarding their third stage of labour management approach. However, the midwives were strongly of the view that women must have a preference and make a choice, which should be based on their needs. Therefore they tried to understand the woman's unspoken preference in other ways.

7.2.2. 2. Theme Two: 'The midwife', consisting of sub-themes 'Confidence of the midwife' and 'Midwife's ideology of normal birth'.

In Study Two several participants felt that, although midwives valued women's preferences, their ability to respond to these assumed preferences was

constrained by the confidence of the midwife in third stage of labour management approaches. These participants felt that if midwives were confident in conducting both approaches, they would give the woman balanced information regarding these approaches and support the woman in her choice. However, participants were also aware that this was the ideal and, in practice, midwives often lacked confidence in expectant management. Midwives felt that this lack of confidence would result in giving information to the woman that favoured active management.

All the participants in Study Two felt that midwives' confidence regarding third stage management approaches was increased by them understanding how both approaches worked and seeing and practising them on a regular basis in practice. Begley et al.'s (2012) study also highlighted how midwives felt being experienced in conducting expectant management had a positive effect on their third stage of labour care. As discussed previously in this thesis, some of the midwives in Begley et al.'s (2012) study felt that when they initially started conducting expectant management they overestimated blood loss and intervened more often by giving an uterotonic drug. However, when they became more experienced they worried less about blood loss and intervened less often. It is perhaps not surprising then that, as stated previously in this thesis, studies have shown that if midwives are experienced and feel confident in conducting an expectant third stage of labour management approach, blood loss during the third stage of labour or shortly after is reduced (Begley, 1990; Rogers et al., 1998).

Midwives in Study Two also felt that if midwives had a strong ideology of normal birth then they would be more confident in conducting and supporting a physiological third stage, with an expectant third stage management approach. This is because of their belief that a woman could birth her baby physiologically, with minimal intervention, and an expectant third stage of labour management approach supports this belief. Midwives in Noseworthy et al.'s (2013) study also discussed how they felt that their practice philosophies, as well as the woman's beliefs regarding birth, were strong factors that influenced their third stage of labour management.

7.2.2.3. Theme Three: 'Working within an organisation and its sub-themes 'Trust guidelines' and 'Expectations of the organisation'.

Midwives in Study Two felt that working within an organisation influenced their use of third stage management approaches. They felt they were guided, and at times felt pressured, by Trust guidelines and the expectations of their colleagues. All midwives spoke about pressures they felt to follow the Trust's guidelines, which recommended active management for all women. Participants also spoke of the pressure they felt from being judged by their work colleagues. It was evident in the interviews that this pressure was due to the fear of not following the Trust guidelines and there being an adverse outcome as a result. Emphasis on adverse outcomes is reflected in our culture that amplifies risk (Dahlen 2010; 2015). The concept of risk, the belief that it can be controlled and prevented and the effect this has on healthcare, has been discussed previously in this thesis. The Irish midwives in Begley et al.'s (2012) study and the midwives in Jangsten et al.'s (2010) study also discussed how working within an organisation with guidelines recommending an active management approach affected their third stage of labour practice. Midwives in Begley et al.'s (2012) study also identified the pressures midwives felt from other healthcare professionals to conduct active management of the third stage of labour, as active management was recommended in hospital guidelines. This suggests that when midwives' colleagues and practice guidelines do not support them in providing care for women autonomously, they feel vulnerable. If midwives feel vulnerable they are increasingly likely to provide an active management approach, as recommended by Trust guidelines, instead of individualised care.

All the midwives in Study Two discussed managing the tension between supporting women's choices, managing risk and the expectations of the organisation by ideally, providing women with information regarding both third stage management approaches and discussing and recommending why an active management approach might be more suitable for them, if they had any risk factors for PPH. However, the midwives would recommend expectant management for women with no risk factors for PPH who, they felt, wanted a normal physiological labour and birth, as they believed expectant management

was part of a normal birth. Midwives also commented that they would support women who had risk factors for PPH if they made an informed choice to have expectant management, but would be more prepared to intervene if needed. However, the midwives in Study Two were again also hinting that this ideal could not always be maintained due to the pressure they felt to follow Trust guidelines, especially if they had risk factors for PPH.

The findings regarding what midwives in Study Two felt needed to be present in order to recommend to women one third stage of labour approach over another are also highlighted in Begley et al.'s (2012) and Jangsten et al.'s (2010) studies. All the midwives in these studies believed that if the woman had a normal physiological labour and birth, then no intervention during the third stage of labour was necessary, but if the woman had risk factors for PPH they would advise active management. However, if a woman had risk factors for PPH and wanted to have an expectant management approach they would support her choice, but were prepared to intervene quickly if needed. Although midwives in Jangsten et al.'s (2010) study believed that no intervention during the third stage of labour was necessary if the woman had a normal physiological labour, they also discussed how most of them conducted active management of the third stage of labour for all women, because this was hospital policy. However, several midwives in the Jangsten et al.'s (2010) study also discussed basing their third stage of labour management approach on the individual woman's needs rather than hospital policy.

7.2.2.4. Theme Four: 'Changes in childbirth', consisting of sub-themes 'Change in practice' and 'Change in how we as a society view pregnancy and birth'.

It was also evident that changes in how we in the UK and many other countries view pregnancy and childbirth, emphasising a more normal model of childbirth, has influenced many women and midwives views. These changing views have led to changes in practice, reflecting a more normal approach to childbirth.

These changes in practice were also seen by midwives as influencing their use of the active and expectant third stage of labour management approaches.

Midwives in Study Two talked about delayed cord clamping, water births and birthing at a midwife-led unit, and how these promoted normal birth, which

included a physiological third stage. Consequently, this increased the possibility that the woman would opt to have a physiological third stage and, as a result, the number of women having an expectant third stage of labour management approach had increased. However, these changes in childbirth, promoting normal birth for women at low risk of obstetric interventions, are in conflict with international (WHO, 2012; 2018), national (NICE, 2017; RCM, 2018; RCOG, 2016) and local third stage of labour guidelines and recommendations that advise active management of labour for all women. Active management is clearly an intervention that does not support a normal physiological third stage of labour. Therefore, this increased emphasis on normal birth does not appear to have extended to the third stage of labour. It was evident that midwives felt tensions between wanting to promote normal birth, of which they saw expectant management as part, yet working within an organisation and a maternity care culture that supports active management for all women, yet promotes normal birth for women at low risk of obstetric complications..

7.3. Conclusion

The findings from Study One and Study Two add to and build on previous research conducted outside of the UK. Study One, as well as other research studies identified, found a statistically significant increase in the incidence of PPH (defined as blood loss 500 mL or over) with expectant management compared with active management. A statistically non-significant incidence in the relationship between third stage management approaches and incidence of severe PPH (defined as blood loss of more than 1000 mL) was also reported in Study One. Also, more women who received expectant management required treatment for excessive bleeding compared with women who received active management. However, once those women who initially received expectant management were converted to active management or just given the first-line uterotonic drug, they were slightly less likely to need additional treatment for managing continuing PPH, compared with women who received active management and experienced a PPH.

Study One may suggest that the uterotonic drug may be slightly more effective or just as effective in reducing blood loss if given as a treatment for excessive

blood loss rather than to prevent excessive blood loss. This indicates that expectant management is a reasonable option for women at low risk of PPH giving birth at a midwife-led unit by midwives, who are confident and experienced in both third stage of labour management approaches.

Study Two and other research studies found that what the woman wanted regarding her third stage of labour management approach was central to midwives' decision making regarding the woman's third stage of labour care. However, Study Two found that midwives' felt that they needed to ensure that the woman made an informed choice based on her needs. Furthermore, that the woman's needs were assessed by the midwife reviewing her for risk factors for PPH, discussing with her how she wanted her labour and birth to be, and by the woman's behaviour during their interaction. Based on this assessment the midwife would provide the woman with information to make an informed choice. Midwives in Study Two were also aware that if women had risk factors for PPH, in reality their choice regarding third stage of labour approaches was limited. Furthermore, the choice a woman made might also change as the woman's priorities changed.

Study Two as well as other research studies also found that midwives were aware that facilitating the woman to make an informed choice was influenced by the confidence of the midwife in conducting both third stage of labour management approaches, and the midwife's ideology of birth, as well as by the organisation in which the midwife practised. Study Two also found that midwives felt that changes in practice, emphasising a more normal model of childbirth, have helped to support normal birth. This has resulted in an increase in expectant third stage of labour management. However, it is evident that midwives still feel vulnerable when conducting an expectant management approach. This is because third stage of labour guidelines and recommendations still advocate active management for all women, which is within keeping of a more medical model of childbirth.

7. 4. Factors that may have influenced this research project's findings

The questionnaire completed by the midwives (in the exploratory phase of Study One) found that midwives providing care during the time period in which data was collected for the main study, were reasonably confident with both management approaches. However, the midwives did not feel quite as confident in expectant management. This is important, as stated previously in this thesis; studies have shown that if midwives were experienced and felt confident in conducting both third stage of labour management approaches, blood loss during the third stage of labour or shortly after was reduced when using these approaches (Begley, 1990; Begley, 2012; Rogers et al., 1998). Consequently, in Study One the midwives not feeling quite as confident in expectant third stage management, might have contributed to an actual increase in the incidence of PPH, or, the midwives visually over-estimating the blood loss with expectant management. This reduced confidence of midwives in expectant management may have resulted in a documented increase in incidence of PPH. However, in Study One it is unknown to what extent confidence affected their skill in conducting third stage of labour management approaches, and the effect it had on the incidence of PPH or severe PPH.

Blood loss was estimated in Study One by the midwives weighing and/ or visually estimating this blood loss, which, as discussed previously in this thesis, are not accurate methods of assessing this loss. However, in clinical practice blood loss during the third stage of labour or shortly after is commonly measured by, weighing and visual estimation by the healthcare practitioner (Diaz, Abalos & Carroli, 2018). Taking a venous blood sample from the woman to examine haemoglobin concentration (Hb) or conducting spectrophotometry are more precise measurements of blood loss (Diaz, Abalos & Carroli, 2018). However, they are invasive techniques, carrying with them risks for the woman, for example increased risk of infection and discomfort. The increased risks associated with these invasive techniques may be viewed as an unnecessary intervention for women, who are at low risk of PPH and do not have any signs or symptoms of excessive blood loss. Furthermore, spectrophotometry is difficult to perform and is not available in most maternity units.

A formal power calculation was not conducted for Study One, therefore any non- statistically significant result may have been due to the inadequacy of the sample size or the rarity of the event for these women. However, the minimum events-per-variable ratio suggested by Peduzzi et al. (1996) was easily met for all studies, suggesting that the study was adequately powered with respect to all analyses.

Study One consisted of a retrospective cohort study, as discussed previously in this thesis; observational studies can be more susceptible to confounding bias because of non-randomisation of participants (Greenhalgh, 2019). Researchers also have no control over research interventions, reducing the reliability of the study. Additionally, researchers in retrospective cohort studies have no control over the data collected and used in the study (Greenhalgh, 2019), reducing the reliability and validity of these research studies and the generalisability of their findings. However, Study One instigated activities to increase the reliability, validity and generalisability of the study.

Study Two consisted of a small study sample and as a result I did not know whether, if I interviewed more midwives with similar experiences, then further ideas would have been presented. However, as discussed in this thesis, I purposively chose this sample of midwives because I believed they had the experience and skill that I was interested in exploring. I also believed these midwives would be able to articulate their understanding in an interview situation. Furthermore, after the follow-up interviews were conducted I felt data saturation had occurred in those interviews and that I had explored thoroughly the midwives' understandings.

In Study Two I was also known to the study participants and this could have influenced the participants' responses in the interviews, although perhaps the participants saw me as an equal and were more open with me as a result. Additionally, as well as a postgraduate researcher I am also a practising midwife who works at midwife-led units, consequently my prior views and experience as a midwife could also have negatively influenced Study Two's

findings. However, as discussed previously in this thesis, I instigated activities to reduce these issues.

This research project, consisting of two studies, was conducted by one part-time postgraduate researcher supported by her research supervisors, therefore there were limited resources regarding time and money.

7.5. Further research

Further research studies could be conducted similar to Study One at other midwife-led units, to investigate this area of maternity care further and add to the body of evidence. As commented previously in this thesis, studies informing international and national third stage of labour practice guidelines and recommendations are mainly of low quality. They were also conducted in obstetric-led units. Hence these studies probably cannot be generalised to midwife-led units, therefore further studies are needed. Study One, as well as other research studies, also found that expectant management was a reasonable option for women at low risk of PPH. Study One found that an expectant third stage of labour management approach was the intended third stage of labour management approach for 38.4% of the women, even though active management of the third stage of labour was recommended by international, national and Study One's hospital guidelines. Midwives in Study Two and other research studies also felt that expectant management was a desirable option for some women. Therefore further studies into this area of maternity care are necessary.

Further studies could be conducted to examine active and expectant management, investigating the outcomes of blood loss and clinical symptoms experienced by the women due to this blood loss, during the third stage of labour or shortly after. Investigating this outcome would be more beneficial than just blood loss for women at low risk of PPH. This is because well-nourished, healthy women are able to compensate for a blood loss of up to 1000 mL (Blackburn, 2008; Cunningham & Williams, 2001). As a result, a blood loss up to 1000 mL may be considered physiological in a woman depending on her

physiological response to that loss (WHO, 1996). Also as stated previously in this thesis blood loss during the third stage of labour is difficult to assess. Hence, it would be more beneficial to monitor clinical symptoms and as well as blood loss, because if the woman is asymptomatic and her blood loss is less than 1000 mL, it would suggest that she has compensated for this loss and may not need any intervention.

Further studies could consist of prospective studies that examine the relationship between active and expectant management and blood loss, during the third stage of labour or shortly after. Prospective studies would enable the researcher to have more control over the data used for the study. Therefore, the researcher could request the data needed for the study and missing data could be minimised (Hackshaw, 2015), increasing the validity and reliability of the study and reducing bias in these types of studies (Greenhalgh, 2019).

Other studies could be conducted comparing the relationship between active management and the group of women who intended to have expectant management but were converted to active management, and the incidence of and treatment for PPH. This is important as discussed previously in this thesis; Study One and other research studies found that although more women who received expectant management needed treatment for excessive bleeding compared with women who received active management, once these women who received expectant management were converted to active management, or just given the first-line uterotonic drug, they were slightly less likely to need additional treatment for managing continuing PPH. This was in comparison to women who received active management and experienced a PPH. This may suggest that the uterotonic drug may be slightly more effective than, or just as effective at reducing blood loss, if given as a treatment for excessive blood loss rather than to prevent excessive blood loss.

Further studies should be conducted to examine identified risk factors for PPH with the use of an expectant and active third stage of labour management approaches. This is important as Study One found that the identified risk factors of maternal BMI (categorised as BMI of 35 kg /m² or above and BMI up to 35

kg/m²); maternal age (categorised as aged over 40 years and aged up to 40 years); and baby's birthweight (categorised as over 4.0 kg and 4.0 kg or under) had minimal effect on the incidence of PPH or severe PPH.

Findings from Study Two, as well as other research studies, indicated tensions between midwives, who value a woman's choice regarding her third stage of labour management approach, and providing care for women who do not have a preference or want to be told what to do. Tensions were also evident in Study Two between midwives adhering to their natural birth ideology, working with women who have a more functional approach to birth and midwives working within risk-averse maternity services. Further exploration of these tension would be interesting to try to gain a fuller understanding of factors that midwives feel influence their third stage of labour management approaches. This would help to address any possible changes in practice or education, to ensure midwives feel supported to provide women with information to make an informed choice. More studies could be conducted involving interviews with midwives to explore their understanding regarding factors they feel shape, facilitate or constrain their use of third stage management approaches in midwife-led units. Study Two was a small study and interviewing more midwives may lead to more ideas being presented.

A qualitative study could be conducted with women to explore their understanding regarding third stage of labour and management approaches, as Study Two suggested that women may not value the third stage of labour as much as midwives. Additionally, maternity care should be woman-centred, as well as based on the best available evidence; therefore, exploring women's understanding regarding third stage of labour management approaches could help the maternity services in providing care to meet their needs.

7.6. Implications for practice

The results of Study One could be used to decide the sample size needed for future studies in this area; as discussed previously in this thesis, Study One did not conduct a power calculation as Literature Review One did not find any suitable studies to enable one to be conducted.

Findings from Study One add to and expand on other high quality research studies' findings in this area of maternity care and could be used to inform midwives' practice. Midwives would then be able to discuss with the women they provide care for the findings from Study One and the other research studies, enabling women to make an informed choice. As previously discussed in this thesis, practice guidance by NICE (2017) and RCM (2018) recommends that women should be given information on the benefits and harm of both active and expectant management, to support them making an informed choice. This information should be based on research evidence that is valid and generalisable to that woman. Therefore, if a woman is at low risk of PPH and chooses to birth at midwife-led unit the findings from Study One would be generalisable to her. However, we need to acknowledge that not all women want to make a choice and they may choose to accept what the midwife recommends.

The findings from Study Two and other research studies could also be used to discuss with a woman why a midwife might feel she may want to choose one third stage of approach over another, or why one third stage of labour approach might be more suitable for her. This would enable the woman's third stage of labour approach to reflect her individual needs, helping to enhance her birth experience.

Findings from Study One and Two and findings from other studies in this area could be used to provide evidence to inform practice guidelines and recommendations for midwife-led units. Having separate practice guidelines and recommendations for midwife-led units is important, as discussed previously in this thesis and reflected in the findings of research studies including Study One and Two; practices and outcomes during the third stage of labour are influenced by the healthcare professional, the woman they provide care for and the setting they provide care for this woman in. Therefore, the international and national third stage of labour practice guidelines and recommendations (NICE, 2017; RCM, 2018; RCOG, 2016; WHO, 2012; 2018), which are based on research studies of varying quality and conducted in

obstetric-led-units, may not be generalisable to midwives practising in midwife-led units.

Expectant management is supported by the findings of Study One and Two, as well as other research studies, as being a reasonable option for women at low risk of PPH, who want to birth with minimal intervention at a midwife-led unit. Therefore, midwives practising in this setting should be given the opportunity to gain the knowledge and skills to conduct both active and expectant third stage of labour management approaches. Trusts, along with Higher Education institutions, should provide education and study days to facilitate this. Additionally, student midwives should be equally exposed to both third stage management approaches during their training, either in the clinical setting or simulated, so they are confident and skilful in both third stage approaches on qualification. Training could also look at how to support choice for women who do not explicitly express a preference. For example, teaching student midwives the skills to be able to assess a woman's behaviour during their interaction with her and the possible implication of this behaviour with regard to how she might want her labour and birth, including the third stage, to unfold

Maternity services and educational institutions providing undergraduate and postgraduate maternity courses should address the themes and tensions identified in Study Two and other studies, discussed previously in this thesis. This will help to inform practice and education and assist in any change in practice or education, to ensure midwives and student midwives feel supported to provide women with information to make an informed choice regarding their third stage care.

7.7. Conflict of interest

There was no conflict of interests in the conduct of this study by the postgraduate researcher.

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