This page has been left intentionally blank

# University of Southampton

Faculty of Environmental and Life Sciences

School of Health Sciences

**Factors Influencing Midwives' Views and Decisions about Outpatient Induction of Labour with Vaginal Dinoprostone**

by

**Lisa Kïrsten Smith**

BA (Hons), B (Mid), RM

ORCID ID 0000-0003-0724-289X

Thesis for the degree of Doctor of Philosophy

August 2022

# University of Southampton

## Abstract

Faculty of Environmental and Life Sciences

School of Health Sciences

Doctor of Philosophy

Factors Influencing Midwives' Views and Decisions about Outpatient Induction of Labour with Vaginal Dinoprostone

by

Lisa Kïrsten Smith

The research presented in this thesis explores midwives' views and decisions about outpatient induction of labour to avoid prolonged pregnancy using vaginal dinoprostone (prostaglandin $E_2$).

Over 33 per cent of pregnant women underwent induction of labour in England and Wales in 2019/20 – an increase of 60 per cent over the past 10 years. The resultant demands on capacity for inpatient care have led many Trusts to implement outpatient induction of labour (OPIOL). The limited evidence available suggests women are highly satisfied with this approach although others express ambivalence about going home and prefer inpatient management. Staff also influence uptake of any intervention yet there is a dearth of evidence that considers their views and decisions about OPIOL.

Critical realist discourse analysis was used to explore aspects of physical and social reality that mediate midwives' views and decisions about OPIOL within a large teaching hospital in the South of England. Descriptive statistics were used to contextualise OPIOL outcomes within overall induction of labour activity. Semi-structured interviews were then used to explore midwives' views and decisions about OPIOL.

The findings demonstrate that few women had the opportunity to experience OPIOL and women eligible for the intervention were not offered it routinely. While midwives' talk orientated towards choice and personalisation and normalising birth discourses, risk and safety discourses featured heavily in their talk. Midwives sought sanctuary in the safety net of their organisational guideline to determine women's eligibility for outpatient management but remained uneasy about the possibility of uterine hyperstimulation and lack of surveillance at home. Some midwives were also uncertain about how to interpret the significance of earlier assessments for reduced fetal movements in pregnancy even when findings had been normal.

This small, local study contributes to a wider body of literature about risk work tensions in maternity care decision-making. A deeply pernicious fear of adverse outcomes exists amongst staff, and they are rightly cautious when undertaking any risk assessments. Increasing fetal surveillance is seen as a way to provide assurance of fetal wellbeing. The findings of this study provide support for an induction of labour team, to enhance familiarity and confidence around decision-making about OPIOL with vaginal dinoprostone. Midwives may also benefit from additional multiprofessional support when making decisions. Alternatively, catheter balloon induction may be preferable to staff as the risk of uterine hyperstimulation is minimised.

# Table of Contents

# Table of Tables

# Table of Figures

# Research Thesis: Declaration of Authorship

Print name: Lisa Smith

Title of thesis: Factors Influencing Midwives' Views and Decisions about Outpatient Induction of Labour with Vaginal Dinoprostone

I declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;

Signature: ..... Date:.....

# Acknowledgements

I would like to thank a number of people for supporting me to complete this research. Firstly, I am forever indebted to my supervisors Dr Ellen Kitson-Reynolds, Prof Julie Cullen and Dr Elizabeth Cluett. Thank you for your expertise, enthusiasm and encouragement over the past 5 years. Your support has been invaluable in sustaining the self-belief and motivation I needed to realise this project. Your coaching helped me refine my research question, milestones have been realistic and achievable and your comments have been incredibly insightful.

I would also like to thank Jane Rogers for her mentorship and encouraging me to apply for the Consultant Midwife Trainee programme. This is a three-year programme and supports midwives in Wessex to undertake a number of placements to develop clinical expertise, as well as research, quality improvement and leadership skills. I would also like to thank Health Education England for funding this programme and for making a very significant contribution to my university fees. I had other clinical mentors during the programme and I would like to thank them too: Clara Haken, Suzanne Cunningham and Hannah Leonard. They understood the demands of the programme and respected the time commitment to the PhD.

I would also like to thank my friends and family for being so understanding about the time commitment involved in completing this project. You have all provided snippets of respite and distraction when needed and given me lots of motivation to stick with it. We have shared many delicious meals, countryside walks and parkruns over the past 5 years and all these things have enabled me to return to my laptop refreshed and energised.

Finally, I want to thank my children Alia and Ronin who have become adults while I've completed this research. Not only are you wonderfully grounded and fantastic company, but your ceaseless commitment to GCSE and further education deadlines have inspired and motivated me, and you have shared brilliant study tips that have been exceptionally helpful.

# Definitions and Abbreviations

Amniotomy (ARM) ..... Colloquially known as ‘breaking the waters’, this procedure may be offered to women in a number of different clinical circumstances. A midwife or doctor uses a small hook to artificially rupture the membranes around the fetus during a vaginal examination. In the context of induction of labour, amniotomy may lead to initiation of contractions (National Collaborating Centre for Women's and Children's Health, 2008).

Augmentation of labour..... Augmentation may be used to treat delay in labour if there are poor uterine contractions. The process involves similar procedures to induction of labour such as amniotomy and an oxytocin infusion in order to increase the frequency, duration and strength of contractions (World Health Organisation, 2014).

BBA..... Born before arrival. Used to describe a birth which occurs before the arrival of a midwife or doctor. This may occur unexpectedly at home or en route to a birth centre or hospital.

Bishop score..... A measure of cervical readiness prior to onset of labour. Calculated by assessment of cervical dilatation, length, consistency and position, as well as station (position) of the fetal head in relation to the ischial spines (National Collaborating Centre for Women's and Children's Health, 2008). The calculation of the Bishop score is described in Appendix I

Cardiotocography (CTG)..... Cardiotocography is a screening tool which can enable midwives and doctors to monitor fetal wellbeing and identify signs of hypoxia. An ultrasound transducer is applied to the woman’s abdomen to record the fetal heartbeat and another device is applied to monitor the frequency of contractions. Alternatively, a fetal scalp electrode may be attached to the fetal head to improve the quality of the recording. Many NHS Trusts use NICE guidance to interpret intrapartum recordings although guidance is also available from the International Federation of Gynecology and Obstetrics (FIGO) (National Institute for Health and Care Excellence, 2014b; Ayres-de-Campos *et al.*, 2015). Intrapartum recordings can be categorised as normal,

suspicious or pathological, and concerns about fetal wellbeing may prompt further interventions such as caesarean birth or assisted vaginal birth (National Collaborating Centre for Women's and Children's Health, 2008). Prior to the onset of contractions, computerised cardiotocography may be offered to women with additional risk factors such as prolonged pregnancy, antepartum haemorrhage or severe hypertension. It enables automated evaluation of the recording and is associated with a significant reduction in perinatal mortality (Grivell *et al.*, 2015). Clinicians are advised never to rely on cardiotocography alone when making an assessment about fetal wellbeing.

Cervical ripening/priming .... An artificial process to stimulate the softening, effacement (shortening) and dilatation of a woman's cervix. This can include membrane sweeping or stripping, pharmacological or mechanical methods. The term is frequently used interchangeably with induction of labour. The World Health Organisation considers cervical ripening as a discrete phase within its induction guidance whereas NICE guidance describes this phase at the commencement of the induction of labour process (World Health Organisation, 2011; National Institute for Health and Care Excellence, 2021).

CRDA ..... Critical Realist Discourse Analysis

ECF ..... Extreme case formulation. Often used to justify criticism and simultaneously bolster the speaker's position or argument (Potter and Wetherell, 1987; Edwards, 2000; Wiggins, 2017)

Induction of labour (IOL) ..... The World Health Organisation defines induction of labour as a process to artificially stimulate the uterus to initiate labour (World Health Organisation, 2011). This includes pharmacological, mechanical or surgical methods to stimulate the onset of uterine contractions.

Membrane sweep/stripping A vaginal examination offered to women in which a doctor or midwife will 'sweep' a finger in a circular motion around the cervix to separate the fetal membranes from the cervix. This procedure releases prostaglandins which can soften and dilate the cervix and may lead to onset of contractions, reducing the need for formal

induction of labour (National Collaborating Centre for Women's and Children's Health, 2008; Finucane *et al.*, 2020).

MVP..... Maternity Voices Partnership. Following publication of the Better Births report, clinical commissioning groups are required to employ a lay person chair to engage women and families to co-produce maternity services (NHS England, 2017c).

NHS……National Health Service

NHSR ..... NHS Resolution

NICE..... National Institute of Health and Care Excellence

NMC ..... Nursing and Midwifery Council

ONS ..... Office for National Statistics

OPIOL ..... Outpatient Induction of Labour

OPRA ..... **O**utpatient **Pr**iming for Induction of L**a**bour randomised controlled trial (Wilkinson *et al.*, 2015).

PET ..... Pre-eclampsia

$PGE_2$..... Prostaglandin $E_2$ – also known by its generic drug name dinoprostone.

PMA..... Professional Midwifery Advocate. An employer-led model of clinical supervision. Nationally recognised non-statutory role in restorative supervision, education, training and quality improvement (NHS England, 2017a)

RCM..... Royal College of Midwives

RCOG ..... Royal College of Obstetricians and Gynaecologists

RCT ..... Randomised Controlled Trial

SROM ..... Spontaneous rupture of membranes

This page has been left intentionally blank

# Chapter 1 Research introduction

## 1.1 Introduction

I aim to make an original contribution to the understanding of midwives' views and decisions about outpatient induction of labour using vaginal dinoprostone[1]. This chapter provides the background and rationale for the research study and describes the structure of the thesis layout.

## 1.2 Background to the research study

Induction of labour is a procedure to initiate cervical dilatation and onset of contractions in order to expedite birth when there is a risk to the mother or baby of remaining pregnant (National Collaborating Centre for Women's and Children's Health, 2008). For women and birthing people with uncomplicated pregnancies, systematic review evidence comparing induction from 37 weeks of pregnancy to expectant management demonstrates a reduction in perinatal death, a decrease in the likelihood of caesarean birth and little or no difference in the likelihood of assisted vaginal birth (Middleton *et al.*, 2020). National guidance recommends a policy of induction of labour from 41 weeks to avoid prolonged pregnancy although induction may be recommended earlier if other complications arise (National Institute for Health and Care Excellence, 2021).

Over 33 per cent of pregnant women underwent induction of labour in England and Wales in 2019/20, an increase of 60 per cent over the past 10 years (NHS Digital, 2020). This increase reflects additional fetal surveillance and policy drivers to halve stillbirth and brain injuries by 2025 (NHS England, 2016; Royal College of Obstetricians and Gynaecologists, 2017; Norman *et al.*, 2018; Widdows *et al.*, 2018). These changes have been associated with a fall in the stillbirth rate in England and Wales from 5.1 to 3.8 per 1000 live births between 2010 and 2020 (Office for National Statistics, 2021b).

Pharmacological, mechanical and surgical methods may be used to induce labour. Vaginal dinoprostone gel, tablets and pessaries are commonly used pharmacological agents (World Health Organisation, 2011). With a woman's consent, the process involves cervical assessment and administration of the product into the posterior fornix of the vagina (Figure 1-1). Alternatively, use of low-dose oral misoprostol (25mcg) is supported by national guidance, having been licensed for use as part of induction of labour in the UK in 2021 (National Institute for Health

[1] also known as also known as prostaglandin $E_2$

and Care Excellence, 2021; NHS Specialist Pharmacy Service, 2021). While pharmacological preparations are recommended by national guidance, a possible side effect is hyperstimulation of the uterus which is associated with changes in fetal heart rate pattern, uterine rupture and fetal hypoxia (National Institute for Health and Care Excellence, 2021).

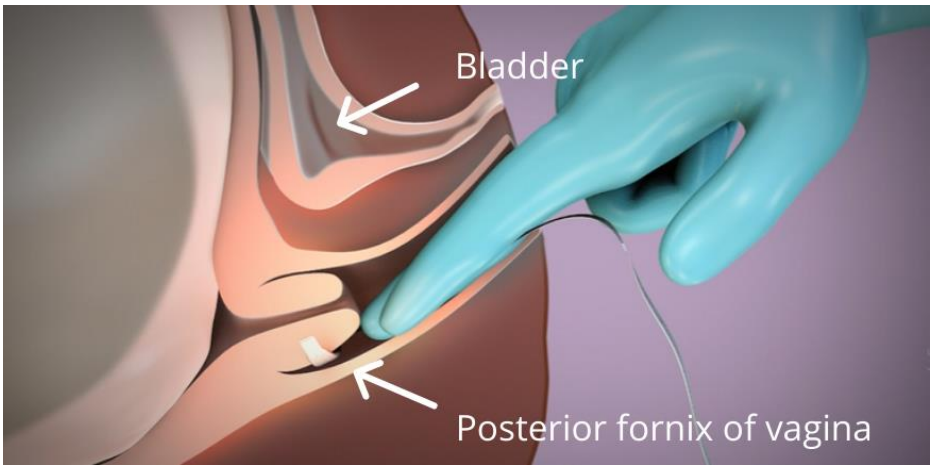



Figure 1-1: Administration of dinoprostone pessary into the posterior fornix of the vagina (Toronto Video Atlas of Surgery, 2019)

Mechanical methods such as balloon catheters and osmotic cervical dilators may also be used to induce labour. These devices are associated with a lower likelihood of uterine hyperstimulation and are recommended where pharmacological methods are unsuitable (for example, after previous caesarean birth or woman's preference) (National Institute for Health and Care Excellence, 2021). Balloon catheters are inserted through the woman's cervix into the extra-amniotic space and inflated with water to stretch the cervix. Osmotic cervical dilators are inserted into the cervix and swell as they absorb water, thereby stretching the cervix (de Vaan *et al.*, 2019).

Amniotomy is a surgical method of induction of labour and may be offered to women once the cervix has started to soften and dilate (National Collaborating Centre for Women's and Children's Health, 2008). The procedure involves a midwife or doctor passing a small hook through the cervix to rupture the membranes around the fetus. An oxytocin infusion is typically offered in addition to amniotomy and when used together, this is considered the most effective way to induce labour overall (National Institute for Health and Care Excellence, 2021).

Women undergoing induction of labour frequently report poor experiences, lack of information and autonomy, poor support, long delays and greater pain relief requirements (Reid *et al.*, 2011; Murtagh and Folan, 2014; O'Dwyer *et al.*, 2015; Schwarz *et al.*, 2016; Jay, Thomas and Brooks, 2018; Coates *et al.*, 2019). It is also widely recognised that induction activity increases the workload on busy labour wards and cost the NHS an additional £600 per induction compared to

labours that start spontaneously (Carroll *et al.*, 2016; Widdows *et al.*, 2018; NHS England, 2021; Robertson *et al.*, 2021). Outpatient induction of labour (OPIOL) has the potential to reduce bed occupancy costs to services and offers women an alternative to inpatient induction although there is little evidence available to guide practice (Alfirevic *et al.*, 2020).

With rising numbers of women being offered induction of labour, OPIOL has become an attractive option for trusts. In a survey of 164 UK NHS Trusts by Sharp, Stock and Alfirevic (2016), around 19 per cent had introduced outpatient management, or were planning to do so. Despite adverse events being rare, some clinicians are sceptical about using vaginal dinoprostone for OPIOL (Henry *et al.*, 2013) and how women should be monitored once they go home (Rauf *et al.*, 2011; Sharp, Stock and Alfirevic, 2016). There is evidence that NHS Trusts undertake appropriate risk assessment and stratification prior to making a decision to discharge women and those at high risk of complications are not offered OPIOL (Sharp, Stock and Alfirevic, 2016).

## 1.3 Rationale for research

At the outset of this thesis, it is appropriate to describe my motivation to undertake research about OPIOL. As part of my professional development as a consultant midwife trainee in 2015, I had an opportunity to develop a research proposal and OPIOL had recently been implemented in the NHS Trust where I was employed. Available evidence indicates women's satisfaction with OPIOL is high, yet there is a dearth of qualitative research about women's and staff views and experiences of OPIOL.

## 1.4 Research aims and objectives

Agee (2009) recommends starting with a broad, overarching research question which will guide study design and satisfy ethical review committees and can accommodate new questions as the project takes shape, and so my initial intention was to explore women's and staff views and experiences of OPIOL with vaginal dinoprostone. Due to the iterative and inductive nature of qualitative research, refinement of research questions is not unusual, and authors offer reassurance for novices (Agee, 2009; Thomas and Hodges, 2010; Wiggins, 2017). As my research progressed, it became evident that few women had the opportunity to undergo outpatient management and so I decided I would add further to the body of knowledge with a focus on midwives' views and decisions about OPIOL with vaginal dinoprostone. I was also keen to understand how midwives justified their decisions and managed their professional credibility and accountability. My research aims and objectives are described in Table 1-1.

Table 1-1: Aims and objectives

| **Research question** | |
|---|---|
| Factors influencing midwives' views and decisions about outpatient induction of labour (OPIOL) with vaginal dinoprostone. | |
| **Research aims** | **Research objectives** |
| 1. Investigate indications for induction of labour in a tertiary hospital | To contextualise OPIOL activity within overall induction of labour activity over the study period |
| 2. Describe the characteristics of women eligible for OPIOL | To summarise demographic characteristics of women at eligible for OPIOL |
| 3. Describe outcomes of women eligible for OPIOL | To determine outcomes of women eligible for OPIOL and what happened to them following admission to hospital for their initial induction of labour assessment |
| 4. To explore women's views and experiences of OPIOL | To identify factors that influence women's preferences for OPIOL or inpatient management |
| 5. To explore midwives' views and experiences of OPIOL | To identify factors that influence midwives' decision-making and preferences for OPIOL or inpatient management |

## 1.5 Outline of the thesis

In Chapter 2, I describe the systematic approach adopted to identify existing literature about women's and staff views of OPIOL. I then present and summarise the key findings and explain how these informed my research approach. Chapter 3 outlines in detail the critical realist methodology adopted for this research and quantitative and qualitative methods. I also discuss access to the study site, ethical considerations and potential conflicts of interest given my role as a Consultant Midwife at the NHS Trust where the research was undertaken. In chapter 4, I present the quantitative findings; I provide data about overall induction of labour activity as well as outcomes of women who were eligible for OPIOL. In chapter 5, I present the qualitative findings and identify factors influencing participant talk about OPIOL. I discuss the principal findings in

chapter 6 and how they relate to the wider literature and contemporary UK maternity strategy. Chapter 7 summarises the strengths and limitations of my research while in chapter 8, I reflect on the implications for practice and the contribution made to the midwifery body of knowledge in terms of both midwifery practice and research. In the final chapter, I present a summary of my findings and present recommendations for maternity services and policy makers and consider future topics for further research.

This page has been left intentionally blank

# Chapter 2 Literature review

## 2.1 Introduction

The purpose of this chapter is to explore, describe and critically analyse the current research evidence base related to the views and experiences of women and staff of OPIOL using vaginal dinoprostone. I describe the systematic literature search process and present the findings and their applicability to my area of research. A narrative synthesis approach was used to describe and critically analyse the outcome data (Booth, Papaioannou and Sutton, 2016). Finally, this chapter identifies gaps in the literature and justifies the aim and objectives of my research.

## 2.2 Systematic literature review method

### 2.2.1 Systematic search method

A systematic search was conducted to retrieve evidence about women's and staff views and experiences of OPIOL. A research protocol was developed and was based on a pre-existing template by Booth, Papaioannou and Sutton (2016) (Appendix II). A research protocol should include a clearly defined scope and one of the simplest frameworks available is PICO which enables researchers to describe the population, intervention, comparison group and outcomes of interest (Bettany-Saltikov and McSherry, 2016). It also provides a clear audit trail to enhance replicability (Booth, Papaioannou and Sutton, 2016).

The protocol enabled me to focus on women with healthy pregnancies as this is the cohort eligible for OPIOL in my research setting. I included studies that examined the use of vaginal dinoprostone rather than other methods of induction of labour such as misoprostol and balloon catheters as these were not used in my research setting. In terms of outcomes, I was specifically interested in research about women's and staff views of OPIOL to gain an understanding of influencing factors. The presence of a comparison group was not significant as I wanted to retrieve any research about OPIOL whether there was an inpatient comparison group or not.

My protocol also described the literature selection process, data extraction and quality assessment of the evidence. For example, I selected primary research (e.g., randomised controlled trials, cohort studies, questionnaires and qualitative studies) and I excluded published extracts and conference posters as I anticipated that methods and findings would be described in insufficient detail. I selected papers published in the English language to avoid interpreter costs. Health sciences databases Cumulative Index of Nursing and Allied Health Literature (CINAHL),

Embase, Medline, Scopus and Web of Science were searched using keywords and relevant subject headings. Search criteria were identified and refined using an iterative pearl-growing technique (Booth, Papaioannou and Sutton, 2016). Keywords included:

- Variants of the drug used for the intervention, for example 'prostaglandin', 'dinoprostone', '$PGE_2$', 'Prostin' and 'Propess';
- Different terms for the intervention, for example 'induction of labour', 'cervical priming', 'cervical ripening', the intervention setting such as 'outpatient', 'ambulatory', 'home'; and
- Experiential outcome keywords such as 'views', 'experiences' and 'attitudes'.

Boolean operators AND and OR were used to help combine the drug name, intervention, intervention setting and experiential outcomes. Selected electronic databases are listed in **Error! Reference source not found.**and database searches are included in Appendix IV. To avoid publication bias, a grey literature search was also conducted (Appendix V) (Booth, Papaioannou and Sutton, 2016).

Retrieved studies were imported into a bibliographic database, which was used to remove duplicate records. The bibliographic database search tool was then used to identify irrelevant papers not related to induction of labour of a live pregnancy at term gestation. This enabled me to identify and exclude titles relating to hysteroscopy, intrauterine device insertion, pregnancy loss and non-human studies. Of the remaining papers, abstracts were then retrieved to establish whether studies met the pre-defined inclusion criteria. Primary research was included, while letters, editorials, conference posters and abstracts were also excluded. Full papers were then retrieved for further evaluation and quality assessment. Reference and citation searching was also undertaken to identify further relevant studies (Centre for Reviews and Dissemination, 2009; Booth, Papaioannou and Sutton, 2016) (Appendix VI and Appendix VII). Figure 2-1 provides a summary of the literature search strategy using a standardised PRISMA flow chart (Booth et al. 2016). Search alerts were created to ensure relevant articles published after October 2018 were retrieved for review and the literature search was repeated in its entirety in August 2021.

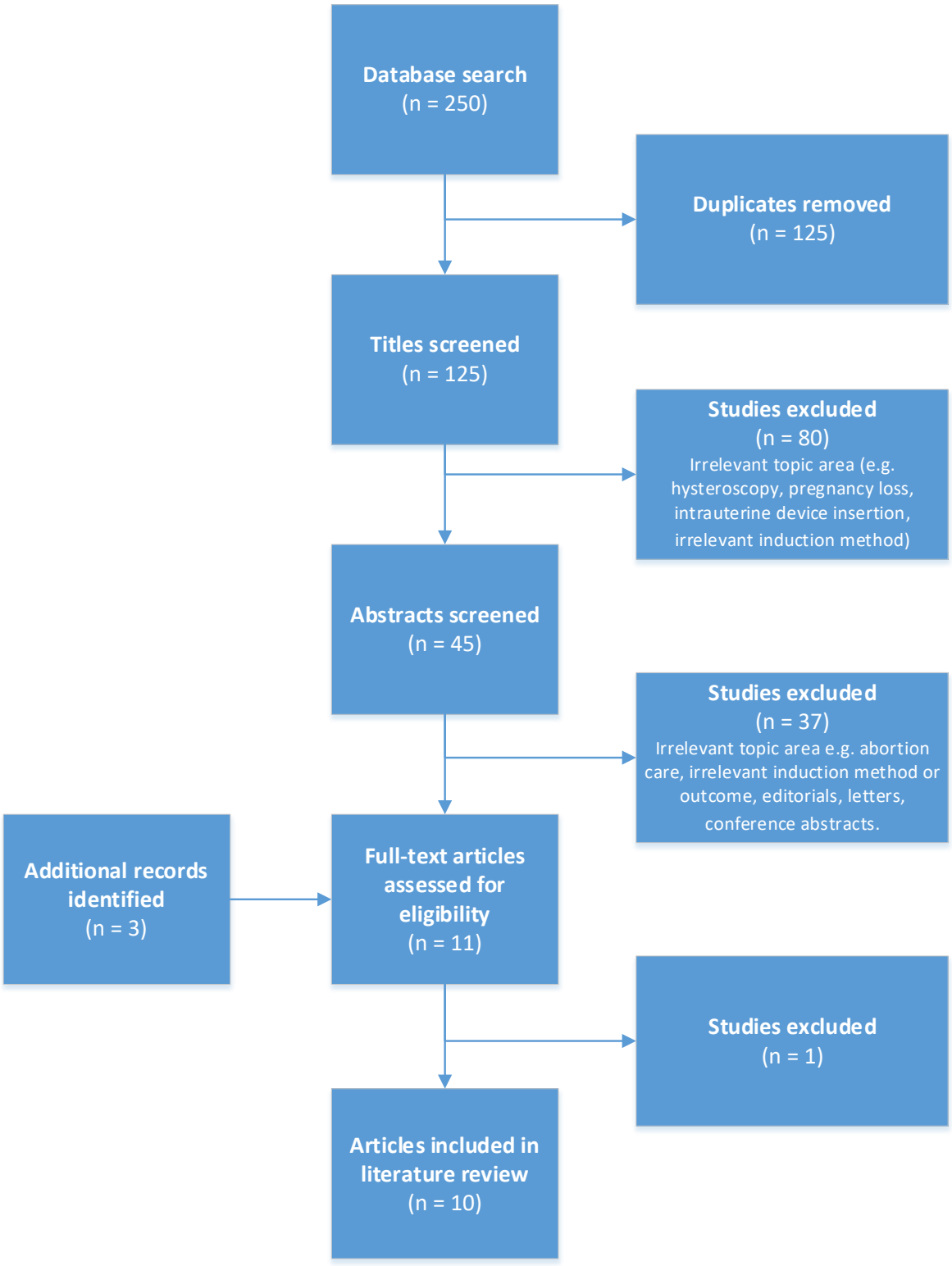



Figure 2-1: PRISMA flow diagram of study search selection process (Booth, Papaioannou et al. 2016)

### 2.2.2 Quality assessment

Full papers were then quality assessed using Critical Appraisal Skills Programme (CASP) and Best Evidence Topics tools and are included in Appendix VIII and Appendix IX (Critical Appraisal Skills

Programme, 2013; Booth, Papaioannou and Sutton, 2016; Best Evidence Topics, 2018). The tools I chose differed depending on the research design. For example, the randomised controlled trial checklist included questions about concealment and blinding, whereas the survey checklist included a question about response rate. All of the tools prompted consideration of strengths and weaknesses of the studies, and this helped me determine whether I could feel confident in the findings and informed my synthesis of the evidence.

### 2.2.3 Data extraction and synthesis

Due to the heterogeneity of the included studies, a narrative synthesis of the findings was conducted (Arai *et al.*, 2007; Booth, Papaioannou and Sutton, 2016). A narrative synthesis is a descriptive review of the characteristics and outcomes of the research evidence which can be used when methods are substantially different from one another, thereby making meta-analysis unfeasible (Arai *et al.*, 2007; Booth, Papaioannou and Sutton, 2016). Narrative synthesis may include tables to support textual descriptions of the studies themselves (e.g., study location, population, methods and main findings). Reviewers can explore the evidence further by grouping themes together or by drawing conceptual maps (Arai *et al.*, 2007). In my synthesis of the evidence, I present textual descriptions of the literature. I consider research location and applicability to the United Kingdom, methodological approach, outcome measures and themes. In my narrative, I highlight areas of weak evidence or where methods or interpretation were unclear.

## 2.3 General description of the literature

The final ten studies included in the literature review are included in Table 2-1. The table provides a summary of location, included participants and the main findings.

Table 2-1: Summary of included studies about women's and staff views and experiences of OPIOL using vaginal dinoprostone

| Study | Participants | Location | Summary of design |
|---|---|---|---|
| Awartani, Turnell and Olatunbosun (1999) | 50 OPIOL<br><br>50 inpatient | Saskatoon, Canada | A prospective non-randomised study using vaginal dinoprostone gel. Compared outcomes, duration of hospital stay and maternal satisfaction. |
| Biem *et al.* (2003) | 300 participants randomised | Saskatoon, Canada | A randomised controlled trial (RCT) using a vaginal controlled release dinoprostone pessary. Compared birth outcomes, duration of hospital stay, time avoided in hospital for outpatient group and maternal satisfaction. |
| Coates *et al.* (2021) | 21 PROBIT-F participants<br><br>(14 received dinoprostone pessary; 7 received balloon catheter) | Southeast England, UK | Qualitative study comparing women's experiences of OPIOL with vaginal dinoprostone pessary compared to double balloon catheter using semi-structured interviews and thematic analysis. Women who had taken part in a wider feasibility trial[2] were recruited to interview. |
| Howard *et al.* (2014) | 362 participants | Adelaide, Australia | A discrete choice experiment to determine women's preferences around setting for induction of labour. Sibling study to Wilkinson *et al.* (2015) **O**utpatient **Pr**iming for Induction of L**a**bour (OPRA) randomised controlled trial |

[2] PROBIT-F randomised controlled trial comparing outpatient induction of labour with dinoprostone pessary versus balloon catheter by Bhide, A. *et al.* (2020) 'Prostaglandin insert dinoprostone versus trans-cervical balloon catheter for outpatient labour induction: a randomised controlled trial of feasibility (PROBIT-F)', *Pilot Feasibility Studies*, 6, DOI: https://doi.org/10.1186/s40814-020-00661-7.

| Study | Participants | Location | Summary of design |
|---|---|---|---|
| | | | and included 260 of its participants and an additional 102 pregnant volunteers. |
| O'Brien *et al.* (2013) | 15 participants | Liverpool, UK | Qualitative study of women's experiences of OPIOL with vaginal dinoprostone pessary and remote fetal monitoring using semi-structured interviews and thematic analysis. Sibling study to Rauf *et al.* (2011). |
| Oster *et al.* (2011) | 16 OPRA participants | Adelaide, Australia | Qualitative study of women's experiences of inpatient and OPIOL using semi-structured interviews and thematic analysis. Sibling study to OPRA trial in which vaginal dinoprostone gel was used. |
| Rauf *et al.* (2011) | 70 participants undergoing OPIOL | Liverpool, UK | Feasibility of OPIOL with vaginal dinoprostone pessary and remote fetal monitoring which also included evaluation of women's views. Data collected using semi-structured, self-report diary which was completed at least 2-hourly. 51 completed diaries collected. Sibling study to O'Brien *et al.* (2013). |
| Sutton, Harding and Griffin (2016) | 57 participants undergoing inpatient IOL | Subiaco, Australia | Prospective questionnaire of women's attitudes and opinions towards outpatient induction of labour with single balloon catheter and/or vaginal dinoprostone. Completed prior to commencement of inpatient induction process, after cervical ripening but before ongoing induction, and after birth but prior to discharge from hospital. |
| Turnbull *et al.* (2013a) | 819 OPRA participants | Adelaide, Australia | Questionnaires to measure women's anxiety and depression at enrolment to OPRA trial and |

| Study | Participants | Location | Summary of design |
|---|---|---|---|
| | | | postpartum questionnaire to measure satisfaction, experiences, depression and infant feeding 7 weeks after giving birth. Sibling study to OPRA trial. |
| Turnbull *et al.* (2013b) | 208 midwives | Adelaide, Australia | Quasi-experimental cross-sectional study to assess impact of OPIOL on midwives in terms of work autonomy, job demands and job satisfaction. Sibling study to OPRA trial. Questionnaire completed two weeks prior commencement of OPRA RCT and two years later, near the end of the trial. |

### 2.3.1 Country of origin

Of the ten studies retrieved, five were conducted in Australia. Of these five, four related to the OPRA RCT which compared outcomes of women undergoing OPIOL with vaginal dinoprostone gel versus inpatient management. Two of the studies were conducted in Canada and three in the UK, two of which were by the same research group.

It can be problematic to generalise findings from other countries where funding models differ and maternity care is generally more medicalised (Benoit *et al.*, 2010). In addition, the training, responsibilities and accountabilities of maternity professionals varies across the globe. For instance, in Australia, most women give birth within obstetric units, care is largely led by obstetricians, and 30 per cent of births take place within the private sector. In Canada, most women are cared for by obstetricians, family physicians and obstetric nurses, although maternity care is paid for by provincial insurers funded via taxation. In contrast, care is generally led by midwives or shared with obstetricians in the UK and there has been a drive to further expand alongside and freestanding birth centres in line with evidence of positive outcomes associated with midwife-led continuity of care models (National Maternity Review, 2016; Sandall *et al.*, 2016; Sandall *et al.*, 2016b; NMPA Project Team, 2017).

Regarding the intervention of induction of labour specifically, as in Canada and Australia, this is typically undertaken in obstetric led units in the UK (National Institute for Health and Care Excellence, 2014b). In contrast, counselling and appointment bookings for induction of labour

amongst healthy women with prolonged pregnancies is typically undertaken by midwives in the UK. There is evidence that clinical behaviour and discourse around birth between midwives and women is increasingly risk-averse in the UK and that while midwives may outwardly promote a normal birth philosophy, this is not played out in reality (Scamell and Alaszewski, 2012; Healy, Humphreys and Kennedy, 2016). This evidence suggests an increasingly medicalised model of maternity care in the UK and so I considered that evidence from Australia and Canada about women and staff experiences of OPIOL would be generalisable within the UK.

### 2.3.2 Methodology

Six of the ten studies used a quantitative methodology to explore outcomes such as satisfaction, acceptability and preferences about OPIOL. Three were experimental in design including a randomised controlled trial (Biem *et al.*, 2003) and a prospective non-randomised trial (Awartani, Turnell and Olatunbosun, 1999) which compared women's satisfaction between OPIOL and inpatient management amongst other outcomes. Howard *et al.* (2014) used a discrete choice experiment to determine women's preferences in terms of journey time to hospital, the number of trips required as well as preferred location and whether this varied depending on the facilities available. The remaining three studies were observational in nature using a survey design through the administration of questionnaires (Turnbull *et al.*, 2013a; Turnbull *et al.*, 2013b; Sutton, Harding and Griffin, 2016). Turnbull *et al.* (2013a) and Sutton, Harding and Griffin (2016) used questionnaires to determine acceptability to women of OPIOL versus inpatient management. Turnbull et al (2013b) used a questionnaire design to determine whether OPIOL had an impact on midwives' workload, stress and job satisfaction.

Two of the ten studies used a qualitative methodology. Oster *et al.* (2011) used purposive sampling amongst OPRA participants to select 16 women from different demographic backgrounds in order to obtain diverse insights (Hunt and Lathlean, 2015). Semi-structured interviews were conducted to capture rich data about both inpatient and OPIOL experiences (Tod, 2015). The interviews were then transcribed, read and re-read to identify initial ideas or codes about the data which were then grouped into overarching themes (Braun and Clarke, 2006). The interviews were conducted between seven weeks and four months after birth which may have introduced recall bias. However, appropriate methods were used to achieve data saturation and identity themes (Lathlean, 2015). Coates *et al.* (2021) recruited 21 women from a feasibility trial comparing OPIOL with dinoprostone pessary versus balloon catheter. Semi-structured interviews were conducted between six weeks and approximately three months after birth. The interviews were transcribed and then coded using an existing conceptual framework developed through systematic review of the existing literature. New descriptive codes were generated where

relevant. Coates *et al.* (2021) noted no new themes were identified in the final interviews and tentatively suggest data saturation was reached although Braun and Clarke (2019) argue saturation is difficult to assess rigorously.

Mixed methods were used to explore women's views and experiences of OPIOL in two companion studies by Rauf *et al.* (2011) and O'Brien *et al.* (2013). Rauf et al. (2011) used a prospective survey research design to capture both quantitative data and open comments which were analysed using an interpretive approach. Women rated on a 4-point scale at least 2-hourly how well they were coping, comfort, satisfaction and location of preference as well as recording open comments. Following participation in the first study, women were invited to participate in semi-structured interviews which were analysed thematically in the paper by O'Brien et al. (2013).

## 2.4 Outcomes

### 2.4.1 Satisfaction

Satisfaction with OPIOL was one of the most commonly reported outcomes and included in the results of four of the ten studies (Awartani et al. 1999, Biem et al. 2003, Rauf et al 2011 and Turnbull et al. 2013a). Three of the studies used numerical or Likert scales to measure satisfaction. This is a common approach although some question how reliably attitudes can be captured in this way, and whether the increments in scales reflect significant differences (Jones and Rattray, 2015).

Awartani et al. (1999) compared outcomes of 50 women undergoing OPIOL at one hospital with 50 women undergoing inpatient IOL at another. Satisfaction with the method of induction was assessed by telephoning women following postnatal discharge. Significantly higher rates of satisfaction were found amongst women managed as outpatients (96% versus 56%; $p<0.0001$). It is possible that selection bias may have contributed to this difference as management practices and care culture may have differed between the two hospitals (Nelson, Dumville and Torgerson, 2015). In addition, it is unclear how satisfaction was measured, and while not significant, there were more nulliparous women in the inpatient group versus outpatients (62% versus 46%) which may have influenced women's perceptions.

Biem et al. (2003) conducted a RCT to compare outcomes amongst 300 women undergoing OPIOL and inpatient induction of labour. To avoid interviewer bias, satisfaction was assessed on a scale of 0 to 9 during an automated computer-based interview using a telephone keypad every 4 hours during the first 12 hours following IOL commencement. In addition, overall satisfaction with

labour and birth was measured on the first day postpartum. During the first 12 hours of the induction process, significantly higher levels of satisfaction were found amongst women managed as outpatients (56% versus 39%; p=0.008). However, there was no difference in satisfaction overall when assessed on the first day postpartum.

Rauf et al. (2011) collected data from women undergoing OPIOL with remote fetal monitoring using self-report diaries which were completed at least 2-hourly using a 4-point Likert scale. They found 46 women out of 51 were satisfied or very satisfied that they were being adequately monitored at home.

Turnbull et al. (2013a) used questionnaires to measure self-reported psychosocial outcomes on enrolment to the OPRA trial and seven weeks after giving birth. These were developed from a previous thematic analysis and presented in a 5-point Likert scale format although definitions used for each are unclear. Satisfaction was one of the outcomes assessed and no significant differences were found between women allocated to the OPIOL and inpatient IOL arms of the trial (mean difference of -0.16 (95% CI -0.33 to 0.02)). However, around 50 per cent of participants did not require induction at all. This means satisfaction and other outcome scores may not reflect women's experiences of OPIOL or inpatient induction. Similarly, completion of the questionnaire may not have been consistent as some women ticked 'non-applicable' if labour started spontaneously and induction was not required. Ambiguity of items in a scale can undermine the face validity of questionnaires (Jones and Rattray, 2015).

Finally, Turnbull et al (2013b) hypothesised that OPIOL could improve reduce midwives' workload and improve their sense of autonomy and job satisfaction. They used questionnaires to measure these outcomes two weeks prior to the start of the OPRA trial and two years later, near the completion. The impact of OPIOL on job satisfaction was measured using a Likert scale. Turnbull et al (2013b) found 93 per cent of midwives felt outpatient priming had made no difference or improved their job satisfaction, and 2 per cent felt their satisfaction had decreased a little or a lot. Turnbull et al (2013b) acknowledge that 21 per cent of midwives had no experience in OPIOL at all and 69 per cent were 'somewhat experienced'. The unfavourable responses were amongst midwives who worked in areas where OPIOL had resulted in an increase to workload. This means that the findings of this study cannot be generalised to other settings in which midwives work exclusively in an induction of labour suite.

### 2.4.2 Safety

Safety emerged as another frequently reported outcome and was discussed in five of the ten studies. This theme emerged during interviews with women (O'Brien et al. 2013 and Oster et al.

2011) and was identified as disconfirming evidence to the subtheme 'enduring the hospital' in the paper by Coates *et al.* (2021). In addition, one of the questionnaires asked about safety (Turnbull et al. 2013a). An experimental study by Howard et al. (2014) asked women about acceptable travel time to hospital which may reflect perceived safety although the reasons behind desirable proximity to hospital were not explored.

Oster et al. (2011) found that while women considered the home environment to be more comfortable, the hospital was considered a place of safety with access to medical professionals if an emergency arose, offering women more peace of mind. Some participants expressed apprehension or fear of being at home, anxious about how their bodies would react to the vaginal dinoprostone gel or whether they would know if something was wrong. Women having their first baby were uncertain they would recognise the onset of labour. Other women felt reassured at home providing they had access to professional advice if they were concerned.

Similarly, while Coates *et al.* (2021) found that while most women preferred the familiarity of being at home during OPIOL, some women expressed the benefit of being hospital as staff were nearby which helped them feel safe.

Safety emerged as the theme '*the importance of a virtual presence*' in the study by O'Brien et al. (2013) in which women underwent OPIOL with remote fetal monitoring. While some women were reassured by this technology, others were left feeling uncertain and anxious about whether anyone at the hospital was looking at the recording of their baby's heartbeat. Women were reassured if there was contact from the hospital as it showed they were still being monitored, and this was especially important for women having their first baby.

In contrast, Turnbull et al. (2013a) found women randomised to receive OPIOL had higher scores relating to safety than those in the inpatient arm, with a 5-point Likert scale mean score of 3.72 (SD 0.83) versus 3.55 (SD 0.80); 95% CI -0.16 (-0.03 to -0.29) for inpatients. This difference may have reflected the fact that around half of the participants did not receive the intervention. In this respect, it is uncertain whether scores related to induction of labour setting or some other factor.

Distance from the hospital influenced women's perception of safety in the study by Oster et al. (2011).

> '*So I guess if you were to live quite a distance it may, and if you have quick labours it might be a concern.*' (Hospital 1, P4, Inpatient, pg. 383).

However, Turnbull et al. (2013a) found only 15 per cent of respondents randomised to receive OPIOL agreed or strongly agreed with the statement '*I was worried that I would not make it back*

*to hospital on time*' although nearly a third agreed or strongly agreed with the statement '*I was worried about how long I should wait at home*'. This suggests a third of women were worried they might not recognise the signs of labour or a problem, but most felt they would reach the hospital in a timely way. It is important to note that participants may not have received the intervention which could undermine the reliability and generalisability of the responses given (Nelson, Dumville and Torgerson, 2015).

Howard et al. (2014) examined women's preferences for OPIOL, compared to basic inpatient and enhanced inpatient care. The authors found women were prepared to accept a travel time of approximately 31 minutes per trip to have OPIOL. However, it is unclear why women responded this way and whether this related to safety concerns or the burden of having to make more than one trip to the hospital during the OPIOL process and overall journey time.

Pregnancy complications also influenced perceived safety, with women more likely to express a preference for inpatient management (Oster et al. 2011). Similarly, inpatient management was felt to be safer if a second dose of dinoprostone gel was required.

### 2.4.3 Comfort

Comfort emerged as a theme in interviews with women in the three studies which used this method (Oster *et al.*, 2011; O'Brien *et al.*, 2013; Coates *et al.*, 2021). Oster *et al.* (2011) contrasted the discomfort of being in hospital with the comfort of being at home and how these environments had an impact on women's therapeutic experience. Excerpts from interviews contrast the disruptive routine of hospital, bright lights, machines and an uncomfortable bed versus the comforting familiarity of being in one's own home following normal routines. Having one's own bed and pillow, greater freedom and support from family and loved ones enhanced women's experience at home and helped them to relax. However, one of the women found being in hospital more relaxing as this meant she did not have to worry about childcare commitments. The inclusion of disconfirming evidence enhances the credibility of this study (Polit and Beck, 2006).

O'Brien *et al.* (2013) found a similar theme amongst women having OPIOL in their research '*labouring in their comfort zone*'. Women appreciated having greater freedom of movement at home, being able to use their own bed and toilet, social support and being surrounded by their own belongings. This sense of the familiar and the distraction of everyday activities helped pass the time, and women felt less self-conscious about their coping strategies, and were more able to relax and get some sleep. Correspondingly, women having OPIOL felt their movement, privacy and routines were more likely to be restricted if they were in hospital. Those with previous

inpatient IOL experiences recollected feeling more vulnerable, the environment being noisy and not being able to get any sleep, and having less autonomy being '*stuck in bed*' or '*strapped to monitors*'. One woman described the ward sounding like '*a torture chamber*' (O'Brien et al. 2013, p. 328).

As well as assessing the feasibility of OPIOL with remote fetal monitoring, Rauf et al. (2011) used 4-point Likert scales in self-report diaries to assess women's experiences at least 2-hourly and found 46 out of 51 were comfortable wearing the device and 48 out of 51 coped well or very well. Free text in the diaries indicated women's home environment played a part in this favourable response:

> '*Having irregular contractions. Can walk around house, have a drink, food, lie in bed etc.*' (Rauf et al. 2011, p.4).

Coates *et al.* (2021) discuss comfort within the theme *'the importance of place'* where hospital was a place to be endured due to lack of familiarity, boredom, delays, disruptive hospital routines, as well as poor sleep for women and their partners alike. In contrast, women expressed a preference for being at home where they were more comfortable, could use their own bath or bed, and eat their own food. More support was available, and women felt it helped them maintain some aspects of a '*natural*' birth.

### 2.4.4 Pain

Only two of the studies considered pain outcomes. Biem et al., 2003 found no significant difference in pain scores between women managed as outpatients or inpatients during the first 12 hours of the induction process. Pain was considered by Coates et al. (2021). Most of the fourteen women who received the dinoprostone pessary found insertion mildly uncomfortable and two described it as 'scratchy'. Four women described contraction pain as unbearable following pessary insertion, and some expressed concern about not knowing whether the pain was normal.

### 2.4.5 Control

Coates *et al.* (2021) identified ownership of the induction process as a key theme and while some women felt there was no choice but to accept induction, they used strategies to retain some control over the process. This included deciding to become a research participant as well as seeking information about the steps involved and taking time to consider their options. Others felt they had no control over the process and were disappointed they had gone to the trouble of

making a birth plan which was no longer going to be used. Views of the dinoprostone pessary were negative at the outset and some women found contractions increased very quickly. In contrast, induction with the balloon catheter was seen as more '*natural*' and gentler versus being '*drugged up*'. Regardless of the method was used initially, women regarded an oxytocin drip as an inevitable part of the process, and while a third of women had not wanted an epidural at the start of the procedure, half of the women accepted one.

Similarly, O'Brien *et al.* (2013) discuss autonomy in their subtheme '*the next best thing to normal labour*'. Women expressed disappointment labour had not started normally and expressed concerns that they were no longer going to be able to realise their birth plans. Furthermore, interventions such as epidural and forceps were seen as an inevitable part of inpatient induction. In contrast, the option of being at home motivated women to take part in the trial and taking part afforded women an opportunity to experience labour at home and have more autonomy. Women felt more in control being at home and able to '*deal with it by myself*' and the environment provided an experience '*as close as going into labour naturally as I could have got*' (O'Brien et al. 2013, pg. 329). In addition, Oster *et al.* (2011) found women talked about the sense of freedom they experienced at home where they were free do whatever pleased them such as go for a walk or lie down and watch television.

Turnbull et al. (2013a) investigated psychosocial outcomes in their postpartum questionnaire including self-efficacy, readiness, and control. These outcomes were developed from a previous thematic analysis and presented in a 5-point Likert scale format although definitions used for each are unclear. While 50 per cent of the participants did not receive induction, there were significantly lower mean scores for inpatient induction versus OPIOL for these outcomes. Mean differences for self-efficacy, readiness and control were -0.17 (95% CI -0.03 to -0.3), -0.22 (95% CI -0.07 to -0.3) and -0.13 (95% CI -0.003 to -0.26) respectively.

### 2.4.6 Stress, anxiety and depression

Three of the studies considered whether OPIOL affected participants' stress levels or increased anxiety and depression scores (Biem *et al.*, 2003; Turnbull *et al.*, 2013a; Turnbull *et al.*, 2013b). Turnbull et al. (2013a) conducted an enrolment questionnaire which showed no difference between women randomised to receive OPIOL or inpatient management in terms of responses to anxiety or depression scales. This demonstrates that the prospect of receiving OPIOL did not seem to influence women's mental health. Similarly, Biem et al. (2003) compared anxiety scores of women who had commenced the induction process. Mean scores reported 4-hourly in the first 12

hours were not significantly different amongst the outpatient and inpatient groups with a score of 1.4 (SD 1.7) versus 1.6 (SD 1.8) (P=0.27) respectively.

Seven weeks after birth, Turnbull et al. (2013a) asked women to complete a questionnaire to assess psychosocial outcomes using a 5-point Likert score. The stress outcome was significantly lower amongst those randomised to OPIOL management with a mean of 3.16 (SD 0.92) versus 3.37 (SD 0.93); 95% CI -0.13 (-0.003 to -0.26) amongst inpatients although the reason for this is not explored. Postnatal depression and anxiety scores assessed using validated scales did not differ significantly between inpatient and outpatient groups.

Turnbull et al. (2013b) considered the impact of the introduction of OPIOL on midwives' stress levels and 89 per cent felt it had made no difference or decreased stress levels, whereas seven per cent responded their stress levels had increased a little or a lot. Similarly, 85 per cent of midwives felt OPIOL had made no difference or decreased workload, whereas 12 per cent responded it had increased a little or a lot. As only 10 per cent of respondents reported being 'highly experienced' with OPIOL, the overall findings concerning midwives' stress may not accurately reflect the views of the group of clinicians most directly involved in outpatient management, potentially undermining generalisability.

### 2.4.7 Preferred environment for induction of labour

Howard *et al.* (2014) conducted a discrete choice experiment to determine women's preferences around setting for induction of labour. Respondents included 260 OPRA trial participants who were sent the survey instrument seven weeks after birth, as well as 102 pregnant volunteers. Amongst other attributes, women were asked to state their preferred environment for induction including their own home, basic inpatient care and enhanced inpatient care. Women were significantly more likely to choose OPIOL versus basic inpatient care (OR 1.771; 95% CI 1.445 to 2.178; p<0.0001). OPIOL was also preferred over basic inpatient care with increasing familiarity with the midwife versus a rostered midwife only (OR 1.099; 95% CI 1.016-1.191; p=0.021), being in the first pregnancy (OR 2.325; 95% CI 1.703 to 3.190; p<0.00001), having a university education (OR 1.570; 95% CI 1.150 to 2.155; p=0.0052) and being older (OR 1.094; 95% CI 1.061 to 1.128; p<0.00001). Overall, women were willing to accept an extra 1.42 trips to hospital (2.42 trips total) and travel time of approximately 31 minutes per trip to have OPIOL. In contrast, the study found being of a non-English speaking background was associated with a preference for basic inpatient care over OPIOL (OR 0.145; 95% CI 0.105-0.201; p<0.00001) as was having had a previous experience of IOL (OR 0.633; 95% CI 0.465-0.865; p<0.0041).

Similarly, Rauf *et al.* (2011) found 47 out of 51 women stated home as their location of preference in self-report diaries which were completed at least 2-hourly during OPIOL.

In contrast, Sutton, Harding and Griffin (2016) found women were unhappy about the prospect of induction in an outpatient setting. This study used a prospective 3-part questionnaire completed before and during an inpatient induction process as well as after birth. While most were induced with balloon catheters (72 per cent), a combination of both a catheter and vaginal dinoprostone was used amongst 14 per cent of women, and 3.5 per cent were induced using dinoprostone only. The remaining women (10.5 per cent) did not require induction and so completed no further questionnaires. Women were asked whether they were happy to go home using a visual analogue scale ranging from 0 (not happy to go home) to 10 (happy to go home). The results showed 66.7 per cent, 75 per cent and 66.7 per cent felt unhappy or equivocal about OPIOL respectively. In contrast, 33.3 per cent, 25 per cent and 33.3 per cent were happy about OPIOL, scoring 7-10 on the visual analogue scale. In addition, when asked prior to the commencement of the induction process, 29.5 per cent of women responded that they would be worried about OPIOL due to their social circumstances. In this study, it is possible that low levels of acceptability of OPIOL may have been influenced by nearly 50 per cent of women being induced due to complications such as diabetes and hypertension which makes application of the findings to a low-risk population problematic.

Turnbull *et al.* (2013a) asked women to complete a questionnaire to assess psychosocial outcomes using a 5-point Likert score and there was no difference in the environment outcome mean scores between outpatient and inpatient management. As already stated, around 50 per cent of participants did not require induction at all which means the environment outcome score, amongst others, may not reflect women's experiences of OPIOL or inpatient induction.

### 2.4.8 Other psychosocial outcomes

Turnbull et al. (2013a) investigated psychosocial outcomes in their postpartum questionnaire relating to social support, environment, self-efficacy, readiness, stress, control, information, safety and satisfaction, most of which have already been discussed in the sections above. In terms of social support, the 5-point Likert scale mean score for OPIOL was higher versus inpatient management (3.92 (SD 0.80) versus 4.17 (SD 0.66) mean difference -0.25 (95% CI -0.13 to -0.37). Similarly, the mean score for information was also higher for those randomised to OPIOL (3.63 (SD 0.74) versus 3.80 (SD 0.76) mean difference -0.18 (95% CI -0.06 to -0.29).

## 2.5 Chapter summary

The literature review highlights the limited evidence about women's and staff views and experiences of OPIOL using vaginal dinoprostone. Many women expressed a preference for the home environment and reported high levels of satisfaction. They felt more comfortable, were able to keep to their usual routines, had more support around them and could get more rest than if they were in an unfamiliar hospital environment. OPIOL was also associated with a greater sense of self-efficacy and control, and women felt the environment was more conducive to the promotion of the physiological processes of labour. Women were prepared to accept a travel time of approximately 31 minutes and an extra 1.4 trips to hospital to have OPIOL, which was particularly favoured by older, university-educated, nulliparous women. OPIOL was not associated with an increase in stress, anxiety and depression scores amongst women.

The literature suggests some ambivalence in terms of perceived safety of OPIOL and highlighted tensions in the wider discourses in maternity care. Women expressed a desire to be close to health professionals in case any problems arose, required reassurance while they were at home that the induction process was progressing normally and felt uncertain about when to return to hospital. Preferences for OPIOL appeared to be mediated by other factors and women with pregnancy complications, previous experience of induction or not having English as a first language were more likely to express a preference for inpatient management. However, discourse around physiological birth was also evident as women expressed the comfort of being at home and feeling able to relax in their own environment and women considered OPIOL as '*the next best thing to normal labour*'.

In terms of staff views and experiences, only one study was retrieved (Turnbull et al. 2013b). Midwives reported that OPIOL did not unduly affect their workload, stress or job satisfaction. This finding is likely to be because the study focussed on the views of midwives working in a range of clinical settings rather than those working exclusively in the clinical area most directly affected by the change in pathway. This dearth of evidence needs to be addressed further since it has already been established that clinical decision-making is likely to be influenced by clinicians' anxiety and perceived risks (Scamell and Alaszewski, 2012; Grobman, 2015; Healy, Humphreys and Kennedy, 2016). Of particular note, the OPRA trial found women randomised to receive OPIOL were more likely than those in the inpatient arm to have a non-reassuring fetal heart recording which meant they were not discharged home after all (Wilkinson *et al.*, 2015). It is important to investigate the views and experiences of staff about OPIOL as it is likely this has an impact on uptake of the intervention as well as women's experiences.

This page has been left intentionally blank

# Chapter 3 Methodology

## 3.1 Introduction

In this chapter I justify the critical realist approach underpinning my research. I also describe the study design including the research setting, sampling, data collection, analysis methods and ethical considerations.

## 3.2 Philosophical underpinning

A researcher's philosophical stance helps them to formulate appropriate research questions and has a critical influence on guiding their approach and methods (Creswell, 2013). For example, a researcher adopting a positivist stance may wish to conduct experimental research or collect data for retrospective analysis while a researcher with an interpretivist stance may decide to observe people's actions or interview them.

While number of philosophical approaches were considered (Appendix X), I adopted a critical realist stance to explore the factors influencing midwives' views and decisions about OPIOL with vaginal dinoprostone. Critical realism combines a positivist ontology that acknowledges the presence of a mind independent reality with a constructionist epistemology; a social reality in which humans interact and make sense of one another and the world around them (Bhaskar, 1997; Maxwell, 2012). Roy Bhaskar introduced critical realism in *A Realist Theory of Science* in 1975. He was critical of the reductionism of a purely positivist approach which attempts to discern causal laws in the natural world. He argued that positivism assumes researchers are completely unbiased in their approach, variables can be controlled and that causal forces identified in a closed system such as a laboratory will always stand true in vivo (Bhaskar, 1997). Instead, Bhaskar argued that phenomena are perceived and interpreted by people and understood within scientific constructs and models subject to bias and assumptions. Bhaskar asserted that consequently, even the most rigorously conducted experimental science is an inherently social and anthropocentric activity.

Bhaskar developed transcendental realism as an alternative theoretical model to positivism. Later called critical realism, Bhaskar argued that natural phenomena in the real world take place in a complex, open and layered system where there may be a great number of mediating influences. He argued that while many natural phenomena are directly observable, others can only be understood by examining their effects as they may not be directly observable otherwise.

Furthermore, they may only be triggered in certain circumstances or conditions. He described these potentialities for action as 'generative mechanisms' which are contingent on complex factors and conditions within the environment (Bhaskar, 1997 p.46).

Critical realism can also help us understand social reality although there is some question about the extent to which the social world can be considered to be 'real' and studied in the same way as the natural world (Bhaskar, 1979). This is because it is a highly complex and dynamic open system with many interdependencies and is perceived differently by individuals. Nevertheless, social structures and entities such as government, healthcare and financial markets shape the social environment in which people live and interact with one another, and in this sense demonstrate 'real-ness' just like rocks and trees in the natural world (Bhaskar, 1979; Pawson and Tilley, 1997; Maxwell, 2012). In a similar way, while culture-bound and specific to a time and place in history, social norms, beliefs and ideologies mediate our actions and 'ways of being', yet impose some boundaries on our behaviour (Willig, 1999 p.41; Maxwell and Mittapalli, 2010).

Zachariadis, Scott and Barrett (2013) argue that the purpose of critical realist research is not to assume or to try to determine causality between distinct events. Rather, researchers should focus on understanding the process and conditions which trigger (or do not trigger) underlying generative mechanisms, leading to the events people experience and observe. The term retroduction is used to describe the inferences and hypotheses researchers make to explain these generative mechanisms (Bhaskar, 1997).

## 3.3 Study design

While mixed methods research is typically associated with pragmatism, it can also be used in critical realist research to provoke deeper explanatory insights into the underlying generative mechanisms within the wider physical and social environment on people's actions and decisions (Maxwell, 2012). Mixed methods is aligned with critical realism's retroductive methodology, using both quantitative methods to identify data patterns, and qualitative research to illustrate and elaborate on those findings in order to uncover the mechanisms and conditions that produce the observed behaviour and events (Zachariadis, Scott and Barrett, 2013).

Mixed methods research challenges the commonly held philosophical assumption that differing epistemological standpoints are mutually exclusive (Creswell and Plano Clark, 2018). In this respect, mixed methods can produce a deeper, integrative analysis than using one approach alone – a notion described as complementarity (Zachariadis, Scott and Barrett, 2013; Turnbull and Lathlean, 2015). I therefore anticipated that a mixed methods approach would derive a

comprehensive understanding of the factors influencing midwives' views and decisions about OPIOL with vaginal dinoprostone.

In mixed methods research, a quantitative or qualitative core component is adopted alongside a supplemental and less dominant component (Morse and Niehaus, 2009). The core component tackles the key aims and objectives of the research and is conducted with a higher degree of rigor than the supplemental component, meaning the findings could be published independently (Morse and Niehaus, 2009). The same cannot be said about the supplemental component which is only conducted to obtain the information needed to support the core component. This means that the supplemental component is generally referred to as a strategy rather than a method, and findings cannot be published independently. Other authors argue that the components may be equally weighted in terms of the rigor in which they are conducted and the contribution they make to the findings (Creswell, 2015; Schoonenboom and Johnson, 2017).

A commonly used notation system to describe mixed methods approaches uses 'qual' and 'quant' to signify qualitative and quantitative methods respectively, capitalisation signifies the core component and '→' or '+' signifies whether data is analysed sequentially or concurrently (Morse and Niehaus, 2009; Schoonenboom and Johnson, 2017). I adopted an explanatory sequential mixed methods approach (quant → QUAL) in which quantitative data collection and analysis preceded and informed the qualitative phase (Creswell, 2015) (Figure 3-1). The qualitative phase was the core component of my research and contributed most to my findings, being used to generate explanatory insights about the quantitative data and to make inferences about the factors influencing midwives' views and decisions about OPIOL. In contrast, an exploratory mixed methods design (qual → QUANT) uses qualitative research strategies at the outset to identify areas for further exploration using quantitative methods (Creswell, 2015). Other combinations can be used flexibly in order to answer the research question (Morse and Niehaus, 2009; Schoonenboom and Johnson, 2017).


Figure 2-1: Explanatory sequential mixed methods design (Creswell, 2015)

While mixed methods research is increasingly popular, there is little guidance available on critical realist study design (Morse and Niehaus, 2009; Fletcher, 2017). Realist evaluation frequently uses mixed methods and is often used to help implement and evaluate health and social care policy interventions and their outcomes (Pawson and Tilley, 1997). While realist evaluation

acknowledges the role of human agency and recognises that people's actions are mediated by wider social structures, it offers little insight into individual sense-making and strategies used to justify thoughts and actions (Porter, 2015; Wiggins, 2017).

Analysing talk enables critical realist researchers to gain deep insights into individual's sense-making and how it is mediated and co-constituted by aspects of their social and physical reality. These are described as extra-discursive factors, and scaffold talk rather like threads woven through cloth (Wetherell, 2001a; Sims-Schouten, Riley and Willig, 2007; Sims-Schouten and Riley, 2019). Institutional factors such as government policy influence individual talk, as can material factors such as education, employment and income (Sims-Schouten, Riley and Willig, 2007; Stevens, 2019). In addition, personal embodiment can also mediate talk. For example stress and anxiety can affect how people articulate themselves and make sense of the world around them. Lupton (2012) defines embodiment as 'complex and dynamic admixtures of cultural, social and biological processes' (p.330). In this sense, embodiment considers the person as a whole, not only in a biological sense, but also emotionally, culturally and socially (Anastas, 2019).

While talk can enable individuals to represent their accounts of the material, social and conceptual world in both written and verbal forms, it is also an action-orientated, social practice (Wetherell, 2001a; Riley, 2002). Consequently, text and talk are not neutral tools; they are used in purposeful ways to create a shared understanding during interactions and take on a truth of their own or be used to deny alternative accounts (Riley, 2002; Te Molder, 2015). In other words, language is more than 'just talk' and is neither a straightforward reflection of reality 'out there', nor a cognitive map of what is 'in here' (Cromby and Harper, 2009; Adams, McCreanor and Braun, 2013 p.345). This means researchers can analyse talk to identify aspects of the physical and social reality that mediate sense-making, and can explore discursive strategies people adopt to achieve their aims, whether social or political (Potter and Wetherell, 1987; Wiggins, 2017). For example, they may use rhetorical or persuasive devices such as extreme cases or contrasts to make a point, counterclaims are used to ward off or inoculate against potential criticism and talk can be peppered with hesitations (Silverman, 2001; Riley, 2002; Jingree and Finlay, 2008). Interactions may also feature hedging which is a characteristic of tentative, provisional or conditional talk which can often mark problematic topics in which the speaker is trying to avoid challenge or criticism. It is also used to enable the speaker to remain noncommittal until the position of the other person becomes clearer (Wiggins, 2017). People may also incorporate widely understood tropes in their talk and orientate towards particular discourses that suit their agenda or situation (Hall, 1992; Goodman, 2017). In this way, talk is not only a reflection of the subjective world of individuals and their reality, it is also used to rationalise, justify and affect the thoughts and actions of both the speaker and those listening (Fairclough, 2003; Cromby and Harper, 2009).

While I considered several alternative approaches to analysing participant talk (Appendix XI), my method was informed by Sims-Schouten, Riley and Willig (2007) who used critical realist discourse analysis (CRDA) to analyse women's talk on motherhood, childcare and employment. CRDA combines a number of strategies with discourse analysis, and I anticipated this would help me identify extra-discursive factors influencing participant talk about OPIOL as well as wider discourses influencing maternity care. I also anticipated that it would enable me to investigate how participants justified the accounts they gave which I considered would provide additional explanatory insights. I adapted the CRDA approach, and the steps are summarised as follows:

1. My literature review in Chapter 2 highlighted factors influencing women's views of OPIOL and very limited evidence about staff views. I anticipated that the factors identified could mediate midwives' views and decisions about OPIOL. These included demographic characteristics of the women undergoing OPIOL as well as the themes identified, which included comfort and safety, echoing wider societal discourses around risk and patient safety and physiological birth.
2. A retrospective analysis of induction of labour data between July 2015 and June 2018 was undertaken in order to describe the clinical context in which OPIOL takes place and establish the clinical outcomes of those undergoing OPIOL.
3. Data from the two preceding steps helped inform the third part of the study. Participants took part in semi-structured interviews to explore how physical embodiment, institutional and material factors as well as wider discourses mediated views and decisions about OPIOL. As described by Sims-Schouten, Riley and Willig (2007) talk was analysed in the following ways to examine how women orientated towards extra-discursive factors:
    i. Discursive practice – influenced by conversation analysis and discursive psychology highlighting the action-orientation of talk i.e., the strategies individuals adopt to achieve their aims during an interaction.
    ii. Foucauldian discourse analysis – to identify the wider discourses which feature in participants' talk, and how participants orientate themselves towards them.
    iii. Critical realist level of analysis – the influence of the extra-discursive factors on discourse including social and political institutions as well as those relating to an individual's personal embodiment and their material resources.

## 3.4 Setting

The study was set in a tertiary NHS teaching hospital in England situated in a city with a population of over 286,000. The hospital serves a wide urban and rural population of around 3.7 million people. Census figures from 2011 showed 77 per cent of the city's population were white

British. The city's population is ethnically diverse with 153 languages spoken and over 26 per cent of pupils living in households where English is not spoken as a first language. The number of people aged 15 to 34 in the city exceeds the national average, largely due to a significant student population (City Council Name Witheld, 2016). The city is more deprived than comparator cities, and ranks 55th out of 317 local authorities in England. Nineteen of the city's neighbourhoods are amongst the 10 per cent most deprived nationally (City Council Name Witheld, 2020). The hospital also serves nearby small towns and surrounding rural areas, with an aging and more affluent population (Clinical Commissioning Group Name Witheld, 2017).

The hospital has a range of specialist services including neurosciences, cardiac care, allergy and immunology, children's intensive care and a level three neonatal unit which cares for babies from 24 weeks of gestation. The maternity hospital cares for around 5500 women a year and is a regional centre for fetal and maternal medicine. It is the only hospital in the Local Maternity and Neonatal System to offer OPIOL.

Induction of labour takes place in a dedicated four-bedded suite set within the obstetric Labour Ward. The beds are separated by curtains and there is a shared toilet. In each bed space there is a wall-mounted fetal monitor, a chair for partners and an adjustable bedside dining trolley. There is no communal space in this area and no window. The midwife caring for the women is situated in an office opposite the room and women use the call bell system to request assistance.

In 2019, approximately 28 per cent of women underwent induction of labour – equating to 4 or 5 women a day (NHS Trust, 2019). At the beginning of the study, the induction suite had a core team of three midwives, with one rostered each day to work in daytime hours. Shifts not filled by the core team were filled by experienced midwives from the Labour Ward. By the end of data collection period, the core induction team had reduced to one member, and staff covering this area were rostered over a 24-hour period rather than daytime hours only. Induction of labour appointments are scheduled in an electronic diary with six appointment slots throughout the day. However, induction is also offered outside of those hours as clinical need dictates.

Women undergoing induction usually remain in the induction suite most of the day until care is handed over to a Labour Ward midwife to commence an oxytocin infusion, or the woman is transferred to the Antenatal Ward to allow her to rest for the night. The women in the induction suite usually have an opportunity to mobilise around the hospital site during the early stages of the process.

## 3.5 Access

I am employed as a Consultant Midwife with responsibility for providing clinical expertise in the delivery of midwifery care within the study setting. I also counsel women and arrange induction of labour appointments as part of my role. In this respect, I am considered a member of the direct care team according to the following definition:

> *'Direct care is provided by health and social care staff working in 'care teams', which may include doctors, nurses and a wide range of staff on regulated professional registers, including social workers. Relevant information should be shared with them, when they have a legitimate relationship with the patient or service user.'*
>
> (National Data Guardian 2013, p.120)

## 3.6 Ethical and safety considerations

### 3.6.1 Ethical approval

Ethical approval was sought through the University and the NHS research ethics process and was granted by the East Midlands Leicester Central Research Ethics Committee on 2nd January 2019 (Appendix XII and Appendix XIII). England's Common Law Duty of Confidentiality and the European-wide General Data Protection Regulation (GDPR) assure the confidentiality of patient records, and the Health Research Authority provides guidance to researchers wishing to access records (Health Research Authority, 2018; Information Commissioner's Office, 2018a). When patient consent cannot be reasonably obtained or where other methods of data collection are not viable, researchers are required to make an application to the Confidentiality Advisory Group (CAG) if they wish to access and process patient data (Health Research Authority, 2017a). The CAG has an advisory role and counsels the Health Research Authority to determine whether there is a lawful basis to access patient data. I sought advice from the CAG and the local data controller and was advised that an application was not required as a member of the direct care team with legitimate access to patient records (National Data Guardian, 2013; Health Research Authority, 2017a; Pillinger-Cork and Health Research Authority, 2018).

### 3.6.2 Safeguarding concerns

In the event of safeguarding issues being identified during the study, researchers have a responsibility to identify concerns, share information and take prompt action by informing the relevant health and social care organisations. This would mean terminating the interview if this

was in progress and following national and local guidance on safeguarding children and vulnerable adults (NHS Trust, 2017; HM Government, 2018). While it is best practice to discuss the referral with the family and gain consent for information sharing, it may not always appropriate to do so e.g., if the safety of the child or researcher would be compromised in doing so (HM Government, 2018). I have relevant experience working with families requiring additional support at Universal, Early Help and Child Protection levels and no concerns were identified during the interviews.

The ethics committee also required assurance about how any mental health concerns would be addressed during data collection and it was decided that the interview would be terminated in order to facilitate further discussion. In my role, I am familiar with tools to screen for anxiety and depression and feel confident about discussing referral to mental health services in accordance with national guidance (National Institute for Health and Care Excellence, 2014a). Once again, no concerns were identified during the interviews.

### 3.6.3 Issues with clinical practice

It was anticipated that poor clinical practice could be identified during data collection and the ethics committee wanted assurance about how this would be addressed. As a registered health professional, I have a responsibility to challenge poor practice in accordance with the NMC Code (Nursing and Midwifery Council, 2018). I am experienced in clinical supervision and risk management processes as a Consultant Midwife and a Professional Midwifery Advocate (PMA) (NHS England, 2017b). While no concerns were identified during data collection, in these circumstances feedback would typically involve an open discussion with the professional involved to explore human factors and any learning from the incident as well as observing Trust risk management procedures (NHS Trust, 2020b).

### 3.6.4 Safety considerations

Trust and University lone working policies were also considered, and a health and safety risk assessment was completed prior to the commencement of data collection as a University requirement. Interviews were conducted in daytime hours and I phoned a colleague before and after visiting participants' homes. The University also provides professional indemnity and clinical trials insurance to researchers.

### 3.6.5 Potential conflicts of interest

Issues around conflict of interest were explored during the design of the study. The ethics committee asked whether staff would feel under pressure to take part and how my role as a

Consultant Midwife might influence responses which could undermine validity (Kent, 2015). I have no line management responsibilities and one of the key aspects of my role is to consult with colleagues about gaps and challenges in clinical pathways. In this respect, clinicians are willing to express both positive and negative views about clinical issues. Furthermore, there is an increasing emphasis on embedding a safety culture and greater openness and transparency within maternity services and healthcare in general both at a national and local level following the publication of the Mid-Staffordshire, Morecambe Bay and Ockenden reports (Francis, 2013; Kirkup, 2015; Ockenden, 2020). The Trust is also participating in national safety initiatives such as the Saving Babies' Lives Care Bundle, Maternity Safety Champions and the Maternity and Neonatal Safety Collaborative (NHS England, 2016; NHS Improvement, 2016;2018). The aim of these initiatives is to reduce avoidable harm by using a quality improvement approach, increasing transparency and embedding systems learning to engage clinicians to improve quality and safety. In this regard, clinicians are encouraged to speak openly and honestly about service challenges and areas for improvement and given my previous experiences, I felt reassured staff would be able to express their views freely during interviews.

### 3.6.6 Data protection and anonymity

In light of the EU General Data Protection Regulation (GDPR) 2018, researchers are required to demonstrate that data processing is lawful, fair and transparent (Information Commissioner's Office, 2018a). This means being able to demonstrate that the data is being used for a legitimate purpose, that it is used only for the purposes outlined and that data is limited to what is required for the purposes of the study. In addition, the regulations demand that data should be anonymised or pseudonyms used where possible, and any personal data kept for as short a time as possible. Retrospective data was anonymised and women and staff taking part in interviews were given a unique participant code to act as a pseudonym. The file linking the participant code with women's personal data is stored separately in a password protected file separate from the interview transcripts. The research data is stored securely in a password protected file on the University of Southampton computer network and is being stored securely for a minimum of ten years in accordance with the University Data Management Policy (University of Southampton, 2012).

Furthermore, GDPR requirements require researchers to be explicit about how data is processed and stored and so this information was included in participant information sheets (Information Commissioner's Office, 2018b).

## 3.7 Quantitative study

The quantitative study was conducted in three stages. Firstly, overall induction of labour activity over the data collection period was described. Secondly, women eligible for OPIOL were identified and whether they accepted or declined the intervention or became ineligible on the day of induction. Finally, the outcomes of those women who commenced the OPIOL pathway were explored. These steps are now described in more detail.

### 3.7.1 Stage 1 – overall induction of labour activity

The first part of the quantitative aspect of the study used retrospective, routinely collected hospital data about the overall number of women who underwent induction of labour between July 2015 and June 2018, as well as indications for induction, parity and gestation. This data collection period corresponded with the commencement of the OPIOL pathway at the Trust and covered three years to yield as much data as possible. Data were exported from the maternity information database by the Trust's maternity information data manager as a Microsoft® Excel® spreadsheet which was processed in a secure location on the NHS Trust's server. Data processing commenced with exclusion of women who experienced medical termination of pregnancy, late fetal demise and stillbirths. This decision was made because these women are cared for elsewhere in the hospital and not included in the induction of labour suite activity.

The remaining data was analysed to describe the clinical context in terms of activity and acuity as it was considered that these might influence women's and staff views and experiences of OPIOL.

#### 3.7.1.1 Indication for induction of labour

Indication for induction of labour is selected by the midwife at the time of data entry into the maternity information database using checkboxes and multiple indications can be selected. In addition to the pre-defined checkboxes of indications for induction, there is an 'other' checkbox with a free text field enabling staff to describe other reasons for induction. As indications for induction were described in various ways by the staff at time of data entry, Microsoft® Excel® filters were used to identify abbreviations of common indications (e.g., reduced fetal movements, reduced FMs, RFMs etc.). Similarly, free text entries were grouped together where appropriate (e.g., meconium and suspicious cardiotocography were grouped together as suspected fetal compromise). This enabled the 'other' indications to be identified and quantified from the free text entries. Indications for induction were then presented as percentages and this was analysis was handled easily by Microsoft® Excel®.

### 3.7.2 Stage 2 - identification of nulliparous women eligible for OPIOL

The next stage involved identifying women eligible for OPIOL to avoid prolonged pregnancy at a gestation of 40 weeks and 10 to 12 days. I used the parity and gestation columns of the Microsoft® Excel® spreadsheet to identify nulliparous women offered induction between 40 weeks plus 10 and 12 days of gestation. Using the NHS Trust's outpatient induction of labour inclusion and exclusion criteria (Appendix XIV), I was then able to identify and exclude women who were not eligible for OPIOL. A data collection tool was used to ensure a consistent approach (Appendix XV). Women were excluded in a number of ways according to the NHS Trust guideline exclusion criteria:

- Where a medical reason was given for induction
- If BMI was 40 or more
- If women were aged 35 or more at the time of induction of labour
- Estimated journey time more than 30 minutes from the hospital.

Journey time was estimated using combination of local knowledge and Google Maps although I had to accept that actual journey time is dependent on time of day and traffic conditions (Stewart, 2021).

Once I had identified a cohort of nulliparous women who received induction of labour to avoid prolonged pregnancy, women's hospital notes were ordered from the NHS Trust's health records department. These were either physical or scanned copies on the NHS Trust's electronic data management system. Health records were then reviewed to determine whether any other risk factors were documented. Eligibility was assessed once more according to the Trust's OPIOL inclusion and exclusion criteria (Appendix XVI). Other demographic data was also collected about the women from their health records to determine whether these were linked to any difference in uptake of OPIOL. Information was collected about women's age, education, employment, ethnic group and smoking status.

Record entries relating to the induction of labour assessment were then examined to determine whether women were eligible for OPIOL on the day of assessment and whether the intervention was accepted or declined. While reviewing the women's records, it became apparent that some women were eligible for OPIOL, but it was not documented whether they were offered the intervention, declined it or were not asked about it and so these formed a fourth category 'missing data'. The categories are summarised below:

- Women who became ineligible for OPIOL due to new complications arising on the day of assessment

- Women who accepted OPIOL
- Women who declined OPIOL
- Missing data

Once these categories had been established, I imported and analysed data using IBM® SPSS®, a statistical analysis software program. While it is also possible to create tables and graphs using Microsoft® Excel®, it is primarily used to store and process data (Dancey, Reidy and Rowe, 2012). SPSS® enabled me to create data output tables reliably and easily, and examples of the output are included in Chapter 4. Descriptive statistics were used to compare demographic characteristics (age, education, employment, ethnic group, smoking status). As discussed in the literature review, Howard *et al.* (2014) noted some differences in women's preferences about OPIOL in their research. Older, university-educated women were more likely to prefer outpatient management and women from a non-English speaking background were more likely to prefer inpatient management.

### 3.7.3 Stage 3 - outcomes of women who commenced OPIOL pathway

In the next stage, I considered clinical outcomes of women who commenced the OPIOL pathway. These are shown in Table 3-1 and were selected as they were consistent with other studies about induction of labour. It was considered that these outcomes would help describe the 'reality' of OPIOL which could then be triangulated with women's and staff accounts of induction. Outcome data was extracted from medical records into Microsoft® Excel®. Data analysis is described in the next section.

Table 3-1: Outcomes of women undergoing OPIOL

| |
|---|
| • Primary reason for readmission to hospital following commencement of OPIOL pathway<br>• Change in Bishop score and cervical dilatation on readmission<br>• Oxytocin augmentation required<br>• Mode of birth<br>• Place of birth<br>• Time avoided in hospital (time of readmission minus time of initial discharge following commencement of induction process)<br>• Vaginal dinoprostone administration to birth interval<br>• Apgar score <7 at 5 minutes of age<br>• Admission to neonatal unit within first 24 hours |

### 3.7.4 Statistical methods

Descriptive statistics were used to present the data. Nominal or categorical variables such as mode of birth or smoking status were presented as a percentage. Ordinal variables are similar to nominal variables but there is a clear ordering from low to high e.g., Bishop score, cervical dilatation and Apgar score which are expressed as whole numbers in electronic records[3]. Normally distributed numerical or continuous variables such as age and time avoided in hospital were presented as a mean. Gestational age was not normally distributed as there were a few outliers at an early gestation. As these outliers would skew the average, gestation was presented as a median (Dancey, Reidy and Rowe, 2012).

When comparing characteristics of women who accepted or declined OPIOL, inferential statistics were not used due to the small sample size meaning it was unlikely that observed differences would achieve statistical significance. Outcomes of women who commenced the OPIOL pathway were analysed as above and standard deviation and interquartile range were then used to describe variation around the mean and median values respectively.

### 3.7.5 Missing data

As described in section 3.7.2, it became apparent during data collection that it was not always clear whether women were offered OPIOL. This meant I had four categories; women who were ineligible for OPIOL after their initial assessment, those who were offered OPIOL and accepted, those who declined, and those for whom there was missing data. Missing data can reduce sample size and statistical power and therefore undermine the validity of research and distort conclusions since calculations will be made on incomplete data (Dancey, Reidy and Rowe, 2012; Kim and Mallory, 2014). It is important to consider the prospect of missing data at the research design stage and how this will be handled as this can help researchers determine if data is missing at random. This is determined by comparing the characteristics of individuals in the missing data group to determine if they differ from the rest of the data. Various statistical methods have been devised to replace the data with a best 'guess', including imputation of mean or modelled values although this can reduce variability in the data set (Dancey, Reidy and Rowe, 2012 p.189; Kim and Mallory, 2014). Where data is not missing at random, it can reveal systematic influences and

[3] In handwritten records, clinicians will often document a range for cervical dilatation if it falls somewhere between two values (e.g., 2-3cm). Similarly, an 'anterior lip' might be used to describe a very thin rim of cervix that is between 9cm and 10cm dilated. However, electronic record keeping usually forces the clinician to choose one number or another. Cervical dilatation is a relatively subjective assessment, and examination findings may vary from one clinician to another.

further explanatory insights about social circumstances (Nguyen *et al.*, 2018). For example, people experiencing social deprivation are least likely to participate in research, and more likely to be lost to follow up and this can be particularly problematic in longitudinal research (Rothenbühler and Voorpostel, 2016). Similarly, people living in rented accommodation, women caring for elderly relatives, working mothers and lone parents are characteristics associated with increased likelihood of attrition (Rothenbühler and Voorpostel, 2016; Nguyen *et al.*, 2018).

I reasoned there could be systematic influences responsible for missing data in my research and that the data was not missing at random. I anticipated this could reveal further insights into midwives' views and decisions about OPIOL to be explored further during research interviews.

## 3.8 How the quantitative data informed the qualitative component

Quantitative data were analysed prior to qualitative data collection, and the findings are presented in Chapter 4. The sequential explanatory mixed methods research design meant I was able to gain an understanding of the research context, determine the number of women eligible for OPIOL, the number of women discharged home and their outcomes. Having this information prior conducting the qualitative, core component of my mixed methods research gave me additional insights which informed the interviews (Creswell, 2015).

## 3.9 Qualitative study

In the qualitative study, I aimed to explore factors influencing midwives' views and decisions about OPIOL. I was also keen to understand how midwives justified their decisions and managed their professional credibility and accountability.

### 3.9.1 Participants

Inclusion and exclusion criteria for staff and women are provided in this section. I considered that a flexible and pragmatic to recruitment of participants would satisfy the ethical review panel whilst enabling me to approach people with a range of views and experiences of OPIOL (Charmaz, 2014). At the outset of my research project, I had intended to recruit women eligible for OPIOL in order to explore their views and experiences as well as those of the staff providing care. I also aimed to recruit staff involved directly in the induction of labour process within the hospital, or those involved in antenatal counselling and provision of information about OPIOL. However, as already described, over the course of my study my focus shifted towards factors influencing midwives' views and decisions. The inclusion criteria are included below in table 3-2.

Table 3-2: Inclusion criteria

| Inclusion | Justification |
|---|---|
| • Midwives in the induction of labour team or experienced in providing induction care<br>• Community midwives who book women for induction of labour | • To obtain views of staff directly involved in information-giving and providing care to women undergoing OPIOL. |

I continued to recruit women to the study to gain an insight into their views and experiences. Inclusion criteria are shown in Appendix XVI and associated findings are presented as a case study in Chapter 5 to supplement the main findings.

### 3.9.2 Sample size

While quantitative researchers calculate the sample size required to demonstrate whether findings have reached significance, qualitative researchers rely on the concepts of data saturation, theoretical sufficiency or information power to help them feel confident about the validity of their findings (Charmaz, 2014; Malterud, Siersma and Guassora, 2015). Data saturation originates in grounded theory research where data collection and analysis are conducted concurrently, and researchers adopt an iterative, theoretical approach to sampling and coding to expand on emerging themes. Data saturation is achieved once no new themes emerge from the data (Charmaz, 2014; Hennink, Kaiser and Marconi, 2017). A sample size of 6 to 30 participants is suggested in the literature (Guest, Bunce and Johnson, 2006; Baker and Edwards, 2012; Hennink, Kaiser and Marconi, 2017). However, data saturation is contingent on the quality of the questions posed and the rapport between respondent and researcher (Polit and Beck, 2006; Baker and Edwards, 2012). Furthermore, the specific characteristics and experiences of participants influences the richness of the data obtained as do the methods used to analyse the qualitative data (Crouch and McKenzie, 2006; Malterud, Siersma and Guassora, 2015).

Braun and Clarke (2019) are critical about the concept of data saturation, emphasising that limitations of time and resources mean analysis rarely reaches a fixed end point. Rather, researchers make pragmatic decisions about sample size and when to stop coding. Furthermore, ethics committees require more certainty over sample size and are likely to reject strategies based on theoretical sampling where recruitment continues indefinitely until saturation is achieved. Frequently, convenience sampling and a willingness to participate in research is also key

but presents a risk of mining limited viewpoints (Malterud, Siersma and Guassora, 2015). Instead, I adopted a purposive sampling strategy to recruit up to 12 midwives and 12 women.

### 3.9.3 Recruitment procedure

Clinicians were invited to participate using posters in clinical areas and via internal communications 'Maternity Mail' newsletter and 'Theme of the week'[4] (Appendix XVII, Appendix XVIII, Appendix XIX). I also visited the induction suite several times a month on an ad hoc basis and talked informally to the induction midwives about the study. Members of staff approached me directly and were given a participant information leaflet (Appendix XX).

Social media and posters in the induction of labour suite were used to recruit women to the study (Appendix XXI, Appendix XXII). The obstetric diary was also reviewed to identify women who might be eligible to participate. Those eligible for OPIOL were given a participant information leaflet with an expression of interest form during their initial admission (Appendix XXIII). This was completed and given to a member of staff, then returned to me.

Setting a modest recruitment target of 2 participants a month meant I was able to remain motivated and could ring-fence a small amount of time each week to recruitment activities. A widely cited paper reflecting on the difficulties of recruitment acknowledges that it can be disheartening for junior researchers and it is often not clear at the project outset which strategies will be most effective (Patel, Doku and Tennakoon, 2003). Recruitment challenges are explored further in Chapter 7.

The recruitment procedure is summarised in Figures 3-2 and 3-3.

[4] Theme of the week is a bullet point summary of new guidance or changes in practice sent via email to clinical staff. It is also displayed in clinical areas for a week and discussed within incoming staff at each handover meeting.

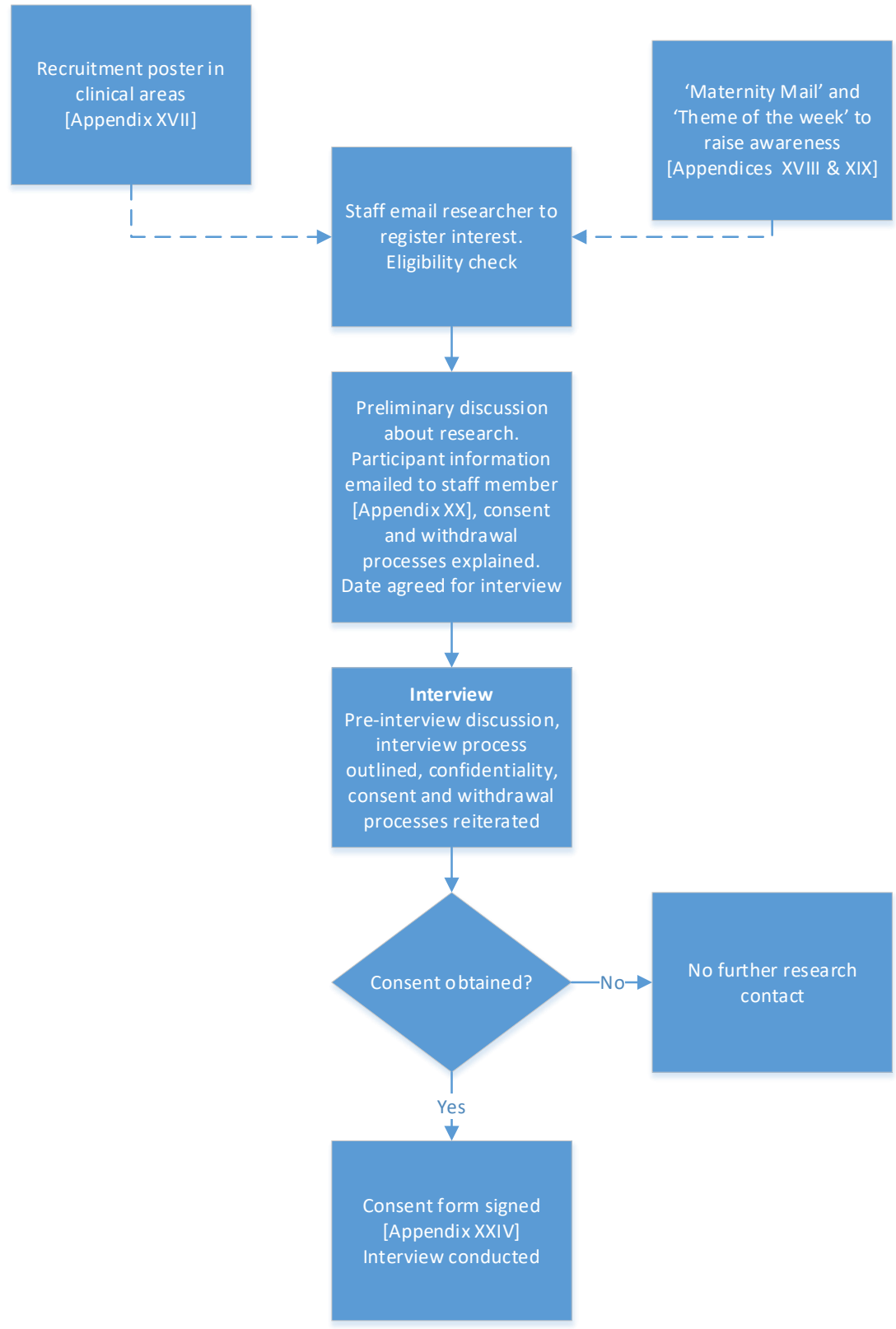



Figure 3-3: Recruitment of clinicians

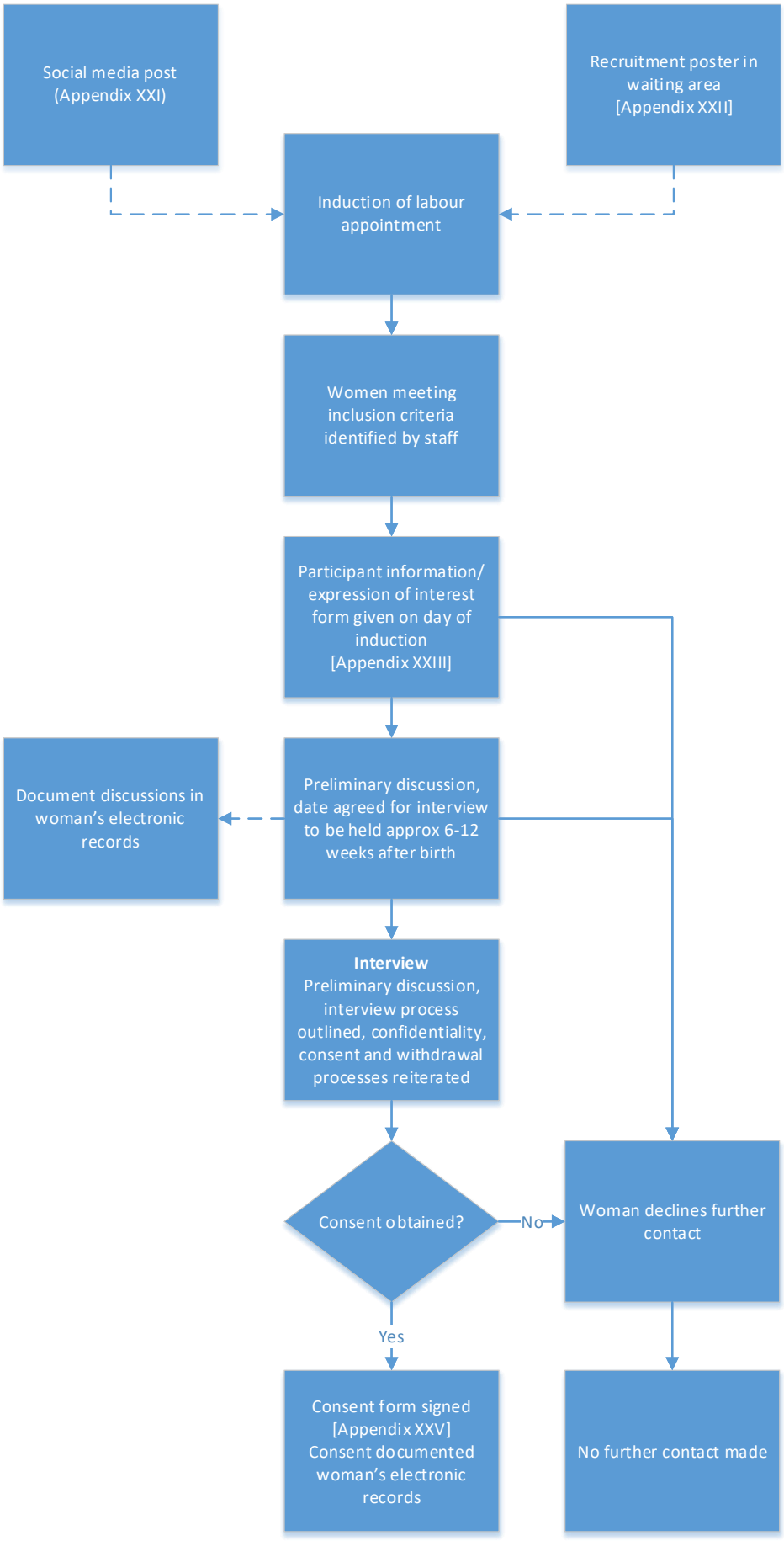



Figure 3-4: Recruitment of women

### 3.9.4 Consent and withdrawal procedures

Members of staff and women participating in the interviews in the qualitative part of the study were given the opportunity to review a participant information leaflet before deciding to take part (Appendix XX and Appendix XXIII). Once they had registered their interest, a date was arranged for the interview. On the day of the interview, I obtained written consent and maintained a site file in accordance with Good Clinical Practice recommendations (National Institute for Health Research, 2016) (Appendix XXIV and Appendix XXV).

I explained to participants that they could withdraw from the study at any time. In this situation, any transcripts would be deleted and withdrawn from the analysis if the request to withdraw was received prior to submission of the final thesis. For participants wishing to withdraw after that, direct quotes will not be cited in papers prepared for publication.

### 3.9.5 Interviews

Semi-structured interviews were chosen as an appropriate qualitative method to gather data about factors influencing views and decisions about OPIOL. Semi-structured interviews provide some flexibility to explore new themes raised by participants whilst enabling the researcher to maintain some control and direction and keep within a time-frame acceptable to both parties (Carey, 2010; Tod, 2015). Developing interviews questions is an iterative and reflexive process and questions may be tested and refined further by piloting them to avoid inclusion of leading questions or pre-conceived biases (Agee, 2009; Maxwell, 2012). An interview schedule should also include a checklist to avoid missing important details such as introductions, explaining the purpose of the interview, obtaining consent, explaining withdrawal procedures and thanking the participant at the end of the interview (Charmaz, 2014; Tod, 2015). An interview checklist and topic guide were developed with feedback from my supervision team to ensure it worked as intended (Appendix XXVI). The checklist and topic guide were submitted as part of the ethical approval process and this satisfied the committee about the kinds of questions that would be asked (Carey, 2010).

Participants had the option of being interviewed at the hospital, the local freestanding birth centre or at their home and a digital audio device was used to record the interviews. Participants had the option to decline recording and for handwritten notes to be taken instead. However, all the participants agreed for their interviews to be recorded.

Prior to commencing the interviews, sound quality of the digital audio device was checked. This recorded voices clearly despite some background noise e.g., a fan in the room, ward activity outside the interview room.

### 3.9.6 Qualitative data analysis

#### 3.9.6.1 Transcription

Researchers have faced criticism for failing to include explicit details about transcription methods which demonstrate the quality and trustworthiness of the data (Davidson, 2009). While some researchers prefer to use professional transcription services, I decided to transcribe the interviews myself to build familiarity with the data (Lapadat and Lindsay, 1999; Goodman, 2017). Interviews were played at half-speed to make transcription easier. This phase was time-consuming, and a 30-minute interview took between two and three hours to transcribe.

A decision had to be made about how much detail to include in the transcription. Some researchers use naturalised transcription and the most commonly cited method is the Jeffersonian notation system (Gibson, 2010; Goodman, 2017; Wiggins, 2017). Researchers use this approach to add codes and symbols to their transcriptions to indicate pauses, changes in speed of talk and intonation, gestures, laughter and overlapping speech. Naturalised transcription is often used in conversation analysis and discursive psychology as it enables researchers to explore *how* people express themselves. In contrast, other discourse analysis approaches such critical discourse analysis tend to examine *what* people are saying i.e., the content of talk (Wetherell, 2001a).

One of the criticisms of naturalised transcription is that the detailed nature of transcription can make it difficult to read and detracts from what is actually said (Gibson 2010; Ochs 2006). Speech patterns and transcriptions of accented talk may also reveal the ethnicity or background of the speaker and be problematic from a confidentiality point of view in small communities (Oliver, Serovich and Mason, 2005). Furthermore, it may be difficult to know where to stop and what is relevant to the talk and what is not (Gibson 2010) and despite assertions that analysis is more objective, researchers may still be biased in their interpretations as they are essentially selecting, translating and interpreting what they have heard into a written form (Goodman, 2017). For example, in their work with HIV-positive men, Oliver, Serovich and Mason (2005) discuss the possible multiple interpretations of repeated sniffing by one participant when transcribing the interview recording; was he was crying, did he have a cold or was he taking drugs? This was resolved by the research team when talking to the interviewer who confirmed the participant had a cold. This example demonstrates potential misinterpretation that may arise after the interview

when re-reading or analysing the transcript. Ten Have (1990), a proponent of conversation analysis, acknowledges that researcher assumptions and the availability of various interpretations may introduce bias, and recommends a reflexive approach so decision-making is transparent.

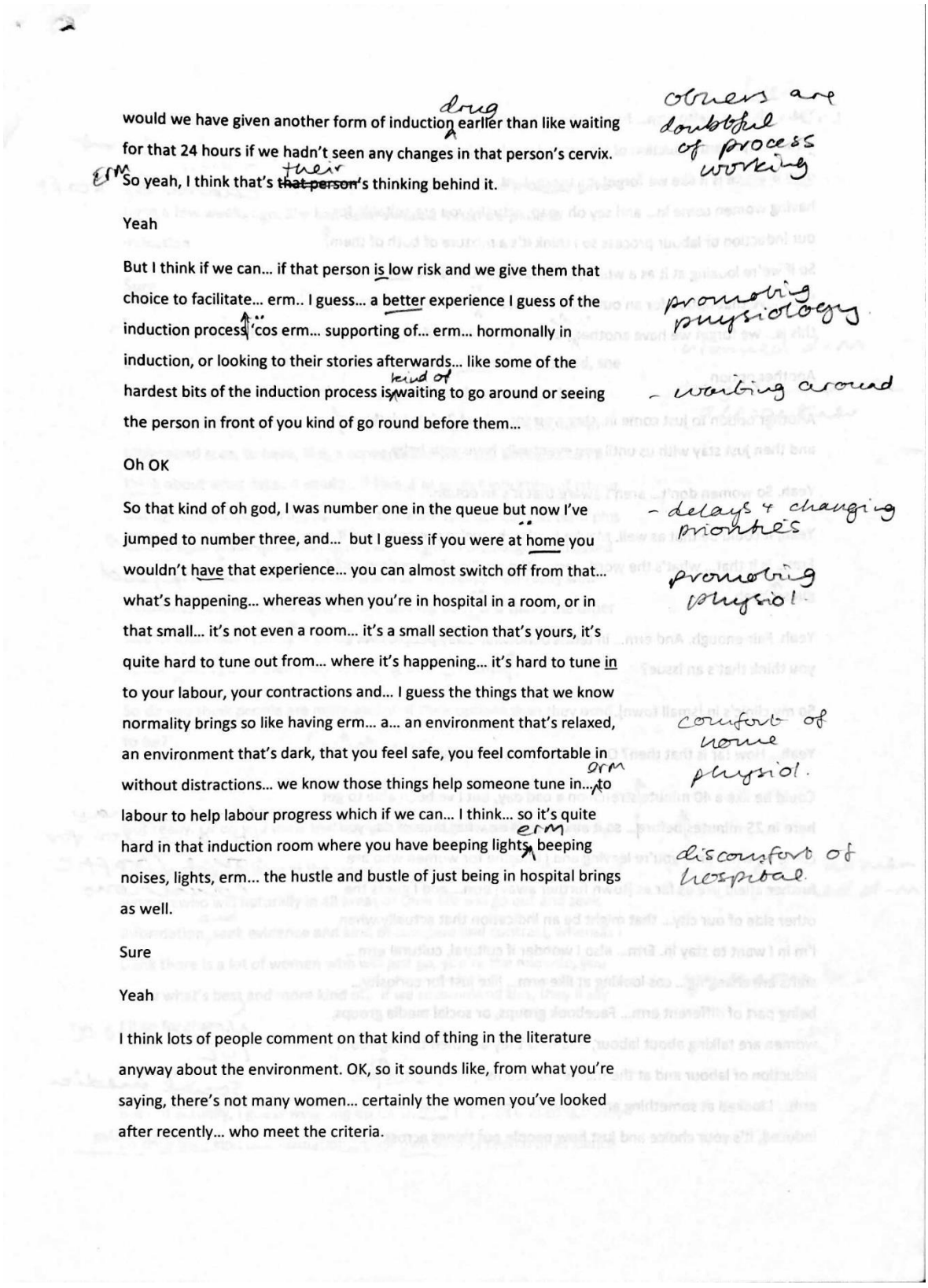
For this project, I used a very simplified notation system derived from Du Bois *et al.* (1993) and Gibson (2010) (Table 3-3). These codes were chosen as they added further insight into the action-orientation of talk e.g., the speaker's use of humour and emphasis as well as hesitation or rising intonation to navigate or hedge around a point of uncertainty or sensitivity.

Table 3-3: Transcription conventions adapted from Du Bois, Schuetz-Coburn et al. (1993) and Gibson (2010)

| **Transcription element** | **Meaning** |
|---|---|
| Underlining | Where the speaker uses emphasis |
| .. | A short pause |
| ↑ | Rise in intonation |
| ↓ | Fall in intonation |
| [laughter] | Where the speaker makes a vocal noise e.g., laughter |

#### 3.9.6.2 **Preliminary reading**

Transcripts were double spaced and printed with space down the sides for corrections, jottings and memos (Saldaña, 2015). I read the transcripts several times while listening back to the recording to check for accuracy and adding details such as pauses and emphasis. This stage added a further one to two hours to the overall transcription time. I also made some initial notes in the margins and identified aspects of talk which were surprising or striking in some way (Saldaña, 2015) (Figure 3-4). Once checked for accuracy, I added line numbers to the electronic versions of the transcripts and italicised my questions. As there were only two people involved, no identifiers were needed to identify who was speaking.



would we have given another form of induction drug earlier than like waiting for that 24 hours if we hadn't seen any changes in that person's cervix.

erm So yeah, I think that's ~~that person~~ their's thinking behind it.

Yeah

But I think if we can... if that person is low risk and we give them that choice to facilitate... erm.. I guess... a better experience I guess of the induction process 'cos erm... supporting of... erm... hormonally in induction, or looking to their stories afterwards... like some of the hardest bits of the induction process is kind of waiting to go around or seeing the person in front of you kind of go round before them...

Oh OK

So that kind of oh god, I was number one in the queue but now I've jumped to number three, and... but I guess if you were at home you wouldn't have that experience... you can almost switch off from that... what's happening... whereas when you're in hospital in a room, or in that small... it's not even a room... it's a small section that's yours, it's quite hard to tune out from... where it's happening... it's hard to tune in to your labour, your contractions and... I guess the things that we know normality brings so like having erm... a... an environment that's relaxed, an environment that's dark, that you feel safe, you feel comfortable in without distractions... we know those things help someone tune in... erm to labour to help labour progress which if we can... I think... so it's quite hard in that induction room where you have beeping lights erm beeping noises, lights, erm... the hustle and bustle of just being in hospital brings as well.

Sure

Yeah

I think lots of people comment on that kind of thing in the literature anyway about the environment. OK, so it sounds like, from what you're saying, there's not many women... certainly the women you've looked after recently... who meet the criteria.

Figure 3-5: Example of transcript after preliminary reading

#### 3.9.6.3 **Critical realist discourse analysis**

After preliminary reading, extracts were selected for further analysis. Saldaña (2015) recommends novice researchers use manual coding when learning how to analyse qualitative data rather than using software such as Nvivo. This involves printing transcripts, cutting out extracts, and then putting them into thematic groups. However, I copied and pasted extracts into a Microsoft® Excel® spreadsheet as it enabled me to search the data for regularly occurring words, as well as being able to filter data easily. The spreadsheet had seven columns: participant identification code, line numbers, the extracted passage then a further three columns for the critical realist discourse analysis i.e., discursive psychology, Foucauldian discourse analysis and extra-discursive factors. Lastly, I added a final column to make reflexive notes during the analysis phase to enhance transparency so I could reflect on meanings constructed by the talk (Figure 3-5).

I found it was easiest to start by examining the talk in detail and describing what was said and how it was said (Wiggins, 2017). This enabled me to identify discursive devices and what the speaker accomplished in their account (Ferndale *et al.*, 2017; Goodman, 2017). For example, reported speech can enhance the authenticity and credibility of the speaker's account and stake inoculation can enable speakers to express controversial views and simultaneously deflect criticism. Fairclough (2003) also recommends reflection on what is *not* said as this can identify issues speakers wish to avoid or do not deem significant.

Interpretive repertoires were also identified. These are recurrent discursive patterns identified through discourse analysis in which people use culturally familiar concepts, metaphors, descriptions, figures of speech or tropes that coalesce around a topic or theme (Wetherell, 1998; Edley, 2001; Lewis-Beck, Bryman and Liao, 2004; Ceuterick *et al.*, 2021). They are action-orientated and used by people as 'common sense' building blocks in conversation, often in association with an alternate repertoire, to present and legitimise different versions of reality and create a shared understanding (Lewis-Beck, Bryman and Liao, 2004 p.507; Ceuterick *et al.*, 2021). For example, feminists may be portrayed in talk as people wanting equality for women versus talk which characterises them based on their physical appearance, sexuality and demeanour (Edley, 2001). Edley (2001) asserts that rather like books borrowed from a library, these interpretive repertoires provide ways in which people can talk about feminists and expressing how they perceive others think about feminists. In my study, the deployment of interpretive repertoires enabled midwives to present their views and decisions about OPIOL in a culturally familiar way.

| Respon | Line | Extract | Discursive psychology | Foucauldian discourse analysis | Extra-discursive factors | Notes |
|---|---|---|---|---|---|---|
| KWSX | 21 | When we first started the trial of it, erm.. I would have a few people come through and they'd go home, and then the reduced fetal movements guideline came in and that was all a bit.. difficult to interpret, erm.. so then I think on discussion with a lot of the doctors when I had questions, they'd say, 'keep them in.' So, at that point, I took that as if they had any episodes of reduced fetal movements at term, then they'd need to be an inpatient, especially if their induction was for reduced fetal movements. | The midwife uses a hedge 'all a bit' to soften her presentation of the view that the reduced fetal movements guideline was difficult to interpret. This suggests she is aware that the researcher was guideline author or perhaps to save face that she is unclear about the guidelines for women presenting with reduced movements in late pregnancy. | Safety discourse | Embodiment - normal physiological parameters | Reflexivity - hard to tell if aimed at researcher or trying to save face<br><br>Ever narrowing window |
| KWSX | 35 | So we'd discuss all the options, do a set of observations to make sure they were all ok before we start, erm.. do a thirty minute CTG and then do an internal examination and, erm.. assess their cervix. If they're appropriate for a [pessary] then, erm.. I'd insert that, have a one hour post-[pessary] CTG and then, erm.. if within that hour I would then phone [telephone triage], erm.. to let them know that they're going to go home | Midwife presents herself as safe practitioner who discusses options. | Safety discourse | Embodiment - normal physiological parameters | Reflects wider technocratic risk discourse that is prioritised in maternity care over the emotional aspects of care in which women are presented as passive recipients of advice and care (Ferndale et al 2017). Alternatively, this focus could just reflect the way the question was framed. |

Figure 3-6: Example of CRDA analysis using Microsoft® Excel®

Subject positions were identified in terms of how midwives presented themselves when talking about the induction process, or in relation to women or colleagues. While subject positions can help us understand more about people's perspectives and how they construct their identities, they are carefully crafted and can change within and between conversations in reaction to the subject positions of others (Edley, 2001). This stage of the analysis helped me to understand how midwives managed their professional credibility and accountability in talk about OPIOL.

In the Foucauldian discourse analysis phase, discourses were identified and it was noted how midwives orientated towards and reproduced these in their talk (Carabine, 2001). Discourses provide an insight into institutions, social structures, relationships and power and can shape how we think, feel and act with some being privileged over others (Edley, 2001; Wiggins, 2017). They differ from interpretive repertoires which are smaller, more fragmented and deployed more flexibly by individuals (Edley, 2001). This stage of my analysis was also informed by discourses apparent in my literature review as well as my knowledge of strategic policy initiatives in maternity care. Some critical realist authors use the term retrodiction to describe the application of existing knowledge to explain outcomes in a new setting, while retroduction refers to inferences made within the current investigation about generative mechanisms and outcomes, and how they relate to the observed reality (Mingers, 2004; Price and Martin, 2018).

The third stage of the critical realist discourse analysis focussed on extra-discursive factors influencing OPIOL and these were informed by the literature review in Chapter 2. Institutional factors, and factors relating to people's material resources were identified, as were those relating to an individual's personal embodiment (Cromby and Standen, 1999; Sims-Schouten, Riley and Willig, 2007).

Using Microsoft® Excel® filtering options, I was able to group extracts by extra-discursive factor or the wider available discourse for further analysis. This meant I was able to get a sense of how frequently a particular factor or discourse was apparent in the data (Saldaña, 2015). Where possible, I used participants' own language to describe the factor, described as in vivo coding by Saldaña (2015). This enabled me to use participants' language to group exemplars thematically. Exemplars for each factor were then identified and shared with my research supervisors who acted as critical peer reviewers to ensure descriptive validity and enhance credibility of the findings (Maxwell, 2012).

## 3.10 Integration of quantitative and qualitative findings

Mixed methods research has a point of interface where the findings of the core and supplemental components of the study are integrated (Morse and Niehaus, 2009). In my research, this was conducted by incorporating relevant data from the quantitative study within the narrative of the core, qualitative component of my findings in Chapter 5. Interfacing the data in this way, enabled me to address any unexpected findings and enhance the integrity of my study (Schoonenboom and Johnson, 2017).

## 3.11 Rigour

Researchers need to ensure potential bias is minimised and results are more likely to be accurate and objective (Lacey, 2015). Quantitative research uses the concepts of validity and reliability. Validity describes the extent to which the chosen method or tool measures what it is supposed to whereas reliability concerns the consistency or repeatability of the measurement. Mandatory data fields (e.g., demographic details, dates, time of induction, birth outcome) helped assure the validity of my research. Reliability was enhanced by using a data collection tool. However, retrospective data collection can introduce bias into research where data fields are not mandated by electronic systems, and may reflect clinician or patient preferences, and practical issues such as time of day and activity (Agniel, Kohane and Weber, 2018).

In terms of the qualitative part of my study, researchers tend to use the concept of trustworthiness to describe high quality research. According to Lincoln and Guba (1985; 1994), trustworthiness is determined by five key aspects:

- Credibility or confidence in accuracy of the findings
- Transferability of the findings to other settings
- Dependability or repeatability of the research
- Confirmability or neutrality of the findings
- Authenticity is achieved by clearly articulating the reality of participants' lived experiences to ensure '*adequate accounts of nonmainstream lives*'.

(Lincoln and Guba, 1985; Guba and Lincoln, 1994 p. 106)

Credibility can be demonstrated by having an appropriate professional background and experience to carry out a research project (Shenton, 2004; Polit and Beck, 2006). In this respect, as a Consultant Midwife, I have responsibility for providing clinical expertise in the delivery of

midwifery care. Credibility has also been enhanced by peer review during the doctoral programme through the completion of the required milestones. Engaging in regular academic supervision also provided me with a vital 'sounding board' and further exploration of methods, interpretations and emerging themes (Polit and Beck, 2006).

Credibility can also be assured by the way research is conducted and using recognised methods which are clearly described (Morse, 2015) alongside in-depth interviews and exemplars. In addition, I integrated disconfirming evidence in my analysis (Polit and Beck, 2006; Goodman, 2017; Wiggins, 2017). Member checks can also improve credibility as it provides participants an opportunity to review and comment on transcripts of their interviews or early thematic analysis (Birt *et al.*, 2016). In this study, while participants were offered a copy of the transcripts of their interview, explicit member checking was not considered practicable in the time frame for a novice researcher.

Transferability was considered, and while there was only time to collect data from one setting, I have described my research setting and the characteristics of women eligible for OPIOL to allow others to make inferences about how the findings may apply in their own Trust (Morse, 2015).

Dependability of the research can be achieved by describing the research process in as much detail as possible and ensuring transparency of decisions made (Braun, Clarke and Hayfield, 2019). The notes and memos I made during the project were retained and referred to when describing the methods and limitations.

Confirmability was enhanced by keeping a reflexive diary on the challenges of maintaining an analytical distance while being an 'insider' at the Trust (Burns *et al.*, 2012; Kent, 2015). This enabled me to reflect on potential bias and assumptions made during the research process and to consider how participants may have chosen their words carefully to present themselves in a favourable light (Byrne *et al.*, 2015; Goodman, 2017). Braun and Clarke reject the notion that the researcher is an objective data collector and that themes *emerge* entirely from the data. Instead, they acknowledge the active role the researcher plays as they generate themes based on decisions and selections of data they make during their analysis (Braun and Clarke, 2006; Braun, Clarke and Hayfield, 2019). Reflexive analysis of the interview process also provided an opportunity for me to learn from mistakes and to avoid asking closed and leading questions.

## 3.12 Chapter summary

This chapter has provided justification for the adoption of CRDA approach using mixed methods. Critical realism acknowledges how aspects of participants' physical and social reality affect their sense-making (Bhaskar, 1997; Willig, 1999). In addition, it recognises the agency individuals have to influence others and transform the world around them (Cromby and Nightingale, 1999). This approach enabled me to bridge both realist and social constructionist standpoints to produce a more comprehensive analysis of the factors influencing participants' talk about OPIOL.

# Chapter 4 Quantitative results

## 4.1 Introduction

The quantitative results are presented in the current chapter and describe the research context in which OPIOL takes place in terms of overall induction activity between July 2015 and June 2018. The characteristics of women eligible for OPIOL on admission to hospital are also described and clinical outcomes of those who accepted OPIOL are presented. Missing data is presented alongside the results as this was a significant finding. Qualitative findings are presented in Chapter 5.

## 4.2 Indications for induction of labour

Between July 2015 and June 2018, 4402 women underwent induction of labour. Of these, over 52 per cent were women expecting their first baby, and the median pregnancy gestation was 40 weeks. More than one reason was cited for induction with 4826 cited indications overall (Appendix XXVII). Figure 4-1 shows the reasons for induction as a percentage of overall cited indications. Induction to avoid prolonged pregnancy was the most common indication cited for induction of labour (21.6%), followed by pre-labour rupture of membranes (13.6%) and reduced fetal movements (12%).

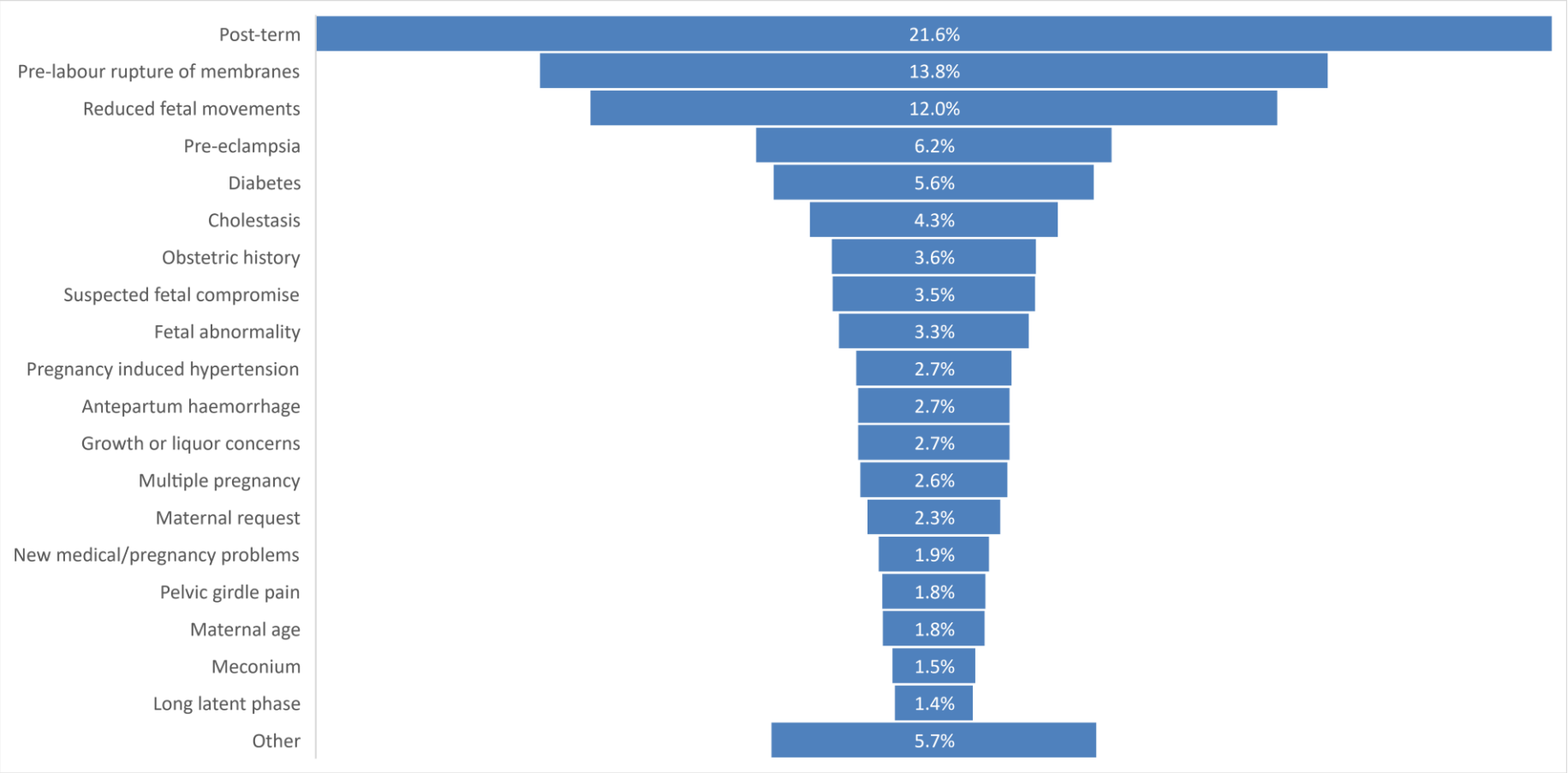



Figure 4-1: Indications for induction of labour July 2015 to June 2018

## 4.3 Characteristics of women eligible for post-dates OPIOL

Of the 2306 nulliparous women offered induction of labour between July 2015 and June 2018, 187 (8.1 per cent) were eligible for inclusion in the data analysis. These women were at low risk of complications, offered induction at a gestation of 40 weeks and 10 to 12 days and lived within 30 minutes' journey time of the hospital. An additional twenty-three women were eligible for OPIOL according to the NHS Trust's guidance but did not meet the study eligibility criteria as they were being induced for other indications (maternal request and pelvic girdle pain). These women were excluded from the analysis although it was noted that none of them underwent OPIOL. Three women were not eligible for outpatient management according to Trust guidance having a gestation of 40 weeks and 13 days. However, requests for OPIOL had been negotiated and agreed following a consultation with a senior clinician. As these women did not meet the study's eligibility criteria, outcomes were excluded from the overall data analysis.

Table 4-1 summarises characteristics of the 187 women at low risk of complications who were eligible for post-dates OPIOL. After an initial assessment, 53 women were subsequently found to be ineligible according to the Trust guideline. Of this group, two thirds of the women were already experiencing uterine contractions and others were found to have abnormal fetal or maternal observations, ruptured membranes or a high presenting part, all of which are exclusion criteria for outpatient management. Of the 81 women offered OPIOL, 11 declined and 70 women received the dinoprostone pessary.

A significant finding was that there was missing data for 53 women in terms of whether they were offered OPIOL. While eligible for OPIOL, it was not clear in the narrative of their maternity records whether this option was discussed or offered. This group are also included in Table 4-1.

Table 4-1: Characteristics of women eligible for OPIOL pathway on admission to hospital

| Characteristic | | Accept | | Decline | | No longer eligible* | | Missing data | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | *n* | % | *n* | % | *n* | % | *n* | % | *n* | % |
| **Total** | | 70 | 37.4 | 11 | 5.9 | 53 | 28.3 | 53 | 28.3 | 187 | 100 |
| **Age** | Mean (SD) | 28.4 | (4.6) | 26.7 | (4.0) | 29.0 | (4.5) | 28.9 | (4.3) | 28.6 | (4.5) |
| **Ethnicity** (not stated for 1 record) | All other ethnic groups combined | 5 | 29.4 | 2 | 11.8 | 5 | 29.4 | 5 | 29.4 | 17 | 9.1 |
| | Any other white background | 8 | 30.8 | 0 | 0.0 | 8 | 30.8 | 10 | 38.5 | 26 | 14.0 |
| | White British | 56 | 39.2 | 9 | 6.3 | 40 | 28.0 | 38 | 26.6 | 143 | 76.9 |
| **BMI** | Mean (SD) | 25 | (4.0) | 25.5 | (6.3) | 26.3 | (4.3) | 28.1 | (6.6) | 26.3 | (5.2) |
| | 18.5 to 24.9 | 40 | 45.5 | 6 | 6.8 | 20 | 22.7 | 22 | 25.0 | 88 | 47.1 |
| | 25 to 29.9 | 21 | 38.9 | 3 | 5.6 | 21 | 38.9 | 9 | 16.7 | 54 | 28.9 |
| | 30 to 34.9 | 8 | 28.6 | 0 | 0.0 | 11 | 39.3 | 9 | 32.1 | 28 | 15.0 |
| | 35.0 to 39.9 | 1 | 5.9 | 2 | 11.8 | 1 | 5.9 | 13 | 76.5 | 17 | 9.1 |
| **Education** (not stated for 2 records) | Secondary | 8 | 29.6 | 3 | 11.1 | 8 | 29.6 | 8 | 29.6 | 27 | 14.6 |
| | College | 23 | 30.3 | 2 | 2.6 | 28 | 36.8 | 23 | 30.3 | 76 | 41.1 |
| | University | 38 | 46.3 | 6 | 7.3 | 17 | 20.7 | 21 | 25.6 | 82 | 44.3 |
| **Employment** | Full time | 55 | 36.4 | 9 | 6.0 | 44 | 29.1 | 43 | 28.5 | 151 | 80.7 |
| | Part time | 9 | 36.0 | 2 | 8.0 | 7 | 28.0 | 7 | 28.0 | 25 | 13.4 |
| | No paid employment | 5 | 50.0 | 0 | 0.0 | 2 | 20.0 | 3 | 30.0 | 10 | 5.3 |
| | In education | 1 | 100.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 0.5 |
| **Bishop score** | Median (IQR) | 3 | (2.75 -4) | 3 | (2-6) | 6 | (4-7) | 4 | (3-7) | 4 | (3-6) |

As the number of women eligible for OPIOL was small, it was not possible to calculate whether there were any significant differences between the groups in terms of demographic characteristics. Of the women eligible for OPIOL, the mean age was 28.6 and mean BMI was 26.3kg/$m^2$. Most women worked full time (80.7 per cent) and university educated (44.3 per cent). In terms of ethnicity, 76.9 per cent were of white British background, reflecting local 2011 census data (City Council Name Witheld, 2016).

In terms of those who accepted OPIOL, most were of white ethnic background, university-educated and working full time. Howard *et al.* (2014) noted some differences in women's preferences about OPIOL in their research. Older, university-educated women were more likely to prefer outpatient management and women from a non-English speaking background were more likely to prefer inpatient management.

Of note, women who were offered OPIOL had a lower BMI than those women where there was missing data around offer of outpatient management. A clear offer of OPIOL was made to 52.3 per cent of women with a BMI of 18.5 to 24.9kg/$m^2$. In contrast, for 76.5 per cent of women with a BMI of 35 to 39.9kg/$m^2$, there was missing data around offer of OPIOL. Women with a BMI of up to 39.9m/kg are eligible for OPIOL according to Trust guidance. While missing data can reduce sample size and undermine the validity of research due to incomplete data, it can also reveal systematic influences on people's decision-making and social circumstances (Dancey, Reidy and Rowe, 2012; Kim and Mallory, 2014; Rothenbühler and Voorpostel, 2016; Nguyen *et al.*, 2018). In this case, it suggests midwives were either unaware that women with a BMI of 35 to 39.9kg/m2 were eligible for OPIOL or they preferred not to discuss the option of OPIOL with this group. The issues around missing data are considered further in section 7.3.

## 4.4 Clinical outcomes of women discharged home for OPIOL

Of the 70 women who agreed to OPIOL and received a dinoprostone pessary, 48 were subsequently discharged home. Table 4-2 describes outcomes of women discharged for OPIOL and reasons for readmission. Of the 48 women discharged, 15 remained at home overnight, only returning to the hospital to continue the induction of labour process the following day. Median time avoided in hospital was 12 hours and 53 minutes (range 2 hours 40 minutes to 25 hours and 8 minutes) and the minimum pessary to birth interval was 6 hours and 27 minutes. The woman returned to hospital in labour and just over an hour later her baby was born by category one caesarean due to fetal concerns. This is the most urgent grade of caesarean and national guidance

recommends a decision to birth interval of 30 minutes (National Institute for Clinical Excellence, 2021). The baby was in good condition with an Apgar score of 9 at 5 minutes of age. Thirty-three women were readmitted later in the evening or overnight and the most common reason for readmission was suspected labour (n=24) followed by suspected rupture of membranes (n=5). Other reasons for readmission included concerns about maternal or fetal wellbeing and in one case the pessary became dislodged. For the OPIOL group overall, there was progression in the Bishop score of two points and a median cervical dilatation change of 1cm. Following amniotomy or spontaneous rupture of membranes, 33 women required an oxytocin infusion as part of their ongoing induction of labour. Median pessary to birth interval was 32 hours and 21 minutes.

Table 4-2: Outcomes of women discharged home for OPIOL

| | **OPIOL** | |
|---|---|---|
| **Outcome** | *n=48* | % |
| **Time at home (median)*** | 12hr 53min | |
| Interquartile range | 6hr 25min – 21hr 17 min | |
| Minimum - maximum | 2hr 40min – 25hr 8min | |
| **Reason for readmission** | | |
| Suspected labour | 24 | 50.0 |
| Ongoing induction | 15 | 31.2 |
| Suspected ruptured membranes | 5 | 10.4 |
| Reduced fetal movements | 1 | 2.1 |
| Suspected abnormal observations | 1 | 2.1 |
| Gastrointestinal symptoms | 1 | 2.1 |
| Pessary dislodged | 1 | 2.1 |
| **Cervical status change (median)** | | |
| Bishop score initial (and readmission) | 4 | (6) |
| Cervical dilatation initial (and readmission) | 1 | (2) |
| **Oxytocin required** | | |
| Yes | 33 | 68.8 |
| No | 15 | 31.2 |
| **Pessary to birth interval (median)** | 32hr 21min | |
| Interquartile range | 23hr 59min – 44hr 25min | |
| Minimum - maximum | 6hr 27min - 62hr 27min | |

*Time of discharge to time of readmission to hospital

Table 4-3 describes birth outcomes of women who had OPIOL. Of the 48 women discharged home, 29 (60.4 per cent) had a vaginal birth although 16 required assistance with forceps or ventouse. The remaining 19 women (39.6 per cent) required an unplanned caesarean, 10 of which were for suspected fetal compromise. None of the babies required resuscitation or admission to the neonatal unit.

Table 4-3: Birth outcomes of women discharged home for OPIOL

| Outcome | OPIOL | |
|---|---|---|
| | *n=48* | % |
| **Birth outcomes** | | |
| **Unplanned caesarean birth** | **19** | **39.6** |
| Suspected fetal compromise | 10 | 20.8 |
| Slow progress[5] | 6 | 12.5 |
| Unsuccessful induction | 3 | 6.3 |
| **Assisted vaginal birth** | **16** | **33.3** |
| Slow progress | 9 | 18.8 |
| Suspected fetal compromise | 7 | 14.6 |
| **Unassisted vaginal birth** | **13** | **27.1** |
| **Neonatal Apgar score (median)** | **9** | |
| Minimum - maximum | **8 - 10** | |
| **Neonatal unit admission** | **0** | |

## 4.5 Clinical outcomes of women not discharged following administration of dinoprostone pessary

Table 4-4 shows the clinical features of the women who commenced the OPIOL pathway but were subsequently not discharged home. Of the 70 women who agreed to OPIOL and received a

[5] Slow progress or delay in labour is determined by a clinician's assessment and may be an indication for intervention. Timeframes are based on national guidance (NICE 2014b). In the first stage of labour, it is defined as cervical dilatation of less than 0.5cm an hour. For nulliparous women in the pushing stage, referral is made to an obstetrician for a review of care after two hours of active pushing unless there are other concerns beforehand, and birth would be expected to be achieved within three hours.

pessary, 22 continued on an inpatient pathway. Uterine activity and fetal heart rate concerns prompted ongoing monitoring to check fetal wellbeing.

Table 4-4: Clinical features of women not discharged following administration of dinoprostone pessary

| Characteristic | Inpatient | |
|---|---|---|
| | *n=22* | % |
| Reason not discharged | | |
| Uterine activity | 10 | 45.5 |
| Fetal heart rate concerns | 8 | 36.4 |
| Other fetal concerns | 2 | 9.1 |
| Hyperstimulation | 1 | 4.5 |
| Ruptured membranes | 1 | 4.5 |

Of the 22 women not discharged home, there were fetal wellbeing concerns for 11 of them (Appendix XXVIII). Nine women continued the induction pathway as inpatients due to concerns with fetal heart rate concerns in order to continue or repeat monitoring later. One of the women experienced hyperstimulation of the uterus with fetal heart changes and the pessary was removed. In addition, two women were transferred to the antenatal ward due to other fetal concerns and the narrative for both cases reported 'very active baby' which is not an exclusion criterion for OPIOL in Trust guidance.

Overall, amongst the 22 women who received the pessary but not discharged home, there were no serious adverse neonatal outcomes. One baby was admitted to the neonatal unit following birth around 50 hours after administration of dinoprostone. The admission was due to additional work of breathing attributed to poor neonatal transition from intra- to extra-uterine life and the baby discharged less than 4 hours later. The median birth interval from time of administration of pessary was 35hr 37min for this group (range 12hr 33min to 51hr 6min). This suggests there were no urgent concerns requiring immediate birth of the baby following administration of dinoprostone.

## 4.6 Chapter summary

This chapter has presented the quantitative findings of the study and has highlighted that few women had the opportunity to experience OPIOL during the study period. Overall, of 2306 nulliparous women undergoing induction of labour between July 2015 and June 2018, 187 (8.1 per cent) were initially eligible for outpatient management and inclusion in the study. Following an initial assessment some women had developed new complications or contraindications for outpatient management, some declined OPIOL, and only 48 women were subsequently discharged home over the three-year period. For a further 53 women, there was no documented evidence in the narrative that the pathway had been discussed or offered. While the absence of data certainly affects the reliability of the quantitative findings, it was also a significant finding and is considered further in Chapter 7. Similarly, of the 70 women who were about to commence the OPIOL pathway, 22 remained in hospital following administration of the pessary, largely due to uterine contractions and fetal concerns and this was explored further in interviews with midwives.

This page has been left intentionally blank

# Chapter 5 Qualitative findings

## 5.1 Introduction

The aim of the following chapter is to describe the factors influencing midwives' views and decisions about OPIOL in the research setting. A critical realist discourse analysis (CDRA) was informed by the literature review and enabled me to synthesise interview data with quantitative results. I provide exemplars to demonstrate the extra-discursive factors and wider discourses that featured in participant talk. The interactional effects of participants' talk are also explored as well as the discursive devices midwives used to manage accountability and justify decisions (Fairclough, 2003; Sims-Schouten, Riley and Willig, 2007; Wiggins, 2017). As described in chapter 3, where possible, I used participants' own language to describe and group exemplars thematically Saldaña (2015).

## 5.2 Participants

Five midwives were recruited, three of whom worked in the induction of labour suite regularly, providing care to all women undergoing induction. Local NHS Trust guidance supports midwives to make autonomous decisions about eligibility for OPIOL following a risk assessment. The midwives performed an initial assessment prior to commencing the induction process to confirm eligibility and to ensure women were making informed decisions about their care. Two midwives who worked predominantly in a community setting were also recruited. I felt it was important to consider the views and decisions of this group of staff as they provide continuity of care to women throughout pregnancy. This means they are likely to have a good insight about eligibility for OPIOL or whether inpatient management would be more appropriate due to pregnancy complications. They counsel women about the risks and benefits of induction of labour towards the end of pregnancy and help support women's decision-making. One woman who underwent OPIOL to avoid prolonged pregnancy was also recruited to take part. Extracts from the interview are presented at the end of the chapter as a case study and I consider how her account supports the views presented by the midwives. Participant identification codes are used here to protect anonymity.

## 5.3 OPIOL is not 'run of the mill'

While 2306 nulliparous women were offered induction of labour over the 3-year study period, 187 met the eligibility criteria for post-dates OPIOL yet only 48 women were discharged home. Participants corroborated the quantitative findings in their accounts and indicated that few women met the eligibility criteria and that were not discharged home for OPIOL frequently.

**Extract 1: Participant KWSX 134-137**

134 ↑Do you know what? Recently, we haven't had a lot of post.. in
135 my experience on the days I've been doing them, we haven't had a lot of post-dates
136 inductions, erm.. I've given [the pessary], I gave two [pessaries] yesterday, erm.. but for
137 inpatient inductions.

The midwife uses a rhetorical question as a persuasive device to strengthen her point of view in an indirect way to minimise any threat (Frank, 1990). She corrects herself with a hedge 'In my experience'. Hedging is frequently characteristic of tentative, provisional or conditional talk, and can often mark problematic areas in which the speaker is trying to avoid challenge or criticism. It can also enable a speaker to appear noncommittal about a point of view until the position of the other person becomes clearer (Wiggins, 2017).

The midwife in the following extract also uses hedges in her repetition of 'I think' and talks tentatively about her experiences of OPIOL.

**Extract 2: Participant B9AL 180-182**

180 Erm.. I think we.. [inaudible] not that recently.. I think one of them recently hasn't fitted,
181 like, the outpatient induction of labour process. Erm.. looking after people in labour
182 who've come in.. trying to remember off the top of my head [laughter].

The midwife indicates that the Trust guideline's eligibility criteria is a factor responsible for low rates of outpatient management and she is unable to recollect any recent offers of OPIOL. Laughter and idiomatic talk 'off the top of my head' politely signals she is ready to move away from this topic (Koester, 2006; Eerdmans and Di Candia, 2007).

The midwife in the following extract claims that eligibility criteria is the key factor responsible for low rates of OPIOL.

**Extract 3: Participant ZV8J 311-318**

311 I think the biggest factor is just the.. the criteria. It's just too small. That it's too.. not many
312 women in today's day and age are going to fit that criteria, erm.. yeah, we just don't have
313 that many post-dates, low-risk. And whilst I think.. I think I looked at, erm.. reason for
314 induction being, I think the biggest.. one of the biggest was post-dates, they're usually..
315 it's very rare in this day and age for them to come in without having had any issues in their
316 pregnancy. Erm.. I think if you just had the criteria as post-dates and then.. even if they've
317 been in for different various things in their pregnancy, that they could still have it if it was
318 okayed by a doctor, I think that would make it easier.

The midwife asserts her point of view with repetition, emphatic talk e.g., 'the biggest factor', 'it's just too small', 'very rare', and idiomatic talk 'in this day and age'. This is illustrative of assessment or evaluative talk and is used to accentuate her point that few women are eligible for OPIOL (Wiggins, 2017). She goes on to suggest that more women could have OPIOL 'if it was okayed by a doctor'. This suggests some reticence to make the final decision about OPIOL and that enhanced multiprofessional working and shared decision-making would improve rates.

In this extract the midwife clearly orientates towards the wider risk discourse in maternity care and an 'ever-narrowing window of normality' (Scamell and Alaszewski, 2012). Dahlen (2016) also recognises the contemporary tendency to try and label pregnancy as either high risk or low risk when the reality is rarely so cut-and-dried. Dahlen goes on to argue that midwives frequently find themselves 'dancing in the grey zone' to protect themselves professionally whilst also preserving women's rights and this is seen when the midwife wants a decision to be 'okayed by a doctor'. Furthermore, since multiprofessional working is recognised as a key safety feature in maternity care, it also enables the midwife to present herself as a team player (National Maternity Review, 2016; NHS England, 2016).

The midwife in the following extracts identifies that restricted eligibility criteria creates a further conundrum in that midwives are not familiar with the OPIOL process.

**Extract 4: Participant JN3W 132-138**

132 I think it is because fear of the unknown. Because I think historically, we've not done it. I
133 think the reason you're not getting good numbers is your criteria is too limited. So your..
134 the criteria is term plus, postdates, low risk, primip. Erm.. so.. just that group is gonna

reduce the numbers that can fall into it. And then you factor in, you know, like the trace may be, erm.. not being great or reassuring should I say. Or.. they haven't felt the baby move. And then you're going to knock off a few of those. Erm.. so that's one issue is that your criteria group, your inclusion group. The other is the midwives aren't used to doing it.

The midwife suggests there is a 'fear of the unknown' about OPIOL as an infrequently offered intervention and cites the contribution of eligibility criteria and newly arising risk factors to the low rates of uptake. Notably, there is a pronoun footing shift in this extract from 'historically we've not done it' to 'the reason you're not getting good numbers'. This kind of device can be used to help manage accountability and identity of the speaker, and in this case, shifted some responsibility to me in my role as consultant midwife to resolve the problem (Wiggins, 2017). She also indicates another reason for low rates of OPIOL is because staff are not familiar with the process, linking back to her opening statement 'fear of the unknown'.

The next midwife openly admits that she forgets the OPIOL option is available. This is highlighted in the following two extracts.

**Extract 5: Participant B9AL 246-251**

.. also when I'm thinking about my own practice is it, like, we forget it's there, that you've been so used to having women come in.. and say 'oh yeap, actually you are suitable for our induction of labour process,' so I think it's a mixture of both of them. So if we're looking at it as a whole, is it that sometimes we forget we ha.. have that option for an outpatient induction.. that we think actually, this is.. we forget we have another side path.

**Extract 6: Participant B9AL 256-257**

Erm.. is it that.. what's the word? Erm.. the profile of ↑it has ↑dropped I ↑guess. Yeah.

A rapid pronoun footing shift is noticed from 'I' to 'we' in the first extract i.e., 'when I'm thinking about my own practice' to 'we forget it's there', a strategy people sometimes use to avert criticism (Wiggins, 2017). The midwife asserts her point by using the word 'actually' a couple of times, active voicing and emphasis ('you are suitable'). She then goes on to describe OPIOL as a 'side path' suggesting it is not likely to become a routinely offered option. The rising intonation in the second extract indicates some hesitation in offering the explanation that the profile of OPIOL has dropped (Fraser, 1990; Edwards and Potter, 2005).

The following participant indicates OPIOL is not routine and offers a solution to raise awareness of the intervention.

**Extract 7: Participant JN3W 189-196**

189 I think, erm.. maybe it needs promoting more, because.. and some of the, erm.. because I
190 think that because where it's not done very frequently, it's an unusual thing to happen as
191 opposed to run of the mill and on our radar, so I think to.. prom.. I think I think it probably
192 would be worth promoting it.

193 *For the midwives or the women?*

194 With the midwives. Midwives. Er… both. So both. I mean.. in fact both would be important
195 because if you promoted it to the women and the women requested it then the midwives
196 would, erm.. be more likely to do it, wouldn't they?

There is some hesitation here as the midwife formulates her response. She uses distinctive idioms 'run of the mill' and 'on our radar' to highlight the catch-22: that midwives having more clinical experience of OPIOL would make it more of a routine option. Koester (2006) suggests the relational purpose of idiomatic talk is to engage others and create a sense of solidarity through a shared understanding.

The midwife suggests that staff should be the target of OPIOL promotion, adding emphasis and repetition of the word 'midwives' in her response. She then corrects herself in response to the suggestion in the question from the researcher that women could be target of promotion as well. In doing this, she aligns herself with what she perceives to be the subject position of the researcher.

Training for dinoprostone pessary insertion also influenced midwives' views and decisions about outpatient induction. When OPIOL was launched in 2015, training was offered to all the midwives and covered eligibility criteria, how to insert the pessary and indications for removal. The intention of the training was to ensure that midwives working in the community could explain the option of OPIOL to women in their clinics and midwives managing the induction process would be familiar with administration and removal. One of the midwives provides an evaluation of the training in the following extract.

**Extract 8: Participant ZV8J 205-209**

205 Well.. the training, when it was launched [laughter].. when it was launched, the training
206 we had was about an hour and that was it really. And yes, it is tricky. It's trickier, it's
207 definitely.. it takes more skill than just putting a [dinoprostone tablet] in. Erm.. just I think
208 because of the way, the.. the shape of it and the way it is. Erm.. so very recently I couldn't
209 put one.. I couldn't get one in a lady.

The midwife's evaluation of the training is made clear by her derisive laughter and she admits that the pessary can be difficult to insert. She goes on to provide an example of a situation where she faced some difficulty inserting the pessary into the correct location in the posterior fornix. This can be difficult to reach as it is a recess at the top of a woman's vagina and is situated behind the cervix. Furthermore, the manufacturer recommends that once the pessary has been inserted, it should then be rotated into a horizontal position to help it stay in position. However, it can easily become dislodged by accidentally pulling the tail of the pessary as the examiner's fingers are removed from the woman's vagina.

Working in the induction suite regularly, the midwife provides support and training to other members of staff to insert the pessary. She describes some of the difficulties they have with pessary insertion in the following extract.

**Extract 9: Participant ZV8J 224-235**

224 So I.. you know, I've made a point of saying 'if you can't get it in, do not do it,' because it's
225 a waste of twenty-four hours that you just can't back when it comes to induction. It's not
226 going to do anything if it's just sat in the.. at the introitus, it's not working where it should
227 be.

228 *Do you think that's a factor, when, you know, say it's not you [or your colleague] doing*
229 *inductions?*

230 One hundred per cent. One hundred per cent.

231 *So people aren't familiar with the product?*

232 No. No. If they're not.. confident at putting it in, erm.. or making sure it's in the right
233 place.. then yeah.. it will just..

234 *They're not going to offer it. They'll just go for.*

235 What's easiest. Absolutely. Absolutely.

Here the midwife constructs an extreme case formulation (ECF) to highlight the difficulty of pessary insertion experienced by some of her colleagues. These formulations are often used to justify criticism and simultaneously bolster the speaker's position or argument (Potter and Wetherell, 1987; Edwards, 2000; Wiggins, 2017). The midwife starts to build her claim by highlighting to the listener 'I make a point of saying' and uses both active voicing and emphasis 'if you can't get it in, do not do it'. The midwife then incorporates the ECF: 'It's not going to do anything if it's just sat in the..' as if she is going to say vagina, but then switches to 'at the introitus'. The introitus is the entrance of the vagina and to a midwife, it would be a ridiculous and patently obvious notion as the pessary would have no effect whatsoever. Maximising the contrast by claiming the pessary is found lying at the very opposite end of the vagina to where it should be, the midwife makes this nonliteral statement to convey her point that some of her colleagues face difficulty with pessary insertion.

While I offer a leading statement towards the end of this extract *'They're not going to offer it. They'll just offer…'* the midwife interrupts and uses repetition of 'Absolutely' to confirm her agreement that inpatient induction with the more familiar dinoprostone tablet is offered instead.

These extracts demonstrate that OPIOL is not well embedded in practice to the extent that midwives are unfamiliar and reluctant to offer outpatient management, or they forget this option is even available. Midwives attributed this to the guideline eligibility criteria being restrictive and limited opportunities for training. The midwives also orientated towards the risk and patient safety discourse in their explanations in that few women reached the end of pregnancy without some kind of complication. This reduced opportunities for midwives to become more familiar with OPIOL and meant the intervention was not successfully embedded.

Greenhalgh (2018) emphasises the complex social, organisational and behavioural considerations linked to successful implementation of evidence-based healthcare interventions, highlighting that staff are not passive recipients of clinical guidance and pathways. Instead, people conduct their own appraisal of interventions, and often develop their own workarounds and modifications. These may be based on their own cognitive biases, intuition and heuristics to assist rapid decision-making in the context of managing the pressures of everyday clinical practice (Kahneman, 2011). Successful implementation requires the intervention to be practically coherent with a clear purpose and benefits which are easily understood by staff and patients (Sanders, Foster and Ong,

2011; May, 2013). Operational capability is also a key requirement in terms of ensuring people have the right skills and resources to deliver the intervention, while limited opportunities to participate in its delivery inevitably undermines engagement and the routinisation of the intervention (May, 2013).

## 5.4 Women's expectations

Midwives perceived that women's hopes and aspirations of their labour and birth experience influence decision-making about induction of labour with some being more prepared than others to face the prospect of induction. The midwife in the following extract indicates that once women are in the hospital, they do not wish to return home without their baby and suggests this is another reason rates of OPIOL are low.

**Extract 10: Participant JN3W 20-21**

20 Some of them come and feel that, you know, they're coming in, and.. that they will stay in.
21 And the end process would be, the next time they go home will be with their baby.

The midwife in this extract indicates that women's expectations of induction influence uptake of OPIOL. However, this interpretation was not entirely reflected in the quantitative data; of the 81 women offered OPIOL, only 11 declined. Furthermore, by orientating towards women's expectations, the participant avoids discussing clinician views and decision-making of OPIOL at this stage.

Some of the midwives attributed limited counselling in antenatal appointments to women having unrealistic expectations as the following extract illustrates.

**Extract 11: Participant ZV8J 133-139**

133 ..So she'd come in with the thought.. as in, she hadn't
134 brought, you know, brought her bags into the induction suite or anything. She was like
135 'well I'm here to have my [pessary] and go home.'

136 *Oh right*

137 So she hadn't been properly counselled about the induction process prior which then
138 leaves it up to you on the day which of course then causes disappointment. So, erm.. she
139 was disappointed.

The midwife uses reported speech to enhance the credibility of what she is saying and by providing a negative example, she indicates that improved antenatal counselling about the induction process would improve women's experiences (Wiggins, 2017). The midwife in the next extract expresses the same concerns, this time about the expected duration of labour following induction.

**Extract 12: Participant KWSX 182-185**

182 I think women don't.. aren't counselled properly about induction in the antenatal process.
183 The amount of expectations I have to.. manage is quite tricky because women come in,
184 they still come in thinking they're going to come in for their induction and have their baby
185 in the afternoon.

Here the midwife minimises the difficulties faced as 'quite tricky', which helps soften her comment about women having unrealistic expectations (Wiggins, 2017). In doing so, she avoids her comment being interpreted as one which apportions blame or criticism of the women concerned.

Another midwife integrates her observation of women's expectations of a straightforward and expeditious birth following induction into her counselling about OPIOL in the following extract.

**Extract 13: Participant B9AL 64-67**

64 ..I think it's also taking
65 out the first bit of when you get induced, you're not having your baby on that ↑day.. I think
66 people often think they're having their baby on that day that my induction's booked but
67 actually no, this is a, erm.. a slow process..

Here the midwife uses a discourse marker 'but actually no' to make her position clear to the listener (Fraser, 1990). In doing so, she contrasts women's expectations against the reality of the induction process.

In the following extract the midwife's intonation and idiomatic talk 'they just don't have a clue' indicates her opinion that some women are unprepared for the experience of induction, and those with a 'vague idea' have heard about it through friends. She orientates to a wider interpretive repertoire that women's hopes and aspirations for their labour and birth experience are seldom aligned with reality.

**Extract 14: Participant KWSX 248-253**

..but, like I say, because I don't know what's been said to them antenatally, I don't just assume that they know. I talk through everything again. Because, sometimes.. sometimes, they just don't have a clue what to expect. Or they have a vague idea based on what their friends have said, but of course that's just their friend's personal experience, it's not the overall experience of an induction.

In contrast, the midwives working in the community articulated the detailed discussions they had with women about OPIOL, and induction more generally, during antenatal appointments.

**Extract 15: Participant B9AL 31-39**

So I try and.. so, erm.. kind of, comes in so if someone's low risk.. I touch on it a little bit at the thirty-six week appointment and that.. I might at the thirty-eight week appointment, like, I say 'actually, when I see you at forty weeks these are the kind of things we're going to be offering, would you have a chance to look at it.. ↑online?' So, generally NHS choices and places I point them to about induction of labour for more information, and also our trust ↑website 'cos you can get some of the leaflets online for ↑them.

*Yeah*

So that's my first, kind of, step.. so when I see them, erm.. at forty weeks, talking about a sweep isn't the first time they've heard about it.

Here the midwife uses reported speech as a persuasive device to enhance the credibility and authenticity of her account (Wiggins, 2017). The midwife also demonstrates how informed decisions are supported by continuity of care and orientates towards the wider discourse of choice and personalised care in line with the national *Better Births* agenda (National Maternity Review, 2016).

In the next extract, the midwife articulates the challenges she faces in balancing women's expectations against the possible reality of the induction process in the face of significant time pressures.

**Extract 16: Participant 8UJT 86-91**

erm.. and also the expectation that we're, we're the NHS, we're a busy service and sometimes inductions don't happen, erm.. and trying to

88 cover that in a half an hour appointment is really, really challenging, erm.. but I would hate
89 to think that one of my women would come to an induction and not be fully informed,
90 erm.. because I think information is power so the more.. the more information we can give
91 them, the more empowered they are to then make the decision that suits them best.

Through repetition ‘really, really challenging’ and emphasis 'hate to think', she demonstrates to the listener the deep and personal sense of obligation and responsibility she feels when counselling women and their partners when the resource of time is at a premium. She also orientates towards the wider discourse of the NHS under pressure in ‘we’re the NHS, we’re a busy service’ and the harms of work left undone to both patients and care providers alike (Iacobucci, 2017; Ball, 2020). Furthermore, use of the maxim 'information is power' enables the midwife to present herself as someone who prioritises informed decision-making (Jingree and Finlay, 2008).

In addition to the quality of counselling about induction of labour, an interpretive repertoire or culturally familiar way of talking about induction of labour became apparent, that induction was ‘never part of the plan’. As previously described in section 3.9.6, interpretive repertoires are recurrent discursive patterns identified through discourse analysis which centre around a topic or theme (Wetherell, 1998; Edley, 2001; Lewis-Beck, Bryman and Liao, 2004; Ceuterick *et al.*, 2021). The midwife in the following extract suggests that women rarely anticipate the possibility of induction of labour being offered to them, and that this influences how they make decisions about it.

**Extract 17: Participant ZV8J 187-190**

187 ..When you see.. When you see birth plans, induction is never part of it, is it, ever
188 really? So people don’t plan for it, so I guess when it comes to it, they very much put their
189 trust in you because I think, we, the majority of the time are recommending it, they think
190 ‘well if you’re recommending it, you tell me what’s best.’ Does that make sense?

In contrast, the midwife in the following extract suggests women at high risk of complications have received more counselling and are generally better prepared for the prospect of induction of labour by the end of pregnancy.

**Extract 18: Participant 8UJT 237-240**

237 ..erm.. the higher risk women, they've already had
238 conversations with either [the consultant midwife] or consultants or just other team
239 members about expecting induction towards the end of their pregnancy so I think they've
240 had longer to process it.

The midwife in the following extract highlights a different perspective about women's preparedness around the prospect of induction of labour. In her experience, women are proactive in seeking support with decision-making around induction from a wide range of sources outside of NHS maternity services.

**Extract 19: Participant B9AL 266-273**

266 ..Erm.. also I wonder if cultural,
267 cultural, erm.. shifts are changing.. 'cos looking at, like, erm.. like, just for curiosity.. being
268 part of different erm.. Facebook groups, or social media groups, the women are talking
269 about labour, and how they are then talking about induction of labour and at the moment
270 it seems quite ↑negative, like, erm.. I looked at something and it said, 'oh you don't have
271 to be induced, it's your choice,' and just how people put things across is, erm.. I guess,
272 things like.. and speakers and writers like Milli Hill, for example, how they put information
273 across, I think a lot of women are seeking more information.

The midwife demonstrates her professional curiosity in current social media discourse around women's autonomy and supporting informed decision-making in maternity care by disclosing her membership of various groups. In doing so, she orientates towards the wider discourse of choice and personalisation in maternity care, and name-checking Milli Hill, a well-known author and founder of the *Positive Birth Movement,* adds credibility to her account. She then includes reported speech to illustrate an example of a woman declining induction. This acts as a persuasive device to emphasise her point about women making informed decisions about their care.

The midwife expands on her comments in the following extract and indicates that some women are more proactive than others about seeking alternative sources of information to support their decision-making. In contrast, other women will rely on advice from their midwife.

**Extract 20: Participant B9AL 291-295**

291 Looking at my.. looking at the women I see I think it's a specific group of ↑women who
292 will naturally in all areas of their life will go out and seek information, and seek evidence

293 and kind of compare and contrast, whereas I think there is a lot of women who will just
294 go, 'you're the midwife, you know what's best,' and more, kind of.. if we recommend this,
295 they'll say 'I'll go for that.'

The midwife quickly corrects herself at the beginning of this extract when referring to women as 'my women'. In doing so, she averts any potential criticism about not recognising women as autonomous individuals. With rising intonation, she tentatively suggests that some women share characteristics that mean they are more likely to make informed decisions than others who may be more accepting of midwives' recommendations. Another midwife makes a similar observation in the next extract.

**Extract 21: Participant 8UJT 40-43**

40 Erm.. a lot of women are up for being induced on their term plus twelve, erm.. again
41 because of the dynamics of the women that I look after, they're very intelligent women and
42 they want to know the nitty gritty, the guidelines, they want to know the research and I will
43 bring up the guideline and go through that with them, erm..

The midwife clearly identifies educational status as a unifying characteristic of the group of women wishing to have detailed discussions to support their informed decision-making. This reflects the quantitative results in the preceding chapter as well as findings in the literature review in Chapter 2. Howard *et al.* (2014) found older, university-educated women expecting their first baby were more likely to prefer OPIOL versus inpatient management whereas women expecting their subsequent babies or those who were non-English speaking were more likely to prefer inpatient management.

In summary, midwives perceived that women's expectations and knowledge of the induction of labour process influenced uptake of OPIOL. Induction of labour was never 'part of the plan', yet once offered induction the women expected to have their baby later in the day rather than returning home overnight. In this respect, my findings echo other literature about women's expectations and experiences of induction of labour (Brown and Furber, 2015; Jay, Thomas and Brooks, 2018; Coates *et al.*, 2019; Coates *et al.*, 2021). For many women, a recommendation of induction of labour comes as a surprise and represents a significant shift away from their expectation of a spontaneous labour in a birth centre environment (Jay, Thomas and Brooks, 2018; Coates *et al.*, 2019). Women are often unfamiliar with the induction process and many

access social media to inform and enhance confidence in their decision-making (Coates *et al.*, 2019; Wright, Matthai and Meyer, 2019). Some women think of induction as '*the drip in your arm*' which may (but not always) be offered later in the induction process (Brown and Furber, 2015; Coates *et al.*, 2019; Coates *et al.*, 2021 p.409). Some are unaware of the initial cervical priming phase as well as the duration of the induction process and it is frequently assumed that labour will ensue soon after administration of vaginal dinoprostone (Jay, Thomas and Brooks, 2018; Coates *et al.*, 2021). They may also become anxious if the process is delayed due to high activity or staff shortages when they have previously been told that the birth of their baby should be expedited due to an increased likelihood of stillbirth associated with prolonged pregnancy (Jay, Thomas and Brooks, 2018).

My quantitative results showed 187 women were eligible for OPIOL over the three period. While 53 were subsequently found to be ineligible on the day of admission, 70 women accepted OPIOL, 11 declined and for 53 women there was no clear evidence OPIOL had been discussed or offered. This suggests women's expectations of the induction process and the perception that they would have their baby quickly were not the only contributory factors explaining the low rate of OPIOL.

## 5.5 Being 'bog standard normal'

Midwives talked at length about risk assessment prior to OPIOL which enabled them to present themselves as safe and credible practitioners. Admissions to the maternity day assessment unit featured in the midwives' accounts. This unit offers women same-day and urgent outpatient access to additional checks by midwives and doctors which are not possible in community settings. Common presentations include concerns about reduced fetal movements and hypertension. Many assessment outcomes are reassuring, and women are discharged home and can remain on a midwife-led care pathway for the rest of their pregnancy unless complications arise. Admission to hospital or further outpatient obstetric follow-up is organised for those requiring additional care.

In the first extract, the midwife articulates her risk assessment process.

**Extract 22: Participant ZV8J 17-21**

17 And if they say they have [read the leaflet] and I can see that they're eligible, so they're
18 completely low-risk, you know, no admissions to the hospital in their pregnancy, so they've
19 had a good pregnancy, they've been straightforward etcetera. And if they say yes, then.. I
20 will say if they're aware that they can have [the pessary] as an outpatient, and, erm.. most

21 of the time, they come knowing that they can.

The midwife defines a low-risk status as having had a 'good pregnancy' that has been 'straightforward' with 'no admissions'. The midwife in the next extract explains how she would take the admissions into consideration.

**Extract 23: Participant B9AL 49-54**

49 So yes, looking back from antenatally, so, I guess, talking through their medical history from
50 booking them, that's kind of.. I guess.. where the risk assessment bit starts, and looking
51 back throughout their pregnancy, so looking at, erm.. their, kind of, admissions into day
52 assessment unit, why they're seen in day assessment unit, erm.. is it reduced movements,
53 bleeding, like, what else is going on, I guess, through their history that, kind of, comes into
54 that risk assessment ↑point.

The admissions prompt additional concern about 'what else is going on' and feature in the midwife's decision-making. Day unit assessments also feature in the following extract.

**Extract 24: Participant ZV8J 67-70**

67 So, say they've been into the day unit. So say they're post-dates, first baby but post-dates,
68 but they've been into the day unit two or three times with reduced fetal movements. Or
69 they've been into the day unit with query SROM[6], query PET[7] or something like that, then
70 usually they're not eligible. They need to be completely low risk.

This extract suggests that regardless of the assessment outcome, any day unit admissions are likely to raise midwives' concerns about women's low-risk status, meaning it is less likely they will be considered suitable for outpatient management. This again reflects the wider risk discourse in maternity care and the 'ever-narrowing window of normality' (Scamell and Alaszewski, 2012).

Normal baseline maternal observations and reassuring fetal cardiotography (CTG) also featured in explanations about risk assessment processes as the following extract illustrates. In contrast, observations outside normal parameters raised concerns about OPIOL as the following extract highlights.

[6] SROM – spontaneous rupture of membranes
[7] PET – pre-eclampsia

**Extract 25: Participant 80-85**

Anything that is not.. bog standard normal. So I wouldn't send them home with a [pessary] in if there were concerns about movements, erm.. growth, if.. if.. erm.. if there were concerns maternal with blood pressure. So anything that falls out of the remit of normality, I would not be sending them home. Or if I thought that the CTG was not meeting the criteria, I wouldn't send them home. And if.. if they had more uterine.. if they had uterine activity very quickly following the insertion, I wouldn't send them home.

Here the midwife provides some examples to illustrate the risk assessment process used to gain assurance of normality before making a decision to discharge a woman for OPIOL. Inclusion of the colloquial British term 'bog standard normal' enables the midwife to activate a shortcut in creating a shared understanding between herself and the researcher to present herself as a credible and safe practitioner (Koester, 2006). It also enables the midwife to be 'systematically vague' about specific aspects of the risk assessment e.g., how much uterine activity would be considered abnormal (Wiggins, 2017 p.161).

The midwife in the following extract is more explicit about her assessment of fetal cardiotocography and eligibility for OPIOL.

**Extract 26: Participant ZV8J 42-45**

So the CTG has to be normal as well, as in, like, completely normal. Not 'oh, they've had one decel but it's fine but for the other thirty minutes.' No. It has to be completely normal. Erm.. so yeah, they have to fulfil all those steps first before we can send them home.. or before we'd be happy to send them home with a [pessary].

The midwife articulates her point vividly using changes in emphasis and reported speech to present the alternative view to her own. Framing the talk this way validates her approach and offers strong inoculation against any criticism of her professional credibility or accountability (Wiggins, 2017).

Midwives frequently cited reduced fetal movements and related Trust guidance in their risk assessment process and expressed uncertainty about how to interpret historic episodes where investigations were reassuring, and the baby was now moving normally. Was the fetus still at risk or could the midwife confidently offer OPIOL? The midwife in the following extract highlights the uncertainties and how this reduces rates of OPIOL.

**Extract 27: Participant KWSX 21-24**

When we first started the trial of it, erm.. I would have a few people come through and they'd go home, and then the reduced fetal movements guideline came in and that was all a bit.. difficult to interpret, erm.. so then I think on discussion with a lot of the doctors when I had questions, they'd say, 'keep them in.'

The midwife uses a hedge 'all a bit' to soften her criticism of the reduced fetal movements guideline being difficult to interpret, which is unsurprising as I was guideline author. It also allows her to acknowledge the difficulties and clinical uncertainties surrounding interpretation and management of reduced fetal movements while distancing herself somewhat from the decisions made to continue with inpatient induction.

The following midwife questions how episodes of reduced fetal movements are defined with any report invariably being defined as such, which then has an impact on any subsequent risk assessments and management.

**Extract 28: Participant ZV8J 328-334**

Are they just feeling a bit anxious, they've had a busy day. Sometimes, you can go.. go over all of this on the phone but they just want the reassurance of hearing that heartbeat. So is that really reduced movements or is that just anxiety we're treating? So you know, when you have all this reduced movements, well is it really? I suppose you could get the doctor. But then that probably takes time I guess, and trying to get that.. and trying to unpick all those bits when the woman's in.. with a doctor who hasn't got a lot of time. Maybe, just.. I don't know.

The midwife uses a rhetorical question here as a persuasive device that is simultaneously face-saving in order to soften her critique of a controversial topic (Frank, 1990).

My quantitative results highlighted that reduced fetal movements were the third largest indication for induction of labour overall, accounting for 12 per cent of all indications for induction between July 2015 and June 2018. However, by the time I was interviewing midwives in 2019, this had increased to over 14 per cent (NHS Trust, 2020a). This reflects national recommendations to raise women's awareness of the importance of fetal movements and its link to fetal wellbeing (NHS England, 2019b).

In the following extract, the midwife expresses some frustration about the consequences of the uncertainties around optimal management of reduced fetal movements in term pregnancies.

**Extract 29: Participant KWSX 319-323**

319 And then when they come in for their induction the next day, we can't trace their baby
320 because it's moving so much. And they're the ones that really frustrate me because then
321 I'm having to hold on a CTG, and then, almost neglect the rest of my women, who are here
322 for valid reasons, to hold on a woman who really doesn't need to be induced because her
323 baby is fine [laughter].

The midwife demonstrates an affective display to highlight her frustration. This is accomplished by emphasis on certain words e.g., 'really frustrate me' and 'valid' as well as constructing a humorous argument to back her claim by demonstrating the paradoxical situation in which she regularly finds herself.

The midwife goes on to articulate that another reason the rate of OPIOL is low is because women report reduced fetal movements at the end of pregnancy to secure a date for induction of labour.

**Extract 30: Participant KWSX 348-351**

348 And women aren't stupid. They know how to get an induction if they want it. So it makes
349 you question how realistic their.. what they're saying is. Are they just coming in to say,
350 'oh, I've got reduced movements,' because they want induction but actually their baby's
351 moving fine. When they come in and their baby's moving so much you can't trace them.

This passage starts with an irrefutable statement 'women aren't stupid' which is used to build consensus and emphasise the factuality of the account (Wiggins, 2017). Discursively, this is also a widely used and understood type of construction to convey behaviour or a way of thinking that demonstrates the agency of the subject. In this case, it is used to draw attention to the subversion of institutional guidelines by women feigning reduced fetal movements – a strategy highlighted elsewhere in the literature (Walker and Thornton, 2018). She constructs an extreme case formulation to emphasise her point 'their baby's moving so much you can't trace them.' This evaluative talk is not a neutral representation of reality (Potter and Wetherell, 1987). It is deliberately constructed to emphasise the point and drive it home (Edwards, 2000; Wiggins, 2017).

In summary, the extracts presented above highlight that maternity day assessment unit reviews and admissions to hospital raised midwives' concerns about the suitability of outpatient

management even if review findings had been normal. This included presentations with reduced fetal movements although there were instances where staff expressed doubt and even some frustration about the validity of these claims. Where there was any doubt about eligibility for OPIOL, midwives said they would refer to obstetric colleagues.

These findings reflect my quantitative results. Out of the 187 eligible for OPIOL, 53 were ineligible on the day of admission due to fetal or maternal concerns. In addition, of the 70 women who commenced the OPIOL pathway, 22 were not actually discharged home due to new concerns about maternal or fetal wellbeing following administration of the dinoprostone pessary.

These findings echo the wider risk discourse in maternity care and the 'ever-narrowing window of normality' (Scamell and Alaszewski, 2012). Dahlen (2016) notes the tendency to try and label women as either high risk or low risk when the reality is more nuanced, and some midwives will tolerate more clinical uncertainty than others (Page and Mander, 2014). In my research, the midwives' focus on episodes of reduced fetal movements in pregnancy also reflects the ongoing strategic national ambition to reduce stillbirth and brain injury within the Saving Babies Lives Care Bundle as women often report reduced or a change in fetal movements prior to fetal demise (NHS England, 2019b). The care bundle recommends women are given written information about the importance monitoring fetal movements and they are advised to attend for fetal monitoring if concerned. The care bundle also advises that induction of labour is discussed with women if they present with concerns at the end of pregnancy. However, a stepped-wedge, cluster-randomised trial conducted in the UK and Ireland to evaluate a bundle of care around management of reduced fetal movements found no significant reduction in the likelihood of stillbirth, and a significant increase in induction of labour (40.7 per cent of women in the intervention group versus 35.8 per cent in the control group (adjusted OR 1.05 (95% CI 1.02-1.07) p<0.0015)). There were also significant increases in caesarean birth and admission to neonatal unit for more than 48 hours in the intervention group (Norman *et al.*, 2018). This highlights the tension between responding appropriately to women's reports of reduced fetal movements and clinicians' concerns about the possibility and consequences of over-management (Smyth *et al.*, 2016).

## 5.6 Cervical assessment

Women's cervical status was another factor that influenced midwives' decisions and featured in talk about OPIOL. The quantitative data showed the median Bishop score of women offered

OPIOL was 3 (interquartile range 2.75-4) compared to 4 (interquartile range 3-7) for those where no offer was documented. This was also reflected in interviews and women with a favourable Bishop score were usually offered inpatient induction rather than the option of going home for 24 hours with a dinoprostone pessary in situ. In the first extract, the midwife clearly indicates that cervical status has an impact on the number of women eligible for OPIOL.

**Extract 31: Participant 8UJT 141-145**

141 Erm.. I think the only woman I've had… was hoping for [the pessary] if she could go home
142 and then when she went in, she was ARMable. Erm.. and I think that was.. that was the
143 only.. the only thing, you know, all of a sudden there was a complete change because they
144 wanted to break her waters and start things. Erm.. but that was probably the only one,
145 yeah.

The midwife identifies some of the uncertainties of the induction of labour process here and how women's experiences can change 'all of a sudden' and 'there was a complete change' based on the cervical assessment of 'being ARMable'. This is well understood, idiomatic talk used by midwives and obstetricians to describe a woman's cervix when it is dilated enough to be able to rupture the membranes around the baby. An oxytocin infusion then usually follows which has an impact on women's experience of labour as continuous fetal monitoring is recommended (National Institute for Health and Care Excellence, 2014b). However, describing someone as 'being ARMable' focuses attention on cervical status and away from woman's bodily autonomy (Mobbs, Williams and Weeks, 2018).

Similarly, another midwife describes how cervical status influences decision-making in the following extract.

**Extract 32: Participant JN3W 102-109**

102 OK.. so.. erm.. I feel it's very important the process as normal as possible, because, you
103 know, if a cervix is one centimetre open you can ARM it, but it's whether it's in that
104 woman's best interests and often if it's unfavourable with length then, erm.. it isn't, don't
105 think. So I would take into account the length of the cervix, the dilatation, so anything
106 under two centimetres dilated, and two centi.. and if it's long as well, I would want to give
107 some hormone like a prostaglandin for.. for those. This is with no uterine activity. Erm.. if
108 I've got a fully effaced cervix or a very thin cervix and it is two centimetres, I would do an
109 ARM.

The midwife justifies her decision-making around mode of induction by providing descriptive detail of cervical assessment and how this will impact her evaluation of what she thinks is in the 'woman's best interests' in terms of choice of induction method. She also highlights that uterine activity is another consideration in her decision-making as dinoprostone would generally be avoided in this situation to avoid hyperstimulation.

Another midwife describes her decision-making process in a similar way in the following extract.

**Extract 33: Participant ZV8J 92-98**

92 ..If I think in six
93 hours' time I will be able to ARM this cervix but it just.. just needs a little bit of softening
94 and some contractions, then I will give them a [dinoprostone tablet]. But if I think oh, this is
95 going to need a bit more… and ↑that.. just comes with experience.. if I think this is going to
96 need a bit more than two [dinoprostone tablets], you know, or more than one
97 [dinoprostone tablet] then I think [pessary]. So that's.. that's where the Bishop score is a bit
98 difficult sometimes because it doesn't necessarily fit every cervix if that makes sense.

Here the midwife emphasises the importance of clinical experience in decision-making by giving a detailed account of cervical assessment and decision-making around whether to give the pessary or not. The effect of this talk midwife-to-midwife is that it enables her to describe her decision-making and also demonstrate her clinical expertise.

The participant in the next extract suggests a Bishop score of four would prompt consideration of inpatient management with a dinoprostone tablet.

**Extract 34: Participant KWSX 176-180**

176 Erm.. most women are very happy. I've had one, that has been quite upset, and where she
177 was a Bishop score of four.. I always give women the option as well. I say, you're in the in-
178 between, you can have the [pessary] and the twenty-four hour or the [dinoprostone
179 tablet] and this re-examine in six hours, and ninety-five per cent of the time they will say
180 [dinoprostone tablet].

The midwife demonstrates that women are offered choices in some circumstances. While the woman is again defined by her cervical status here 'she was a Bishop score of four', the midwife goes on to portray women as active agents in their labour experience. In doing so, the midwife

presents herself to the researcher as someone who involves women in decision-making therefore orientating to the wider discourse around choice and personalised care.

In summary, midwives indicated that women's cervical status influenced the offer of OPIOL. While the Trust guideline suggests outpatient management is appropriate when the cervix is more than 2cm dilated and women are not experiencing contractions, midwives said they would generally offer inpatient management in this situation. This finding highlights a lack of congruence between the Trust and the midwives' practice which is more aligned with national guidance updated in 2021 which provides recommendations on method of induction based on Bishop score. This advises the use of amniotomy and oxytocin infusion amongst women with a Bishop score of more than 6 as it is more effective than vaginal dinoprostone at achieving vaginal birth within 24 hours amongst this cohort (National Institute for Health and Care Excellence, 2021).

Similarly, other research about OPIOL with vaginal dinoprostone has excluded women with a favourable Bishop score. Awartani, Turnell and Olatunbosun (1999),Biem *et al.* (2003) and Farmer *et al.* (1996) excluded women with a Bishop score of 7, 6 and 5 or more respectively. Stock *et al.* (2014) conducted a retrospective cohort study amongst 1536 nulliparous women having induction of labour to avoid prolonged pregnancy. While 225 were already ineligible due to medical contraindications, prior to the point of induction, a further 319 were excluded, 172 of whom were found not to require further require cervical ripening. Similarly, Wilkinson *et al.* (2015) randomised 827 women prior to the induction appointment and approximately half of participants subsequently did not receive the intervention. Some of the women went into labour, others were found to have a favourable Bishop score and did not require cervical priming.

My findings highlight the importance of discussing how decisions about induction of labour are made based on cervical status and how this may influence the options offered on the day of induction. This would help prepare them for the possibility of either returning home or continuing an inpatient induction.

The other key finding in this section is how the language used by midwives to describe cervical status and management can focus attention away from women's bodily autonomy and presents the induction process in a mechanistic way e.g., when describing someone as '*being ARMable*' or '*she was a Bishop score of four*'. While there was evidence of involving women in decision-making, putting cervical status centre stage in this way can depersonalise care and presents women as passive recipients of treatment rather than autonomous individuals (Mobbs, Williams and Weeks, 2018; Cox and Fritz, 2022). This is significant in view of the fact that women frequently report poor experiences of induction of labour, feel out of control and undermined,

and do not feel like they are treated as individuals (Brown and Furber, 2015; Jay, Thomas and Brooks, 2018; Coates *et al.*, 2019; Coates *et al.*, 2021).

## 5.7 Travel time to hospital

Trust guidance indicates women are ineligible for outpatient management if they live more than 30 minutes' drive from the hospital. However, the midwives did not consider journey time was particularly relevant in their decision-making since it could vary by time of day as the following extract highlights.

**Extract 35: Participant B9AL 262-266**

262 Could be, like, a 40 ↑minute stretch on a bad day, but I've been able to get here in 25
263 ↑minutes before.. so it all depends on what time of day you come in, what time you're
264 leaving and I imagine for women who are further afield, like, as far as [town further away]
265 erm.. and, I guess, the other side of our city.. that might be an indication that, actually,
266 'when I'm in I want to stay in'.

Here the midwife indicates that journey time may feature in women's decision-making and this corroborates the findings in the literature review. Howard *et al.* (2014) found women were prepared to accept an additional 1.4 trips to hospital and a journey time of 31 minutes (73 minutes total).

The midwife in the following extract agrees that distance is not a factor in her decision-making.

**Extract 36: Participant JN3W 114-120**

114 Erm.. well, the distance because most of the catchment area is fairly close, I have to say,
115 it's not primarily on my radar. Erm.. if they were out in the sticks somewhere, you know,
116 in the [rural area] and they were a multip and they've got a history of.. you know,
117 frequent labours then obviously I would be a bit more, erm.. that.. that I would take into
118 consideration. Erm.. or if there was issues with transport and stuff like that, I would take
119 that into consideration. But if they were a [city] lady, you know, it's not going to take.. a
120 long time to get in to the hospital. So it's not really a big problem.

Here the midwife presents an extreme case formulation to illustrate a situation when distance may be a factor in her decision-making e.g., being 'out in the sticks' or a multiparous woman who

would be ineligible for OPIOL anyway. This type of discursive device is used to emphasise or even exaggerate a point and simultaneously bolsters the speaker's position or argument (Edwards, 2000; Wiggins, 2017). The midwife also indicates other material factors that would influence decision-making such as availability of transport.

Women's preferences were also taken into consideration as the following extract illustrates.

**Extract 37: Participant KWSX 103-106**

103 Erm.. we'd always make sure women were happy to go home and, erm.. if they didn't feel
104 like they could make it back in a timely manner then sometimes they.. we always give
105 them the option to stay. Erm.. but we wouldn't necessarily say, 'oh you live x amount of
106 miles away, you can't have it.'

In summary, midwives adopted a personalised approach to journey time and women living further afield were given the option of inpatient or outpatient management. Other research about OPIOL with vaginal dinoprostone often excludes women living more than 30 to 40 minutes away (Stock *et al.*, 2014; Wilkinson *et al.*, 2015). This reflects the fact that OPIOL requires women to make an additional round trip to hospital. Biem *et al.* (2003) and Farmer *et al.* (1996) were less explicit about journey time, stating that they included women living in the city area. Howard *et al.* (2014) asked women what was acceptable and found they were prepared to accept an additional 1.4 trips to hospital and a journey time of 31 minutes (73 minutes total). In contrast, the extracts in this section show midwives did not consider travel time to be a significant factor when making decisions about OPIOL since this varied depending on the time of day.

## 5.8 Workload 'swings and roundabouts'

The midwives indicated that OPIOL did not increase their workload. In fact, sending someone home would typically reduce it as there would be one less person to monitor in the induction suite that day as the following midwife explains.

**Extract 38: Participant KWSX 118-130**

118 It actually makes our lives a lot easier.

119 *Tell me a little bit more about that.*

120 Because women.. if they go for an outpatient or inpatient [pessary] induction, they're, like

you said, they're only with us for a couple of hours, and then they transfer either home or upstairs to the antenatal ward. Whereas women with [the dinoprostone tablet], we then do their mid-points [fetal monitoring] and regular obs and, erm.. and things like that throughout the day. So they're still under our care within the induction room, whereas women who've had the outpatient [pessary] they're at home. We're still at aware of them and we make a note on our Labour Ward board that they're at home and we anticipate a call from them at some point potentially.. erm.. for them to come back in again, so the Labour Ward coordinator's aware as well as [the telephone triage]. Erm.. so they are on people's radar, but where they're not physically in the building, it's one less patient that we've got to manage, almost.

In this extract, the midwife provides the backing to her claim that OPIOL reduces workload by detailing the typical management of those women undergoing inpatient management to illustrate her point. However, using 'aware', 'on people's radar' and the hedge 'almost' at the end indicates there is still some mental workload involved in terms of consideration of care activity to follow.

The following extract offers a similar view to the previous one.

**Extract 39: Participant ZV8J 270-271**

Well, if.. they go.. if they're all straightforward and they all go home then it makes my workload much lighter.

The midwife in the next extract initially suggests OPIOL reduces workload in the induction suite but if labour does not ensue overnight, the women return 24 hours later, resulting in an increase in workload that day.

**Extract 40: Participant JN3W 179-183**

..if you're going to send them home then you haven't really got them.. there, have you, to, erm.. be doing observations and CTGs on, so effectively it would be reduced workload.. on the day that you're giving it. But if it hadn't worked and they arrived.. the next day then you've got an extra one added on to your list haven't you? So, swings and roundabouts.

When asked whether outpatient induction reduces the workload, the midwife uses a distinctive idiomatic phrase 'swings and roundabouts' to articulate that it brings no net benefit to workload.

An idiom is a phrase widely understood by speakers of a language and conveys something different to its literal meaning. In this sense, idioms have a relational purpose by engaging the listener by using a shared understanding. Idioms can also be used to allow the speaker to express their opinion more indirectly, and are observed to occur more frequently towards the end of conversations where they summarise the speaker's views, and politely signal readiness to move on to the next topic (Koester, 2006; Eerdmans and Di Candia, 2007).

There is little wider evidence available about midwives' views of OPIOL and the effect on workload. Turnbull *et al.* (2013b) found OPIOL did not unduly affect midwives' workload, stress levels or job satisfaction. However, one of the limitations of this study is that focussed on the views of midwives working in a range of clinical areas rather than those working exclusively in the clinical area most directly affected by the change in pathway. My findings indicate that workload did not seem to be a major factor influencing midwives' decisions about OPIOL. Outpatient management meant workload was reduced one day but was potentially increased the next when the induction process would resume, unless the woman went into labour in the meantime.

## 5.9 Safety and effectiveness

Frequent contractions (tachysystole), prolonged contractions (hypertonus) and hyperstimulation affecting the fetal heart rate is a potential side effect of any dinoprostone formulation. When compared to a placebo, the dinoprostone pessary demonstrated greater odds of uterine hyperstimulation than the tablet (OR 2.97; 95% CI 1.36-5.73 versus OR 1.99 CI 0.78-4.25) (Alfirevic *et al.*, 2016). However, when comparing the pessary with all dinoprostone formulations head to head, there is no significant difference in the likelihood of hyperstimulation (RR 2.15; 95% CI 0.89-5.21) (Thomas *et al.*, 2014). Lack of ongoing fetal surveillance at home was problematic for some of the midwives and they expressed concerns about the safety of OPIOL, particularly since nulliparous women were going to be experiencing contractions for the first time as the following extract illustrates.

**Extract 41: Participant ZV8J 74-79**

74 ..it's quite a decision
75 to send someone home with a drug that you can't monitor and then you then rely on the
76 woman who is her first baby, this isn't her second or third baby it's her first baby, to
77 recognise when things might not be quite right, which isn't always easy when a woman's
78 never experienced contractions before. She won't necessarily always know what's normal,

79 or what she should be looking out for. Does that make sense?

The following extract corroborates the midwives' concerns about lack of surveillance whereas inpatient induction offers more opportunities for observation maternal and fetal wellbeing.

**Extract 42: Participant JN3W 146-152**

146 Well I think it is the unknown isn't it? And also you're sending somebody off, you've put,
147 erm.. you've put in.. a drug which is.. is still acting. So it's, you know… And you've got no
148 control over what's going on. Whereas, you know, at least if they are an inpatient, you
149 know, if you've got concerns you can speak to the lady, or you know, you've got more of a
150 dialogue going on with the woman. So you've got more of a feel of what's happening.
151 Whereas send the woman off home and, you know, basically she's gone.. off your radar.
152 So, I think they get anxious about that.

The midwife articulates her point in a rather mechanistic way e.g., having 'no control' over action of drug, women being 'off your radar' and unsurveilled. Use of the pronoun 'you' engages the listener to put themselves in the shoes of the person making the decision about OPIOL. The midwife then switches to using 'they': 'So, I think they get anxious about that.' This effect of this talk is that she is able to distance herself from sharing her colleagues' concerns and avoids having to express her own views. Pronoun shifts like this help speakers manage their identities and accountability (Wiggins, 2017).

**Extract 43: Participant JN3W 31-39**

31 So personally, after they've had the CTG, I wouldn't send them home straight away, so I'd
32 just want to see, once.. I like to keep them for an hour, or.. at least an hour or two because,
33 erm.. I like to see just what the.. how the absorption rate is going. So, I let them have a
34 wander, usually send them off for a cup of coffee at the [main hospital site]. And then,
35 erm.. obviously with instructions if anything.. they get, anything like bleeding, excessive
36 pain etcetera then to come straight back. But I let them have a little wander for a couple of
37 hours. Erm.. then they come back, we have a bit.. another discussion, see if there's
38 anything going on. Erm.. at that point I might have another listen in, just to make sure
39 everything is fine.

The midwife uses stake confession to reduce the likelihood of criticism for her deviation from the guideline e.g., 'so personally' and 'I like to see' (Potter, 1996). There is some minimisation e.g., 'a little wander' and 'I might have another listen in' to make the actions more acceptable to the listener. In line 33 she hints that the rationale for her practice is due to concerns about drug action 'see just what the.. how the absorption rate is going'. The midwife expands on her concerns about hyperstimulation in the following extract.

**Extract 44: Participant JN3W 45-49**

45 Becau.. the reason I personally do, is because I've had a few ladies with [the pessary]
46 who've hyperstimulated. So I, erm.. and I've sort.. I have thought about it, and although we
47 have a standard, that x number of milligrams is released every hour, erm.. do we know that
48 for sure? And I err.. I like to err on the side of caution with my practice so that's why I make
49 sure that, erm.. they're not hyperstimulating before I send them home.

Here the midwife articulates her concerns about the action of the drug more clearly and provides examples of direct experience of hyperstimulation to back her claim. She uses a rhetorical question 'do we know that for sure?' as a persuasive device to question the pharmokinetics of the pessary (Frank, 1990). She presents herself as a safe practitioner by using an idiomatic expression that she likes to 'err on the side of caution'. Another midwife expresses the same concerns about the pessary in the following anecdote.

**Extract 45: Participant ZV8J 271-273**

271 Erm.. I think there was only one or two situations where I think
272 they had.. the [pessary] but, erm.. I hadn't sent her home straight away and I can't
273 remember why, it was a couple of years ago. I hadn't sent her home straight away..

**Extract 46: Participant ZV8J 289-295**

289 ..but the trace progressively got worse and she ended up with a cat one
290 section. So, erm.. I think if it's going to go bad, it tends to go bad fairly quickly. Usually, I
291 think. So, erm.. that.. that rang alarm bells, the fact that within the hour of monitoring she
292 was, you know, already that uncomfortable.

293 *Yeah. Does that happen with [the dinoprostone tablet]?*

294 It can do. It can do. It doesn't seem like it happens as much with the [dinoprostone tablet].
295 But it can do. It doesn't feel like it happens as often.

This account does not seem to correspond with the quantitative data. Of the 22 women not discharged home, six had an unplanned caesarean due to concerns about fetal wellbeing and none of the babies in this group were admitted to the neonatal unit. The median birth interval from time of administration of pessary was 35 hours and 6 minutes for this group (range 12hr 33 mins to 51hr and 6 mins). This demonstrates that over a three year period, birth of the baby usually happened some time after the pessary was administered.

Systematic review evidence shows no significant difference in the likelihood of hyperstimulation when comparing the pessary with other dinoprostone formulations (Thomas *et al.*, 2014). However, the midwife echoes the previous midwife's concern about pharmacokinetics in the next extract.

**Extract 47: Participant ZV8J 301-304**

301 I think there's some belief that with the [pessary] you can't
302 control absorption. So whilst it's only meant to release nought point three milligrams an
303 hour, they could be absorbing the whole ten milligrams in one bit, in one hit, which is why
304 they can hyperstimulate, or why we've had so many hyperstimulate.

Use of 'I think' and 'there's some belief' demonstrates use of hedging to manage accountability so it is initially difficult to tell whether she shares the belief (Wiggins, 2017). She then goes on to say 'which is why.. we've had so many hyperstimulate', indicating with the pronoun 'we' that she has personal experience of this and shares the view.

During the early stages of the research project, I became aware that another hospital in the region had withdrawn the pessary from their hospital formulary. That NHS Trust had never offered OPIOL, and the pessary had only previously been used for inpatient induction, including women at high risk of complications. One of the midwives mentioned this during her interview.

**Extract 48: Participant JN3W 153-159**

153 And there's bad
154 publicity about [the pessary].

155 *Erm.. do you.. do you want to tell me a bit more about that?*

156 When I say bad publicity.. Erm.. there is at least one hospital in the region that has

157 withdrawn it because of hyperstimulation. And, erm.. we have, since we've started using
158 it, we've had some cases of hyperstimulation so.. those midwives are a little bit reticent
159 now in using it. So I think, erm.. I think that's.. that's what's.. fuelled it a bit.

The midwife makes a claim that colleagues are reluctant to use the pessary because of 'bad publicity'. By including the decision of another hospital to withdraw the pessary in addition to local cases she justifies her claim. She then uses the demonstrative pronoun 'those' when referring to other midwives' experiences and concerns. The effect of this talk enables the midwife to distance herself and avoid articulating her own position on the matter. She minimises the situation in 'what's.. fuelled it a bit' and this enables her to minimise her statement and hedge around the extent of the problem (Wiggins, 2017). Another midwife makes a similar comment about problematic experiences with the pessary in the extract below.

**Extract 49: Participant KWSX 165-171**

165 I'm not too aware of their circumstances because I haven't had any bad experiences with
166 [the pessary]. It's just there's a bit of a rumour going around. Not a rumour because it is
167 true, like, women.. who.. some midwives who have given [the pessary], the women have
168 had cat one sections from the antenatal ward. So they're quite cautious of it, and it's just
169 in professional conversations that you have around inductions that those stories are
170 mentioned. Erm.. so I'm quite willing to give [the pessary]. I know other midwives are a bit
171 more cautious.

By reporting the experiences of other colleagues, the midwife is able to distance herself from sharing safety concerns about the pessary. She emphasises it is a 'rumour', then almost immediately asserts the truth and premise of the claim. She goes on to refer to the accounts of her colleagues as both 'professional conversations' which underlines the trustworthiness of the claims made but she then goes on to refer to the accounts as 'stories'. While her colleagues are 'cautious' to use the pessary, she is 'quite willing' to give it. The resultant effect of this talk is that is unclear whether she shares the concerns of her colleagues or is trying to accommodate and to an extent, justify, alternative views to her own. This kind of hedged construction highlights some delicacy around the subject area and deflects potential criticism (Silverman, 2001; Wiggins, 2017).

The midwife continues to explain the potential impact these fears have on women's experiences of induction of labour in the following extract.

**Extract 50: Participant KWSX 274-281**

Erm.. and, like I say, I haven't had a bad experience with an outpatient induction. Some of them don't work, some of them come back in labour. It's all down to the woman, but.. like I say, I think people's views are clouded by other midwives' experience, erm.. and are a lot more cautious, because I've come in on a nightshift and certain midwives have been on and women have had a [pessary] in the morning and they're still on a CTG in the evening in the induction suite and you sort of think.. These wouldn't be outpatient, they'd be inpatient but I think women are.. midwives are.. some midwives are certainly much more cautious about it because of a few adverse outcomes.

At the outset of this excerpt, the midwife highlights she has not had any adverse outcomes with the pessary but reiterates that colleagues have concerns. She asserts that efficacy varies between individuals 'it's all down to the woman' and then returns to safety concerns and that other midwives' 'views are clouded' which means they practice more cautiously. She identifies prolonged periods of fetal monitoring as a strategy used by midwives to try to avoid adverse outcomes. This extract highlights that adverse events amongst women at higher risk of complications managed as inpatients influence midwives' views about outpatient management.

Midwives also orientated towards the safety discourse in interviews when asked about advice-giving prior to discharge home. At this point, responsibility for ongoing surveillance was clearly handed over to women. This reflects wider discourses around individualisation of responsibility for health surveillance as well as the choice and personalised care agenda. However, this left women undergoing OPIOL facing a paradoxical situation as they were instructed to relax yet stay alert to potential problems.

**Extract 51: Participant 8UJT 66-72**

..because we are introducing a drug into their system, erm.. and it's just making sure that they know that it's.. it's not.. it's something to be.. be.. something to.. I'm looking for a word.. it is to take seriously but also at the same time we want them to be relaxed so it's really, really difficult, erm.. but just giving them ideas for what to look out for, but I don't think that's any different from what we'd say normally in the pregnancy, you know, watch baby's movements, make sure if your waters break let us know, that kind of thing. So yeah.

The midwife takes some time to articulate her point and she expresses this with difficulty. There are false starts, hesitation and hedging (Wiggins, 2017). She even explicitly states 'I'm looking for a word' and 'it's really, really difficult'. Use of 'just giving them ideas for what to look out', and, more specifically, the word 'just' suggests she wishes to minimise the inherent contradictions in advice given to women and that she recognises the difficulty in telling someone to stay relaxed, yet alert to potential problems. Use of 'so yeah' in this way signals recognition of a rather unsatisfactory conclusion and that the speaker is ready to change the subject (Grivičić and Nilep, 2004).

Another midwife gives a similar response.

**Extract 52: Participant JN3W 53-60**

So just generally to, erm.. keep an eye on movements and, erm.. that they would need to contact us if, erm.. the membranes go. Or they feel that they're getting contractions frequently, so any more… I would tell them to come back in if they're contracting two in ten. Erm.. if there's any bleeding. All the obvious ones. Erm.. er.. or any concerns basically. So that would be the advice I give them but generally to carry on as normal. Erm.. if the [pessary] comes out, as long as, you know, it's not contaminated then they could just slip it back in again. If it has come out or they've lost it then, erm.. to come in. That sort of ↑thing.

In describing the advice she gives in a systematic way, the midwife presents herself as a safe and credible practitioner and someone who aims to normalise the birth experience. By emphasising the word 'generally' she adds some weight to the recommendation to continue normal activities to demonstrate some counterbalance to all the things that could go wrong.

Similarly, the midwife describes the safety-netting talk she would usually give to women prior to discharge.

**Extract 53: Participant ZV8J 238-245**

Erm.. so they're on the CTG for an hour and as long as you're happy with that, then I will tend to give them all the information as in, erm.. what to look out for when they go home, double check that they are going.. that they are just going home, that they're not going to go for a little wander into the [local national park] or something. Erm.. so you know, I say to them, you know, 'if it falls out, this is what you need to do. If you start contracting,

243 strongly, frequently, regularly, this is what you need to do. If you start bleeding, if your
244 waters go.. erm.. if you have reduced fetal movements erm.. if you become unwell or
245 have any side effects, erm… then let us know.'

Again, safety and surveillance is prioritised at the point of discharge, whereas other aspects of wellbeing such as relaxation and nutrition are not mentioned. Reported speech and detailed lists in this account make the midwife's account of discharging women home very credible and enables her to position herself as a safe practitioner.

Similarly, one of the midwives is positive about the role of the telephone triage service in safety-netting and management in the following extract.

**Extract 54: Participant KWSX 108-114**

108 ..because, the thing is, if they phone up and say, 'oh, my waters
109 have broken,' or 'oh, I'm contracting regularly,' if they're not going to get in for the next
110 hour, the person at the end of the phone on [telephone triage] can always say 'well,
111 you've got the string, just take the [pessary] out.' Because that's all we would do.
112 Obviously we'd then monitor them and bits like that if they were in hospital, but the first
113 step would be to take the [pessary] out, which because it's got a handy string, it's a pretty
114 easy thing for the woman to do.

Despite concerns about lack of surveillance and hyperstimulation, midwives also expressed their doubts about efficacy of the pessary. However, the evidence suggests no difference in the likelihood of vaginal birth within 24 hours between the pessary and other dinoprostone formulations (Thomas *et al.*, 2014).

**Extract 55: Participant JN3W 166-167**

166 So, I think if it works,
167 they're very happy with it.

Here the midwife adds emphasis to the word 'works' suggesting some doubt about the effectiveness of the pessary.

**Extract 56: Participant 8UJT 136-137**

136 Erm.. personally, I haven't known any women from [the pessary] have a BBA
137 [laughter]. But, you know, at least then we would know it was working. But yeah.

The midwife constructs an extreme case formulation to express some doubt about efficacy of pessary. A 'BBA' is used to describe a baby born unexpectedly in the community e.g., at home or in the car, before the arrival of a trained professional. This is an uncommon event affecting less than 1 per cent of births.

In the next extract, a midwife presents her view that OPIOL can delay the induction process.

**Extract 57: Participant B9AL 214-219**

214 Erm.. I think they were saying, thinking about it, that actually, if that person was with us,
215 instead of being home for twenty-four hours, they would've had an examination ↑sooner
216 maybe and then thinking, OK fine, would we have given a, erm.. a pessary ↑earlier, erm..
217 or.. sorry, not the pessary.. but would we have given another form of induction drug
218 earlier than, like, waiting for that twenty-four hours if we hadn't seen any changes in that
219 person's cervix. Erm.. so yeah, I think that's their thinking behind it.

As in the passage above, the midwife uses hedges and rising intonation to gently present the view that OPIOL adds delay to the birth process. Using indirect reporting helps to distance herself from what was said. This face-saving technique can help the speaker appear more polite and deflect criticism (Fairclough 2003; Koestler 2006). In literature comparing OPIOL with inpatient management, there seems to be mixed evidence in terms dinoprostone administration to birth interval with dinoprostone. Stock *et al.* (2014) found the interval was shorter for those undergoing inpatient induction (22.5 hours (95% CI 21.1-23.9) versus 35.45 hours (95% CI 34.4-36.5) $p<0.001$) but Biem *et al.* (2003) found no difference. Other studies comparing OPIOL and inpatient management in terms of vaginal birth within 24 hours and had mixed results e.g., no difference (Farmer *et al.*, 1996; Wilkinson *et al.*, 2015) or less likely with OPIOL (Salvador, Lynn Simpson and Cundiff, 2009; Cundiff *et al.*, 2017). It is likely that where differences exist, these can be explained by confounding variables such as differences in operational practices around management of OPIOL.

In line with the uncertainty of the available research evidence, one of the midwives expressed more data was needed to test the effectiveness OPIOL with a dinoprostone pessary.

**Extract 58: Participant ZV8J 298-299**

298 I think if you really wanted to.. test how effective it is
299 then we need to give it to more women.

She continues her argument that widening eligibility criteria for OPIOL could provide more data and assurance of effectiveness in the extract below.

**Extract 59: Participant ZV8J 304-307**

304 Erm.. I
305 suppose that's the only thing that I can think of that would make a difference, so you'd get
306 a bigger group of women to truly understand how it works. Our group of women that we
307 have is just so small. It's just not..

Another midwife shares a similar view that more evidence is needed.

**Extract 60: Participant KWSX 285-287**

285 I think it's.. it's still a relatively new.. thing that's happening in the [hospital] so I don't
286 think we have.. enough.. evidence to say.. like I say, it all depends on how women react to
287 it..

The midwife employs hedging 'I think' 'I don't think' and hesitates, indicating some difficulty expressing her point of view. The interactional effect of this talk is that it enables the speaker to manage her accountability and distance herself from making a strong commitment to OPIOL as an intervention.

In summary, while OPIOL is supported by NICE guidance, and women eligible for outpatient management at the NHS Trust are at low risk of complications, midwives expressed considerable concern about women expecting their first baby being 'off radar' and whether they would be able identify signs and symptoms of hyperstimulation. While some attempt would be made to encourage women to relax and encourage normal physiological processes, midwives described in detail the safety-netting advice they would give women prior to discharge. They also gave accounts of 'rumours' and 'stories' of adverse events amongst women managed as inpatients at high risk of complications to back their claims. However, it was unclear whether these events had been caused by the pessary itself or were a complication of high-risk pregnancy. In contrast,

midwives also expressed doubts about the efficacy of the pessary and wanted further evidence data about patient outcomes.

The wider literature about OPIOL with vaginal dinoprostone indicates it is a feasible and safe option for women and their babies following appropriate risk assessment although studies have been insufficiently powered to detect significant differences in rare adverse outcomes such as stillbirth or neonatal death. More commonly occurring events such as neonatal unit admission, low umbilical arterial cord gas and low Apgar score at 5 minutes of age are often used instead, either individually or combined as a composite outcome. While there is a lack of consistency in the way researchers define these variables, this approach can maximise statistical power in order to identify significant differences in maternal and neonatal morbidity (Herman *et al.*, 2021). However, the wider literature suggests no significant differences in adverse maternal or neonatal outcomes between inpatient versus outpatient management (Awartani, Turnell and Olatunbosun, 1999; Biem *et al.*, 2003; Salvador, Lynn Simpson and Cundiff, 2009; Stock *et al.*, 2014; Wilkinson *et al.*, 2015; Cundiff *et al.*, 2017).

## 5.10 A middle road

An interpretive repertoire *OPIOL as a middle road* emerged during data analysis and midwives indicated outpatient management offers women the opportunity to avoid a medicalised induction of labour process. This echoes a theme from the literature review in chapter 2 in which OPIOL was seen as '*the next best thing to normal labour*' (O'Brien *et al.*, 2013 p.326). Midwives described the home as a place of comfort where women are more likely to feel more relaxed whereas the hospital environment was described as a busy, noisy place that can disrupt birth physiology as the following extracts illustrate.

**Extract 61: Participant 8UJT 5-9**

Erm.. So it would be mainly the primips because that's really all we offer, erm and just trying to explain to them that we are trying to keep as many hormones going as possible to work with the induction, erm.. and just trying to explain how the induction works with being at home and how that's a positive thing and actually being in hospital you don't need to stay here, erm.. and just try and get.. draw back a bit of that normality for them..

The midwife orientates towards the normalising birth discourse by talking about hormones and promoting physiological processes. In stating the need to 'keep' hormones going, to 'work with' the induction, the midwife implies that an inpatient experience can inhibit those things. She

reasons that being at home helps 'draw back a bit of that normality' and in doing so, infers that being in hospital is an abnormal experience for most healthy women. Similarly, midwives indicated that noise, lights and activity could undermine physiological processes as the following extract illustrates.

**Extract 62: Participant B9AL 237-239**

237 so it's quite hard in that induction room where you have beeping lights,
238 erm.. beeping noises, lights, erm.. the hustle and bustle of just being in hospital brings as
239 well.

Midwives identified that lack of privacy, and hospital routines and procedures also limited women's freedom to move around.

**Extract 63: Participant B9AL 91-96**

91 the induction room is quite small, that it's.. I guess, there's not.. not much privacy when
92 you're being induced and you come into ↑hospital, erm.. that you cannot.. almost, like,
93 being stuck into this building of.. 'how far can I go?' They ask you. 'So when you say I can go
94 for a wander for a bit, so how far am I allowed to go?' And so you, kind of, have that, kind
95 of.. I guess, they're in our house, they think they're in our house and we're controlling, like,
96 what they do, like, rules-wise..

The midwife paints a vivid picture of women being 'stuck' 'in our house' emphasising the lack of control women have over their induction experience and includes reported speech to add authenticity and credibility to her account (Wiggins, 2017). Including words like 'allowed', 'controlling' and 'rules', the midwife manages her subject position clearly, presenting herself to the researcher as someone who is fully cognisant of the wider human rights discourse in maternity care.

She goes on to explain that being at home offers more distractions and means women are not waiting around in the induction of labour suite for the dinoprostone to take effect. This period of 'waiting to go around' is portrayed as a difficult period of the inpatient induction experience for women. It refers to a time when the woman's cervix is open enough for the midwife to be able to rupture the membranes around the baby, and she is taken to continue the induction process in a private labour ward room.

**Extract 64: Participant B9AL 225-230**

..like, some of the hardest bits of the induction process is waiting to go around, or seeing the person in front of you, kind of, go round before them..

*Oh OK*.

So that kind of 'Oh god, I was number one in the queue but now I've jumped to number three,' and.. but, I guess, if you were at.. home you wouldn't have that experience.. you can almost switch off from that..

As well as optimising physiological processes, OPIOL was seen as a good option for women feeling ambivalent about the induction process as the following extract illustrates.

**Extract 65: Participant JN3W 167-169**

Some women who don't particularly want to be induced like the idea because it gives them another twenty-four hours and maybe a bit of a kickstart..

In suggesting OPIOL offers 'a bit of a kickstart' the midwife orientates to the normalising birth discourse in that very little intervention may be required to initiate the physiological processes of labour.

Similarly, the midwife in the following extract articulates that OPIOL provided an opportunity for women to adjust expectations of their birth experience.

**Extract 66: Participant 8UJT 168-175**

Erm.. it's challenging because if they were coming in for [the pessary], they're low risk primips so they could've had anywhere from a homebirth to [the alongside birth centre or the freestanding birth centre] and then I think it's such a shock to the system to go to labour ward, erm.. and have very little time to give their body to work with the things that we've given them. It's.. it's as soon as your waters are broken you're.. you're on the drip, you're on the CTG, erm.. instead of.. instead of almost giving them time and making them feel like they've given it the best shot that they could, erm.. it's a very.. it's not a rushed process, but it's a very regimented process..

The midwife discusses procedural aspects of induction of labour within the labour ward environment in a mechanistic way e.g., a 'shock to the system' and a 'regimented process' and

indicates that one intervention inevitably leads to another. She contrasts this with her view that OPIOL offers women more time for labour to become established and makes women feel they've had 'the best shot' at a normal labour without 'the drip' or 'the CTG'. However, the reality of the OPIOL experience is that over two-thirds of women required an oxytocin infusion as part of their induction.

In the following extract, the midwife is asked to expand on her observation that inpatient management is mechanistic.

**Extract 67: Participant 8UJT 194-197**

194 Conveyor belt ↑system? A 'we've started now, let's continue, let's.. let's get her as far as
195 we can get her'. Erm.. if.. if it's busy, erm.. then I think they're thinking about staffing,
196 erm.. you know, will we have someone to look after her on a night shift if we're not
197 getting anywhere with the induction.

Here the midwife orientates towards the NHS under pressure discourse and constructs an argument that poor staffing contributes to a mechanistic approach. A rise in intonation here highlights the delicacy of the subject and use of reported speech is used to add authenticity to what she is saying.

However, midwives highlighted that not all women wanted to be discharged home for OPIOL and some felt safer having inpatient induction, reflecting the findings of the literature review.

**Extract 68: Participant ZV8J 167-169**

167 Erm.. I remember having
168 one woman who could've gone home but had opted to stay. She said, 'Oh, could I just
169 stay, I just feel safer staying.' I think only one woman.

The midwife uses reported speech to add credibility to her claim that some women prefer inpatient induction as they feel safer in hospital (Wiggins, 2017). She suggests this preference is not the norm 'I think only one woman'.

Another midwife indicates OPIOL can be a frightening prospect for some women in the following extract.

**Extract 69: Participant B9AL 56-61**

56 Erm.. also looking is it something that person wants, because the idea for someone coming
57 into hospital, being assessed, giving them medication and going home again.. to them,
58 some people that can be really frightening and actually 'no, I want to start it, I want to stay
59 in hospital and feel safe and secure.' I think that person's opinion of what they see as
60 normal or safe for them comes into it massively as well, into how I then.. what I, kind of,
61 recommend to that person.

The midwife enhances the credibility and acceptability of this preference through use of reported speech and articulation of women's fears and justification to remain in hospital. She makes it clear to the researcher that she individualises care around women's preferences and in doing so, she orientates towards the wider choice and personalisation agenda promoted by the *Better Births* National Maternity Review (2016).

In summary, midwives expressed that OPIOL provided a middle road for women by enhancing the physiological process of labour. They also argued that OPIOL provided women with an opportunity to avoid the hustle and bustle of hospital environment for a few hours. These findings corroborate those in Chapter 2 in which the comfort of home emerged as a theme in the wider literature about OPIOL. Women expressed they had freedom of movement and felt able to relax and continue with their usual routines surrounded by their loved ones (Oster *et al.*, 2011; O'Brien *et al.*, 2013; Coates *et al.*, 2021), and while quantitative data shows no difference in birth outcomes between inpatient and outpatient management, women's satisfaction may be higher with OPIOL (Alfirevic *et al.*, 2020). However, as highlighted in the wider literature, the midwives in my study indicated that some women prefer to have inpatient induction of labour and feel safer in hospital rather than returning home for OPIOL.

## 5.11 Case study

In this section I present a case study of a woman who underwent OPIOL to highlight areas of congruence and incongruence with midwives' accounts. At the outset of my research, I intended to recruit and interview women eligible for OPIOL to explore their views and experiences of outpatient management. As described in my quantitative findings, very few women actually underwent OPIOL over the three-year period. I was able to recruit one participant who underwent induction of labour to avoid prolonged pregnancy. She was discharged home with a vaginal dinoprostone pessary and returned overnight experiencing contractions and had an unassisted

vaginal birth of a healthy baby later that day. I conducted the interview approximately three weeks later.

In the first extract, the woman indicates that the midwives caring for her appeared to have some reservations about OPIOL. This concurs with interviews with the midwives who highlighted that OPIOL is not a well embedded practice, and that it is not 'run of the mill'.

**Extract 1: 33-41**

33 The, erm.. the midwives looking after me.. were, erm.. I had a student and a midwife
34 looking after me. They were brilliant. But I think they, erm.. I could sense that maybe..they
35 didn't do it.. outpatient, outpatient induction very often and maybe they had a bit of
36 anxiety about ↑it. Erm..

37 *Yeah. What made you think that?*

38 Erm.. it was just the way in which they would communicate with me about it and, erm..
39 they were like 'oh, we'll see you after your assessment,' things like that and then 'we'll
40 discuss with the doctor' and I was like, 'OK, yeah, I understand you need to run it past the
41 doctor before I go home and things.'

There is hesitation throughout, minimisation when she says 'just the way' and rising intonation at the end of line 36 which indicate she is delicately expressing her point of view (Riley, 2002; Wiggins, 2017). She also includes reported speech about the midwives wanting to talk to the doctor, a discursive device frequently used to add authenticity to an account (Wetherell, 1998; Wiggins, 2017). This corresponds with one of the midwives' accounts in which cases where there was any uncertainty about eligibility for OPIOL would be 'okayed by a doctor' (Extract 3).

The participant continues to describe her experience and reports that she had an additional fetal monitoring trace prior to being discharged despite the first one being normal. This corresponds with the midwives' concerns about the potential risk of hyperstimulation in their accounts and concern about women being 'off radar' at home and unsurveilled.

**Extract 2: 49-51**

49 So it was about a good hour or so I was monitored afterwards and then erm.. I was sent off
50 for a walk and then they wanted to monitor me again before we went ↑home. So I'm not
51 sure why, erm.. quite what the.. like, guideline is for monitoring at all. Erm..

The participant questions the rationale for prolonged fetal monitoring and this is evident by changes in emphasis e.g., 'hour', 'again' and 'guideline'. This echoes one of the midwives' accounts where women were sent for 'a little wander' after administration of the pessary and then offered additional fetal monitoring prior to discharge home. This deviation from the NHS Trust guideline was rationalised as a way to feel more assured about fetal wellbeing and to exclude any hyperstimulation of the uterus.

In the following extract, she goes on to explain that the midwives were concerned about sending her home as she was experiencing some uterine contractions.

**Extract 3: 65-69**

65 erm.. yeah, like.. like the midwives were brilliant in the
66 erm.. [hospital] but I just.. I could just sense that they weren't.. they were like, 'oh, if you
67 start tightening any more, we don't want you to go home.' I could just sense that they
68 weren't quite maybe as comfortable as me going home as.. as I felt that I was comfortable
69 about going home.

In this extract, the participant uses reported speech to add authenticity to her account and strengthens her point that the midwives were reluctant to discharge her (Wiggins, 2017). This corresponds with the midwives' concerns about potential hyperstimulation associated with induction and lack of ongoing fetal surveillance at home.

In the following extracts, I contrast the participant's descriptions of the beginning of her induction in the hospital with her experience at home which corresponds with the interpretive repertoire 'OPIOL as a middle road' highlighted by the midwives.

**Extract 4: 24-29**

24 Erm.. so when I
25 went in we.. had to wait a little while in, like, a separate room and then we were taken into
26 the little, erm.. induction room. The only thing about that room is that it's very small and
27 very, very hot and there's no windows or any air really – there's only one little fan. Erm..
28 and then I was given a leaflet about induction of labour and then popped on the monitor
29 and then the process started.

Here the participant tries to minimise critical remarks about the hospital's induction of labour environment by prefixing her comments with 'the only thing'. She then emphasises the words

'small', 'hot' and 'air' to accentuate her discomfort. She returns to her views on the hospital environment in the following extract.

**Extract 5: 54-56**

54 It's just.. it was just because of the room.. that it's very restrictive in there
55 so.. so.. and it was a really hot day.. and I don't know.. you just felt really lethargic and all I
56 wanted to do was get up and move around and walk about really, that's the only thing.

Both of these extracts correspond with some of the midwives' comments about inpatient induction as well as wider research about women's poor experiences of inpatient induction of labour (Brown and Furber, 2015; Jay, Thomas and Brooks, 2018; Coates *et al.*, 2019; Coates *et al.*, 2021 p.411). In contrast, the participant describes her experience at home positively in the following extract.

**Extract 6: 71-73**

71 Erm.. so we had some like snacks and things, just pottered around, went on my ball, erm..
72 and I was using my TENs machine and, erm.. then.. I sent my husband off to, erm.. to go for
73 a sleep.

She describes being able to mobilise freely, being close to her husband and having access home comforts whilst in the early stages of labour. She returns to these benefits later in the interview.

**Extract 7: 211-215**

211 It was just nice to be able to, you know, erm.. get something to eat and
212 drink when you want and, erm.. you know, lay where you want.. you've got all the space,
213 you know, you're not confined, I've got my ball. 'Cos I'm quite tall, the balls, like.. the balls
214 at the hospital aren't big enough for me to sit on so it was nice to, erm.. be able to use
215 that and yeah..

This corresponds with the midwives accounts as well as the wider evidence about OPIOL which highlights the comforts of home and high rates of satisfaction (Oster *et al.*, 2011; O'Brien *et al.*, 2013; Coates *et al.*, 2021).

The participant also appreciated a phone call from one of the midwives in the telephone triage team who are informed of women undergoing OPIOL and provide a telephone wellbeing check.

**Extract 8: 73-79**

Actually before that, [the telephone triage] rung.. so that's really nice that they.. I really liked that they rang and..

*Were you expecting them to call?*

Yes. Erm.. the midwife at the hospital said, erm.. 'They're going to call you tonight at ten o'clock, but if they don't call you make sure you ring them'. And I really liked that they were like, checking in to.. you know.. check that everything was alright 'n things so that was really nice.

This echoes the importance of ongoing dialogue with a health professional identified in wider research about OPIOL and the feasibility of remote fetal monitoring (Rauf *et al.*, 2011; O'Brien *et al.*, 2013). Women found the 'virtual presence' of a health professional reassuring while they were being monitored remotely, although some were concerned no-one was looking at the trace in the hospital. In contrast, women who received telephone contact felt more relaxed and reassured afterwards. While the study found remote fetal monitoring was feasible and acceptable, it has not been implemented more widely and is not used in my research setting.

Overall, this case study underlines the importance of environment during the induction process and corresponds with the midwives' interpretive repertoire 'OPIOL as a middle road'. It also highlights how uncertainty about eligibility for outpatient management was perceived from a woman's perspective, concurring with the theme that OPIOL is not 'run of the mill'. Unlike the midwives' accounts, the woman did not express concerns about safety and instead, talk about the comforts of home featured strongly. The limitation of this case study is that it only provides one point of view and it is possible that interviews with women who were not discharged home due to new concerns about theirs or their baby's wellbeing may have had different perspectives about safety.

## 5.12 Chapter summary

The preceding chapter highlighted that few women underwent OPIOL during the study period. This chapter has identified some explanatory insights for this observation in terms of the factors mediating midwives' views and decisions about OPIOL. Institutional factors such as guidelines and eligibility criteria featured frequently in talk, and midwives considered that eligibility criteria were too restrictive and limited uptake of OPIOL. Midwives also described material factors which

presented opportunities and constraints affecting overall uptake of OPIOL. They considered women's access to antenatal counselling shaped expectations of the induction process and in their interview responses, midwives demonstrated efforts to enhance informed decision-making, orientating towards the wider discourse around choice and personalised care. However, available consultation time presented challenges and meant these discussions were not always delivered entirely to the midwives' satisfaction. As a result, they considered that women were generally unprepared for the realities of labour and birth, and midwives suggested this affected uptake of OPIOL as women were reluctant to leave the hospital again without their baby. In contrast, my quantitative findings indicated few women declined OPIOL when it was offered to them. Furthermore, community midwives articulated that many women were very well informed about their options and linked this kind of readiness to women's educational status.

Aspects of women's personal embodiment also featured in midwives' talk, and women's health status, hospital admissions and pregnancy history were scrutinised carefully during risk assessments. This also enabled the midwives to present themselves as safe and credible practitioners. Induction of labour was discussed in a mechanistic manner and cervical status featured frequently in accounts in a rather disembodied way. On the other hand, midwives talked more holistically about the need for women to feel comfortable and safe. Midwives presented OPIOL as a 'middle road' along which the physiological processes of labour could be optimised and an opportunity to avoid the labour ward 'conveyor belt' at least temporarily. The comforts of home versus the discomfort of the hospital environment were also highlighted in the case study. Midwives also acknowledged that some women felt safer in hospital and were not happy to be discharged.

Training and exposure to OPIOL were identified by the midwives as important mediating factors influencing colleagues' willingness to offer outpatient management, a theme echoed in the case study. Midwives clearly orientated towards the risk and patient safety discourse and the 'ever-narrowing window of normality' in their talk (Scamell and Alaszewski, 2012), and particularly in talk about hyperstimulation which is a side effect of dinoprostone formulations. Midwives expressed concerns about pharmokinetics and it was clear that lack of ongoing surveillance at home was another factor mediating the offer of OPIOL.

This page has been left intentionally blank

# Chapter 6 Discussion

## 6.1 Introduction

In this chapter, I integrate my qualitative and quantitative findings and consider them in relation to existing research about OPIOL and the wider discourses mediating contemporary maternity care in the UK. I have used the research question and objectives to structure the chapter as follows:

What factors influence midwives' views and decisions about outpatient induction of labour using vaginal dinoprostone?

The specific objectives of the research were:

- To investigate indications for induction of labour in a tertiary hospital
- To describe the characteristics of women eligible for outpatient induction of labour
- To describe the outcomes of women eligible for outpatient induction of labour
- To identify the wider discourses as well as the embodied, material and institutional factors that mediate midwives' views and decisions about OPIOL
- To critically analyse how midwives justify their views and decisions about OPIOL
- To critically analyse how midwives manage professional credibility and accountability in talk about OPIOL.

## 6.2 Indications for induction of labour

The first objective was chosen to help contextualise OPIOL activity within the overall induction workload of a tertiary hospital. I reasoned that clinical workload, particularly if women's pregnancies were at high risk of complications, could impact midwives' overall risk perception and their views and decision-making about OPIOL of women at low risk of complications. Between July 2015 and June 2018, 4402 women underwent IOL, excluding women who underwent IOL for medical termination of pregnancy, late fetal loss or stillbirth. Prolonged pregnancy was the most common indication for induction of labour (21.5%), followed by pre-labour rupture of membranes (13.6%), reduced fetal movements (12%), pre-eclampsia (6.2%) and diabetes (5.6%). Low risk indications such as maternal request and pelvic girdle pain made up a very small proportion of inductions overall (2.3% and 1.8% respectively).

The qualitative data included midwives referring to challenging accounts of high-risk inpatient inductions while talking about low-risk outpatient induction and it was suggested that these incidents 'clouded' midwives' views about outpatient induction. While the following sections illustrate that very few women eligible for OPIOL were discharged home, it is uncertain whether acuity and activity in the induction suite affected midwives' views and decision-making about outpatient management. An ethnographic approach such as participant observation may have elicited additional insights (Holloway and Galvin, 2015a).

## 6.3 Characteristics of women eligible for outpatient induction

This section summarises the characteristics of women eligible for OPIOL and whether there were any differences between those who accepted, declined or subsequently became ineligible for outpatient management. Evidence from the literature review suggested older, university-educated women were more likely to prefer outpatient management and women from a non-English speaking background were more likely to prefer inpatient management (Howard *et al.*, 2014). I also reflect on some of the difficulties encountered during data collection and identify limitations of the research design.

As prolonged pregnancy represented the most common indication for induction, this suggested there could be a sizeable cohort of nulliparous women at low risk of complications who were eligible for OPIOL. Of 2306 nulliparous women offered induction between July 2015 and June 2018, 187 (8.1 per cent) were at low risk of complications and met the local NHS Trust guideline's eligibility criteria for OPIOL. Midwives suggested the criteria were 'too tight' and also reflected that 'it's very rare in this day and age for [women] to come in without having had any issues in their pregnancy'. This finding concurs with the wider literature around the 'ever-narrowing window of normality' in maternity care which is explored in more detail later in section 6.5.4 (Scamell and Alaszewski, 2012 p.207.

Of the 187 women eligible for OPIOL, 53 subsequently became ineligible on the day of admission (e.g., hypertension, new concerns about fetal wellbeing, ruptured membranes, contractions) leaving 134 women remaining. Of these, 81 were offered OPIOL leaving 53 women where there was missing data around offer of OPIOL.

I established that most women who accepted OPIOL were white British, university-educated, working full time, non-smoking and in the 30-34 age group, reflecting findings in the wider literature (Howard *et al.*, 2014). However, analysis of the missing data offered the most interesting insights and women with a BMI 35.0-39.9 seemed over-represented in this group. Overall, 9.1 per cent of the 187 women eligible for OPIOL had a BMI in this category yet 76.5 per

cent were not offered OPIOL. This suggests that having a BMI 35.0-39.9 reduced the likelihood midwives would offer OPIOL. I consider this further in section 7.3.

## 6.4 Outcomes of women eligible for outpatient induction of labour

This section summarises the outcomes of women who accepted OPIOL and relates them to the wider literature. This objective was chosen to describe the 'reality' of OPIOL which could then be triangulated with interview data with the midwives about their views and decision-making.

The principal finding was that while 2306 nulliparous women were offered induction of labour between July 2015 and June 2018, very few women underwent OPIOL. Of the 81 women offered OPIOL, 70 women accepted, and 48 women were discharged home. Twenty-two women were not discharged from hospital to continue outpatient management, largely due to uterine activity and fetal heart rate concerns. However, there were no urgent concerns requiring early intervention to expedite birth in these cases. This suggests that clinicians are vigilant when making decisions about outpatient management which concurs with the qualitative findings.

Wilkinson *et al.* (2015) also noted vigilance amongst clinicians making decisions about OPIOL in their randomised trial, and women and staff were aware of the randomisation allocation prior to the commencement of the induction process. Amongst women allocated to the outpatient arm, staff reported more adverse reactions to the dinoprostone gel, including non-reassuring fetal monitoring trace, and this resulted in women not being discharged home after all. It is not always possible to blind participants and staff to randomisation allocation and this can influence clinical behaviours and decision-making, leading to concealment bias (Higgins and Thomas, 2021).

### 6.4.1 Adverse outcomes

There were no adverse maternal or neonatal outcomes amongst the 70 women who received the dinoprostone pessary. A clear limitation to my study design was sample size and it was never an intention to compare OPIOL with inpatient management outcomes. Other research about OPIOL has made this comparison but has been underpowered to detect significant differences in rare adverse outcomes. Neonatal unit admission, umbilical cord gas and Apgar score are frequently used as surrogate markers for adverse neonatal outcomes and the wider literature suggests no significant differences between inpatient versus outpatient management (Awartani, Turnell and Olatunbosun, 1999; Biem *et al.*, 2003; Salvador, Lynn Simpson and Cundiff, 2009; Stock *et al.*, 2014; Wilkinson *et al.*, 2015; Cundiff *et al.*, 2017). It is important to consider that only two of the

studies were RCTs which reduces the likelihood of selection bias (Henderson and Page, 2007; Nelson, Dumville and Torgerson, 2015). Biem *et al.* (2003) randomised women immediately after administration of the dinoprostone pessary. Conversely, Wilkinson *et al.* (2015) randomised at an antenatal appointment when the induction was scheduled and approximately half did not require induction, largely due to spontaneous onset of labour prior to the scheduled induction appointment. The remaining studies were based on observational data which can introduce selection bias. This is because some of the women may be excluded from receiving outpatient management due to further risk stratification by clinicians during the initial induction assessment resulting in a change to inpatient management.

Stock *et al.* (2014) reported one neonatal death and two cases of serious neonatal morbidity (meconium aspiration and neonatal encephalopathy) in the OPIOL group. The authors indicate that all three women experienced long labours, oxytocin augmentation and operative births indicating that there were no urgent concerns relating to administration of the dinoprostone gel.

Wilkinson *et al.* (2015) reported one perinatal death in the outpatient group, although this occurred after randomisation but prior to the commencement of induction. There were six cases of hypoxic ischaemic encephalopathy overall – three in each of the OPIOL and inpatient groups. The authors comment that this corresponds with an incidence of seven in 1000 which is more than expected for a technologically advanced country like Australia where a rate of one to three in 1000 would be expected. As one affected baby was also unexpectedly growth restricted, the trial eligibility criteria were revised. Women with suspected growth restriction were required to have a scan prior to the intervention, and women were excluded if they had gestational diabetes controlled by diet or a BMI over 35. No significant differences were found in adverse outcomes between those randomised to outpatient or inpatient management before or after this protocol modification.

Wilkinson *et al.* (2015) also reported two maternal admissions to intensive care of women who had undergone OPIOL (postpartum haemorrhage and eclampsia). These incidents were not found to be related to the intervention and there was no significant difference in the rate of postpartum haemorrhage between OPIOL and inpatient groups. Stock *et al.* (2014) reported postpartum haemorrhage greater than 1000ml and found no difference between outpatient and inpatient groups.

These data suggest that OPIOL with dinoprostone is a feasible and safe option for women following appropriate risk assessment although studies have been insufficiently powered to detect significant differences in rare adverse outcomes. The forthcoming multicentre CHOICE study (cervical ripening at home or in- hospital—prospective cohort study and process evaluation)

intends to compare outcomes, as well as cost-effectiveness and women's and partner's views (Stock *et al.*, 2021).

Due to concerns about uterine hyperstimulation associated with vaginal dinoprostone and its use in outpatient settings, there has been considerable interest in OPIOL using mechanical devices which are inserted intracervically to stimulate the release of endogenous prostaglandins (Sharp, Stock and Alfirevic, 2016). When compared to vaginal dinoprostone, a balloon catheter is less likely to cause hyperstimulation with fetal heart changes (RR 0.35 95% CI 0.18-0.67; 7 studies 1685 women) (de Vaan *et al.*, 2019). While there is a tendency for vaginal birth not to be achieved within 24 hours and caesarean birth may be more likely with a balloon catheter compared to vaginal dinoprostone, this is not statistically significant (de Vaan *et al.*, 2019).

There has been some concern that the use of balloon catheters is associated with an increased risk of intrapartum infection, with a reported rate of 11.3 per cent (Gommers *et al.*, 2017). However, comparison with vaginal dinoprostone formulations suggests the difference is not statistically significant (McMaster, Sanchez-Ramos and Kaunitz, 2015; de Vaan *et al.*, 2019). Diederen *et al.* (2018) conducted a systematic review of 26 studies including 8292 women and found the likelihood of adverse events such as pain, unintended amniotomy, bleeding and malpresentation during balloon induction was low (range 0 per cent to 0.26 per cent of which pain and/or discomfort was the most commonly reported concern).

Wilkinson, Adelson and Turnbull (2015) conducted a pilot study in South Australia comparing inpatient and outpatient induction of labour with a double (Cook's) balloon catheter. Most women found insertion of the catheter and waiting for it to work physically uncomfortable, particularly when toileting. Nevertheless, 91 per cent of women were satisfied with the method. In terms of clinician preferences, ninety clinicians responded to a questionnaire and 67 per cent of midwives and 72 per cent of doctors stated they were more comfortable sending women home overnight with a catheter than dinoprostone. Balloon induction may have training and workflow implications as two-thirds of midwives and half of doctors considered that availability of trained staff for insertion was problematic.

In summary, this evidence suggests that induction of labour with mechanical devices such as balloon catheters is safe, effective and reliable and provides a good alternative to vaginal dinoprostone. While not previously recommended, recently updated NICE guidance recommends offering mechanical methods where pharmacological agents are not suitable, or if women express a preference for this method (National Institute for Health and Care Excellence, 2021).

### 6.4.2 Time avoided in hospital

My findings showed median time avoided in hospital was 12 hours and 53 minutes amongst women who were discharged for OPIOL. This is a little longer than other published research, which ranges from 7 hours and 30 minutes to 11 hours and 45 minutes (Biem *et al.*, 2003; Adelson *et al.*, 2013; Stock *et al.*, 2014). My findings showed 15 women (31.3 per cent n=15/48) spent the entire night at home while 33 returned to the hospital for an earlier assessment, largely due to suspected labour or ruptured membranes. These findings suggest that while women have an opportunity to spend some time at home during the induction process, they may not necessarily be well rested prior to their return to hospital. Wider research findings indicate high rates of satisfaction with OPIOL (Awartani et al. 1999, Biem et al. 2003, Rauf et al 2011 and Turnbull et al. 2013a). Being at home provides women with a sense of experiencing '*the next best thing to normal labour*' (O'Brien *et al.*, 2013 p.328) and allows greater freedom of movement and privacy.

### 6.4.3 Mode of birth outcomes

Of the 48 women who underwent OPIOL, 29 (60.4 per cent) had a vaginal birth. Thirteen women (27 per cent) of women had an unassisted vaginal birth and 16 (33.3 per cent) required assistance with forceps or ventouse. The remaining 19 women (39.6 per cent) required an unplanned caesarean. These figures are not dissimilar to those in the wider literature examining outcomes of nulliparous women only. Stock *et al.* (2014) reported an unassisted vaginal birth rate of 29 per cent, assisted birth rate of 35.8 per cent and 35.2 per cent of women required a caesarean. They reported no differences in birth outcomes between inpatient and outpatient groups although mean dinoprostone to birth interval was significantly shorter for inpatients (22.5 hours versus 35.45hours $p<0.001$).

Research by Awartani, Turnell and Olatunbosun (1999), Cundiff *et al.* (2017) and Salvador, Lynn Simpson and Cundiff (2009) included multiparous women and the likelihood of unassisted vaginal birth was higher, ranging between 44.1 per cent to 82 per cent. Similarly, there was wide variation in the caesarean birth rate amongst women undergoing OPIOL, ranging between 4 per cent (Awartani, Turnell and Olatunbosun, 1999) to 38 per cent. In addition to heterogeneity of participants, differences in reported birth outcomes may also reflect trends in global caesarean section rates over the publication period of the studies reviewed. Caesarean rates have increased globally from 16 million or 12.1 per cent of 131.9 million livebirths in 2000 to 29.7 million or 21.1 per cent of 140.6 million livebirths in 2015 (Boerma *et al.*, 2018).

### 6.4.4 Summary – outcomes of women eligible for OPIOL

In summary, outcomes of women undergoing OPIOL were broadly in line with those in the wider literature and 60 per cent had an unassisted or assisted vaginal birth. Median time avoided in hospital was 12 hours and 53 minutes and there were no adverse outcomes. There was some evidence of clinician reticence to proceed with outpatient management and of the 70 women who accepted outpatient management, 22 were subsequently not discharged. Choosing this objective enabled me to determine that there had been no serious outcomes associated with OPIOL and descriptive statistics were a satisfactory way to approach data analysis given the small data set. This objective also provided additional context when conducting interviews with midwives regarding their views and decisions about OPIOL, enabling me to identify when midwives' talk did or did not correspond with the observed reality.

## 6.5 Factors mediating midwives' views and decisions about OPIOL

This section summarises the key institutional, material and embodied factors that mediate midwives' views and decisions about OPIOL. I identify and explore the impact of wider discourses in contemporary maternity care and how they influence midwives' talk and actions. As already described, I adopted a CDRA informed by (Sims-Schouten, Riley and Willig, 2007). This approach combines a realist ontology with a social constructionist epistemology which conceptualises a stratified reality where aspects of our physical and social worlds, including underlying structures and mechanisms, interact and mediate our decisions and actions. This enabled me to identify factors which inform and mediate midwives' sense-making and decisions about OPIOL, and may explain the low rate of OPIOL.

### 6.5.1 Institutional factors

Local NHS Trust guidelines inevitably mediated midwives' views and decision-making about OPIOL and midwives cited the narrow set of eligibility criteria as being responsible for the low rate of OPIOL. Midwives also found it difficult to reconcile guidance about reduced fetal movements with the OPIOL guideline and there was some uncertainty about how to interpret the significance of hospital admissions earlier in pregnancy. Even if the findings had been within normal parameters, midwives articulated that this left 'grey areas' around women's eligibility for OPIOL and they wanted decisions sanctioned or 'okayed by a doctor'. This again demonstrates the tendency to label pregnant women as high or low risk and the 'ever-narrowing window of normality' (Scamell

and Alaszewski, 2012 p.207). The impact of the risk and patient safety agenda and is considered further in section 6.5.4.

Midwives highlighted the catch-22 situation that colleagues were unlikely to offer OPIOL unless regularly assigned to work in the induction of labour suite. Training was also an important factor and while formal training had been delivered prior to the initial introduction of the intervention in 2015, subsequently new midwives learned about OPIOL on the job. However, as OPIOL was not considered to be 'run of the mill', staff had limited opportunities to gain exposure to the OPIOL process.

These findings reflected in the wider literature around the practice implications which surround midwives' fear of scrutiny following adverse events. Midwives often seek sanctuary in guidelines which become 'boundary objects' demarcating midwifery and obstetric led care in order to reduce 'grey areas', and see them as a 'safety net' or even 'something to hide behind' (Hood, Fenwick and Butt, 2010 p.278-9; Hunter and Segrott, 2014 p.721). Following guidelines 'to the letter' is not only seen as a protective mechanism to assure a good outcome for the woman and her baby, it also enables midwives to 'cover [their] backside' and mitigate some of the inevitable finger-pointing and blame that can accompany a poor outcome (Hood, Fenwick and Butt, 2010 p.278; Hall, Tomkinson and Klein, 2012 p.581; Spendlove, 2018; Sonmezer, 2021). However, this can undermine personalisation of care as staff apply guidelines using a 'blanket approach', despite assertions from the former chair of the NICE that 'guidelines are not tramlines' (Dove and Muir-Cochrane, 2014 p.1069; Hodgson, 2016; Spendlove, 2018). Nevertheless, nurses and midwives can face severe sanctions if they exercise clinical judgement rather than referring to a doctor to exercise theirs (Oliver, 2020)[8].

It is difficult for guidelines to provide clinicians with explicit instructions for every eventuality. Midwives and obstetricians inevitably accept different levels of uncertainty in the birth process and thresholds may vary by day and will also relate to previous experiences, heuristics and 'situated rationalities' which consider workplace pressures and available resources (Tulloch and Lupton, 2003 p.8; Shaw, 2009; Page and Mander, 2014; Quintard *et al.*, 2016; Healy, Humphreys and Kennedy, 2017). Indeed, while technical failures around following guidance can certainly contribute to errors in risk assessment and failure in detection of deterioration, the Each Baby

[8] A care home nurse whose registration was suspended for 12 months by the Nursing and Midwifery Council for failing to commence cardiopulmonary resuscitation on an elderly patient found 'waxy, yellow and almost cold'. The panel concluded the nurse had brought the profession into disrepute and her judgement was impaired.

Counts report recognises that high acuity and activity alongside poor escalation also contribute to poor outcomes (Royal College of Obstetricians and Gynaecologists, 2020).

Dahlen (2016) asserts that very few women are either entirely low or high-risk and this categorisation and that the interests of the unborn baby are often prioritised which can threaten women's autonomy during pregnancy and childbirth. While there is little criticism of women choosing additional monitoring, those declining treatment or seeking care options outside recommended guidance can face moralistic judgements from care-givers and be labelled as 'deviant' (Scamell and Alaszewski, 2016). Rather than 'one size fits all', an alternative approach is a woman-centred, human-rights based care, where professionals are encouraged to 'dance in the grey zone' between normality and risk by ensuring a shared dialogue with women to determine what risks they consider to be acceptable and unacceptable (Dahlen, 2016 p.18). This promotes a more holistic, salutogenic model of care in which the focus is not entirely on risk avoidance and the absence of an adverse outcome (Mathias, Davis and Ferguson, 2021). Rather it promotes the notion of a good birth as one where women's bodily autonomy is respected, decisions are informed and midwives can work confidently within their scope of practice (MacKenzie Bryers and van Teijlingen, 2010; Dahlen, 2016).

Continuity of care models can enhance relationships and reduce uncertainties enabling midwives to feel more confident about advocating for women, individualising care and 'holding space' in the birth room (Seibold *et al.*, 2010; Hall, Tomkinson and Klein, 2012; Dove and Muir-Cochrane, 2014). Continuity also enhances safe care by enabling early access and improving engagement and women are 16 per cent less likely to experience fetal loss or neonatal death and 24 per cent less likely to experience preterm birth (Sandall *et al.*, 2016b; Rayment-Jones *et al.*, 2020). These outcomes were acknowledged in the *Better Births* report and Trusts were subsequently tasked with ensuring 35 per cent of women were booked onto a continuity of carer pathway by March 2020. Furthermore, as women from Black and minority ethnic groups experience higher rates of morbidity and mortality in pregnancy and childbirth than white women, the NHS Long Term Plan also set a specific target to ensure 75 per cent of women from receive continuity from their midwife throughout pregnancy, labour and the postnatal period by 2024 (NHS England, 2019a; MBRRACE-UK, 2020). However, it remains uncertain how best to embed induction of labour within continuity of care pathways as induction is frequently undertaken by core midwifery staff working within the hospital setting and handed over to continuity teams once labour becomes established (NHS England, 2017c).

### 6.5.2 Material factors

Material factors present opportunities and constraints to people's actions in the real world (Sims-Schouten, Riley and Willig, 2007). Here I provide a summary of the key factors mediating midwives' views and decisions which explain the low rate of OPIOL.

Midwives identified that women's socioeconomic and educational status mediated their preparedness to accept an offer of OPIOL. They articulated that 'intelligent' women were enthusiastic about OPIOL and generally more informed about induction than women, having discussed the 'nitty gritty' and research evidence with their midwife. One midwife linked women's socioeconomic status with health 'because they are middle class and they're healthy, they've not actually been in hospital before'. She argued this meant being in hospital was a new and stressful experience, providing further motivation for women to accept OPIOL.

Midwives indicated that women frequently had unrealistic expectations of induction of labour and attributed their lack of preparedness to the quality of antenatal counselling. Midwives suggested this meant women were not prepared to accept an offer of OPIOL and leave the hospital again before the birth of their baby, an event which they expected would happen later the same day. An interpretive repertoire emerged during data analysis that induction of labour was 'never part of the plan' to explain why women were unprepared for induction of labour in general, and in relation to social media, one of the midwives suggested induction of labour was presented in a negative way. However, of the 81 women eligible to proceed with OPIOL, only 11 declined this option. Of the 70 women who accepted OPIOL, 22 subsequently remained in hospital, suggesting there were other factors that explained the low rate of OPIOL.

A more substantial factor explaining the low rate of OPIOL was midwives' concern about the pharmokinetics of the dinoprostone pessary. Of the 70 women who commenced the OPIOL pathway, 22 were not discharged from hospital to continue outpatient management, largely due to uterine activity and fetal heart rate concerns. However, the median birth interval from time of administration of pessary was 35hr 37min for this group (range 11hr 6min to 51hr 6min) and there were no adverse neonatal outcomes, suggesting there were no urgent concerns requiring immediate birth of the baby following administration of the pessary.

Midwives were clearly vigilant about the possibility of hyperstimulation which they perceived as more likely with the dinoprostone pessary than the more commonly used tablet formulation despite evidence to the contrary (Thomas *et al.*, 2014; Alfirevic *et al.*, 2016). They also expressed concerns about lack of ongoing fetal surveillance at home e.g., 'you've got no control over what's going on' and '..it's quite a decision to send someone home with a drug that you can't monitor'.

Midwives confessed 'there's a bit of a rumour going around', 'stories' and 'bad publicity' about the dinoprostone pessary and recounted incidents of hyperstimulation and withdrawal of use in another local hospital to explain why their colleagues were now reticent about using it, preferring to proceed with inpatient induction instead.

This reflects wider literature about rumour and how it tends to crystallise around collective concern and can shape anxieties and risk perception within groups (Rosnow, 1991; Douglas, 1992; Difonzo, Bordia and Rosnow, 1994; Pelletier and Drozda-Senkowska, 2020). Rumour helps people simplify and organise their existing knowledge to create a conceptual explanatory model and commit it to memory; people then seek further evidence that 'fits' the rumour (Difonzo, Bordia and Rosnow, 1994). Seminal wartime research identified the danger of rumour in how it can exaggerate and distort the truth, and induce panic (Allport and Postman, 1947; Caplow, 1947). Rumour tends to arise in times of uncertainty and in the absence of a more robust conceptual model. In addition, some rumours have more cognitive stickiness than others, making them difficult to debunk (Chan *et al.*, 2017a). Clear, concise and consistent messaging is key when attempting to discredit a rumour in order to build trust in the veracity of the new information, making it easier for people to commit to memory (DiFonzo, 2020).

### 6.5.3 Embodied factors

Personal embodiment is a term used to describe the complex interaction of bodily processes with cultural and social factors (Cromby and Standen, 1999; Lupton, 2012; Anastas, 2019). In this section, I summarise embodied factors mediating midwives' views and decisions which may account for the low rate of OPIOL.

Cervical assessment had a notable impact on midwives' decision-making and participants described in detail how they predicted whether a woman's cervix was likely to respond well to induction or not. This determined whether it would be appropriate to use the dinoprostone pessary and discharge someone home for 24 hours, or whether to use the tablet formulation which works over 6 hours on an inpatient basis. In the former case, a woman's cervix would not be dilated, and it would be longer and firmer and so the slow-release pessary would be most suitable. In contrast, a dinoprostone tablet would be used if the cervix was more dilated, shorter and softer and midwives anticipated it would change sufficiently in 6 hours' time to consider proceeding to the next step of artificial rupture of membranes (ARM) and starting an oxytocin infusion. Interestingly, the language midwives used represented the cervix in a rather disembodied way e.g., 'it's unfavourable', 'she was a Bishop score of four' and 'she was ARM-

able'. While used as short-hand between staff to describe clinical characteristics, this kind of language can draw attention away from woman's bodily autonomy (Mobbs, Williams and Weeks, 2018; Cox and Fritz, 2022).

Midwives' descriptions of cervical assessment and decision-making corresponded with the quantitative data. The median Bishop score of women offered OPIOL was 3 (IQR 2.75-4) whereas it was 6 (IQR 4-7) for women who were found to be ineligible on the day of admission. For women where it was unclear whether an offer of OPIOL had been made, the median Bishop score was 4 (IQR 3-7) suggesting this may have factored in midwives' decision-making in terms of the absence of evidence of a clear offer of OPIOL.

Midwives indicated women's preference for inpatient management was another factor explaining the low rate of OPIOL. While midwives presented OPIOL as an opportunity for induction of labour to promote and enhance the woman's own physiological processes of labour e.g., 'work with the induction' and 'tune in' to labour by 'trying to keep as many hormones going', midwives indicated that some women preferred inpatient management and felt safer in hospital. This corresponds with the quantitative data, and of the 81 women who were eligible for OPIOL, 11 women declined.

This finding reflects the contrasting themes of the comfort of home and safety in the wider literature about OPIOL (Oster *et al.*, 2011; O'Brien *et al.*, 2013). Oster *et al.* (2011) established that some women perceived hospital to be a place of safety with easy access to medical professionals if an emergency arose. These women were apprehensive about being at home and were unsure how their bodies would react or whether they would recognise signs of labour. In contrast, access to professionals reassured women undergoing OPIOL which meant they were able to enjoy the comforts of home with more confidence and had an opportunity to 'labour within their comfort zone' (Oster *et al.*, 2011; O'Brien *et al.*, 2013 p.327).

### 6.5.4 Discourses mediating midwives' views and decisions about OPIOL

Adopting a CRDA approach also enabled me to consider the impact of available discourses on midwives' talk and the way they articulated their views and decisions about OPIOL. CRDA incorporates Foucauldian discourse analysis which examines the *relationships* between discursive practice and the wider physical and social reality (Hall, 2001; Wetherell, 2001a; Fairclough, 2003). Furthermore, available discourses not only shape how people talk about a topic, they can also influence attitudes, actions and behaviour (Hall, 1992; Wiggins and Riley, 2010). I anticipated that using Foucauldian discourse analysis would help identify available discourses which would help explain the low rate of OPIOL.

It was very clear that midwives orientated towards risk discourse and the maternity safety agenda during interviews. They took considerable care to describe rigorous risk assessments and that it was 'very rare in this day and age' for women to have uncomplicated pregnancies which meant many were ineligible for OPIOL. Previous admissions to the maternity day assessment unit prompted concerns about 'what else [was] going on' in the pregnancy. Midwives also expressed anxieties about having 'no control' over the OPIOL process. There was talk of 'fear of the unknown' about an unfamiliar process and concern about women being 'off your radar' whilst at home where responsibility for surveillance passed to the women who were simultaneously advised to relax and 'carry on as normal' (Fairclough, 2003; Sims-Schouten, Riley and Willig, 2007; Wiggins, 2017).

The findings underline the deep sense of professional responsibility embodied in midwives' talk and decision-making and reinforce the construction of pregnancy and birth as inherently risky and unpredictable which may account for the low rate of OPIOL at the Trust. These findings reflect the wider literature about the evolution of a 'risk society' where despite substantial investment of time and resources into surveillance, management and control of risks, there is greater anxiety about potential hazard and harm than ever (Beck, 1992). Beck argues vociferously against the 'shaky throne' of probabilistic reasoning which assumes all risks can be eliminated, and reminds us of unintended consequences and harms of intervention (Beck, 1992 p.58).

Nevertheless, it is undeniable that stillbirth, brain injuries or the death of a mother have a devastating impact on families. In 2015, the UK was ranked 24th out of 49 high-income countries[9] and the stillbirth rate in England and Wales was 4.5 per 1000 live births[10] (Office for National Statistics, 2015; Flenady *et al.*, 2016). Claims for birth-related injuries also threaten the sustainability of the NHS as the cost of clinical negligence claims is rising faster year-on-year than NHS funding (National Audit Office, 2017). Over 1000 obstetric legal claims were presented to the Clinical Negligence Scheme for Trusts (CNST) in 2019/20. While these represented nine per cent of overall claims, they accounted for 50 per cent of the total value of new claims, almost £2.4 billion (NHS Resolution, 2021).

At the end of 2015, in the face of slow improvement in the rate of stillbirth, rising legal claims, the publication of the Morecambe Bay Report (Kirkup, 2015), and the landmark legal case of Montgomery v Lanarkshire Health Board [2015], the Health Secretary, Jeremy Hunt announced a

[9] Late stillbirths from 28 weeks' gestation
[10] Stillbirths from 24 weeks' gestation

new national maternity safety ambition (Department of Health, 2015). The Government provided £4 million to help Trusts halve the rates of stillbirths, neonatal and maternal deaths and intrapartum brain injuries in England by 2030, a target that was later brought forward to 2025. NHS England, NHS Resolution and the Royal Colleges implemented safety and quality improvement initiatives and a national review of maternity services was commissioned. A timeline of these events and initiatives are summarised in Figure 6-1 and are described in more detail in 0.

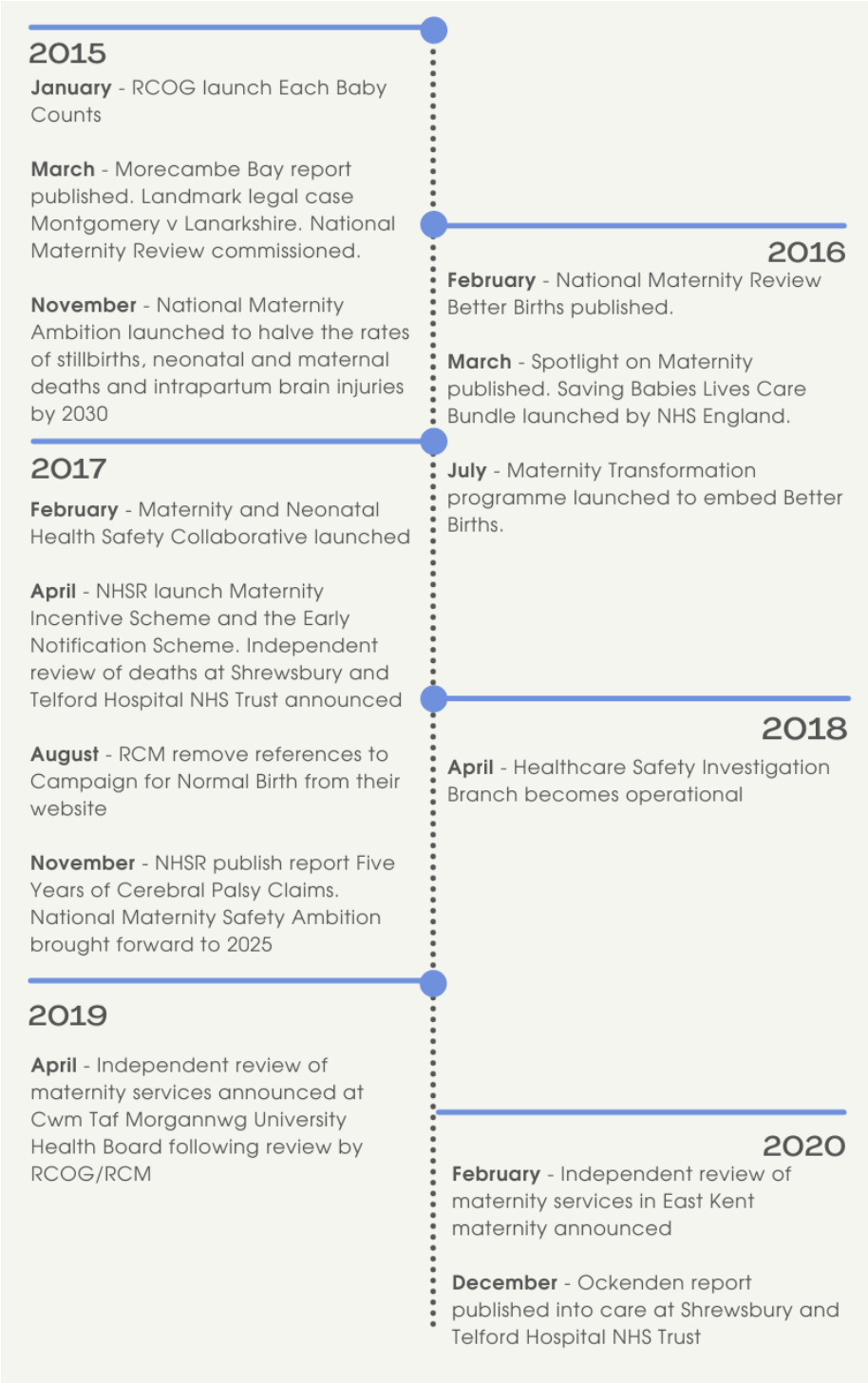



Figure 6-1: Maternity safety timeline

While the stillbirth rate in England and Wales fell to 3.8 per 1000 live births in 2020 (Office for National Statistics, 2021a), Sonmezer (2021) suggests increasing quality assurance demands have led to the development of an audit culture and managerialism in maternity care. While clinical governance and risk management are integral to the delivery of high-quality care, the likelihood of events such as stillbirth and maternal death are frequently overestimated and the risk of iatrogenic harm is underestimated, and there is a tendency to frame adverse events as avoidable and predictable. This can also undermine the delivery of evidence-based, personalised care to women as birth is increasingly seen as an event which can be standardised, and that it is possible to exclude clinical uncertainty (Seibold *et al.*, 2010; Scamell, 2016; Sonmezer, 2021). In addition, risk management processes are frequently framed in a negative way by staff who experience a deeply pernicious fear of blame to the extent that clinicians experience anxiety about possible future error (Shaw, 2009; Seibold *et al.*, 2010; Ferndale *et al.*, 2017; Spendlove, 2018). Scamell (2016 p.14) suggests a 'fear factor of risk' has evolved which undermines midwives' confidence. This can undermine midwives' status as autonomous professionals and leave them feeling like 'semi-professionals' or 'clockwork toys' (Spendlove, 2018 p.33; Sonmezer, 2021). Obstetricians and midwives frequently feel a deep sense of personal failure, guilt and shame following poor outcomes and involvement in investigations and legal proceedings often has a significant impact on wellbeing and the way they practice (Page and Mander, 2014; Wahlberg, Högberg and Emmelin, 2019). Fear of litigation can be a 'constant companion' even for those not directly involved in incidents which can undermine confidence in decision-making (Symon, 2006; Hood, Fenwick and Butt, 2010 p.278; Scamell, 2016).

This pressure to 'get it right' can lead to anxiety, stress and burnout amongst clinicians (Hood, Fenwick and Butt, 2010; Spendlove, 2018). Over one third of 5661 UK obstetricians and gynaecologists met the burnout criteria in a nationwide survey in 2017-18 (Bourne *et al.*, 2019). Two-thirds of 1997 UK midwives reported moderate to severe work-related burnout in the WHELM study (Hunter *et al.*, 2019).

Stress and burnout are also associated with an increased likelihood of defensive practices, up-tariffing risks and referral to senior clinicians and risk avoidance strategies (Hood, Fenwick and Butt, 2010; Seibold *et al.*, 2010; Scamell and Alaszewski, 2016; Bourne *et al.*, 2019; Monson, 2020). Scamell and Alaszewski (2012 p.217) and Ferndale, Meuter et al. (2017 p.411) describe clinicians 'hunting the abnormal' – a strategy identified in my findings and described by others involving additional surveillance of women at low-risk of complications which can have unintended consequences. For example, continuous fetal monitoring is often used when not

indicated and can increase the likelihood of interventions (Hall, Tomkinson and Klein, 2012; Scamell and Alaszewski, 2012; Copeland, Dahlen and Homer, 2014; Healy, Humphreys and Kennedy, 2016; Spendlove, 2018).

This overarching distrust in the birth process means pregnancies are assessed through a 'risk lens' (Healy, Humphreys and Kennedy, 2017 p.373) and has led to increasing medicalisation of birth, an 'ever-narrowing window of normality' (Scamell and Alaszewski, 2012 p.207) and a tendency to try and label pregnant women as high or low risk (Dahlen, 2016). For obstetricians and midwives alike it can be a thin line between timely intervention and 'too much too soon' which can cause iatrogenic harm (Hall, Tomkinson and Klein, 2012 p.581; Miller *et al.*, 2016). Furthermore, inappropriate use of continuous fetal monitoring and early intervention rarely receive criticism (Healy, Humphreys and Kennedy, 2016;2017).

While the risk discourse pervaded many of the interviews, there was evidence of alternative discourses around choice and personalised care in line with the national *Better Births* agenda (National Maternity Review, 2016). This discourse has its roots in the Winterton Report and Changing Childbirth which sought, for the first time, views from women, consumer groups and midwives about the development of maternity services (Department of Health, 1993). Recommendations focussed on putting women at the centre of decision-making, giving them more choice and control over their pregnancy and birth, and recognised the importance of continuity of care.

Reflecting this discourse, midwives mobilised maxims such as 'it's their choice' and 'information is power' in their accounts and were reflective about their use of words such as 'allowed', 'control' and 'rules'. In doing so, midwives were able to present themselves in a positive way as supportive of a woman-centred and human rights-based approach (Wiggins, 2017). Midwives also orientated towards the normalising birth discourse when discussing OPIOL by suggesting that being at home promotes physiological processes, enabling women's hormones to 'work with' the induction and 'draw back a bit of that normality'. One of the midwives also highlighted tensions between appointment pressures and the harms of work left undone in relation to the time taken to counsel women about induction of labour (Iacobucci, 2017; Ball, 2020), and orientated towards a wider discourse of the NHS under strain e.g., 'we're the NHS, we're a busy service'.

The International Confederation of Midwives (2018) define the role of the midwife as an accountable professional working in partnership with women to promote a healthy pregnancy and normal birth. In contemporary midwifery care, it can sometimes be challenging to negotiate the tensions between risk management responsibilities and promoting physiological birth. On one hand, midwives are expected to promote physiological birth processes and women's sense of self-

efficacy, as well as advocating for women whose birth choices may differ from those recommended. This can create a tenuous 'illusion of control' where women's choices and birth experiences are foregrounded and adverse outcomes are presented as being entirely avoidable through careful planning and assessment (Ferndale *et al.*, 2017 p.425). On the other hand, midwives can undermine women's confidence and sense of wellbeing by constant risk assessments and safety talk to ensure the safety of the fetus. Here, the 'precious cargo' can take priority in interactions and decisions, presenting ethical issues around fetal personhood and the role of the mother simply as a container (Hall, Tomkinson and Klein, 2012; Lupton, 2012 p.329; Copeland, Dahlen and Homer, 2014; Ferndale *et al.*, 2017). Indeed, from the very first antenatal appointment, women are counselled about the risks of smoking, poor diet, infections, lying in the wrong position, lack of exercise and are coached to participate in the constant surveillance of fetal and maternal wellbeing (Lupton, 2012; Ferndale *et al.*, 2017).

In summary, midwives frequently orientated towards the risk discourse when discussing their views and decisions about OPIOL. Midwives positioned themselves as safe and credible practitioners by articulating their systematic and detailed approach to risk assessment to determine women's eligibility for OPIOL. Alternative discourses mediated midwives' talk and participants expressed that OPIOL offered an opportunity to promote physiological processes. Midwives also articulated how they supported informed decision-making, demonstrating a woman-centred and human-rights based approach. The incorporation of these alternative discourses reflects the complex position midwives occupy when caring for women and the tension between identifying and managing risk whilst promoting physiological processes and ensuring positive, woman-centred birth experiences.

### 6.5.5 Summary – factors mediating midwives' views and decisions about OPIOL

Adopting a critical realist approach enabled me to analyse the institutional, material and embodied factors as well as the impact of the wider risk discourse on midwives' views and decisions about OPIOL, and helped explain the observed reality of the low rate of OPIOL. Several factors were identified that explained the low rate of OPIOL within the hospital. Trust guidelines inevitably mediated midwives' decisions about OPIOL. Furthermore, midwives expressed difficulty reconciling guidance about reduced fetal movements with subsequent decisions about outpatient management. In addition, midwives suggested that lack of staff training and opportunities to regularly undertake OPIOL meant their colleagues were less confident about offering OPIOL. Midwives were also vigilant about possibility of hyperstimulation and this meant women started

the OPIOL pathway but were subsequently not discharged home due to concerns about uterine activity and fetal wellbeing. Some women declined OPIOL and midwives attributed this to women feeling unprepared for induction of labour more generally and women feeling safer in hospital. The risk discourse also mediated midwives' talk and decision-making about OPIOL, and concerns were expressed about lack of monitoring at home. My findings contribute to existing evidence on the invocation of wider discourses in the construction of pregnancy as an inherently risky state.

## 6.6 How midwives justify their views and decisions about OPIOL

As well as enabling the identification of wider discourses and other factors mediating midwives' views and decisions about OPIOL, CRDA also enabled me to analyse how views and decisions were justified. Rather than a simple reflection of our individual conceptual model of the world around us, talk is action-orientated and is deployed purposefully and persuasively. Also known as rhetorical devices, discursive devices enable us to shape reality by influencing what others think or do (Fairclough, 2003; Goodman, 2017; Wiggins, 2017). In this section, I review my analysis of the discursive devices used by midwives to justify their views and decisions about OPIOL and in table 6-1 I summarise how these relate to the observed reality of the low rate of OPIOL.

Table 6-1: Discursive devices used to justify views and decisions about OPIOL

| **Discursive device** | **Description** | **Examples** | **Interpretation** |
|---|---|---|---|
| Extreme case formulation | Used to emphasise or even exaggerate a point and simultaneously bolsters the speaker's position or argument (Edwards, 2000; Wiggins, 2017). Also used to justify criticism or blame (Potter and Wetherell, 1987). | their baby's moving so much you can't trace them | Few women eligible for OPIOL as being induced due to reduced fetal movements (which have now resolved). |
| | | It's not going to do anything if it's just sat in the.. at the introitus | Some midwives find the pessary is difficult to insert. |

| Discursive device | Description | Examples | Interpretation |
|---|---|---|---|
| Evaluative talk | Construction of a version of reality which is not neutral - quickly builds shared understanding and emphasises the factuality of the account (Potter and Wetherell, 1987; Wiggins, 2017). | And women aren't stupid. They know how to get an induction if they want it. | Few women eligible for OPIOL as some feigning reduced fetal movements to secure a date for induction. |
| Idiomatic talk | Relational purpose of to engage others and create a sense of solidarity through a shared understanding. Also used to allow the speaker to express their opinion more indirectly, and are observed to occur more frequently towards the end of conversations where they summarise the speaker's views, and politely signal readiness to move on to the next topic (Koester, 2006; Eerdmans and Di Candia, 2007). | it's not done very frequently, it's an unusual thing to happen as opposed to run of the mill | Low rate of OPIOL means midwives have few opportunities to become more familiar with the process. |

| Discursive device | Description | Examples | Interpretation |
|---|---|---|---|
| | | the next day then you've got an extra one added on to your list haven't you? So, swings and roundabouts. | There is no net benefit to OPIOL for the midwife in terms of workload. |
| Intonation and emphasis | Rise in intonation suggests questioning, uncertainty, unwillingness to commit to a view (Fraser, 1990; Edwards and Potter, 2005). | if that person was with us, instead of being home for twenty-four hours, they would've had an examination ↑sooner maybe | Belief that OPIOL may delay induction process. |
| | Emphasis of point indicative of evaluative talk (Wiggins, 2017) | I think the biggest factor is just the.. the criteria. It's just too small. | Eligibility criteria restricts number of women who can have OPIOL. |
| | | we can't trace their baby because it's moving so much. And they're the ones that really frustrate me [..] | Difficulty in interpreting significance of reduced fetal movements at term gestation means normal movements often resume by which stage inpatient induction is already underway. |
| Pronoun footing shift | Helps speakers manage their identities and accountability e.g., to avoid criticism or | .. also when I'm thinking about my own practice is it, like, we forget it's there | Low rate of OPIOL means midwives forget the option exists. |

| Discursive device | Description | Examples | Interpretation |
|---|---|---|---|
| | distance themselves from views (Wiggins, 2017) | | |
| | | if you've got concerns you can speak to the lady, or you know, you've got more of a dialogue going on with the woman. So you've got more of a feel of what's happening. Whereas send the woman off home and, you know, basically she's gone.. off your radar. So, I think they get anxious about that. | Midwives concerned about lack of surveillance at home. |
| Reported speech | Persuasive device which adds credibility and authenticity of the speaker's account (Wiggins, 2017). | Are they just coming in to say, *'oh, I've got reduced movements,'* because they want induction but actually their baby's moving fine. | Few women eligible for OPIOL as being induced due to reduced fetal movements. |
| | | So the CTG has to be normal as well, as in, like, completely normal. Not *'oh, they've had one decel but it's fine for the other thirty* | Few women meet eligibility criteria due to concerns about fetal monitoring. |

| Discursive device | Description | Examples | Interpretation |
|---|---|---|---|
| | | *minutes.'* No. It has to be completely normal. | |
| | | Erm.. I remember having one woman who could've gone home but had opted to stay. She said, *'Oh, could I just stay, I just feel safer staying.'* I think only one woman. | Some women prefer inpatient induction of labour. |
| Rhetorical question | Persuasive device that strengthens assertion and is simultaneously face-saving in order to soften critique of a controversial issue (Frank, 1990). | although we have a standard, that x number of milligrams is released every hour, erm.. do we know that for sure? | Lack of trust in drug action. |
| | | So you know, when you have all this reduced movements, well is it really? | Few women eligible for OPIOL as many are induced earlier for reduced fetal movements. |
| Stake inoculation | Enables speakers to openly express alternative or controversial views and simultaneously deflect criticism (Wiggins, 2017). | it's because the majority of the time, we're inducing women that don't need it. That's my personal opinion. | Few women eligible for OPIOL as many are induced earlier for reduced fetal movements. |
| Stake confession | Enables speaker to avoid criticism through | So personally, after they've had the CTG, I | Lack of trust in drug action. |

| Discursive device | Description | Examples | Interpretation |
|---|---|---|---|
| | early admission to particular position or interest (Potter, 1996). | wouldn't send them home straight away, so I'd just want to see, once.. I like to keep them for an hour, or.. at least an hour or two because, erm.. I like to see just what the.. how the absorption rate is going. | Justification of additional surveillance. |
| Minimisation and hedging | Softens statements and helps manage accountability. Enables people to discuss delicate topics (Silverman, 2001; Wiggins, 2017). | and that was all a bit.. difficult to interpret, erm.. | It was difficult to reconcile guidance about historic episodes of reduced fetal movements when determining eligibility for OPIOL in context of now normal fetal movements. |
| | | I think there's some belief that with the [pessary] you can't control absorption.<br><br>those midwives are a little bit reticent now in using it. So I think, erm.. I think that's.. that's what's.. fuelled it a bit. | Lack of trust in drug action. Justifies increased surveillance and delay in discharge. |

| Discursive device | Description | Examples | Interpretation |
|---|---|---|---|
| | | But I let them have a little wander for a couple of hours. Erm.. then they come back, we have a bit.. another discussion, see if there's anything going on. Erm.. at that point I might have another listen in, just to make sure everything is fine. | |

These findings illustrate how midwives used discursive devices to justify their views and decisions about OPIOL and help identify factors driving the low rate of OPIOL. The midwives indicated that few women met the eligibility criteria for outpatient management, and it was difficult to reconcile guidance about earlier episodes of reduced fetal movements in their decision-making. In addition, participants expressed that some women preferred inpatient management. As a result, OPIOL was an infrequent occurrence which meant there were few opportunities for colleagues to learn how to insert the dinoprostone pessary and become familiar with the OPIOL process. Furthermore, midwives demonstrated a high degree of vigilance about sending women home and expressed concerns about hyperstimulation and lack of surveillance at home. Overall, it was felt that OPIOL offered no net benefit to workload and concerns were expressed about efficacy and whether it could delay the induction process.

Reflecting the wider literature about pregnancy and birth, OPIOL was constructed as risky and unpredictable and only possible following rigorous risk assessment. Scamell and Alaszewski (2012) identified that midwives sought similar assurance about the absence of risk factors to identify normality. Ferndale *et al.* (2017) describe midwives 'caught in the middle', negotiating space between physiology and a technocratic birth process where risk is constructed as being avoidable through planning, screening and assessments to minimise the vulnerability of pregnant bodies (p.428). Within this discourse, monitoring and tests are minimised, legitimised and routinised e.g., 'what we need to do is pop you on the monitor' (Jackson, Land and Holmes, 2017 p.470;

Spendlove, 2018). Consent is frequently assumed and women's compliance is praised e.g., when listening to the fetal heart 'Here she is! [heartbeat] Beautiful' (Ferndale *et al.*, 2017 p.427).

### 6.6.1 Summary – how midwives justify their views and decisions about OPIOL

Using CRDA enabled me to analyse how midwives justified their views and decisions, and managed professional credibility and accountability in their talk. This approach enabled me to consider the relationship between the wider social conditions mediating the reality of midwives' day-to-day work and the action-orientation of their talk in managing and constructing identities. This was achieved by examining the discursive practices employed by midwives to position themselves and manage their professional identity when discussing views and decisions about OPIOL (Sims-Schouten, Riley and Willig, 2007).

## 6.7 How midwives manage professional credibility and accountability in talk about OPIOL

In this section, I summarise how midwives managed their professional credibility and accountability when talking about OPIOL. These strategies enabled them to present themselves as safe and credible practitioners, whilst upholding their professional responsibilities as a midwife to promote physiological processes of labour and birth and supporting informed decision-making.

### 6.7.1 Safe and credible practitioner

Midwives took considerable care to present themselves as credible and safe practitioners during the interviews by foregrounding their clinical expertise, providing detailed explanation of rigorous risk assessments, giving systematic descriptions around procedural aspects of care and detailing safety-netting discussions with women to ensure adverse outcomes were avoided. Midwives utilised discursive devices to present themselves in this way. For example, reported speech was frequently used to emphasise the credibility of midwives' accounts of their discussions with women e.g., 'I say to them, you know, 'if it falls out, this is what you need to do. If you start contracting, strongly, frequently, regularly, this is what you need to do.'' Furthermore, deviation from Trust guidance to increase fetal surveillance was justified. For example, use of the idiomatic expression 'I like to err on the side of caution' allowed a midwife to present herself as a safe and credible practitioner when justifying her decision to deviate from Trust guidance by delaying discharge and increasing fetal surveillance before proceeding with OPIOL.

Midwives were reflective about some of the uncertainties of clinical practice, in particular the interpretation and management of reduced fetal movements and indicated this meant many women were induced earlier as inpatients. They described guideline interpretation as 'quite tricky' and where there were grey areas one midwife wanted decisions 'OK'd by a doctor'. Another midwife distanced herself rather more from the validity of decisions which enabled her to maintain a more critical stance e.g., 'so then I think on discussion with a lot of the doctors when I had questions, they'd say, 'keep them in' and 'trying to unpick all those bits when the woman's in with a doctor who hasn't got a lot of time'. These constructions enabled midwives to present themselves as safe and credible practitioners by acknowledging the difficulties and clinical uncertainties surrounding interpretation and management of reduced fetal movements. It also enabled them to distance themselves somewhat from the decisions made by doctors and express frustration e.g., 'they're the ones that <u>really</u> frustrate me' versus induction of labour for '<u>valid</u> reasons'.

While midwives were generally keen to present themselves as being in favour of OPIOL, they sometimes constructed their talk in a way which invoked some ambiguity about their real views and those of their colleagues about the safety of OPIOL. Pronoun footing shifts were utilised to help midwives manage their identities and professional accountability, to distance themselves from others or distinguish their views and actions from those of their colleagues (Wiggins, 2017). For example, 'if you've got concerns you can speak to the lady, or you know, you've got more of a dialogue going on with the <u>woman</u> [..] So, I think they get anxious about that.' In this case, the midwife seems to indicate a rationale and preference for inpatient management but then attributes that view to her colleagues. Similarly, simultaneously describing reports of uterine hyperstimulation associated with dinoprostone pessary use as 'rumours', 'professional conversations' and 'stories' enabled another midwife to accommodate the views of her colleagues whilst she remained 'quite <u>willing</u> to give [it]'.

These findings reflect wider literature about tensions in contemporary midwifery practice between the risk discourse and the role of the midwife as an autonomous professional working in partnership with women to promote the physiological processes of birth where 'risk work' is overwhelmingly privileged (Scamell, 2016; Spendlove, 2018 p.23). This seems to contrast with the findings of the Morecambe Bay report which identified an inappropriate pursuit of normal birth amongst midwives (Kirkup, 2015). Instead, midwives often engage in increasingly defensive practices by invoking a need to exclude clinical uncertainty and midwives' talk tends to minimise the possibility of iatrogenic harm associated with interventions e.g., 'what we need to do is pop you on the monitor' (Scamell and Alaszewski, 2012;2016; Ferndale *et al.*, 2017; Jackson, Land and Holmes, 2017 p.470; Spendlove, 2018). This enables midwives to present themselves as 'good

practitioners' whilst minimising their own psychological risk and managing their fear of being involved in an adverse outcome (Hall, Tomkinson and Klein, 2012 p.579).

Dove and Muir-Cochrane (2014) also note this identity work amongst midwives and presenting oneself as a safe practitioner to others. Continuity of care enabled midwives to build trusting relationships with women, allowing them to position themselves as 'risk negotiator' (p.1066). Cultivating trusting relationships with doctors using the 'safe practitioner' identity helped when individualising care for women and mitigated against the blanket application of guidelines.

### 6.7.2 Promoting choice and personalisation of care

While the risk discourse dominated the research findings, midwives also presented themselves as woman-centred practitioners keen to promote informed decision-making. Midwives described their discussions with women about OPIOL over several appointments. This enabled midwives to demonstrate how they orientated towards the wider discourse of choice and personalisation and the continuity of care agenda (National Maternity Review, 2016). One midwife expressed her deep personal and professional commitment to support informed decision-making 'I would hate to think that one of my women would come to an induction and not be fully informed' which she then emphasised again by using the maxim 'information is power'.

Once women arrived for induction, midwives remained keen to highlight how they involved women in decision-making e.g., 'I always give women the option as well' when referring to a choice of induction agents and 'we always give them the option to stay'. However, midwives also articulated that some women were happy to accept recommendations without a great deal of discussion e.g., 'I think there is a lot of women who will just go, 'you're the midwife, you know what's best.''

While the findings reflect the wider discourses around choice and personalisation in maternity care emphasised in both Changing Childbirth and Better Births (Department of Health, 1993; National Maternity Review, 2016), the wider literature highlights the tensions between the choice and risk discourses (Scamell and Alaszewski, 2016). This suggests a more fragile commitment to supporting informed decision-making in which midwives can create an 'illusion of control' by foregrounding women's choices and birth experiences (Ferndale *et al.*, 2017 p.425). Similarly, Seibold *et al.* (2010) distinguishes between midwives 'holding the space' in the birth room, enabling women to 'take ownership of the space' versus 'lending the space' in which the hospital ultimately maintains control of the woman's birth environment and her experience (p.529). The

importance of ownership of the birth environment was also observed in my findings e.g., 'I guess, they're in our house, they think they're in our house and we're controlling, like, what they do, like, rules-wise', almost directly echoing Seibold et al. (p.529) 'It's our house rather than their house, they have to take ownership ..' who identify continuity of carer being paramount to enabling midwives to commit more confidently to the choice and personalised care agenda.

### 6.7.3 Promoting physiological processes of labour

Midwives also presented their awareness of the importance of enhancing normal physiological processes of labour. They articulated a belief that OPIOL optimised these processes and an interpretive repertoire of OPIOL as a middle road emerged during data analysis. They indicated that being at home enabled women to feel more relaxed and helped 'draw back a bit of that normality'. This helped women 'work with the induction' and 'tune in' to labour by 'trying to keep as many hormones going'. In contrast, midwives identified a lack of privacy and freedom of movement during inpatient induction and the hospital environment was not conducive to relaxation e.g., 'beeping noises, lights, erm.. the hustle and bustle of just being in hospital'.

These findings echo O'Brien *et al.* (2013) that OPIOL offers 'the next best thing to normal labour' and the opportunity for women to 'labour within their comfort zone' (p.326). While there is no evidence OPIOL affects mode of birth outcomes, OPIOL is associated with high levels of satisfaction (Awartani et al. 1999, Biem et al. 2003, Rauf et al 2011 and Turnbull et al. 2013a).

As discussed in section 6.5.4, while there is wider evidence that midwives orientate towards the normalising birth discourse and present themselves autonomous professionals striving to promote the physiological processes of birth, the reality is this has become increasingly difficult territory to negotiate in the context of the maternity safety agenda (Copeland, Dahlen and Homer, 2014; Scamell, 2016; Ferndale *et al.*, 2017). The term 'normal birth' itself has come under scrutiny as it suggests normalcy or an ideal, and risks marginalising women for whom intervention is beneficial (Lyerly, 2012). Furthermore, an inappropriate pursuit of normal childbirth has been identified at Morecambe Bay, Shrewsbury and other Trusts and the Birth Trauma association, bereaved parents and safety activists find the term unacceptable (Kirkup, 2015; Ockenden, 2020; Independent Maternity Services Oversight Panel, 2021). This means midwives face significant criticism and sanction for discussing 'normal birth' on social media, and presented as further evidence of the 'cult of normal birth' (Downe, 2017). Instead, there is increasing momentum, although little consensus, about using alternative terms e.g., 'physiological birth', 'straightforward labour and birth' and 'optimal birth' (Leap and Hunter, 2016 p.99). These tensions between risk and normality mean midwives face challenging identity work to present themselves as a 'good

practitioner' or a safe pair of hands to those around them, whilst maintaining their professional integrity in terms of promoting physiological processes and advocating for women (Hall, Tomkinson and Klein, 2012 p.579; Dove and Muir-Cochrane, 2014; Ferndale *et al.*, 2017; Spendlove, 2018).

### 6.7.4 Summary – managing professional credibility and accountability in talk about OPIOL

This section has presented a summary of the wider discourses and social conditions which mediate how midwives present themselves to others and manage their professional credibility and accountability. Most noticeably, midwives orientated to the wider risk discourse and employed discursive practices to present themselves as safe and credible practitioners. However, midwives also orientated towards the Better Births choice and personalisation agenda and normalising birth discourse during interviews, demonstrating their commitment to the role of the midwife as an accountable professional working in partnership with women to promote a healthy pregnancy and normal birth. These findings clearly highlight 'risk work' tensions experienced by midwives.

Midwives presented OPIOL as a 'middle road' to an essentially medicalised process. Use of this 'middle road' interpretive repertoire enabled midwives to maintain their professional integrity by minimising risk and maximising their own sense of psychological safety, while attending to their beliefs and principles about woman-centred care and promotion of physiological birth processes (Hall, Tomkinson and Klein, 2012).

## 6.8 Chapter summary

This chapter has summarised the main findings of the research concerning the factors influencing midwives' views and decisions about OPIOL and how they relate to the low rate of OPIOL. While few women had the opportunity to experience OPIOL, the findings indicate that outcomes were good. Critical realist discourse analysis was used to identify factors that could explain the observed reality and key findings are summarised in table 6-2. The findings demonstrate the key influence of the maternity safety agenda on midwives' views and decisions in terms of their use of guidelines and concerns about hyperstimulation. Midwives also orientated to other discourses around women's autonomy and supporting informed decision-making as well as the normalising birth discourse, demonstrating the risk work tensions in contemporary maternity care.

Table 6-2: Summary of key findings

| **Extra-discursive factors**<br>*Factors which explain the observed reality* | **Wider discourses**<br>*Mediate midwives' talk* | **Interpretive repertoires**<br>*Culturally familiar lines of argument and how midwives orientate towards them* |
|---|---|---|
| **Institutional**<br>Trust guidelines<br>Training and assigned area of work<br><br>**Materiality**<br>Socioeconomic and educational factors<br>Antenatal counselling<br>Pharmacokinetics<br><br>**Embodiment**<br>Cervical status<br>Comfort and feeling 'safe' | Risk work and maternity safety agenda<br><br>Choice and personalisation<br><br>Normalising birth<br><br>NHS under pressure | • **OPIOL as a middle road** - allows midwife to present herself positively as someone who is committed to normalising the birth process<br><br>• **Induction wasn't part of the plan** – inadequate counselling and women's expectations of labour and birth |
| **<u>Proposed mechanisms which explain the low rate of OPIOL</u>**<br>• 'Hunting the abnormal' – guideline interpretation variances, prolonged periods of fetal monitoring<br>• Negative talk and rumour about drug action<br>• Familiarity with process/availability of experiential knowledge | | |

# Chapter 7 Strengths and limitations

## 7.1 Introduction

This chapter summarises the strengths and limitations of my research and I reflect on my professional role and how it affected the research process. The strengths and limitations present opportunities for future research which are considered here also.

## 7.2 Research aim and objectives

The research aim and objectives were developed following a rigorous review of the literature which enabled me to identify gaps in the evidence base. My approach was systematic and used recommended techniques to ensure a consistent approach to evaluation of the literature and to provide a clear audit trail of the search process (Centre for Reviews and Dissemination, 2009; Booth, Papaioannou and Sutton, 2016). Search alerts were created to identify further relevant articles for review if published after the initial search was conducted and helped me keep abreast of the evolving evidence base.

Using this systematic approach, I was able to identify literature considering women's' views and experiences of OPIOL, however I realised there was a dearth of evidence about health professionals' perspectives. Recognising the iterative and inductive nature of qualitative research, I formulated a broad overarching research question: women's and staff views and experiences of OPIOL using vaginal dinoprostone. This enabled me refine my approach as the project took shape (Agee, 2009; Thomas and Hodges, 2010; Wiggins, 2017). When it became clear that few women were having OPIOL, I shifted the focus towards midwives' views and decisions and refined the research question and objectives accordingly. As well as identifying factors mediating midwives' views about OPIOL, I explored how they justified decisions and managed their professional credibility and accountability.

## 7.3 Study design

Implementing a methodological approach aligned with critical realism, I adapted an approach described by Sims-Schouten, Riley and Willig (2007) who used mixed methods to explore discursive and non-discursive factors mediating women's talk of motherhood, childcare and employment. Adopting a realist ontology enabled me to explore the social reality influencing

midwives' talk about OPIOL. The constructionist epistemological basis of CRDA enabled me to recognise midwives' agency in interactions when justifying their decisions, and to analyse how they presented themselves to manage their professional credibility and accountability.

However, a limitation of my study design was that I learned about CRDA when I was already conducting interviews and I had originally intended to use thematic analysis as described by Braun and Clarke (2006). Prior to conducting interviews, Sims-Schouten, Riley and Willig (2007) recommend collecting data about relevant government policies and availability of local resources as well data about the participants themselves. This enabled them to identify institutional, material and embodied factors that mediated talk. Working in maternity services and having a good understanding of national maternity strategy mitigated the absence of this stage of data collection to some extent.

Use of retrospective data and semi-structured interviews posed some quandaries; it became apparent there was data missing from women's health records, yet during study design I had incorrectly assumed that women eligible for OPIOL would be routinely offered it. Similarly, during interviews, I was unsure about the extent to which midwives' talk always reflected what was going on in practice. Hollnagel and Wears (2015) describe the critical difference between 'work-as-imagined' versus 'work-as-done' in relation to patient safety. In 'top-down' service improvement where there is little staff involvement in the design and planning phase, managers may assume a guideline or checklist will be implemented as intended. In practice, staff may want to apply guidelines more flexibly to individualise care, or they will sometimes adopt workarounds to save time. In terms of patient safety, this can create latent errors not foreseen in the design and planning phase. A safer approach is to work with staff to map out 'work-as-done' as this more reliably reflects the reality staff face in their day-to-day jobs. Shorrock (2016) extends this conceptual framework to include 'work-as-prescribed', which can be similar to 'work-as-imagined' but more limited in scope reflecting laws, regulations, policies and guidelines. Shorrock also describes 'work-as-disclosed' – a more palatable or understandable version of what actually happens in practice, which can also vary depending on the audience (Figure 7-1).

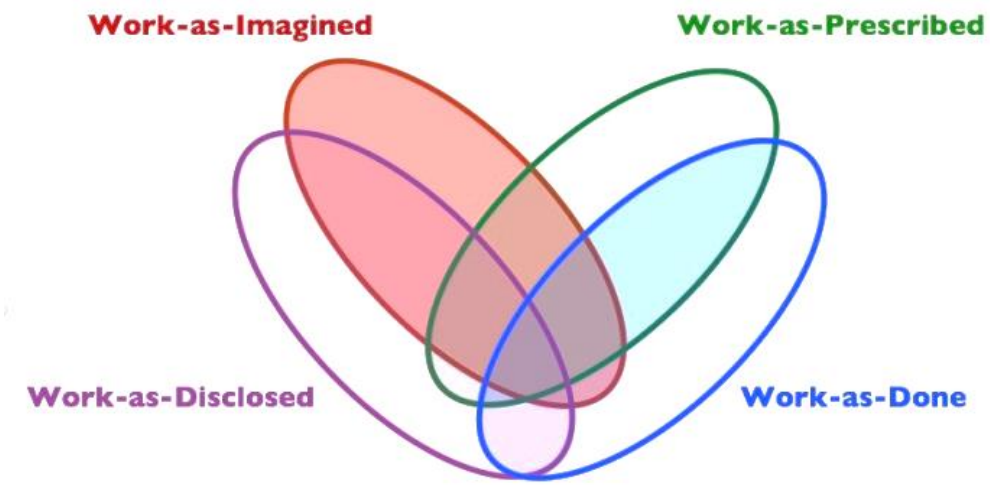



Figure 7-1: Varieties of human work (Shorrock, 2016)

This conceptual framework can also be usefully applied to help consider the validity and reliability of research. In my case, being an 'insider' and a novice researcher led to a significant 'work-as-imagined' assumption being made during study design in that women eligible for OPIOL were not always offered it. For 53 women there was no documentary evidence that an offer of OPIOL was made at the commencement of the induction of labour care episode. This assumption reflected my previous knowledge of working in the clinical area, an understanding of how the OPIOL guideline should work in practice and earlier discussions with midwives, and as a result, I was unable to tell if OPIOL had been offered and declined, or whether OPIOL was simply not offered. The cohort of women with missing data provided some interesting insights and women with a BMI 35.0-39.9 seemed over-represented in this group. Overall, this group accounted for 9.1 per cent of the 187 women eligible for OPIOL, yet over three-quarters of them were not offered OPIOL and so I postulated that BMI could be a relevant factor which mediated offer of OPIOL. Patel, Doku and Tennakoon (2003) emphasise the importance of early and sustained collaboration with the study site. Building a dialogue with staff and explaining the relevance of the research at the outset can help researchers identify those who are most enthusiastic about the project and improve study design. On reflection, piloting the data collection tool would have identified the missing data issue at the research design stage (Dancey, Reidy and Rowe, 2012; Lacey, 2015). Other ways to reduce missing data could include transition to electronic documentation with mandatory fields or adopting a prospective research design. The forthcoming multi-centre CHOICE study aims to do just this, and will compare inpatient and outpatient induction of labour

outcomes with dinoprostone, as well as cost-effectiveness and women's and partner's views, but notably does not explore midwives' views and decisions (Stock *et al.*, 2021).

My research was conducted in one setting only which is another potential limitation. Nevertheless, Creswell (2013) asserts that the intention of qualitative research should not be to generalise, 'but to elucidate the particular, the specific' (p. 157). In addition, the nature of critical realist research and realist evaluation tends to be highly specific to the research context, and local conditions will influence individuals' sense-making and the success or failure of interventions (Pawson and Tilley, 1997; Maxwell, 2012). Pawson and Tilley (1997) describe the term realistic cumulation where multi-centre research helps test and refine knowledge about contextual factors and underlying mechanisms which best explain the observable reality and are likely to be the most important predictors of the success of an intervention. They acknowledge the epistemological limitations of this approach as the social world is in constant flux and local changes can evolve rapidly, and this has certainly been the case in maternity care since 2015. While the wider risk and patient safety discourse is likely to mediate midwives' decision-making in other NHS Trusts, further multi-centre research, particularly in hospitals where more women undergo OPIOL, may elucidate institutional factors which promote uptake. For example, Trust guidelines and eligibility criteria may be more inclusive and there may be more multiprofessional support around decision-making.

## 7.4 Sample size and recruitment

My quantitative findings describe the characteristics of women eligible for OPIOL as well as their clinical outcomes. The strength of this approach was that I was able to triangulate the findings with the interview data, which provided further evidence of midwives' vigilance in their approach to risk assessment. This mixed methods approach also helped mitigate the small number of interview participants (Manzano, 2016). A sample of 6 to 30 participants is suggested in the literature to achieve data saturation, and I was able to recruit six (Guest, Bunce and Johnson, 2006; Baker and Edwards, 2012; Hennink, Kaiser and Marconi, 2017). In terms of data saturation, recurrent themes became apparent during the interviews. However, Braun and Clarke (2019) are critical about the concept of data saturation and argue that ultimately, researchers are likely to encounter time and resource constraints. From my perspective, the recruitment period came to an end, and I made a pragmatic decision not to extend it further. Similarly, during data analysis I reached a point where no new themes emerged from the data. However, despite the small sample size, the focussed aim of the research, recruitment of participants directly involved in induction of labour activity and detailed analysis of the transcripts created 'information power',

which mitigated the small sample size and increased confidence in the findings (Malterud, Siersma and Guassora, 2015 p.1754).

Braun and Clarke (2019) acknowledge the pragmatic decisions made by researchers due to limitations of time and resources and I certainly faced difficulty with recruitment while conducting the study alongside a full-time role. Recruitment of women via the birth environment Facebook pages and posters in the induction of labour suite was not a successful strategy for this study. This may have been because at the time, responses to other posts suggested that women following the page had already had their babies. During the Covid-19 pandemic from March 2020, more pregnant women started following the maternity Facebook pages to get updates about changes to appointments and visiting restrictions. While data collection was already complete by this stage, this prompted reflection on my recruitment strategy. Facebook and other forms of social media are now widely used in health and social science research and provide an inexpensive alternative to traditional recruitment methods (Whitaker, Stevelink and Fear, 2017).

Informal discussions with the induction midwives was a more successful recruitment strategy although they were frequently busy and unable to talk for long. This approach also reminded them that data collection was still ongoing and led to recruitment of staff for interviews. I was unable to recruit women who were eligible for OPIOL on admission but subsequently developed complications like hypertension or concerns about fetal monitoring. This may have been because staff did not understand the rationale for recruitment of this cohort.

Another recruitment strategy that would be considered in future is giving participants a small incentive. A gift token of a notional value can be used to acknowledge that participants are giving up their time. It is recommended that the incentive is given out at the beginning of the interview so there is no pressure or sense of obligation on the participant to respond in a certain way (UK Government, 2020).

## 7.5 Data collection

While I have already described some of the pitfalls I encountered using a retrospective data in section 7.3, a strength of my research is that I devised a data collection tool to ensure a consistent approach when identifying women eligible for OPIOL. Data collection involved review of data extracts from the maternity information database as well as the narrative in women's health records. Where possible I used software to make data processing more efficient and reliable e.g.,

Microsoft® Excel® filters to identify and consolidate common abbreviations and Google Maps to calculate journey time to hospital.

Being a novice researcher led to some missed opportunities during qualitative data collection. For example, one of the issues I encountered was that midwives sometimes used idiomatic talk e.g., 'I like to err on the side of caution' and 'bog standard normal' when describing a woman with no risk factors. This enabled the midwife to activate a shortcut in creating a shared understanding between us (Koester, 2006). However, by permitting the participants to be 'systematically vague' about specific aspects of the risk assessment (Wiggins, 2017 p.161), when listening back to the interviews I sometimes found myself regretting that I had not asked more questions to explore their meaning in more detail.

## 7.6 Data analysis

I involved a statistician at an early stage during study design which helped me devise an appropriate strategy for analysis using descriptive statistics. Appropriate software was used to process and analyse the data and to reduce the likelihood of transcription errors.

In terms of the qualitative analysis, I took steps to ensure the validity and trustworthiness of the findings. Firstly, I transcribed the interviews myself which made me feel assured of their accuracy as well as helping me build familiarity with the data and informing the analysis (Lapadat and Lindsay, 1999; Goodman, 2017). I adopted a very simplified notation system derived from Du Bois *et al.* (1993) and Gibson (2010) to indicate speakers' emphasis and changes in intonation and I included line numbers to provide a clear audit trail in my analysis to enhance confirmability of the findings. I then made memos and coded the transcripts in line with CRDA conventions. I did this manually which as a novice helped me build confidence and familiarity with the technique (Saldaña, 2015). Exemplars were identified and shared with the researcher's supervisors acting as critical peer reviewers to ensure descriptive validity and enhance credibility of the findings (Maxwell, 2012).

## 7.7 Patient and public involvement

I involved the local patient user group early in the project to review participant information leaflets to ensure the language was understandable and appropriate. Early involvement of users of patient services helps researchers to identify and refine research questions, improve study design and seek appropriate ways to disseminate findings. Ethics committees usually require evidence of involvement and emphasise the importance of conducting research *with* participants

(Health Research Authority, 2017b). In future, I would extend patient and public involvement in the development phase of the project by organising a focus group to help identify research questions of interest to the public. Since completion of data collection in early 2020, the local clinical commissioning group have recruited a chair of the local Maternity Voices Partnership (MVP), a national Better Births requirement (NHS England, 2017c). MVPs have a role in quality improvement, co-production and evaluation of maternity services, working collaboratively with maternity staff and commissioners to ensure the views of women and families from all communities are represented to reduce inequalities and improve care (National Maternity Voices, 2020). This means MVPs are ideally placed to contribute to the local research agenda.

## 7.8 Reflections on my professional role

My 'insider status' and experience as a consultant midwife and Professional Midwifery Advocate (PMA) meant I already had an understanding of some of factors influencing midwives' practice and was well aware of the national maternity safety strategy and wider discourses. In my day-to-day role I have observed the impact of the national safety strategies such as Saving Babies' Lives, Each Baby Counts and the NHSR Maternity Incentive Scheme on senior management workload in terms of audit and reporting requirements (NHS England, 2016; Royal College of Obstetricians and Gynaecologists, 2016; NHS Resolution, 2021). In recent years, this awareness has also reached the 'shop floor' and is now included in midwives' mandatory training. Furthermore, my role involves case reviews of adverse incidents and providing support to staff through restorative clinical supervision. This has given me an insight into the stress, guilt and fear that follows an incident and how these events can affect midwives' wellbeing as well as their subsequent clinical decision-making. In addition, my role involves the development of new guidelines and I have been struck by the level of detail demanded by staff to eliminate 'grey areas' to ensure every eventuality is considered to reduce their risk exposure. I am also involved in the implementation of service improvements and project management and so I am aware of some of the factors influencing midwives' readiness to adopt new ways of working. While I was led by the midwives' accounts and the analysis of the interview transcripts, my experiences as a consultant midwife and PMA undoubtedly provided additional insights when analysing the research data.

My role as a consultant midwife could also be perceived as a limitation and I was always aware of the potential that my own opinions could bias findings. While everyone likes to think they are approachable, there is a very real possibility that participants moderated their responses and told me what they thought I wanted to hear. In this sense, there was a very real possibility I was

hearing accounts of 'work-as-disclosed' rather than 'work-as-done' and that people would adjust their accounts to present themselves favourably and make them more palatable to me in my role as a consultant midwife often involved in adverse event reviews (Shorrock, 2016). That said, I am still junior in post and previously known to the participants in less senior roles and so I anticipated this would put participants at ease. Furthermore, my role in service improvement within the organisation means staff are accustomed to telling me when things 'aren't working'. As it transpired, participants acknowledged minor deviations from guidelines (e.g., by undertaking more monitoring than recommended) which provided some assurance about the authenticity of their accounts.

The CRDA approach also helped 'make the familiar strange' to some extent (Atkinson, Delamont and Coffey, 2003 p.17). This enabled me to identify aspects of the conversation midwives found difficult as they deployed discursive devices such as hedging and minimisation, commonly used when navigating sensitive topics. This helped me identify moments when midwives were trying to make things more palatable, suggesting a discrepancy between 'work-as-done' and 'work-as-disclosed' (Shorrock, 2016).

I was also conscious of my own 'risk lens' and that I spend a lot of my time involved in risk-related activities such as supporting women wishing to birth outside guidance, and reviews of clinical incidents. This was a potential threat to interpretive validity if my findings and there was a risk of bias by seeking confirmation of my views in the research data (Allen, 2004; Maxwell, 2012). To a large extent, researcher subjectivity is inevitable and 'immaculate perception' is unattainable (Maxwell, 2012 p.97), and from an epistemological point of view, researchers, like everyone else, construct their own version of the world (Potter and Wetherell, 1987). To combat this, reflective memos were made during data collection and analysis and I found this 'thinking on paper' a helpful way to bracket my own thoughts and a way to consider the intention of the speaker more clearly (Maxwell, 2012 p.99). Furthermore, discursive psychology considers the action-orientation of talk and the effect it has on others around the speaker and so it was entirely reasonable to describe my interpretation and the effect the talk had on me (Goodman, 2017). Triangulating quantitative data and qualitative data also enabled me to confirm that midwives were demonstrably vigilant when making decisions about OPIOL. Detailed transcription and the provision of extracts alongside my analysis of midwives' talk enhance the credibility of my findings, meaning others can read for themselves and determine whether the analysis is convincing.

## 7.9 Chapter summary

In this chapter I have reflected on some of the strengths and limitations of my research, and while small in scale, I adopted rigorous methods to enhance information power as well as the validity and credibility of my findings. I have also considered my role as a consultant midwife and researcher reflexively and I demonstrate how I was able to leverage insider knowledge and maintain an outsider perspective to a certain degree. Recommendations for future research have been considered within this chapter and further multi-centre research using a CRDA approach is recommended. Wider research suggests that factors such as involvement in adverse incidents and stress levels influence clinicians' vigilance and decision-making.

This page has been left intentionally blank

# Chapter 8 Unique contribution to midwifery body of knowledge

## 8.1 Introduction

This study makes an important contribution to knowledge about OPIOL and the impact of risk and patient safety discourses on maternity care more generally. The success of any intervention depends on whether it is offered in the first place and the findings demonstrate vigilance in midwives' decision-making about OPIOL. This chapter provides a summary of the contribution made to existing knowledge and considers implications for practice.

## 8.2 Contribution to midwifery practice

While wider literature about OPIOL with vaginal dinoprostone considers the views and experiences of women, there is a dearth of evidence about clinicians' perspectives and only one study was identified. Turnbull *et al.* (2013b) found most midwives reported no difference to their stress levels, workload and job satisfaction following the implementation of OPIOL.

My findings demonstrate how wider discourses around risk and safety mediate midwives' talk about OPIOL. This is important because while the wider literature indicates women are positive about OPIOL and report high levels of satisfaction, many women may not be offered this intervention due to midwives' fear of a poor outcome. In addition, inpatient induction of labour continues to have a significant impact on capacity within maternity hospitals and women face delays and poor experiences (Coates *et al.*, 2019).

My findings also contribute to existing research about risk talk in maternity care. OPIOL was constructed as risky and unpredictable and only possible following rigorous risk assessment. My research also offers further insights into how midwives justify decisions and manage their professional credibility and has wider applicability in terms of understanding the factors and mechanisms contributing to increasing rates of intervention in pregnancy and birth.

## 8.3 Methodological contribution

My research design also makes a significant methodological contribution as it is the first time that critical realist discourse analysis has been applied to maternity research. The CRDA method

described by Sims-Schouten, Riley and Willig (2007) was adapted and has potential to influence how we explore risk work tensions. It also provides a novel way to consider midwives' agency and how they construct, negotiate and manage their professional credibility. It helped 'make the familiar strange' and offered deeper insights into the factors influencing the success or failure of a new intervention than realist evaluation alone (Atkinson, Delamont and Coffey, 2003 p.17).

CRDA enables researchers to examine the stratified layers of reality from events in the empirical domain which are directly observable or experienced, the domain of the actual where events (and non-events) occur and the domain of the real in which underlying causes or mechanisms exist which may or may not trigger those events and experiences (Bhaskar, 1997; Mingers, 2004). CRDA enabled me to extend this conceptualisation of a stratified reality to consider 'work as imagined' – how an intervention is thought to work in practice, 'work as prescribed' (e.g., Trust and national guidelines and strategies), 'work as done' – the reality faced by clinicians and how interventions are implemented in practice, and the negotiated and constructed reality of 'work as disclosed' which people use to manage social relationships (Hollnagel and Wears, 2015; Shorrock, 2016). These types of work are all 'real' in the sense that they reflect or have the capacity to influence what happens in the real world but are mind-dependent and socially located. CRDA offers a framework to identify factors influencing people's views and decisions and helps close the gap between our understanding of how an intervention ought to be working by revealing what is actually happening in practice.

## 8.4 Implications for practice

This section summarises some of the implications for practice identified in the research data. However, it is likely that women and staff will have other suggestions and a quality improvement methodology could be used to engage stakeholders, and help identify and test other change ideas to increase uptake of OPIOL (Institute for Healthcare Improvement, 2021).

Firstly, midwives indicated that colleagues who worked in the induction of labour suite infrequently preferred to opt for inpatient management whereas those who worked there regularly were more accustomed to the OPIOL process. This suggests having a core team of midwives is a helpful strategy and while this is the current staffing model for this clinical area at the NHS Trust, at the time of data collection there were insufficient team members to cover all the shifts. In addition, even those midwives regularly assigned to work in the induction suite expressed some decision-making challenges and said they often approached doctors with questions about eligibility. This suggests midwives may benefit from more proactive support from a senior midwife or a member of the obstetric team. A short daily multidisciplinary meeting (also

known as a huddle) could help identify women eligible for OPIOL and would be an opportunity to answer any questions. This would also facilitate staff development and training as it would help identify staff members who lack confidence with their decision-making or are unfamiliar with dinoprostone pessary insertion.

Providing midwives with access to regular clinical supervision could also create a reflective space with an opportunity to reflect on decision-making. Clinical supervision can have a positive impact on staff confidence as well as their wellbeing and resilience. In maternity, PMAs work within the A-EQUIP framework, an employer-led model which provides midwives with access to clinical supervision and an opportunity to create a personal action for quality improvement. Other activities encompassed by the A-EQUIP model include involvement in education and development and monitoring and evaluation (NHS England, 2017a).

Interview data suggested midwives perceived a higher likelihood of hyperstimulation with the dinoprostone pessary than the more commonly used tablet formulation. While regular audit of OPIOL outcomes was recommended in the previous NICE guideline, this requirement was removed in the latest version (National Institute for Health and Care Excellence, 2021). Continuation of regular audit, in addition to the risk management processes, could reassure staff of outcomes. The Trust has conducted an audit of OPIOL since implementation but the results have not been widely reported within the organisation and so the findings have not provided staff much assurance. The audit could be simplified, and data gathered prospectively to provide more rapid feedback to staff about their decision-making. The number of women eligible on admission and the number of women discharged home would be helpful data as it may identify differences in vigilance between staff members. Prostaglandin to birth interval is a useful metric as it can help identify where there was hyperstimulation leading to early intervention. Collecting data about Apgar score at 5 minutes and any neonatal unit admissions would also reassure staff about their decision-making. Information would need to be collated and fed back to staff individually and could be summarised and shared more widely in relevant departmental meetings and via appropriate social media channels. For example, the NHS Trust's Workplace App enables employees to sign up to receive relevant updates on their computer or mobile device.

Another implication for practice is consideration of alternative methods of induction. Research shows midwives and doctors feel confident about sending women home with a catheter balloon in situ as it reduces concerns about the possibility of uterine hyperstimulation associated with pharmacological methods (Wilkinson, Adelson and Turnbull, 2015). Mechanical methods of induction such as balloon catheters have been shown to be safe and effective and are now

supported by recently updated national guidance where pharmacological methods are unsuitable (Diederen *et al.*, 2018; de Vaan *et al.*, 2019; National Institute for Health and Care Excellence, 2021).

An interpretive repertoire emerged from interview data that 'induction was never part of the plan' and midwives indicated that many women continue to be unprepared for their induction of labour experience and often expect the baby to be born later the same day. Midwives suggested this meant some women did not want to be discharged home as they were not expecting to leave the hospital again without their baby. Midwives indicated other women felt safer remaining in hospital. While there is a Trust information leaflet explaining inpatient and outpatient induction of labour, it is not clear whether they access it or find it useful. Engaging women via the MVP could provide an opportunity to identify women's information needs and evaluate the entire induction of labour pathway which could potentially identify further areas for improvement.

## 8.5 Chapter summary

My research makes an original contribution to the body of midwifery knowledge about OPIOL. There is limited research about women's experiences, and a before and after questionnaire considered midwives' stress levels, workload and job satisfaction following the implementation of OPIOL (Turnbull *et al.*, 2013b). No other study considers midwives' views and decision-making about OPIOL and I used CRDA in a novel way to provide explanatory insights into the low rate of outpatient management in the study setting. A key finding was midwives' orientation towards risk and patient safety discourses and how they constructed OPIOL as risky and unpredictable in their talk. This is a significant finding because OPIOL is supported by national guidance and is associated with high rates of satisfaction amongst women (Awartani, Turnell and Olatunbosun, 1999; Biem *et al.*, 2003; Rauf *et al.*, 2011; National Institute for Health and Care Excellence, 2021). My findings also make a contribution to existing literature about risk talk in maternity care. Maternity care professionals invoke risk and safety discourses to justify additional fetal surveillance and interventions in pregnancy and birth which are constructed as inherently risky (Shaw, 2009; Seibold *et al.*, 2010; Scamell and Alaszewski, 2012; Healy, Humphreys and Kennedy, 2016; Scamell, 2016; Scamell and Alaszewski, 2016; Ferndale *et al.*, 2017; Healy, Humphreys and Kennedy, 2017; Spendlove, 2018).

Improvement ideas identified from my research data include enhanced coaching and supervision of midwives to build confidence in making decisions about OPIOL, timely feedback of OPIOL outcomes to provide assurance about safety, and engaging stakeholders such as the MVP to review the induction of labour pathway including the methods used. This would highlight priority

areas for improvement and ensure women have the opportunity to make informed decisions about the setting in which induction of labour takes place.

This page has been left intentionally blank

# Chapter 9 Conclusion

## 9.1 Introduction

At the conception of this research project, I planned to explore the views and experiences of women and staff of outpatient induction of labour which had recently been implemented within the local NHS Trust. Wider research indicates women frequently report delays, lack of privacy, loneliness and boredom and restriction of movement during inpatient management (Oster *et al.*, 2011; O'Brien *et al.*, 2013; Coates *et al.*, 2019) and high levels of satisfaction amongst women having OPIOL (Awartani, Turnell and Olatunbosun, 1999; Biem *et al.*, 2003; Rauf *et al.*, 2011). It soon became apparent that few women were having the opportunity to experience OPIOL. My research question was therefore refined as follows:

> What factors influence midwives' views and decisions about outpatient induction of labour using vaginal dinoprostone?

This concluding chapter summarises my research findings and presents recommendations for maternity services, policy makers and researchers.

## 9.2 Research summary

The aim of this research was to identify the factors influencing midwives' views and decisions about OPIOL using vaginal dinoprostone. My findings demonstrated that few women had the opportunity to experience OPIOL and women eligible for the intervention were not offered it routinely. I explored the reasons for this in interviews with midwives and while their talk orientated towards choice and personalisation and normalising birth discourses, ultimately risk and safety discourses were overwhelmingly privileged. Midwives expressed concerns about the safety of the dinoprostone pessary and were concerned about the possibility of uterine hyperstimulation leading to an adverse outcome. They were clearly vigilant when making decisions about OPIOL and some expressed unease about sending women home. Midwives sought sanctuary in the safety net of the NHS Trust guideline to determine women's eligibility. They articulated that it was difficult to reconcile their assessment with other guidance about reduced fetal movements. This meant they were uncertain how to interpret the significance of earlier assessments for reduced fetal movements in pregnancy even when findings were subsequently normal.

My findings contribute to the wider body of literature about risk work tensions in maternity care. Midwives and obstetricians inevitably tolerate different levels of uncertainty in the birth process and thresholds may vary by day and will also relate to previous experiences and consideration of workplace pressures and available resources (Page and Mander, 2014). A deeply pernicious fear of adverse outcomes and the accompanying scrutiny of the investigation process can lead to defensive practices, up-tariffing risks and referral to senior clinicians and risk avoidance strategies to avoid future harm (Hood, Fenwick and Butt, 2010; Seibold *et al.*, 2010; Scamell and Alaszewski, 2016; Bourne *et al.*, 2019; Monson, 2020). Increasing fetal surveillance is seen as a way to provide assurance of fetal wellbeing while the poor specificity and potential harms of such screening are minimised (Healy, Humphreys and Kennedy, 2016;2017).

Continuity of care models can enhance relationships and reduce uncertainties and can help midwives feel more confident when advocating for women's birth choices (Dove and Muir-Cochrane, 2014; National Maternity Review, 2016). However, it remains uncertain how best to embed induction of labour within continuity of care pathways as induction is frequently undertaken by core midwifery staff working within the hospital setting and handed over to continuity teams once labour becomes established. My research findings support having an induction of labour team to ensure midwives are more familiar with the OPIOL process.

Midwives also indicated that women frequently had unrealistic expectations of induction of labour and attributed their lack of preparedness to the quality of antenatal counselling. An interpretive repertoire emerged during analysis that induction of labour was 'never part of the plan' and midwives suggested that some women were reticent about leaving the hospital again before the birth of their baby. Research shows there is a demand for OPIOL and women report high rates of satisfaction. Engaging women via the Maternity Voices Partnership would provide an opportunity to better understand women's information needs and how to approach counselling so they are more prepared for an induction experience.

In the following sections I present recommendations for maternity services, policy makers and researchers.

## 9.3 Recommendations for maternity services

1. **Improved antenatal counselling** – Midwives articulated that women are sometimes unprepared for induction of labour and expect their baby to be born later the same day. Many NHS Trusts provide information leaflets about induction of labour but co-production with the Maternity voices Partnership could explore women's information needs and identify alternative ways to explain the induction of labour process. This would

help ensure women and families have clearer expectations and improve experiences of induction of labour.

2. **Implementing an induction of labour team** – My findings justify having a small team of midwives to provide care to women undergoing induction of labour to ensure a midwife is rostered to work each shift. This is likely to improve uptake of OPIOL because the midwife would be more familiar with eligibility decisions and using the dinoprostone pessary. Conversely, midwives who work in the induction suite less frequently are less familiar with making decisions about OPIOL and more likely to offer inpatient management.

3. **Daily huddle** – Maternity services should offer proactive support to midwives working in the induction of labour suite. A short, daily multidisciplinary meeting or huddle including the induction midwife, the Labour Ward Coordinator and a senior member of the obstetric team could help identify women eligible for OPIOL and support decision-making. This would also facilitate staff development and training as it would help identify staff members who lack confidence with their decision-making or are unfamiliar with dinoprostone pessary insertion.

4. **Regular audit and evaluation** – A quality improvement approach involving co-production with the MVP could be used to identify process and outcome measures that are most important to women and the midwives working in that clinical area. This approach could provide more timely assurance about outcomes. Process measures could include the number of women at low risk of complications on admission and the number discharged home. Reason for ongoing inpatient induction could also be collected. Induction agent to birth interval is a useful process measure frequently used to determine effectiveness of induction. It can also help identify cases of hyperstimulation where birth has been expedited due to fetal concerns. Mode of birth, indication for intervention, Apgar score at 5 minutes, neonatal unit admissions are all appropriate outcome measures. Information would need to be collated and fed back to staff involved and the Maternity Voices Partnership and shared more widely in relevant departmental meetings.

5. **Regular clinical supervision** – Clinical supervision can have a positive impact on staff wellbeing, confidence and resilience and provides a safe space to reflect on challenging situations and decision-making. In maternity, this could be provided by a Professional Midwifery Advocate (PMA) working within the A-EQUIP framework. This would

potentially have wider benefits beyond uptake of OPIOL by enabling midwives to consider how they support women to make informed decisions whilst continuing to undertake effective risk assessments.

6. **Introduction of mechanical methods of induction** – Mechanical methods such as balloon catheter are now recommended in the recently updated NICE guidance where pharmacological methods are unsuitable or where women choose this option (National Institute for Health and Care Excellence, 2021). Research shows a favourable response from staff who feel more confident to proceed with OPIOL as the risk of uterine hyperstimulation is lower (Wilkinson, Adelson and Turnbull, 2015). NHS Trusts should consider implementing a method of mechanical induction for OPIOL such as balloon catheter so women can choose this option if they wish.

## 9.4 Recommendations for policy makers

1. **Funding of maternity services** – While my research did not investigate the impact of maternity staffing levels on midwives' decisions about OPIOL, my findings underline the deep sense of professional responsibility and fear of adverse outcomes embodied in midwives' talk, which reinforces the construction of pregnancy and birth as inherently risky and unpredictable. Fear of an adverse outcome and the guilt and shame that accompanies this can undermine the delivery of evidence-based, personalised care to women as birth is increasingly seen as an event which can be standardised and carefully managed. Poor staffing inevitably exacerbates feelings of uncertainty, leading to defensive practices as well as fatigue, anxiety and burnout amongst clinicians. Staff survey data in March 2021 showed one in 11 staff are considering leaving the sector and over 93,000 whole time equivalent vacancies across the NHS in June 2021 (NHS Digital, 2021; UK Government, 2021). Health Education England figures show an additional 1932 midwives are needed (House of Commons Health and Social Care Committee, 2021a). Staffing shortages have been recognised in the recent *Safety of Maternity Services in England* report and I support the recommendations made by the Health and Social Care Committee to increase funding by £200-350m per annum with immediate effect (House of Commons Health and Social Care Committee, 2021b).

2. **Review clinical negligence law in the UK** – In addition to increased staffing, organisations and policy makers need to review the tort based clinical negligence system and continue work to embed a no blame culture within the NHS. While HSIB investigations aim to

identify the human and organisational factors that contribute to safety incidents, the legal system perpetuates a blame culture as compensation is awarded when negligence is proven. The claims process is inevitably adversarial, which often has a significant impact on staff wellbeing and can elicit defensive behaviours. In contrast, no blame compensation systems such as those in Sweden and New Zealand are associated with more rapid resolution for families and lower costs. They also foster greater openness amongst clinicians who are not deterred in coming forward with safety concerns. The national maternity review Better Births recommended the introduction of a Rapid Resolution and Redress Scheme for maternity services (National Maternity Review, 2016). The UK Government are carrying out a wider review of the process around compensation for NHS patients and are due to publish a consultation paper by the end of 2021 (House of Commons Health and Social Care Committee, 2021c).

## 9.5 Research recommendations

1. My findings invite further mixed methods research about risk work tensions and how they influence uptake of OPIOL. Quantitative research could determine whether the likelihood midwives offer OPIOL varies significantly in relation to factors such as BMI, usual area of work or recent involvement in serious incidents. This approach could utilise logistic regression to develop a model to determine which factors most reliably predict the probability of OPIOL being offered or not (Dancey, Reidy and Rowe, 2012):

    - Characteristics of women e.g., BMI
    - Midwife's usual area of work (i.e., induction of labour team member or not)
    - Most recent experience of making decisions about OPIOL (e.g., last week, in the past month, in the past three months, more than three months ago)
    - Number of years of practice
    - Participation in a Healthcare Safety Investigation Branch interview / involvement in a serious incident in the past year
    - Measure of workplace stress and burnout using validated measures (Hunter *et al.*, 2019).

    These factors may illuminate further insights into how embodied, material and institutional factors feature in midwives' professional lives and sense-making and influence their views and decisions about OPIOL.

Participant observation may also elicit additional insights into how midwives' decisions vary with acuity and activity (Holloway and Galvin, 2015a). These factors may illuminate further insights into how embodied, material and institutional factors feature in midwives' sense-making and how they influence views and decisions about OPIOL.

2. There is an opportunity to evaluate decision-making about OPIOL in other settings and this may help researchers identify explanatory mechanisms and conditions associated successful implementation. However, findings are likely to be highly contextual, and critical realist theory acknowledges that similar results elsewhere cannot be assumed.

3. My research findings also invite further application of CRDA to consider the wider impact of risk and patient safety discourses in maternity care, and how risk is communicated with women. I identified that at the point of discharge, responsibility for ongoing surveillance was clearly handed over to women and a list of potential problems would be recited e.g., reduced fetal movements, bleeding, feeling unwell. This presents a paradoxical situation where women are instructed to relax yet stay alert to potential problems. More research is needed in maternity care about how to deliver safety-netting messages without inadvertently raising anxiety. This has significant implications in the context of rising number of requests for induction of labour and caesarean birth due to maternal fears about the possibility of rare adverse outcomes.

## 9.6 Concluding remarks

Maternity services have experienced considerable policy turbulence over the past few years and strategic workstreams to improve patient safety have continued at pace. While stillbirths in England and Wales were the lowest on record at 3.8 per 1000 in 2020, rates of birth interventions have increased markedly over the past decade (Office for National Statistics, 2021b). Around a third of women now experience induction of labour compared to just under 21 per cent in 2009/10 and increasing bed pressures have led many Trusts to implement OPIOL (Sharp, Stock and Alfirevic, 2016; NHS Digital, 2020). Despite the ongoing focus on safety, maternity services are responsible for the highest value claims submitted to the NHS and reached nearly £2.4 billion in 2019/20. Trusts continue to face considerable regulator and media scrutiny and data collected before the Covid-19 pandemic showed maternity staff reporting high levels of stress and burnout (Bourne *et al.*, 2019; Hunter *et al.*, 2019). Without a review of the legal process around compensation and significant investment in maternity services, clinicians will continue to face the uncertainties of high workload and competing demands in highly pressurised working

environments, exacerbated by high rates of burnout and sickness. These factors heighten the clinical uncertainties when caring for women and families, and discourses around risk and patient safety will continue to be overwhelmingly privileged at the expense of strong advocacy for women.

In this thesis I have examined midwives' views and decisions about OPIOL and provided an insight into how risk and patient safety discourses mediate the options presented to women. In my discussion of the evidence, I have also considered the wider impact of these discourses on women's pregnancy and birth experiences and on the staff providing care. They are likely to erode women's choices by undermining midwives' willingness to deviate from guidelines in order to personalise care to meet individual needs. In addition to improving communication and escalation within maternity services, I argue that safer care can only be achieved by listening to women and families to individualise care as these voices should form an integral part of our risk assessment process.

# List of References

*The Health Act 1999* United Kingdom. Available at: https://www.legislation.gov.uk/ukpga/1999/8/contents/enacted (Accessed: 16th April 2021).

'Montgomery v Lanarkshire Health Board' UKSC 11, [2015] 1 AC 1430.

Adams, J., McCreanor, T. and Braun, V. (2013) 'Gay men's explanations of health and how to improve it', *Qualitative Health Research*, 23(7), pp. 887-899.

Adelson, P.L. *et al.* (2013) 'A cost analysis of inpatient compared with outpatient prostaglandin E-2 cervical priming for induction of labour: results from the OPRA trial', *Australian Health Review*, 37(4), pp. 467-473.

Agee, J. (2009) 'Developing qualitative research questions: a reflective process', *International Journal of Qualitative Studies in Education*, 22(4), pp. 431-447.

Agniel, D., Kohane, I.S. and Weber, G.M. (2018) 'Biases in electronic health record data due to processes within the healthcare system: retrospective observational study', *BMJ*, 361, DOI: https://doi.org/10.1136/bmj.k1479.

Alcoff, L. (2013) ''Foucault's Normative Epistemology'', in Falzon, C., O'Leary, T. and Sawacki, J. (eds.) *A Companion to Foucault*. London: Blackwell, pp. 207-225.

Alfirevic, Z. (2014) 'Oral misoprostol for induction of labour', *Cochrane Database of Systematic Reviews*, Issue 6. Art. No.: CD001338. DOI: https://doi.org/10.1002/14651858.CD001338.pub3.

Alfirevic, Z. *et al.* (2020) 'Outpatient versus inpatient induction of labour for improving birth outcomes (Review)', *Cochrane Database of Systematic Reviews*, Issue 8. Art. No.: CD007372. DOI: https://doi.org/10.1002/14651858.CD007372.pub4.

Alfirevic, Z. *et al.* (2016) 'Methods to induce labour: A systematic review, network meta-analysis and cost-effectiveness analysis', *Health Technology Assessment*, 20. DOI: https://doi.org/10.3310/hta2650.

Allen, D. (2004) 'Ethnomethodological insights into insider-outsider relationships in nursing ethnographies of healthcare settings', *Nursing Inquiry*, 11(1), pp. 14-24.

Allen, R. and Benedetti, M.S. (2019) 'Unravelling US maternal mortality through critical discourse analysis', *Health Education Journal*, 78(6), pp. 681-691.

Allmark, P. and Machaczek, K. (2018) 'Realism and Pragmatism in a mixed methods study', *Journal of Advanced Nursing*, 74, pp. 1301-1309.

Allport, G.W. and Postman, L.J. (1947) *The Psychology of Rumor*. New York: Holt.

Anastas, J. (2019) 'Who Knows? Critical Realism, Philosophy of Mind, Embodiment, and the Science of Social Work'. New York: Oxford University Press.

Arai, L. *et al.* (2007) 'Testing methodological developments in the conduct of narrative synthesis: a demonstration review of research on the implementation of smoke alarm interventions', *Evidence & Policy: A Journal of Research, Debate & Practice*, 3(3), pp. 361-383.

Archer, M. (2003) *Structure, Agency and the Internal Conversation*. Cambridge: Cambridge University Press.

Atkinson, P., Delamont, S. and Coffey, A. (2003) *Key Themes in Qualitative Research: Continuities and Changes*. Walnut Creek, Calif: AltaMira Press.

Awartani, K.A., Turnell, R.W. and Olatunbosun, O.A. (1999) 'A prospective study of induction of labor with prostaglandin vaginal gel: ambulatory versus in-patient administration', *Clinical And Experimental Obstetrics & Gynecology*, 26(3-4), pp. 162-165.

Ayres-de-Campos, D. *et al.* (2015) 'FIGO consensus guidelines on intrapartum fetal monitoring: Cardiotocography', *International Journal of Gynecology & Obstetrics*, 131(1), pp. 13-24.

Baker, S.E. and Edwards, R. (2012) *How many qualitative interviews is enough? Expert voices and early career reflections on sampling and cases in qualitative research*. Available at: https://eprints.ncrm.ac.uk/id/eprint/2273/4/how_many_interviews.pdf (Accessed: 12th April).

Ball, J.E. (2020) '"Care left undone: untold damage"', *Journal of Clinical Nursing*, 29(19-20), pp. 3595-3596.

Battersby, C. *et al.* (2017) 'Term admissions to neonatal units in England: a role for transitional care? A retrospective cohort study', *BMJ Open*, 7(5), DOI: https://doi.org/10.1136/bmjopen-2017-016050.

Beck, U. (1992) *Risk Society: Towards a New Modernity*. London: Sage. Theory, Culture & Society.

Benoit, C. *et al.* (2010) 'Medical dominance and neoliberalisation in maternal care provision: The evidence from Canada and Australia', *Social Science & Medicine*, 71(3), pp. 475-481.

Best Evidence Topics (2018) *Critical Appraisal Checklists*. Available at: https://bestbets.org/links/BET-CA-worksheets.php (Accessed: 11th November 2018).

Bettany-Saltikov, J. and McSherry, R. (2016) *How to do a systematic literature review in nursing*. 2nd edition edn. Oxford: Open University Press.

Bhaskar, R. (1979) *The Possibility of Naturalism*. Brighton: The Harvester Press.

Bhaskar, R. (1997) *The Realist Theory of Science*. London: Verso.

Bhide, A. *et al.* (2020) 'Prostaglandin insert dinoprostone versus trans-cervical balloon catheter for outpatient labour induction: a randomised controlled trial of feasibility (PROBIT-F)', *Pilot Feasibility Studies*, 6, DOI: https://doi.org/10.1186/s40814-020-00661-7.

Biem, S.R. *et al.* (2003) 'A randomized controlled trial of outpatient versus inpatient labour induction with vaginal controlled-release prostaglandin-E2: effectiveness and satisfaction', *Journal of Obstetrics and Gynaecology Canada*, 25(1), pp. 23-31.

Biesta, G. (2010) 'Pragmatism and the Philosophical Foundations of Mixed Methods Research', in Tashakkori, A. and Teddlie, C. (eds.) *Sage Handbook of Mixed Methods in Social and Behavioural Research*. Second edn. London: Sage, pp. 95-117.

Birt, L. *et al.* (2016) 'Member checking: a tool to enhance trustworthiness or merely a nod to validation?', *Qualitative Health Research*, 26(13), pp. 1802-1811.

Bisits, A. (2016) 'Risk in obstetrics: perspectives and reflections', *Midwifery*, 38, DOI: https://doi.org/10.1016/j.midw.2016.05.010.

Boerma, T. *et al.* (2018) 'Global epidemiology of use of and disparities in caesarean sections', *The Lancet*, 392(10155), pp. 1341-1348.

Booth, A., Papaioannou, D. and Sutton, A. (2016) *Systematic Approaches to a Successful Literature Review*. 2nd edn. London: Sage.

Bourne, T. *et al.* (2019) 'Burnout, well-being and defensive medical practice among obstetricians and gynaecologists in the UK: cross-sectional survey study', *BMJ open*, 9(11), DOI: https://doi.org/10.1136/bmjopen-2019-030968.

Boyd, J. and Kerr, T. (2016) 'Policing "Vancouver's mental health crisis": a critical discourse analysis', *Critical Public Health*, 26(4), pp. 418-433.

Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology', *Qualitative Research in Psychology*, 3(2), pp. 77-101.

Braun, V. and Clarke, V. (2019) 'To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales', *Qualitative Research in Sport, Exercise and Health*, 13(2), pp. 201-216.

Braun, V., Clarke, V. and Hayfield, N. (2019) ''A starting point for your journey, not a map': Nikki Hayfield in conversation with Virginia Braun and Victoria Clarke about thematic analysis', *Qualitative Research in Psychology*, DOI: https://doi.org/10.1080/14780887.2019.1670765.

Brown, S.J.S. and Furber, C.M. (2015) 'Women's experiences of cervical ripening as inpatients on an antenatal ward', *Sexual and Reproductive Healthcare*, 6(4), pp. 219-225.

Burns, E. *et al.* (2012) 'Reflexivity in midwifery research: The insider/outsider debate', *Midwifery*, 28(1), pp. 52-60.

Byrne, E. *et al.* (2015) 'Peer interviewing in medical education research: Experiences and perceptions of student interviewers and interviewees', *BMC Research Notes*, 8, DOI: https://doi.org/10.1186/s13104-015-1484-2.

Caddick, N. *et al.* (2017) 'Understanding the health of lorry drivers in context: A critical discourse analysis', *Health*, 21(1), pp. 38-56.

Caplow, T. (1947) 'Rumors in War', *Social Forces*, 25(3), pp. 298-302.

Carabine, J. (2001) 'Unmarried Motherhood 1830-1990: a Genealogical Analysis', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse as Data*. London: Sage, pp. 267-307.

Care Quality Commission (2020) *CQC takes action to drive improvements in maternity services at Nottingham University Hospitals NHS Trust*. Available at: https://www.cqc.org.uk/news/releases/cqc-takes-action-drive-improvements-maternity-services-nottingham-university-hospitals (Accessed: 7th May 2021).

Carey, E. (2010) 'Navigating the Process of Ethical Approval: A methodological note', *Grounded Theory Review: An International Journal*, 9(3), pp. 19-32.

Carroll, F. *et al.* (2016) *Patterns of maternity care in English NHS Hospitals 2013/14*. Available at: https://indicators.rcog.org.uk/media/2016/03/22/10/43/57/597e02e7-9042-4af6-a5ce-e3cd99745eb0/Maternity%20indicators%202013.14_final.pdf (Accessed: 20th March 2016).

Centre for Reviews and Dissemination (2009) *Systematic Reviews - CRD's guidance for undertaking reviews in healthcare*. York: University of York.

Ceuterick, M. *et al.* (2021) 'And they slept happily ever after: Online interpretive repertoires on the use of benzodiazepines and z-drugs', *Health (London, England: 1997)*, DOI: https://doi.org/10.1177/13634593211060770.

Chan, M.S. *et al.* (2017a) 'Debunking: A meta-analysis of the psychological efficacy of messages countering misinformation', *Psychological Science*, 28, pp. 1531-1546.

Chan, S.W. *et al.* (2017b) 'Montgomery and informed consent: where are we now?', *BMJ*, 357, DOI: https://doi.org/10.1136/bmj.j2224.

Charmaz, K. (2014) *Constructing Grounded Theory*. 2nd edition edn. London: Sage.

Chervenak, F.A. and McCullough, L.B. (2017) 'The unlimited-rights model of obstetric ethics threatens professionalism', *BJOG: An International Journal of Obstetrics and Gynaecology*, 124(8), pp. 1144-1147.

City Council Name Witheld (2016) *Strategic Assessment: Population and Demographics*. City Council Name Witheld.

City Council Name Witheld (2020) *Strategic Assessment: Deprivation and Poverty*. City Council Name Witheld.

Clinical Commissioning Group Name Witheld (2017) *Operating Plan 2017/18 to 2018/19*. Clinical Commissioning Group Name Witheld.

Cluett, E.R. and Bluff, R. (2006) *Principles and Practice of Research in Midwifery*. London: Elsevier.

Coates, R. *et al.* (2019) 'Women's experiences of induction of labour: Qualitative systematic review and thematic synthesis', *Midwifery*, 69, pp. 17-28.

Coates, R. *et al.* (2021) 'Women's experiences of outpatient induction of labour with double balloon catheter or prostaglandin pessary: A qualitative study', *Women & Birth*, 34(4), pp. e406-e415.

Cooper, S. *et al.* (2017) 'Media coverage of refugees and asylum seekers in regional Australia: a critical discourse analysis', *Media International Australia*, 162(1), pp. 78-89.

Copeland, F., Dahlen, H.G. and Homer, C.S. (2014) 'Conflicting contexts: midwives' interpretation of childbirth through photo elicitation', *Women & Birth*, 27(2), pp. 126-31.

Cox, C.L. and Fritz, Z. (2022) 'Presenting complaint: use of language that disempowers patients', *BMJ*, 377, DOI: https://doi.org/10.1136/bmj-2021-066720.

Coxon, K. (2014) 'Risk in pregnancy and birth: are we talking to ourselves?', *Health, Risk & Society*, 16(6), pp. 481-493.

Coxon, K. *et al.* (2016) 'Reconceptualising risk in childbirth', *Midwifery*, 38, pp. 1-5.

Creswell, J.W. (2013) *Qualitative Inquiry and Research Design*. Third Edition edn. London: Sage.

Creswell, J.W. (2015) *A Concise Introduction to Mixed Methods Research*. London: Sage.

Creswell, J.W. and Plano Clark, V.L. (2018) *Designing and Conducting Mixed Methods Research*. Third edn. London: Sage.

Critical Appraisal Skills Programme (2013) *CASP Checklists*. Available at: http://www.casp-uk.net/checklists (Accessed: 24th December).

Cromby, J. and Harper, D.J. (2009) 'Paranoia: a social account', *Theory & Psychology*, 19(3), pp. 335-361.

Cromby, J. and Nightingale, D. (1999) 'What's wrong with social constructionism?', in Cromby, J. and Nightingale, D. (eds.) *Social Constructionist Psychology*. Buckingham: Open University Press, pp. 1-19.

Cromby, J. and Standen, P. (1999) 'Taking our selves seriously', in Cromby, J. and Nightingale, D. (eds.) *Social Constructionist Psychology*. Buckingham: Open University Press, pp. 141-156.

Crouch, M. and McKenzie, H. (2006) 'The logic of small samples in interview-based qualitative research', *Social Science Information*, 45(4), pp. 483-499.

Cundiff, G.W. *et al.* (2017) 'Observational study of neonatal safety for outpatient labour induction priming with dinoprostone vaginal insert', *Journal of Obstetrics and Gynaecology Canada*, 39(5), pp. 354-360.

Dahlen, H. (2016) 'Dancing in the grey zone between normality and risk', *Practising Midwife*, 19(6), pp. 18-20.

Dancey, C., Reidy, J. and Rowe, R. (2012) *Statistics for the Health Sciences*. London: Sage.

Davidson, C. (2009) 'Imperatives for Qualitative Research', *International Jounral of Qualitative Methods*, 8(2), pp. 36-52.

de Vaan, M.D.T. *et al.* (2019) 'Mechanical methods for induction of labour', *Cochrane Database of Systematic Reviews*, Issue 10. Art. No.: CD001233. DOI: https://doi.org/10.1002/14651858.CD001233.pub3.

Department of Health (1993) *Changing Childbirth: Report of the Expert Maternity Group Pt.1.* London: Stationery Office.

Department of Health (1997) *The New NHS: Modern, Dependable*. London: The Stationery Office.

Department of Health (2015) *New ambition to halve rate of stillbirths and infant deaths*. Available at: https://www.gov.uk/government/news/new-ambition-to-halve-rate-of-stillbirths-and-infant-deaths (Accessed: 26th April 2021).

Department of Health (2017) *Safer Maternity Care*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf (Accessed: 26th April 2021).

Diederen, M. *et al.* (2018) 'Safety of the balloon catheter for cervical ripening in outpatient care: complications during the period from insertion to expulsion of a balloon catheter in the process of labour induction: a systematic review', *BJOG: An International Journal of Obstetrics and Gynaecology*, 125(9), pp. 1086-1095.

DiFonzo, N. (2020) *Rumor and Communication*. Oxford: Oxford University Press.

Difonzo, N., Bordia, P. and Rosnow, R.L. (1994) 'Reining in Rumors', *Organizational Dynamics*, 23(1), pp. 47-62.

Douglas, M. (1992) *Risk and Blame*. London: Routledge.

Dove, S. and Muir-Cochrane, E. (2014) 'Being safe practitioners and safe mothers: A critical ethnography of continuity of care midwifery in Australia', *Midwifery*, 30(10), pp. 1063-1072.

Downe, S. (2017) *Normal birth: evidence and facts*. Available at: http://www.sheenabyrom.com/blog/2017/8/16/normal-birth-evidence-and-facts (Accessed: 3rd May 2021).

Du Bois, J. *et al.* (1993) 'Outline of Discourse Transcription in Talking Data: Transcription and Coding ', in Edwards, J. and Lampart, M. (eds.) *Discourse Research*. New Jersey: Lawrence Erlbaum Associates, pp. 45-89.

Edley, N. (2001) 'Analysing masculinity: interpretive repertoires, ideological dilemmas and subject positions', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse as Data*. London: Sage Publications Ltd, pp. 189-228.

Edwards, D. (2000) 'Extreme Case Formulations: Softeners, Investment, and Doing Nonliteral', *Research on Language and Social Interaction*, 33(4), pp. 347-373.

Edwards, D. and Potter, J. (2005) 'Discursive Psychology, Mental States and Descriptions', in Molder, H.t. and Potter, J. (eds.) *Conversation and Cognition*. Cambridge: Cambridge University Press, pp. 241-259.

Eerdmans, S. and Di Candia, M. (2007) 'Watching paint dry: the sequentiality of idiomatic expressions in NS-NS and NS-NNS talk-in-interaction', *Discourse Studies*, 9(5), pp. 579-595.

Elsayed, N. (2018) 'Make Great Britain Great Again: Populism and Nationalism in Brexit', *The United Kingdom on the Brink of Brexit*, 36(3), pp. 94-101.

Fairclough, N. (2003) *Analysing Discourse*. London: Sage.

Farmer, K.C. *et al.* (1996) 'A cost-minimization analysis of intracervical prostaglandin E2 for cervical ripening in an outpatient versus inpatient setting', *Clinical Therapeutics*, 18(4), pp. 747-756.

Ferndale, D. *et al.* (2017) '‘You don’t know what’s going on in there’: a discursive analysis of midwifery hospital consultations', *Health, Risk & Society*, 19(7/8), pp. 411-431.

Finucane, E.M. *et al.* (2020) 'Membrane sweeping for induction of labour', *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD000451.2. DOI https://doi.org/10.1002/14651858.CD000451.pub3.

Flenady, V. *et al.* (2016) 'Stillbirths: recall to action in high-income countries', *The Lancet*, 387(10019), pp. 691-702.

Fletcher, A. (2017) 'Applying critical realism in qualitative research: methodology meets method', *International Journal of Social Research Methodology*, 20(2), pp. 181-194.

Flinkfeldt, M. (2020) 'Respecifying 'worry': Service and emotion in welfare encounters', *Qualitative Research in Psychology*, 17(3), pp. 372-395.

Foucault, M. (1988) *Madness and Civilisation*. Translated by Howard, R. New York: Vintage Books.

Francis, R. (2013) *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*. Available at: https://www.gov.uk/government/publications/report-of-the-mid-staffordshire-nhs-foundation-trust-public-inquiry (Accessed: 16th April 2021).

Frank, J. (1990) 'You call that a rhetorical question?: Forms and functions of rhetorical questions in conversation', *Journal of Pragmatics*, 14(5), pp. 723-738.

Fraser, B. (1990) 'An approach to discourse markers', *Journal of Pragmatics*, 14(3), pp. 383-398.

General Medical Council (2020) *Guidance on professional standards and ethics for doctors: decision making and consent*. Available at: https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA (Accessed: 27th April 2021).

Gibson, S. (2010) 'Introducing the data set ', in Forrester, M. (ed.) *Doing Qualitative Research*. London: Sage, pp. 122-134.

Gommers, J.S.M. *et al.* (2017) 'Review article: Risk of maternal, fetal and neonatal complications associated with the use of the transcervical balloon catheter in induction of labour: A systematic review', *European Journal of Obstetrics and Gynecology*, 218, pp. 73-84.

Goodman, S. (2017) 'How to conduct a psychological discourse analysis', *Critical Approaches to Discourse Analysis across Disciplines*, 9(2), pp. 142-153.

Greenhalgh, T. (2018) *How to implement evidence-based healthcare*. Chichester: John Wiley & Son.

Griffiths, P. and Rafferty, A. (2015) 'Outcome Measures', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. 7th edn. Chichester: John Wiley & Son, pp. 455-468.

Grivell, R.M. *et al.* (2015) 'Antenatal cardiotocography for fetal assessment', *Cochrane Database of Systematic Reviews*, p. Issue 9. Art. No.: CD007863. DOI: https://doi.org/10.1002/14651858.CD007863.pub4.

Grivičić, T. and Nilep, C. (2004) 'When phonation matters: The use and function of yeah and creaky voice', *Colorado Research in Linguistics*, 17(1), pp. 1-11.

Grobman, W. (2015) 'Is it time for outpatient cervical ripening with prostaglandins?', *BJOG: An International Journal of Obstetrics & Gynaecology*, 122(1), pp. 105-105.

Guba, E.G. and Lincoln, Y. (1994) 'Competing paradigms in qualitative research. ', in Denzin, N. and Lincoln, Y. (eds.) *Handbook of qualitative research* Thousand Oaks, CA: Sage, pp. 105-117.

Guest, G., Bunce, A. and Johnson, L. (2006) 'How many interviews are enough?: An experiment with data saturation and variability', *Field Methods*, 18(1), pp. 59-82.

Hall, J.N. (2013) 'Pragmatism, evidence, and mixed methods evaluation', *New Directions for Evaluation*, (138), pp. 15-26.

Hall, S. (1992) 'The West and the Rest: Discourse and Power', in Hall, S. and Gieben, B. (eds.) *Formations of Modernity*. Cambridge: Cambridge Polity Press, pp. 56-64.

Hall, S. (2001) 'Foucault: Power, knowledge and discourse', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse Theory and Practice*. London: Sage, pp. 72-81.

Hall, W.A., Tomkinson, J. and Klein, M.C. (2012) 'Canadian care providers' and pregnant women's approaches to managing birth: Minimizing risk while maximizing integrity', *Qualitative Health Research*, 22(5), pp. 575-586.

Halligan, A. and Donaldson, L. (2001) 'Implementing clinical governance: turning vision into reality', *BMJ (Clinical Research Ed.)*, 322(7299), pp. 1413-1417.

Hammersley, M. (2014) 'On the ethics of interviewing for discourse analysis', *Qualitative Research*, 14(5), pp. 529-541.

Hasson, F., McKenna, H. and Keeney, S. (2015) 'Surveys', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. Chichester: Wiley Blackwell, pp. 255-266.

Health Research Authority (2017a) *Determining the need for a CAG application*. Available at: https://www.hra.nhs.uk/documents/256/CAG_pre-application_checklist.pdf (Accessed: 26th May 2018).

Health Research Authority (2017b) *What is public involvement in research?* Available at: https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/ (Accessed: 18th November 2020).

Health Research Authority (2018) *Why is confidential patient information used?* Available at: https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/why-confidential-patient-information-used/ (Accessed: 10th May 2018).

Health Research Authority (2021) *Research involving children*. Available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/ (Accessed: 25th October 2021).

Healthcare Safety Investigation Branch (2020) *Maternity National Learning Reports*. Available at: https://www.hsib.org.uk/maternity/reports-and-publications/ (Accessed: 4th May 2021).

Healy, S., Humphreys, E. and Kennedy, C. (2016) 'Midwives' and obstetricians' perceptions of risk and its impact on clinical practice and decision-making in labour: An integrative review', *Women And Birth: Journal Of The Australian College Of Midwives*, 29(2), pp. 107-116.

Healy, S., Humphreys, E. and Kennedy, C. (2017) 'A qualitative exploration of how midwives' and obstetricians' perception of risk affects care practices for low-risk women and normal birth', *Women & Birth*, 30(5), pp. 367-375.

Henderson, M. and Page, L. (2007) 'Appraising the evidence: what is selection bias?', *Evidence Based Mental Health*, 10(3), pp. 67-68.

Hendricks, V. and Vestergaard, M. (2019) *Reality Lost*. Cham: Springer Open.

Hennink, M.M., Kaiser, B.N. and Marconi, V.C. (2017) 'Code saturation versus meaning saturation: How many interviews are enough?', *Qualitative Health Research*, 27, pp. 591-608.

Henry, A. *et al.* (2013) 'Outpatient Foley catheter versus inpatient prostaglandin E2 gel for induction of labour: a randomised trial', *BMC Pregnancy And Childbirth*, 13(25), DOI: https://doi.org/10.1186/1471-2393-13-25.

Heritage, J. (2001) 'Goffman, Garfinkel and Conversation Analysis', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse Theory and Practice*. London: Sage, pp. 47-56.

Herman, D. *et al.* (2021) 'Composite adverse outcomes in obstetric studies: a systematic review', *BMC Pregnancy and Childbirth*, 21(1), p. 107.

Higgins, C. and Coffey, B. (2016) 'Improving how sustainability reports drive change: a critical discourse analysis', *Journal of Cleaner Production*, 136, pp. 18-29.

Higgins, J. and Thomas, J. (2021) *Cochrane Handbook for Systematic Reviews of Interventions*. Available at: https://training.cochrane.org/handbook/current (Accessed: 30th March 2021).

HM Government (2018) *Working together to safeguard children: a guide to inter-agency working to safeguard and promote the welfare of children*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/729914/Working_Together_to_Safeguard_Children-2018.pdf (Accessed: 25th November 2018).

Hodgson, H. (2016) *David Haslam: getting the guidance right*. Available at: https://www.nice.org.uk/news/feature/david-haslam-getting-the-guidance-right (Accessed: 7th April 2021).

Hollnagel, E. and Wears, R. (2015) *From Safety-I to Safety-II: A White Paper*. Available at: https://www.england.nhs.uk/signuptosafety/wp-content/uploads/sites/16/2015/10/safety-1-safety-2-whte-papr.pdf (Accessed: 29th June 2021).

Holloway, I. and Galvin, K.T. (2015a) 'Ethnography', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. Chichester: Wiley Blackwell, pp. 199-210.

Holloway, I. and Galvin, K.T. (2015b) 'Grounded Theory', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. 7th edn. Chichester: John Wiley & Sons, pp. 185-197.

Hood, L., Fenwick, J. and Butt, J. (2010) 'A story of scrutiny and fear: Australian midwives' experiences of an external review of obstetric services, being involved with litigation and the impact on clinical practice', *Midwifery*, 26(3), pp. 268-285.

Hood, R. (2016) 'How professionals talk about complex cases: a critical discourse analysis', *Child & Family Social Work*, 21(2), pp. 125-135.

House of Commons Committee of Public Accounts (2017) *Managing the costs of clinical negligence in hospital trusts: Fifth Report of Session 2017–19 HC 397*. Available at: https://publications.parliament.uk/pa/cm201719/cmselect/cmpubacc/397/397.pdf (Accessed: 3rd May 2021).

House of Commons Health and Social Care Committee (2021a) *Evaluation of the government's progress against its policy commitments in the area of maternity services in England*. Available at: https://committees.parliament.uk/publications/6560/documents/71747/default (Accessed: 1st July 2021).

House of Commons Health and Social Care Committee (2021b) *The Safety of Maternity Services in England*. Available at: https://publications.parliament.uk/pa/cm5802/cmselect/cmhealth/19/1902.htm (Accessed: 29th July 2021).

House of Commons Health and Social Care Committee (2021c) *Safety of Maternity Services in England: February 2021 meeting*. Available at: https://parliamentlive.tv/Event/Index/45639ffa-9806-4ee1-98cc-f9ef70e0de91 (Accessed: 18th October 2021).

Howard, K. *et al.* (2014) 'Women's preferences for inpatient and outpatient priming for labour induction: a discrete choice experiment', *BMC Health Services Research*, 14, pp. DOI: https://doi.org/10.1186/1472-6963-14-330.

Huma, B. *et al.* (2020) 'Introduction to Special Issue on Discursive Psychology', *Qualitative Research in Psychology*, 17(3), pp. 313-335.

Hunt, K. and Lathlean, J. (2015) 'Sampling', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. 7th edn. Chichester: John Wiley & Sons, pp. 174-184.

Hunter, B. *et al.* (2019) 'Midwives in the United Kingdom: Levels of burnout, depression, anxiety and stress and associated predictors', *Midwifery*, 79, p. DOI: https://doi.org/10.1016/j.midw.2019.08.008.

Hunter, B. and Segrott, J. (2014) 'Renegotiating inter-professional boundaries in maternity care: implementing a clinical pathway for normal labour', *Sociology of Health & Illness*, 36(5), pp. 719-737.

Iacobucci, G. (2017) 'A service under pressure', *BMJ*, 356, p. i6691. DOI: https://doi.org/10.1136/bmj.i6691.

Independent Maternity Services Oversight Panel (2021) *Cwm Taf Morgannwg University Health Board Thematic Maternal Category Report*. Available at: https://gov.wales/sites/default/files/publications/2021-01/independent-maternity-services--oversight-panel-thematic-maternal-category-report.pdf (Accessed: 6th May 2021).

Information Commissioner's Office (2018a) *Guide to the General Data Protection Regulation*. Available at: https://ico.org.uk/media/for-organisations/guide-to-the-general-data-protection-regulation-gdpr-1-0.pdf (Accessed: 25th July 2018).

Information Commissioner's Office (2018b) *Individual rights: the right to be informed*. Available at: https://ico.org.uk/media/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/the-right-to-be-informed-1-0.pdf (Accessed: 25th July 2018).

Institute for Healthcare Improvement (2021) *Quality Improvement Essentials Toolkit*. Available at: http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx (Accessed: 16th July 2021).

International Confederation of Midwives (2018) *Scope of practice of the midwife*. Available at: https://internationalmidwives.org/our-work/policy-and-practice/icm-definitions.html (Accessed: 12th May 2021).

Jackson, C., Land, V. and Holmes, E.J.B. (2017) 'Healthcare professionals' assertions and women's responses during labour: A conversation analytic study of data from One born every minute', *Patient Education and Counseling*, 100(3), pp. 465-472.

Jay, A., Thomas, H. and Brooks, F. (2018) 'In labor or in limbo? The experiences of women undergoing induction of labor in hospital: Findings of a qualitative study', *Birth: Issues in Perinatal Care*, 45(1), pp. 64-70.

Jingree, T. and Finlay, W. (2008) ''You can't do it... it's theory rather than practice': staff use of the practice/principle] rhetorical device in talk on empowering people with learning disabilities', *Discourse & Society*, 19(6), pp. 705-726.

Johnson, R.B. *et al.* (2017) 'Understanding the philosophical positions of classical and neopragmatists for mixed methods research', *Kölner Zeitschrift für Soziologie und Sozialpsychologie*, 69(Suppl. 2), pp. 63-86.

Jones, M.C. and Rattray, J. (2015) 'Questionnaire Design', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. Seventh edn. Chichester: John Wiley & Sons, pp. 413-425.

Kahneman, D. (2011) *Thinking, Fast and Slow*. London: Penguin.

Kent, B. (2015) 'Practitioner research', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. Chichester: Wiley Blackwell, pp. 319-331.

Kim, M. and Mallory, C. (2014) *Statistics for Evidence Based Practice in Nursing*. Burlington, MA: Jones and Bartlett Learning.

Kirkup, B. (2015) *The Report of the Morecambe Bay Investigation: an independent investigation into the management, delivery and outcomes of care provided by the maternity and neonatal services at the University Hospitals of Morecambe Bay NHS Foundation Trust from January 2004 to June 2013*. Available at: https://www.gov.uk/government/publications/morecambe-bay-investigation-report (Accessed: 6th May 2021).

Kirkup, B. (2021) *Independent Investigation into East Kent Maternity Services: Terms of Reference*. Available at: https://www.england.nhs.uk/publication/independent-investigation-into-east-kent-maternity-services-terms-of-reference/ (Accessed: 6th May 2021).

Koester, A. (2006) *Investigating Workplace Discourse*. Abingdon: Routledge.

Lacey, A. (2015) 'The Research Process', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. 7th edn. Chichester: Wiley Blackwell, pp. 15-29.

Lapadat, J. and Lindsay, A. (1999) 'Transcription in research and practice: from standardisation to technique to interpretive positionings', *Qualitative Inquiry*, 5(1), pp. 64-86.

Lathlean, J. (2015) 'Qualitative Analysis', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. 7th edn. Chichester: John Wiley & Sons, pp. 471-487.

Leap, N. and Hunter, B. (2016) *Supporting Women for Labour and Birth: a Thoughtful Guide*. London: Routledge.

Leitch, S. and Palmer, I. (2010) 'Analysing Texts in Context: Current Practices and New Protocols for Critical Discourse Analysis in Organization Studies', *Journal of Management Studies*, 47(6), pp. 1194-1212.

Lewis-Beck, M.S., Bryman, A. and Liao, T.F. (2004) 'Interpretative Repertoire', in Lewis-Beck, M.S., Bryman, A. and Liao, T.F. (eds.) *The SAGE Encyclopedia of Social Science Research Methods*. Thousand Oaks, CA: SAGE Publications, Inc. , p. 507.

Lincoln, Y.S. and Guba, E.G. (1985) *Naturalistic inquiry*. London: Sage.

Listo, R. (2018) 'Gender myths in energy poverty literature: A Critical Discourse Analysis', *Energy Research & Social Science*, 38, pp. 9-18.

Lupton, D. (2012) ''Precious cargo': foetal subjects, risk and reproductive citizenship', *Critical Public Health*, 22(3), pp. 329-340.

Lyerly, A.D. (2012) 'Ethics and "Normal Birth"', *Birth*, 39(4), pp. 315-317.

MacKenzie Bryers, H. and van Teijlingen, E. (2010) 'Risk, theory, social and medical models: a critical analysis of the concept of risk in maternity care', *Midwifery*, 26(5), pp. 488-96.

Malone, C. (2015) 'If the arrogance of 'Musketeer midwives' cost babies their lives they should face court of law', *The Mirror*, 4th March. Available: https://www.mirror.co.uk/news/uk-news/arrogance-musketeer-midwives-cost-babies-5274840 [Accessed 5th June 2021].

Malterud, K., Siersma, V.D. and Guassora, A.D. (2015) 'Sample Size in Qualitative Interview Studies', *Qualitative Health Research*, 26(13), pp. 1753-1760.

Manzano, A. (2016) 'The craft of interviewing in realist evaluation', *Evaluation*, 22(3), pp. 342-360.

Mathias, L.A., Davis, D. and Ferguson, S. (2021) 'Salutogenic qualities of midwifery care: A best-fit framework synthesis', *Women and Birth*, 34(3), pp. 266-277.

Maxwell, J. and Mittapalli, K. (2010) 'Realism as a stance for mixed methods research', in Tashakkori, A. and Teddlie, C. (eds.) *Sage Handbook of Mixed Methods in Social and Behavioural Research*. Second edn. London: Sage, pp. 145-167.

Maxwell, J.A. (2012) *A Realist Approach for Qualitative Research*. London: Sage.

May, C. (2013) 'Towards a general theory of implementation', *Implementation Science*, 8(1), p. 18.

MBRRACE-UK (2020) *Saving Lives, Improving Mothers' Care: Lessons learned to inform maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2016-18*. Available at: https://www.npeu.ox.ac.uk/assets/downloads/mbrrace-uk/reports/maternal-report-2020/MBRRACE-UK_Maternal_Report_Dec_2020_v10_ONLINE_VERSION_1404.pdf (Accessed: 4th May 2021).

MBRRACE-UK (2021) *Perinatal mortality surveillance report: UK perinatal deaths from January to December 2019*. Available at: https://www.npeu.ox.ac.uk/assets/downloads/mbrrace-uk/reports/perinatal-surveillance-report-2019/MBRRACE-UK_Perinatal_Surveillance_Report_2019_final.pdf (Accessed: 25th October 2021).

McGannon, K.R. *et al.* (2016) 'Breast cancer representations in Canadian news media: a critical discourse analysis of meanings and the implications for identity', *Qualitative Research in Psychology*, 13(2), pp. 188-207.

McMaster, K., Sanchez-Ramos, L. and Kaunitz, A.M. (2015) 'Evaluation of a Transcervical Foley Catheter as a Source of Infection: A Systematic Review and Meta-analysis', *Obstetrics & Gynecology*, 126(3), pp. 539-551.

McMullen, L.M. (2018) 'Critical discursive psychology and relational ethics: An uneasy tension?', *Social and Personality Psychology Compass*, 12(11, DOI: https://doi.org/10.1111/spc3.12420).

Middleton, P. *et al.* (2020) 'Induction of labour at or beyond 37 weeks' gestation', *Cochrane Database of Systematic Reviews*, Issue 7. Art. No.: CD00494. DOI: https://doi.org/10.1002/14651858.CD004945.pub5.

Miller, S. *et al.* (2016) 'Beyond too little, too late and too much, too soon: a pathway towards evidence-based, respectful maternity care worldwide', *The Lancet*, 388(10056), pp. 2176-2192.

Mingers, J. (2004) 'Real-izing information systems: critical realism as an underpinning philosophy for information systems', *Information and Organization*, 14(2), pp. 87-103.

Mobbs, N., Williams, C. and Weeks, A. (2018) 'Humanising birth: Does the language we use matter?', *British Medical Journal*, 8th February 2018. Available at: https://blogs.bmj.com/bmj/2018/02/08/humanising-birth-does-the-language-we-use-matter/.

Monson, T.A. (2020) 'Risk attitudes within 'complex youth' assessment and decision making: Professional perspectives', *Child Care in Practice*, 26(2), pp. 210-222.

Montgomery, J. and Montgomery, E. (2016) 'Montgomery on informed consent: an inexpert decision?', *Journal of Medical Ethics*, 42(2), pp. 89-94.

Morgan, D.L. (2014) *Integrating Qualitative and Quantitative Methods: A Pragmatic Approach*. London: Sage.

Morse, J.M. (2015) 'Critical Analysis of Strategies for Determining Rigor in Qualitative Inquiry', *Qualitative Health Research*, 25(9), pp. 1212-1222.

Morse, J.M. and Niehaus, L. (2009) *Mixed method design: principles and procedures*. Walnut Creek: Left Coast Press.

Murtagh, M. and Folan, M. (2014) 'Women's experiences of induction of labour for post-date pregnancy', *British Journal of Midwifery*, 22(2), pp. 105-110.

Nam, S. (2020) 'Cognitive capitalism, free labor, and financial communication: A critical discourse analysis of social media IPO registration statements', *Information, Communication & Society*, 23(3), pp. 420-436.

National Audit Office (2017) *Managing the costs of clinical negligence in trusts*. Available at: https://www.nao.org.uk/wp-content/uploads/2017/09/Managing-the-costs-of-clinical-negligence-in-trusts.pdf (Accessed: 21st April 2021).

National Collaborating Centre for Women's and Children's Health (2008) *Induction of Labour*. Available at: https://www.nice.org.uk/guidance/ng207/evidence/full-guideline-july-2008-pdf-9266823757 (Accessed: 13th September 2015).

National Collaborating Centre for Women's and Children's Health (2008) *Induction of Labour*. Available at: https://www.nice.org.uk/guidance/ng207/evidence/full-guideline-july-2008-pdf-9266823757 (Accessed: 5th March 2016).

National Data Guardian (2013) *Information: to share or not to share*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf (Accessed: 25th July 2018).

National Institute for Clinical Excellence (2021) *Caesarean birth [NG192]*. Available at: https://www.nice.org.uk/guidance/ng192 (Accessed: 1 April 2021).

National Institute for Health and Care Excellence (2014a) *Antenatal and postnatal mental health: clinical management and service guidance Clinical guideline [CG192]*. Available at: https://www.nice.org.uk/guidance/cg192 (Accessed: 5th November 2020).

National Institute for Health and Care Excellence (2014b) *Intrapartum Care: Care of healthy women and their babies during childbirth*. Available at: https://www.nice.org.uk/guidance/cg190/evidence/full-guideline-pdf-248734770 (Accessed: 13th September 2020).

National Institute for Health and Care Excellence (2021) *Induction of Labour*. Available at: https://www.nice.org.uk/guidance/NG207 (Accessed: 8th November 2021).

National Institute for Health Research (2016) *Good Clinical Practice (GCP) Reference Guide*. Available at: https://www.nihr.ac.uk/our-faculty/documents/GCP%20Reference%20Guide.pdf (Accessed: 19th September 2017).

National Maternity Review (2016) *Better Births: improving outcomes of maternity services in England. A five year forward view for maternity care*. Available at: https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf (Accessed: 5th March 2018).

National Maternity Voices (2020) *Purpose and values: position statement*. Available at: http://nationalmaternityvoices.org.uk/about-us/purpose-values/ (Accessed: 18th November 2020).

Nelson, A., Dumville, J. and Torgerson, D. (2015) 'Experimental Research', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. 7th edn. Chichester: John Wiley & Sons, pp. 237-253.

Nguyen, C.D. *et al.* (2018) 'Impact of missing data strategies in studies of parental employment and health: Missing items, missing waves, and missing mothers', *Social Science & Medicine*, 209, pp. 160-168.

NHS Digital (2020) *NHS Maternity Statistics 2019-20: Summary Report Tables*. Available at: https://files.digital.nhs.uk/90/26F020/hosp-epis-stat-mat-summary-tables-2019-20.xlsx (Accessed: 9th March 2021).

NHS Digital (2021) *NHS Vacancy Statistics England April 2015 – June 2021 Experimental Statistics*. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-vacancies-survey/april-2015---june-2021-experimental-statistics (Accessed: 18th October 2021).

NHS England (2014) *Five Year Forward View*. Available at: https://www.england.nhs.uk/publication/nhs-five-year-forward-view/ (Accessed: 8th May 2016).

NHS England (2016) *Saving Babies' Lives Care Bundle*. Available at: https://www.england.nhs.uk/mat-transformation/saving-babies/ (Accessed: 5th November 2020).

NHS England (2017a) *A-Equip: a model of clinical midwifery supervision*. Available at: https://www.england.nhs.uk/wp-content/uploads/2017/04/a-equip-midwifery-supervision-model.pdf (Accessed: 25th November 2018).

NHS England (2017b) *A-EQUIP: a model of clinical midwifery supervision*. Available at: https://www.england.nhs.uk/wp-content/uploads/2017/04/a-equip-midwifery-supervision-model.pdf (Accessed: 15th July 2021).

NHS England (2017c) *Implementing Better Births: a resource pack for Local Maternity Systems*. Available at: https://www.england.nhs.uk/wp-content/uploads/2017/03/nhs-guidance-maternity-services-v1-print.pdf (Accessed: 18th November 2020).

NHS England (2017d) *Maternity and Neonatal Safety Improvement Programme*. Available at: https://www.england.nhs.uk/mat-transformation/maternal-and-neonatal-safety-collaborative/ (Accessed: 26th April 2021).

NHS England (2019a) *NHS Long Term Plan*. Available at: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf (Accessed: 20th May 2021).

NHS England (2019b) *Saving Babies' Lives Version Two: A care bundle for reducing perinatal mortality*. Available at: https://www.england.nhs.uk/publication/saving-babies-lives-version-two-a-care-bundle-for-reducing-perinatal-mortality/ (Accessed: 27th December 2020).

NHS England (2020) *Achieving equitable maternity outcomes*. Available at: https://www.england.nhs.uk/mat-transformation/achieving-equitable-maternity-outcomes/ (Accessed: 6th May 2021).

NHS England (2021) *National Cost Collection for the NHS 2019/20*. Available at: https://www.england.nhs.uk/national-cost-collection/#ncc1819 (Accessed: 8th November 2021).

NHS Improvement (2016) *The Maternity and Neonatal Safety Collaborative*. Available at: https://improvement.nhs.uk/resources/maternal-and-neonatal-safety-collaborative/ (Accessed: 20th November 2018).

NHS Improvement (2018) *A Guide to Support Maternity Safety Champions*. Available at: https://improvement.nhs.uk/documents/2440/Maternity_safety_champions_13feb.pdf (Accessed: 30th November 2018).

NHS Resolution (2017) *Five years of cerebral palsy claims*. Available at: https://resolution.nhs.uk/wp-content/uploads/2017/09/Five-years-of-cerebral-palsy-claims_A-thematic-review-of-NHS-Resolution-data.pdf (Accessed: 22nd April 2021).

NHS Resolution (2018) *Annual report and accounts 2017/18*. Available at: https://resolution.nhs.uk/wp-content/uploads/2018/08/NHS-Resolution-Annual-Report-2017-2018.pdf (Accessed: 21st April 2021).

NHS Resolution (2021) *Maternity Incentive Scheme*. Available at: https://resolution.nhs.uk/services/claims-management/clinical-schemes/clinical-negligence-scheme-for-trusts/maternity-incentive-scheme/ (Accessed: 19th April 2021).

NHS Specialist Pharmacy Service (2021) *Misoprostol*. Available at: https://www.sps.nhs.uk/medicines/misoprostol/ (Accessed: 27th November 2021).

NHS Trust (2017) *Safeguarding children in the maternity services*. NHS Trust Name Witheld.

NHS Trust (2019) *Maternity Data*. NHS Trust Name Witheld.

NHS Trust (2020a) *Indications for induction of labour 2019*. NHS Trust name witheld,.

NHS Trust (2020b) *Maternity risk management policy*. NHS Trust Name Witheld.

NMPA Project Team (2017) *National Maternity and Perinatal Audit: organisational report 2017*. Available at: http://www.maternityaudit.org.uk/downloads/NMPA%20organisational%20report%202017.pdf (Accessed: 19th November 2018).

Norman, G. (2010) 'Likert scales, levels of measurement and the “laws” of statistics', *Advances in Health Sciences Education*, 15(5), pp. 625-632.

Norman, J.E. *et al.* (2018) 'Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial', *Lancet*, 392(10158), pp. 1629-1638.

Nursing and Midwifery Council (2018) *The Code: professional standards of practice and behaviour for nurses, midwives and nursing associates*. Available at: https://www.nmc.org.uk/standards/code/read-the-code-online/ (Accessed: 25th November 2018).

O'Brien, E. *et al.* (2013) 'Women's experiences of outpatient induction of labour with remote continuous monitoring', *Midwifery*, 29(4), pp. 325-331.

O'Dwyer, S. *et al.* (2015) 'Improving induction of labour - a quality improvement project addressing Caesarean section rates and length of process in women undergoing induction of labour', *BMJ Quality Improvement Reports*, 4(1), DOI: http://dx.doi.org/10.1136/bmjquality.u203804.w4027.

Ochs, E. (2006) 'Transcription as theory', in Jawrski, A. and Coupland, N. (eds.) *The Discourse Reader*. London: Routledge, pp. 166-178.

Ockenden, D. (2020) *Emerging findings and recommendations from the independent review of maternity services at The Shrewsbury and Telford Hospital NHS Trust: Our first report following 250 clinical reviews*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/943011/Independent_review_of_maternity_services_at_Shrewsbury_and_Telford_Hospital_NHS_Trust.pdf (Accessed: 10th December 2020).

Office for National Statistics (2015) *Birth characteristics*. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/datasets/birthcharacteristicsinenglandandwales (Accessed: 17th March 2016).

Office for National Statistics (2021a) *Births in England and Wales: summary tables*. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/datasets/birthsummarytables (Accessed: 4th November 2021).

Office for National Statistics (2021b) *Child mortality (death cohort) tables in England and Wales*. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/childmortalitystatisticschildhoodinfantandperinatalchildhoodinfantandperinatalmortalityinenglandandwales (Accessed: 9th March 2021).

Oliver, D. (2020) 'David Oliver: Allow nurses to use their professional judgment', *BMJ*, 368, DOI: https://doi.org/10.1136/bmj.m608.

Oliver, D.G., Serovich, J.M. and Mason, T.L. (2005) 'Constraints and opportunities with interview transcription: towards reflection in qualitative research', *Soc Forces*, 85(2), pp. 1273-1289.

Oster, C. *et al.* (2011) 'Inpatient versus outpatient cervical priming for induction of labour: Therapeutic landscapes and women's preferences', *Health and Place*, 17(1), pp. 379-385.

Page, M. and Mander, R. (2014) 'Intrapartum uncertainty: A feature of normal birth, as experienced by midwives in Scotland', *Midwifery*, 30(1), pp. 28-35.

Patel, M.X., Doku, V. and Tennakoon, L. (2003) 'Challenges in recruitment of research participants', *Advances in Psychiatric Treatment*, 9(3), pp. 229-238.

Pawson, R. and Tilley, N. (1997) *Realistic Evaluation*. London: Sage.

Pelletier, P. and Drozda-Senkowska, E. (2020) 'Towards a socially situated rumouring: Historical and critical perspectives of rumour transmission', *Social and Personality Psychology Compass*, 14(6), DOI: https://doi.org/10.1111/spc3.12532.

Pernecky, T. (2016) *Epistemology and Metaphysics for Qualitative Research*. London: Sage.

Pillinger-Cork, J. and Health Research Authority (2018) Email correspondence with Trust Information Governance Lead and Health Research Authority adviser, 11th July 2018.

Polit, D. and Beck, C. (2006) *Essentials of Nursing Research*. Sixth edn. Philadelphia: Lippincott Williams and Wilkins.

Porter, S. (2015) 'The uncritical realism of realist evaluation', *Evaluation*, 21(1), pp. 65-82.

Potter, J. (1996) *Representing Reality: Discourse, Rhetoric and Social Construction*. London: Sage.

Potter, J. (2001) 'Wittgenstein and Austin', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse Theory and Practice*. London: Sage, pp. 39-46.

Potter, J. and Wetherell, M. (1987) *Discourse and Social Psychology: Beyond Attitudes and Behaviour*. London: Sage.

Price, L. and Martin, L. (2018) 'Introduction to the special issue: applied critical realism in the social sciences', *Journal of Critical Realism*, 17(2), pp. 89-96.

Public Health England (2020a) *Disparities in the risk and outcomes of COVID-19*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/908434/Disparities_in_the_risk_and_outcomes_of_COVID_August_2020_update.pdf (Accessed: 6th May 2021).

Public Health England (2020b) *Maternity high impact area: Reducing the inequality of outcomes for women from Black, Asian and Minority Ethnic (BAME) communities and their babies*. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/942480/Maternity_high_impact_area_6_Reducing_the_inequality_of_outcomes_for_women_from_Black__Asian_and_Minority_Ethnic__BAME__communities_and_their_babies.pdf (Accessed: 7th May 2021).

Quintard, B. *et al.* (2016) 'Acceptability of Health Care-Related Risks: A Literature Review', *Journal of Patient Safety*, 12(1), pp. 1-10.

Rattray, J. and Jones, M.C. (2007) 'Essential elements of questionnaire design and development', *Journal of Clinical Nursing*, 16(2), pp. 234-243.

Rauf, Z. *et al.* (2011) 'Home Labour Induction with Retrievable Prostaglandin Pessary and Continuous Telemetric Trans-Abdominal Fetal ECG Monitoring', *Plos One*, 6(11) DOI: https://doi.org/10.1371/journal.pone.0028129.

Rayment-Jones, H. *et al.* (2020) 'Project 20: Midwives' insight into continuity of care models for women with social risk factors: what works, for whom, in what circumstances, and how', *Midwifery*, 84 DOI: https://doi.org/10.1016/j.midw.2020.102654.

Reid, M. *et al.* (2011) 'The home as an appropriate setting for women undertaking cervical ripening before the induction of labour', *Midwifery*, 27(1), pp. 30-35.

Riley, S. (2002) 'Constructions of equality and discrimination in professional men's talk', *British Journal of Social Psychology*, 41(3), pp. 443-461.

Robertson, K. *et al.* (2021) 'Delay in the induction of labour process: a retrospective cohort study and computer simulation of maternity unit workload', *BMJ open*, 11(9), pp. e045577-e045577.

Rosnow, R.L. (1991) 'Inside rumor: A personal journey', *American Psychologist*, 46(5), pp. 484 - 496.

Rothenbühler, M. and Voorpostel, M. (2016) 'Attrition in the Swiss Household Panel: Are vulnerable groups more affected than others? ', in M, O. *et al.* (eds.) *Surveying Human Vulnerabilities across the Life Course*. Lausanne: NCCR LIVES, pp. 221-242.

Royal College of Obstetricians and Gynaecologists (2016) *Each Baby Counts: Key messages from 2015*. Available at: https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/rcog-each-baby-counts-report.pdf (Accessed: 3rd May 2021).

Royal College of Obstetricians and Gynaecologists (2017) *Each Baby Counts* Available at: https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/each-baby-counts-2015-full-report.pdf (Accessed: 12th October 2017).

Royal College of Obstetricians and Gynaecologists (2020) *Each Baby Counts: 2019 progress report*. Available at: https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/each-baby-counts/each-baby-counts-2019-progress-report.pdf (Accessed: 20th May 2021).

Saldaña, J. (2015) *The coding manual for qualitative researchers*. 3rd edition edn. London: Sage.

Salvador, S.C., Lynn Simpson, M. and Cundiff, G.W. (2009) 'Dinoprostone Vaginal Insert for Labour Induction: A Comparison of Outpatient and Inpatient Settings', *Journal of Obstetrics and Gynaecology Canada*, 31(11), pp. 1028-1034.

Sandall, J. *et al.* (2016) *Relationships: the pathways to safe, high-quality maternity care. Sheila Kitzinger symposium at Green Templeton College, Oxford: Summary report*. Oxford: Green Templeton College. Available at: http://www.gtc.ox.ac.uk/images/stories/academic/skp_report.pdf (Accessed: 24th April 2016).

Sandall, J. *et al.* (2016b) 'Midwife-led continuity models versus other models of care for childbearing women', *Cochrane Database of Systematic Reviews*, 2016, Issue 4. Art. No.: CD004667. DOI: https://doi.org/10.1002/14651858.CD004667.pub5.

Sanders, T., Foster, N.E. and Ong, B.N. (2011) 'Perceptions of general practitioners towards the use of a new system for treating back pain: a qualitative interview study', *BMC Medicine*, 9(1), p. 49.

Scamell, M. (2016) 'The fear factor of risk – clinical governance and midwifery talk and practice in the UK', *Midwifery*, 38, pp. 14-20.

Scamell, M. and Alaszewski, A. (2012) 'Fateful moments and the categorisation of risk: Midwifery practice and the ever-narrowing window of normality during childbirth', *Health, Risk & Society*, 14(2), pp. 207-221.

Scamell, M. and Alaszewski, A. (2016) 'Choice, Risk, and Moral Judgment: Using Discourse Analysis to Identify the Moral Component of Midwives' Discourses', in Crichton, J., Candlin, C. and Firkins, A. (eds.) *Communicating Risk*. London: Palgrave Macmillan, pp. 67-83.

Schiller, R. (2017) *Birthrights comments on midwives and normal birth*. Available at: https://www.birthrights.org.uk/2017/08/15/birthrights-comments-on-midwives-and-normal-birth/ (Accessed: 3rd May 2021).

Schoonenboom, J. and Johnson, R.B. (2017) 'How to Construct a Mixed Methods Research Design', *KZfSS Kölner Zeitschrift für Soziologie und Sozialpsychologie*, 69(2), pp. 107-131.

Schwarz, C. *et al.* (2016) 'Women's perceptions of induction of labour outcomes: Results of an online-survey in Germany', *Midwifery*, 35, pp. 3-10.

Scopus (2016) *Metrics Page*. Available at: https://www.scopus.com/record/pubmetrics.uri?eid=2-s2.0-84920020378&origin=recordpage# (Accessed: 30th December 2016).

Seibold, C. *et al.* (2010) ''Lending the space': Midwives perceptions of birth space and clinical risk management', *Midwifery*, 26, pp. 526-531.

Sharp, A.N., Stock, S.J. and Alfirevic, Z. (2016) 'Outpatient induction of labour in the UK: a survey of practice', *European Journal Of Obstetrics, Gynecology, And Reproductive Biology*, 204, pp. 21-23.

Shaw, M. (2009) 'Health risk and the patient safety agenda', in Hyman, B. *et al.* (eds.) *Risk, Safety and Clinical Practice*. Oxford: Oxford University Press, DOI: https://doi.org/10.1093/acprof:oso/9780198569008.003.09.

Shenton, A.K. (2004) 'Strategies for Ensuring Trustworthiness in Qualitative Research Projects', *Education for Information*, 22(2), pp. 63-75.

Shorrock, S. (2016) *The varieties of human work*. Available at: https://humanisticsystems.com/2016/12/05/the-varieties-of-human-work/ (Accessed: 30th June 2021).

Sign Up to Safety (2016) *Spotlight on Maternity*. Available at: https://www.england.nhs.uk/signuptosafety/wp-content/uploads/sites/16/2015/11/spotlight-on-maternity-guide.pdf (Accessed: 9th March 2016).

Silverman, D. (2001) 'The Construction of 'Delicate' Objects in Counselling', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse Theory and Practice*. London: Sage, pp. 119-137.

Sims-Schouten, W. and Riley, S. (2014) 'Employing a form of Critical Realist discourse analysis for identity research', in Edwards, P., Mahoney, J. and Vincent, S. (eds.) *Studying Organisations Using Critical Realism*. Oxford: Oxford University Press, pp. 46-65.

Sims-Schouten, W. and Riley, S. (2019) 'Presenting Critical Realist Discourse Analysis as a Tool for Making Sense of Service Users' Accounts of Their Mental Health Problems', *Qualitative Health Research*, 29(7), pp. 1016-1028.

Sims-Schouten, W., Riley, S.C.E. and Willig, C. (2007) 'Critical realism in discourse analysis: A presentation of a systematic method of analysis using women's talk of motherhood, childcare and female employment as an example', *Theory & Psychology*, 17(1), pp. 101-124.

Smyth, R.M.D. *et al.* (2016) 'Women's and clinicians perspectives of presentation with reduced fetal movements: a qualitative study', *BMC Pregnancy and Childbirth*, 16(1), p. 280.

Sonmezer, E. (2021) 'Professional autonomy for midwives in the contemporary UK maternity system: part 2', *British Journal of Midwifery*, 29(1), pp. 19-25.

Spendlove, Z. (2018) 'Risk and boundary work in contemporary maternity care: tensions and consequences', *Health, Risk & Society*, 20(1/2), pp. 63-80.

Stevens, A. (2019) ''Being human' and the 'moral sidestep' in drug policy: Explaining government inaction on opioid-related deaths in the UK', *Addictive Behaviors*, 90, pp. 444-450.

Stewart, L. (2021) 'How accurate is Google Maps Journey time?', 5th March 2021. Available at: https://www.ancoris.com/blog/accurate-google-maps-journey-time.

Stock, S.J. *et al.* (2021) 'Cervical ripening at home or in-hospital—prospective cohort study and process evaluation (CHOICE) study: a protocol', *BMJ Open*, 11(5), DOI: http://dx.doi.org/10.1136/bmjopen-2021-050452.

Stock, S.J. *et al.* (2014) 'Home cervical ripening with dinoprostone gel in nulliparous women with singleton pregnancies', *Obstetrics And Gynecology*, 124(2 Pt 1), pp. 354-360.

Sullivan, G. and Artino, A. (2013) 'Analyzing and interpreting data from Likert-type Scales', *Journal of Graduate Medical Education*, 5(4), p. 2.

Sutton, C., Harding, J. and Griffin, C. (2016) 'Patient attitudes towards outpatient cervical ripening prior to induction of labour at an Australian tertiary hospital', *Journal of Obstetrics and Gynaecology*, 36(7), pp. 921-928.

Symon, A. (2006) *Risk and Choice in Maternity Care*. Edinburgh: Churchill Livingstone Elsevier.

Te Molder, H. (2015) 'Discursive Psychology', in Tracy, K., Ilie, C. and Sandel, T. (eds.) *The International Encyclopedia of Language and Social Interaction*. Chichester: John Wiley & Sons, pp. 1-11.

Teddlie, C. and Johnson, R.B. (2009) 'Methodological thought since the 20th century ', in Teddlie, C. and Tashakkori, A. (eds.) *Foundations of Mixed Methods Research*. London: Sage, pp. 62-82.

Teddlie, C. and Tashakkori, A. (2009) 'Paradigm issues in mixed methods research', in Teddlie, C. and Tashakkori, A. (eds.) *Foundations of Mixed Methods Research*. London: Sage, pp. 83-108.

Ten Have, P. (1990) 'Methodological Issues in Conversation Analysis', *Bulletin de Méthodologie Sociologique*, 27(1), pp. 23-51.

Thomas, D. and Hodges, I. (2010) *Designing and Planning Your Research Project: Core Skills for Social and Health Researchers*. London: Sage.

Thomas, G.M. and Lupton, D. (2016) 'Threats and thrills: pregnancy apps, risk and consumption', *Health Risk & Society*, 17(7-8), pp. 495-509.

Thomas, J. *et al.* (2014) 'Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term', *Cochrane Database of Systematic Reviews*, Issue 6. Art. No.: CD003101. DOI: https://doi.org/10.1002/14651858.CD003101.pub3.

Tingle, J. (2021) 'Clinical negligence litigation reform: the link between safety and the law', *British Journal of Nursing*, 30(5), pp. 322-323.

Tod, A. (2015) 'Interviewing', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. 7th edn. Chichester: John Wiley & Sons, pp. 387-400.

Tornberg, A. and Tornberg, P. (2016) 'Muslims in social media discourse: Combining topic modeling and critical discourse analysis', *Discourse Context & Media*, 13, pp. 132-142.

Toronto Video Atlas of Surgery (2019) *Techniques for induction of labour*. Available at: https://pie.med.utoronto.ca/TVASurg/project/ioltechniques/ (Accessed: 27th November 2021).

Tulloch, J. and Lupton, D. (2003) *Risk and Everyday Life*. London: Sage.

Turnbull, D. *et al.* (2013a) 'Psychosocial Outcomes of a Randomized Controlled Trial of Outpatient Cervical Priming for Induction of Labor', *Birth: Issues in Perinatal Care*, 40(2), pp. 75-80.

Turnbull, D. *et al.* (2013b) 'The impact of outpatient priming for induction of labour on midwives' work demand, work autonomy and satisfaction', *Women and Birth*, 26(3), pp. 207-212.

Turnbull, J. and Lathlean, J. (2015) 'Mixed Methods Research', in Gerrish, K. and Lathlean, J. (eds.) *The Research Process in Nursing*. Chichester: Wiley Blackwell, pp. 371-383.

UK Government (2020) *User research*. Available at: https://www.gov.uk/service-manual/user-research/find-user-research-participants (Accessed: 29th October 2020).

UK Government (2021) *NHS staff considering leaving the sector*. Available at: https://docs.cdn.yougov.com/jlwc3la0ho/YouGov%20-%20Healthcare%20workers%20leaving%20the%20sector%20results.pdf (Accessed: 18th October 2021).

University of Southampton (2012) *Research data management policy*. Available at: http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html (Accessed: 24th February 2018).

Valluvan, S. and Kalra, V.S. (2019) 'Racial nationalisms: Brexit, borders and Little Englander contradictions', *Ethnic and Racial Studies*, 42(14), pp. 2393-2412.

Van Dijk, T. (1993) 'Principles of critical discourse analysis', *Discourse & Society*, 4(2), pp. 249-283.

Vlad, E. (2019) 'Hedging, Critical Discourse Analysis and the Original Brexit Affair', *NORDSCI International Conference*. Athens, Greece, 19th August 2019. Available at: https://www.nordsci.org/nordsci-library/p/hedging%2C-critical-discourse-analysis-and-the-original-brexit-affair.

Wahlberg, Å., Högberg, U. and Emmelin, M. (2019) 'The erratic pathway to regaining a professional self-image after an obstetric work-related trauma: A grounded theory study', *International Journal of Nursing Studies*, 89, pp. 53-61.

Wald, D.S., Bestwick, J.P. and Kelly, P. (2020) 'The effect of the Montgomery judgment on settled claims against the National Health Service due to failure to inform before giving consent to treatment', *QJM: An International Journal of Medicine*, 113(10), pp. 721-725.

Walker, K.F. and Thornton, J.G. (2018) 'Encouraging awareness of fetal movements is harmful', *Lancet*, 392(10158), pp. 1601-1602.

Wetherell, M. (1998) 'Positioning and interpretative repertoires: conversation analysis and post-structuralism in dialogue', *Discourse & Society*, 9(3), pp. 387-412.

Wetherell, M. (2001a) 'Debates in Discourse Research', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse Theory and Practice*. London: Sage, pp. 380-399.

Wetherell, M. (2001b) 'Introduction', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse Theory and Practice*. London: Sage, pp. 9-13.

Wetherell, M. (2001c) 'Themes in discourse research: the case of Diana', in Wetherell, M., Taylor, S. and Yates, S. (eds.) *Discourse Theory and Practice* London: Sage, pp. 14-28.

Whitaker, C., Stevelink, S. and Fear, N. (2017) 'The Use of Facebook in Recruiting Participants for Health Research Purposes: A Systematic Review', *J Med Internet Res*, 19(8), DOI: https://doi.org/10.2196/jmir.7071.

Widdows, K. *et al.* (2018) *Evaluation of the implementation of the Saving Babies' Lives Care Bundle in early adopter NHS Trusts in England.* Available at: https://www.manchester.ac.uk/discover/news/download/573936/evaluationoftheimplementationofthesavingbabieslivescarebundleinearlyadopternhstrustsinenglandjuly2018-2.pdf (Accessed: 6th October 2018).

Widdows, K. *et al.* (2021) 'Stillbirth rates, service outcomes and costs of implementing NHS England's Saving Babies' Lives care bundle in maternity units in England: A cohort study', *PLOS ONE*, 16(4) DOI: https://doi.org/10.1371/journal.pone.0250150.

Wiggins, S. (2017) *Discursive Psychology*. London: Sage.

Wiggins, S. and Potter, J. (2008) 'Discursive Psychology', in Willig, C. and Stainton-Rogers, W. (eds.) *The Sage Handbook of Qualitative Research in Psychology*, pp. 73-90. Available at: https://methods.sagepub.com/book/the-sage-handbook-of-qualitative-research-in-psychology.

Wiggins, S. and Riley, S. (2010) 'Discourse analysis', in Forrester, M. (ed.) *Doing Qualitative Research in Psychology*. London: Sage, pp. 135-153.

Wilkinson, C., Adelson, P. and Turnbull, D. (2015) 'A comparison of inpatient with outpatient balloon catheter cervical ripening: a pilot randomized controlled trial', *BMC Pregnancy and Childbirth*, 15. DOI: https://doi.org/10.1186/s12884-015-0550-z.

Wilkinson, C. *et al.* (2015) 'A randomised controlled trial of outpatient compared with inpatient cervical ripening with prostaglandin E2 (OPRA study)', *BJOG: An International Journal of Obstetrics and Gynaecology*, 122(1), pp. 94-104.

Willig, C. (1999) 'Beyond appearances: a Critical Realist approach to social constructionist work', in Cromby, J. and Nightingale, D. (eds.) *Social Constructionist Psychology*. Buckingham: Open University Press, pp. 37-51.

Wing, D.A. *et al.* (2013) 'Misoprostol vaginal insert and time to vaginal delivery: a randomized controlled trial', *Obstetrics and gynecology*, 122(2 Pt 1), pp. 201-209.

World Health Organisation (2011) *WHO recommendations for induction of labour*. Available at: http://apps.who.int/iris/bitstream/handle/10665/44531/9789241501156_eng.pdf;jsessionid=1FD6286F649E39E0594977A0DC5314B4?sequence=1 (Accessed: 25th November 2021).

World Health Organisation (2014) *WHO recommendations for augmentation of labour*. Available at: https://www.ncbi.nlm.nih.gov/books/NBK258875/pdf/Bookshelf_NBK258875.pdf (Accessed: 25th November 2021).

Wright, E.M., Matthai, M.T. and Meyer, E. (2019) 'The Influence of Social Media on Intrapartum Decision Making: A Scoping Review', *J Perinat Neonatal Nurs*, 33(4), pp. 291-300.

Zachariadis, M., Scott, S. and Barrett, M. (2013) 'Methodological Implications of Critical Realism for Mixed-Methods Research', *MIS Quarterly*, 37, pp. 855-879.

# Appendix I The Modified Bishop score

| Cervical feature | Modified Bishop Score | | | |
|---|---|---|---|---|
| | 0 | 1 | 2 | 3 |
| Dilation (cm) | <1 | 1-2 | 2-4 | >4 |
| Length of cervix (cm) | >4 | 2-4 | 1-2 | <1 |
| Station (relative to ischial spines) | -3 | -2 | -1/0 | +1/+2 |
| Consistency | Firm | Average | Soft | - |
| Position | Posterior | Mid/Anterior | - | - |

(National Collaborating Centre for Women's and Children's Health, 2008 p.81)

# Appendix II Literature review protocol

| | |
|---|---|
| Review question | What are women's and staff views and experiences of OPIOL with vaginal dinoprostone (prostaglandin $E_2$)? |
| Type of review | Evidence review |
| Objectives of the review | • To perform a systematic search to retrieve existing evidence about women's and staff views and experiences of OPIOL with vaginal dinoprostone.<br>• To critically evaluate the evidence.<br>• To synthesise the evidence and identify gaps in the literature. |
| Participants | Women at low-risk of complications with term pregnancy<br><br>Excluded:<br><br>• Pre-term pregnancy and other pregnant women at high-risk of complications as not eligible for outpatient management. |
| Intervention | OPIOL using vaginal dinoprostone:<br><br>• Vaginal tablets, pessaries or gel<br>• Controlled-release pessary<br><br>Excluded:<br><br>• Intracervical administration of vaginal dinoprostone as not recommended practice in UK.<br>• Misoprostol ($PGE_1$) excluded due to increased likelihood of uterine hyperstimulation and the required frequency of low-dose oral administration which make it unsuitable for outpatient management (Wing *et al.*, 2013; Alfirevic, 2014).<br>• Balloon catheters (foley, double balloon/Cook's), laminaria tents, hyaluronidase or isosorbide mononitrate (IMN) as intervention of interest is induction of labour. Vaginal dinoprostone |

| | |
|---|---|
| | recommended by National Collaborating Centre for Women's and Children's Health (2008) at time protocol developed. |
| Comparison | • Inpatient IOL; or<br>• No comparison group |
| Outcomes of interest | • Women's views and experiences<br>• Staff views and experiences |
| Type of study | Studies which report women's or staff views and experiences of OPIOL including:<br>• Randomised controlled trials/experimental studies<br>• Cohort studies (prospective or retrospective)<br>• Questionnaires<br>• Qualitative studies<br><br>Excluded:<br>• Evidence where methods unclear e.g., published abstracts only/ conference posters |
| Other inclusion/exclusion criteria | English language only |
| Databases and any date limitations | • CINAHL<br>• Embase<br>• Medline<br>• Scopus<br>• Web of Science<br>• No date limitations applied |

| | |
|---|---|
| Other literature search methods | • Grey literature search<br>• Reference searching<br>• Citation searching |
| Selection process | • Import studies to EndNote<br>• Remove duplicates<br>• Identify and remove irrelevant studies e.g., hysteroscopy, termination of pregnancy, abortion, miscarriage, intrauterine device insertion<br>• Title and abstract review<br>• Retrieve and review full papers |
| Data extraction | Data extraction forms used to review full paper (Booth, Papaioannou and Sutton, 2016) |
| Quality assessment and risk of bias | Relevant CASP quality assessment checklists (Critical Appraisal Skills Programme, 2013) |
| Synthesis | Narrative synthesis |

# Appendix III Electronic databases

**Cinahl**

The Cumulative Index to Nursing and Allied Health Literature. Comprehensive resource of professional literature related to nursing, midwifery, physiotherapy, biomedical and other allied health professions. Supports subject searching by Medical Subject Headings (MeSH terms) which is helpful to capture all relevant titles despite authors using different terms for key concepts, as well as international variation in spelling e.g., MH 'labor, induced' (Booth, Papaioannou and Sutton, 2016).

**Embase**

Similar coverage as Medline but includes additional literature on pharmaceuticals, biotechnology and clinical medicine making its inclusion useful in a literature review concerning a pharmacological intervention.

**Medline**

4600 journals from 1946 onwards. Comprehensive coverage of biomedical literature produced by US National Library of Medicine including around 21.6 million records covering medicine, nursing, dentistry and allied health professions. Supports subject searching by Medical Subject Headings (MeSH terms).

**Scopus**

60 million record database of citations and abstracts including peer-reviewed journal articles, books and conference proceedings. Subjects wide-ranging, including arts, humanities and science. Additional analytical functionality e.g., field-weighted citation impact which compares the number of citations received when compared to the average number since 1996 for a given subject field; citation benchmarking which compares the number of citations received when compared to the average of at least 2500 similar articles in a rolling 18 month window . Also collects data on downloads by Mendeley users and citations in national media, as well as links to Twitter mentions and demographics (Scopus, 2016).

**Web of Science**

90 million record database of peer reviewed journal articles, books and conference proceedings. Subjects include arts, humanities and science. Additional analytical functionality can be used to visualise up to two generations of referenced and citing articles for key papers.

# Appendix IV Database searches

| **CINAHL Plus with Full Text was searched using the EBSCO database 5/8/21**<br>**This is an update of an earlier review conducted on 16/10/18** | | |
|---|---|---|
| Number | Search | Results |
| 1 | (MH “dinoprostone”) | 741 |
| 2 | Dinoprostone | 808 |
| 3 | (MH prostaglandins) | 3,709 |
| 4 | Prostaglandin | 7,495 |
| 5 | PGE2 | 1,426 |
| 6 | Propess | 17 |
| 7 | Prostin | 12 |
| 8 | (MH “Misoprostol”) | 1,880 |
| 9 | Misoprostol | 2,388 |
| 10 | 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 | 10,080 |
| 11 | (MH “Outpatients”) | 48,334 |
| 12 | Outpatient | 105,267 |
| 13 | (MH “Ambulatory care”) | 13,126 |
| 14 | Ambulatory | 53,519 |
| 15 | Home | 209,188 |

| | | |
|---|---|---|
| 16 | 11 or 12 or 13 or 14 or 15 | 344,800 |
| 17 | (MH “Labor, induced” | 3,561 |
| 18 | Induction of labo*r | 3,659 |
| 19 | “Cervical priming” | 80 |
| 20 | “Cervical ripening” | 633 |
| 21 | Induc* labo*r | 6,737 |
| 22 | 17 or 18 or 19 or 20 or 21 | 6,957 |
| 23 | Experience or view or satisfaction or opinion or attitude or perception or belief or perspective or acceptab* | 1,093,034 |
| 24 | 10 and 16 and 22 and 23 | 32 |

| **Embase was searched using the Ovid database for the period 1996 to 2021 week 30 5/8/21**<br>**This is an update of an earlier review conducted on 16/10/18** | | |
|---|---|---|
| Number | Search | Results |
| 1 | Prostaglandin/ | 21,802 |
| 2 | Prostaglandin E2/ | 38,187 |
| 3 | Prostaglandin.mp | 111,931 |
| 4 | Dinoprostone.mp | 843 |
| 5 | PGE2.mp | 26,210 |
| 6 | Prostin | 354 |
| 7 | Propess | 207 |
| 8 | Misoprostol/ | 10,547 |
| 9 | Misoprostol.mp | 11,033 |
| 10 | 1 or 2 or 3 or 5 or 6 or 7 or 8 or 9 | 121,399 |
| 11 | Outpatient/ | 130,662 |
| 12 | Outpatient.mp | 298,021 |
| 13 | Ambulatory care/ | 29,147 |
| 14 | Ambulatory.mp | 131,747 |
| 15 | Home care/ | 49,030 |

| | | |
|---|---|---|
| 16 | Home.mp | 350,701 |
| 17 | 11 or 12 or 13 or 14 or 15 or 16 or 17 | 731,741 |
| 18 | Uterine cervix ripening/ | 2,481 |
| 19 | Cervical ripening.mp | 2,277 |
| 20 | Cervical priming.mp | 287 |
| 21 | Labor induction/ | 10,595 |
| 22 | Induction labo*r.mp | 63 |
| 23 | Induction of labo*r.mp | 6,841 |
| 24 | Induc* labo*r.mp | 1,657 |
| 25 | 18 or 19 or 20 or 21 or 22 or 23 or 24 | 15,270 |
| 26 | Experience or view or satisfaction or opinion or attitude or perception or belief or perspective or acceptab* | 2,559,107 |
| 27 | 10 and 17 and 25 and 26 | 99 |

| **MEDLINE was searched using the EBSCO database 5/8/21**<br>**This is an update of an earlier review conducted on 16/10/18** | | |
|---|---|---|
| Number | Search | Results |
| 1 | (MH “dinoprostone”) | 28,555 |
| 2 | Dinoprostone | 28,707 |
| 3 | (MH prostaglandins E, Synthetic) | 1,539 |
| 4 | Prostaglandin | 122,135 |
| 5 | PGE2 | 23,962 |
| 6 | Propess | 44 |
| 7 | Prostin | 125 |
| 8 | (MH “Misoprostol”) | 4,255 |
| 9 | Misoprostol | 5,634 |
| 10 | 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 | 132,341 |
| 11 | Outpatient | 20,6020 |
| 12 | (MH “Ambulatory care”) | 44,680 |
| 13 | Ambulatory | 170,189 |
| 14 | Home | 316,588 |
| 15 | 11 or 12 or 13 or 14 | 637,914 |
| 16 | (MH “Labor, induced” | 9,685 |

| | | |
|---|---|---|
| 17 | Induction of labo*r | 9,734 |
| 18 | (MH “Cervical ripening”) | 1,183 |
| 19 | “Cervical ripening” | 2,254 |
| 20 | “Cervical priming” | 278 |
| 21 | Induc* labo*r | 23,176 |
| 22 | 16 or 17 or 18 or 19 or 20 or 21 | 24,019 |
| 23 | Experience or view or satisfaction or opinion or attitude or perception or belief or perspective or acceptab* | 2,612,415 |
| 24 | 10 and 15 and 23 | 56 |

| **Scopus**<br>**This is an update of an earlier review conducted on 17/10/18** | | |
|---|---|---|
| Number | Search | Results |
| 1 | Title-Abs-Key(dinoprostone or prostaglandin or PGE2 or propess or prostin or misoprostol) | 203,332 |
| 2 | Title-Abs-Key(outpatient or ambulatory or home) | 1,035,087 |
| 3 | Title-Abs-Key(Induc? AND labo?r) | 814 |
| 4 | Title-Abs-Key("Induction of labo?r") | 5,323 |
| 5 | Title-Abs-Key("cervical priming" or "cervical ripening") | 2,764 |
| 6 | 3 or 4 or 5 | 8,155 |
| 7 | Title-Abs-Key(Experience or view or satisfaction or opinion or attitude or perception or belief or perspective or acceptab?) | 6,557,792 |
| 8 | 1 and 6 and 7 | 58 |

| **Web of Science**<br>**This is an update of an earlier review conducted on 17/10/18** | | |
|---|---|---|
| Number | Search | Results |
| 1 | Dinoprostone or prostaglandin or PGE2 or Propess or Prostin or Misoprostol | 70,442 |
| 2 | Outpatient or ambulatory or home | 403,339 |
| 3 | Induction of labo*r | 5,065 |
| 4 | Induction labo*r | 5,733 |
| 5 | Induc* labo*r | 6,950 |
| 6 | Cervical ripening | 1,318 |
| 7 | Cervical priming | 248 |
| 8 | 3 or 4 or 5 or 6 or 7 | 8,125 |
| 9 | Experience or view or satisfaction or opinion or attitude or perception or belief or perspective or acceptab? | 2,016,340 |
| 10 | 7 and 11 and 17 and 18 | 5 |

# Appendix V Sources of grey literature

**CenterWatch**

Search conducted: 6/8/21

This is an update of an earlier search conducted on 18/10/18

https://www.centerwatch.com/

Database of US clinical trials recruiting participants.

Searched for 'cervical priming'/'cervical ripening'. No relevant records retrieved.

**ClinicalTrials.gov**

Search conducted: 6/8/21

This is an update of an earlier search conducted on 18/10/18

http://www.clinicaltrials.gov

A US-hosted database of ongoing and completed clinical trials in 191 countries. May not include all US clinical trials as not all are required to register by law e.g., observational studies.

Searched using 'pregnancy' and 'induction of labor' category. No relevant records identified.

**Cochrane Central Register of Controlled Trials (CENTRAL)**

Search conducted: 6/8/21

This is an update of an earlier search conducted on 18/10/18

http://www.cochranelibrary.com/about/central-landing-page.html

Registry of published an unpublished controlled and quasi-controlled studies.

Appendix V

| Number | Search | Results |
|---|---|---|
| 1 | Prostaglandin | 7,190 |
| 2 | Dinoprostone | 1,435 |
| 3 | PGE2 | 1,420 |
| 4 | Propess | 60 |
| 5 | Prostin | 76 |
| 6 | Misoprostol | 3,697 |
| 7 | 1 or 2 or 3 or 4 or 5 or 6 | 10,877 |
| 8 | Outpatient | 35,996 |
| 9 | Ambulatory | 23,219 |
| 10 | Home | 49,829 |
| 11 | 8 or 9 or 10 | 99,333 |
| 12 | Cervical ripening | 1,584 |
| 13 | Cervical priming | 320 |
| 14 | Induction of labo*r | 3,828 |
| 15 | Induc* labo*r | 5,079 |
| 16 | 12 or 13 or 14 or 15 | 5,653 |
| 17 | Experience or view or satisfaction or opinion or attitude or perception or belief or perspective or acceptab* | 202,170 |

| | | |
|---|---|---|
| 18 | 7 and 11 and 16 and 17 | 102 |
| 19 | Hysteroscopy or miscarriage or abortion or haemorrhage or “first trimester” or “second trimester” or death or stillbirth or IUD | 108,714 |
| 20 | 18 NOT 19 | 36 |

No new records identified.

**DART-Europe**

Search conducted: 16/8/21

This is an update of an earlier search conducted on 18/10/18

http://www.dart-europe.eu

A collaboration of European libraries providing access to over 151,000 European theses and dissertations.

Searched using ‘outpatient’ or ’ambulatory’ and ‘induction’ and ‘labour or labor’. No new records identified.

Searched using ‘outpatient’ or ’ambulatory’ and ‘priming’ or ‘ripening’ and ‘cervical’. No new records identified.

**DARE (Database of Abstracts of Reviews and Effects)**

Search conducted: 16/8/21

This is an update of an earlier search conducted on 7/10/18

http://www.crd.york.ac.uk/CRDWeb/

NIHR funding to produce DARE and NHS EED ceased at the end of March 2015. However, both databases can still be accessed via the CRD website. Searches of MEDLINE, Embase, CINAHL,

PsycINFO and PubMed were continued until the end of the 2014. Bibliographic records were published on DARE and NHS EED until 31st March 2015.

Searched using 'outpatient'/'ambulatory' and 'induction of labour'/'induction of labor'. No new records identified.

Searched using 'outpatient'/'ambulatory' and 'cervical priming'/'cervical ripening'. No new records identified.

**EthOS**

Search conducted: 16/8/21

This is an update of an earlier search conducted on 18/10/18

http://ethos.bl.uk

Provides access to over 400,000 doctoral theses, hosted by the British Library.

Searched using 'outpatient'/'ambulatory' and 'induction of labour'/'induction of labor'. No new records identified.

Searched using 'outpatient'/'ambulatory' and 'cervical priming'/'cervical ripening'. No new records identified.

**ISRCTN registry**

Search conducted: 16/8/21

This is an update of an earlier search conducted on 18/10/18

http://www.isrctn.com/

A registry of proposed, current and completed clinical trials.

Searched using 'outpatient'/'ambulatory' and 'induction of labour'/'induction of labor'. No new records identified.

Searched using ‘outpatient’/’ambulatory’ and ‘cervical priming’/’cervical ripening’. No new records identified.

**OpenGrey**

Search conducted: 16/8/21

This is an update of an earlier search conducted on 18/10/18

http://www.opengrey.eu/

Database of 700,000 records including unpublished theses and dissertations, conference papers, reports and official publications.

Searched using ‘outpatient’/’ambulatory’ and ‘induction of labour’/’induction of labor’. No new records identified.

Searched using ‘outpatient’/’ambulatory’ and ‘cervical priming’/’cervical ripening’. No new records identified.

**TRIP**

Search conducted: 16/8/21

This is an update of an earlier search conducted on 18/10/18

http://www.tripdatabase.com

Includes links to research evidence as well as other content such as images, videos, patient information leaflets and news.

Searched using ‘outpatient’/’ambulatory’ and ‘induction of labor’/’induction of labour’.

Searched using ‘outpatient’/’ambulatory’ and ‘cervical ripening’/’cervical priming’. Two records identified as above.

# Appendix VI Reference searching

3 new records identified

Howard *et al.* (2014)

Oster *et al.* (2011)

Turnbull *et al.* (2013b)

# Appendix VII Citation searching

**Web of Science search conducted 24/8/21**

This is an update of an earlier search conducted on 11/11/18.

Awartani, Turnell and Olatunbosun (1999) – 8 citations. No new records identified.

Biem *et al.* (2003) – 40 citations. No new records identified.

Coates *et al.* (2021) – 3 citations. No new records identified.

Howard *et al.* (2014) – 21 citations. No new records identified.

Oster *et al.* (2011) – 28 citations. No new records identified.

O'Brien *et al.* (2013) – 20 citations. No new records identified.

Rauf *et al.* (2011) – 9 citations. No new records identified.

Sutton, Harding and Griffin (2016) – 7 citation. No new records identified.

Turnbull *et al.* (2013a) – 21 citations. No new records identified.

Turnbull *et al.* (2013b) – 6 citations. No new records identified.

# Appendix VIII Quality assessment of full papers

Awartani, Turnell and Olatunbosun (1999) – CASP-UK Cohort Study Checklist (Critical Appraisal Skills Programme, 2013)

| | |
|---|---|
| Did the study address a clearly focused issue? | Yes<br><br>OPIOL versus inpatient management – outcomes: safety, effectiveness, length of hospital stay and women's satisfaction. |
| Was the cohort recruited in an acceptable way? | No<br><br>• OPIOL and inpatient groups from different hospitals which may potentially undermine generalisability. While IOL protocol clearly described, there may be differences in management practices around selection of participants and management of labour.<br>• There may also be differences in the local study populations but demographic characteristics were not stated.<br>• Although not statistically significant, there were more primigravid women in the inpatient than outpatient group (62% vs 46%).<br>• Prospective cohort study, non-randomised. |
| Was the exposure accurately measured to minimise bias? | Yes<br><br>Clearly stated how many women managed as inpatient and outpatient. |
| Was the outcome accurately measured to minimise bias? | Definitions given where appropriate.<br><br>Primary outcomes:<br><br>• Neonatal unit admission;<br>• Hyperstimulation defined as single contraction lasting 2 minutes or more, or 5 or more in 10 minutes;<br>• Placental abruption – not defined;<br>• Systemic side effects – not defined.<br><br>Secondary outcomes:<br><br>• Induction to active labour interval – active labour was defined as at least 2 painful contractions in every 15 minutes with cervix fully effaced and 3cm dilated or more and/or ruptured membranes; |

| | |
|---|---|
| | • Induction to birth interval;<br>• Duration of hospitalisation from IOL to discharge;<br>• Number of 2mg doses of prostaglandin stated;<br>• Oxytocin – practices can vary between clinicians and hospitals and protocol not stated. This means unable to tell if differences due to intervention or hospital practices;<br>• Caesarean section;<br>• Apgar score – can be subjective;<br>• Patient satisfaction – not clearly defined. Assessed by telephone after discharge but not stated when this was done or whether a validated scale used;<br>• Blinding of staff and participants not possible. |
| Have the authors identified all important confounding factors? List the ones you think might be important that the author missed. | No<br><br>• There may have been women eligible for OPIOL who were subsequently not discharged home due to concerns. This group may have had less favourable view of OPIOL;<br>• Age, parity, gestational age, bishop score stated. May have been other demographic/clinical differences in populations of the two hospitals. Bishop score was significantly higher at the outset in OPIOL cohort (p=0.001);<br>• Low risk population stated but may have been clinical differences in women who actually went home – not stated whether some became ineligible during the initial assessment potentially making overall OPIOL cohort lower risk. |
| Have they taken account of the confounding factors in the design and/or analysis? | Demographic differences not stated and no adjustment for confounding. |
| Was the follow up of subjects complete enough? | Unclear when telephone follow up. |
| Was the follow up of subjects long enough? | Yes |
| What are the results of this study | Primary outcomes: |

| | |
|---|---|
| | • Neonatal unit admission – no significant difference;<br>• Hyperstimulation – none;<br>• Placental abruption – none;<br>• Systemic side effects – none.<br><br>Secondary outcomes:<br><br>• Induction to active labour interval – no difference;<br>• Induction to birth interval – no difference;<br>• Duration of hospitalisation from IOL to discharge – 3.4 ± 1.2 days for inpatients, 2.8 ± 0.9 days for OPIOL (p=0.004). May have been due to more primparous women in inpatient cohort with additional support needs e.g., breastfeeding;<br>• Prostaglandin – no difference;<br>• Oxytocin – 54% OPIOL versus 34% inpatient (p=0.04);<br>• Caesarean section – no difference;<br>• Apgar score – can be subjective;<br>• Patient satisfaction 96% OPIOL versus 56% inpatients (p<0.0001). |
| How precise are the results? | Descriptive statistics with statistical significance calculated using Chi square tests for proportion data.<br><br>Two-tailed t-test used to calculate difference in means.<br><br>P value <0.05 considered significant. |
| Do you believe the results? | No<br><br>Likely bias due to lack of randomisation, lack of consideration/adjustment for demographic differences and two different hospital sites with potential clinical management variance. |
| Can the results be applied to the local population? | Unclear as demographic characteristics not stated. |
| Do the results of this study fit with other available evidence? | Yes – low incidence of adverse outcomes. |
| What are the implications of this study for practice? | Insufficiently robust study with some bias due to design. |

Biem *et al.* (2003) – CASP-UK randomised controlled trial checklist (Critical Appraisal Skills Programme, 2013)

| | |
|---|---|
| Did the trial address a clearly focussed issue? | Yes<br><br>OPIOL versus inpatient management – outcomes: safety, effectiveness, length of hospital stay and women's satisfaction. |
| Was the assignment of patients to treatment randomised? | Yes<br><br>Computer-generated numbers, sealed opaque envelopes. Randomised immediately after insertion of the controlled release prostaglandin dinoprostone pessary. |
| Were all of the patients who entered the trial properly accounted for at its conclusion? | Yes<br><br>Only one person withdrew after randomisation following episode of tachysystole. |
| Were patients, health workers and study personnel blinded? | Due to the nature of the intervention participants and staff were not blinded. |
| Were the groups similar at the start of the trial? | Yes<br><br>• No difference in the following characteristics: age, parity, gestation, bishop score, reason for induction, enrolling physician;<br>• While other demographic details not included e.g., education, socioeconomic status, as women were randomised it is likely the groups were similar. |
| Aside from the experimental intervention were the groups treated equally? | Yes<br><br>• Both groups had one hour of fetal monitoring after insertion of the pessary;<br>• Both groups rated anxiety, pain and satisfaction every 4 hours. The outpatient group were asked to call the hospital and respond to automated interview on telephone keypad. Satisfaction was rated on scale of 0 to 9. Mean ratings calculated over first 12 hours. High satisfaction defined as mean ≥7; |

| | |
|---|---|
| | • Both groups were asked about overall satisfaction the day after birth using 10 point visual analogue scale;<br>• OPIOL group readmitted 24 hours after administration of pessary. |
| How large was the treatment effect? | Primary outcomes:<br><br>• In labour by 24 hours – no difference;<br>• Birth by 24 hours – no difference;<br>• Satisfaction (proportion with high mean ratings i.e., ≥7 at 4 hourly calls during the first 12 hours after insertion – 83/149 (56%) OPIOL versus 59/150 (39%) p=0.008. Authors state difficult to interpret differences in satisfaction.<br><br>Secondary outcomes:<br><br>• Anxiety first 12 hour – no difference;<br>• Pain first 12 hours – no difference;<br>• Overall satisfaction – no difference;<br>• Duration of hospital stay – no difference;<br>• Hyperstimulation (non-reassuring fetal heart trace) – no difference;<br>• Epidural – no difference;<br>• Placental abruption – no difference;<br>• Arterial and venous cord pH – no difference;<br>• 1 and 5 minute Apgar score – no difference;<br>• Birthweight – 3680g ± 441g OPIOL versus 3800 ± 468g inpatient p=0.03;<br>• Neonatal unit admission – no difference;<br>• IOL to labour interval (defined as at least 2 painful contractions every 15 minutes and cervix 3cm, fully effaced or more and/or spontaneous rupture of membranes or evidence of cervical change) – no difference;<br>• Median time at home – 8 hours;<br>• Induction to birth interval – no difference;<br>• Use of oxytocin – no difference. |
| How precise was the estimate of the treatment effect? | Confidence intervals have been used to express the uncertainty around the median values derived from the sample e.g., median times to labour, time at home for OPIOL and inpatient groups respectively. P values have been calculated to determine whether the differences are significant. However, |

| | |
|---|---|
| | confidence intervals have not been used to describe the treatment effect. Confidence intervals used in this way indicate the upper and lower values between which the true differences observed between the two arms may lie. Confidence intervals used in this way help describe more about the scale or strength of the effect (Cluett and Bluff, 2006). |
| Can the results be applied in your context? (Or to the local population?) | Unclear<br><br>Women's characteristics described - at low risk of complications. However, model of care somewhat different between UK and Canada. |
| Were all clinically important outcomes considered? | Yes |
| Are the benefits worth the harms and costs? | Unclear<br><br>Rare adverse outcomes make it difficult to determine safety. |

Coates *et al.* (2021) – CASP-UK qualitative research checklist (Critical Appraisal Skills Programme, 2013)

| | |
|---|---|
| Was there a clear statement of the aims of the research? | Yes<br><br>The aim of the study is clearly explained: to explore women's experiences of outpatient induction of labour with either dinoprostone pessary or double balloon catheter.<br><br>Qualitative evidence about outpatient induction of labour is highly relevant as women's experiences of inpatient induction are often poor (Reid *et al.*, 2011; Coates *et al.*, 2019). |
| Is a qualitative methodology appropriate? | Yes<br><br>Semi-structured interviews were used to gain a deep insight into women's experiences of outpatient induction with either a dinoprostone pessary or double balloon catheter. Transcripts were coded and analysed thematically. |
| Was the research design appropriate to address the aims of the research? | Yes<br><br>The authors justify their approach in the following ways:<br><br>• Other research focuses on induction of labour in general and uses survey data to compare satisfaction;<br>• When comparing different methods of induction of labour, other studies generally compare pain scores only;<br>• Qualitative data considers experiences of outpatient and inpatient induction rather than different methods of outpatient induction. |
| Was the recruitment strategy appropriate to the aims of the research? | Yes<br><br>As part of a small feasibility study for randomised controlled trial comparing double balloon catheter and dinoprostone pessary, all women were invited to take part. |
| Was the data collected in a way that addressed the research issue? | Yes<br><br>Semi-structured interviews were conducted by an academic researcher (research |

| | |
|---|---|
| | psychologist by background). Semi-structured are an effective way to gather rich data about people's experiences about topics of interest to researchers (Tod 2015).<br><br>Women were contacted at least four weeks after birth to give them time to recover after birth while ensuring recall. Interview duration was appropriate between 18 and 52 minutes and a reflexive diary was maintained to reflect on encounters. Interviews were transcribed verbatim.<br><br>The authors do not make any comment about data saturation although this is often difficult to assess rigorously and its usefulness is often overstated (Braun and Clarke, 2019). |
| Has the relationship between researcher and participants been adequately considered? | The authors have made the professional background of the interviewer explicit. As a research psychologist, it is unlikely the interviewer unintentionally influenced the participants' responses (Tod 2015). |
| Have ethical issues been taken into consideration? | Yes<br><br>The authors detail appropriate ethical considerations including ethics committee approval. They make it explicit that the funder was not involved in the design of the study, data collection or analysis. This reduces the possibility of any conflicts of interest or bias. |
| Was the data analysis sufficiently rigorous? | Yes<br><br>The authors adopted an interpretivist approach which is appropriate for this type of data analysis. They tested a previously published conceptual framework of experiences of induction generated through a previous qualitative systematic review and thematic synthesis. Transcripts were coded according to this framework or new descriptive codes were generated.<br><br>Two other authors coded subsamples of the data to ensure consensus. Themes were reviewed to check fit, identify duplication and to identify disconfirming evidence. |

| | |
|---|---|
| | Participants were also invited to provide feedback about the themes identified.<br><br>Excerpts of the transcriptions are included in the paper which add vivid detail and illustrate the identified themes. By including raw data, this enhances the confirmability of the findings.<br><br>Is it clear how themes derived from data?<br><br>Yes<br><br>The authors present a summary of participant characteristics and whether women were offered dinoprostone or balloon induction. They also provide short extracts to illustrate the themes. |
| Is there a clear statement of findings? | Yes<br><br>**Ownership of induction of labour**<br><br>• Understanding of the induction process – limited understanding of the process<br>• Choice and control in labour and birth – by joining the trial, seeking more information about induction, taking time to make decisions, preparing hospital bag, changing the layout of the birth room. Others felt there was no point or disappointed about change of plan or felt they had no choice about induction.<br>• Experience of method of induction (new sub-theme) – negative preconceptions about pessary, positive about balloon as 'less medicalised' and 'natural'. Insertion mildly uncomfortable or 'scratchy' (pessary) and uncomfortable, similar to cervical screening to painful (balloon). One woman tolerated insertion but pain severe once in place. Women unprepared for having end of balloon catheter left protruding. Balloon removal painless. Future preference for balloon in both groups.<br>• Further intervention (new sub-theme) – two thirds of women required oxytocin – seen as inevitable. Long labour perceived by women as abnormal and fluctuations in frequency were frustrating. If required, the lead up to a caesarean birth exhausting and anxiety-provoking but positive experience of procedure itself. |

| | |
|---|---|
| | • Experience of pain management – over half of women had an epidural although a third expressed that was not their initial intention. Exhaustion was reason women opted for one. Four of 14 women who received pessary reported rapid onset of very strong contractions.<br><br>**Importance of place**<br><br>• Enduring the hospital – lack of privacy in hospital versus being able to do usual activities at home. Boredom, unfamiliarity, lack of facilities for partner to sleep, hospital routines. Understanding of busy hospital but frustrated by delays or having to be assertive. Also expressed benefit of staff being nearby.<br>• Keeping to established rhythms at home – most women expressed preference for being at home as more comfortable, more 'natural', more support available. However, some concerns if pessary or balloon displaced at home or uncertainty about whether pain was 'normal'.<br>• Transition between home and hospital (new sub-theme) – journey time not a concern as nearby. Frustrations around parking and admission process.<br><br>While half the women experienced pain on insertion of the balloon or while it was in situ, there was a clear preference for balloon catheter induction in future. However, they acknowledge that women may have entered the trial as it provided an opportunity to try this method which was not routinely available in the Trust. |
| How valuable is the research? | Unique contribution to the evidence base comparing women's experiences of double catheter balloon versus dinoprostone pessary for outpatient induction of labour. This is significant because dinoprostone induction has long been the nationally recommended agent for induction (National Collaborating Centre for Women's and Children's Health, 2008) although the updated guideline now suggests mechanical methods as an alternative where vaginal dinoprostone is not |

| | |
|---|---|
| | suitable (National Institute for Health and Care Excellence, 2021). |

Howard *et al.* (2014) – survey checklist (Best Evidence Topics, 2018)

How do you rate this paper? 8/10

1.0 OBJECTIVES AND HYPOTHESES

| | |
|---|---|
| 1.1 Are the objectives of the study clear stated? | Yes<br>• To consider aspects of induction of labour services important to women.<br>• To design services that are acceptable to women. |

1.0 DESIGN

| | |
|---|---|
| 2.1 Is the study design suitable for the objectives? | Yes<br><br>Discrete choice experiment to examine women's preferences around IOL. |
| 2.2 Who/what was studied? | 260 participants of OPRA trial at their 7 week postnatal appointment.<br><br>102 pregnant volunteers from antenatal clinic. |
| 2.3 Was this the right sample to answer the objectives? | No<br><br>Inclusion of those who had already undergone induction of labour and birth may have subsequently influenced their preferences. |
| 2.4 Did the subject represent the full spectrum of the population of interest? | Socio-demographic characteristics of pregnant volunteers not distinguished from OPRA participants and summarised together. It would be insightful to determine whether there were any differences in preferences between those women who had had their babies and those who were still pregnant. |
| 2.5 Is the study large enough to achieve its objectives? Have sample size estimates been performed? | Unclear<br><br>Sample size calculated for main OPRA study (requirement for 400 women in each group to achieve 80% statistical power to show a 10% |

| | |
|---|---|
| | reduction in oxytocin use from 50% to 40% in intervention group) (Wilkinson *et al.*, 2015).<br><br>No sample size calculation for this aspect of the study. |
| 2.6 Were all the subjects accounted for? | Yes<br><br>260/515 OPRA participants agreed to answer the questionnaire 7 weeks postnatal.<br><br>102/114 pregnant volunteers agreed to participate. |
| 2.7 Were all appropriate outcomes considered? | Considered the following preferences:<br><br>• Environment while waiting for gels to work – OPIOL, enhanced inpatient, basic inpatient<br>• Availability of pain relief and sleep medication<br>• Who checks on you while waiting for gels to work<br>• Increasing familiarity with midwife (versus rostered midwife only)<br>• Travel time for each trip to closest hospital<br>• Number of trips to hospital |
| 2.8 Has ethical approval been obtained if appropriate? | Yes |
| 2.9 What measures were made to contact non-responders? | Not stated |
| 2.10 What was the response rate? | Pregnant volunteers – consent implied by completion of questionnaire 102/114 (90%) response rate<br><br>OPRA trial participants who completed at 7 weeks postnatal – 260/515 (50%) response rate |

2.0 MEASUREMENT AND OBSERVATION

| | |
|---|---|
| 3.1 Is it clear what was measured, how it was measured and what the outcomes were? | 25 discrete choice sets, each with three different alternative options |
| 3.2 Are the measurements valid? | Validity relates to whether a tool measures what it should and whether it measures it accurately (Jones and Rattray, 2015). Content validity of the attributes was ensured following |

| | |
|---|---|
| | interviews with participants, as well as a multiprofessional workshop. |
| 3.3 Are the measurements reliable? | Reliability relates to the consistency or repeatability of a survey or questionnaire. In this example, the survey was piloted a couple of times prior to final data collection. |
| 3.4 Are the measurements reproducible? | Yes |

3.0 PRESENTATION OF RESULTS

| | |
|---|---|
| 4.1 Are the basic data adequately described? | Yes |
| 4.2 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement? | Yes<br><br>Own home preferred over basic inpatient care by:<br><br>• All women (OR 1.771; 95% CI 1.445 to 2.178; p<0.0001).<br>• Women with university or college degree (OR 1.570; 95% CI 1.150 to 2.155; p=0.0052).<br>• Women in first pregnancy (OR 2.325; 95% CI 1.703 to 3.190; p<0.00001).<br>• Age (per year) (OR 1.094; 95% CI 1.061 to 1.128; p<0.00001).<br><br>Basic inpatient care over own home preferred by:<br><br>• Non-English speaking background (versus English speaking) (OR 0.145; 95% CI 0.105 to 0.201; p<0.00001)<br>• Previous history of obstetric led care (OR 0.443; 95% CI 0.331 to 0.594; p<0.00001)<br>• Previous experience of induction (OR 0.633; 95% CI 0.465 to 0.865; p-0.0041).<br>Number of trips and travel time<br>• Women willing to accept an extra 1.42 trips to hospital (2.42 trips total) and travel time of 30.6 minutes per trip to have OPIOL. |
| 4.3 Are the results internally consistent, i.e., do the numbers add up properly? | Some of the questions not answered. |

| | |
|---|---|
| | E.g., self-rated health 359/362 respondents, number of children stated 351/362, type of care (obstetric clinic, midwife clinic, midwifery group practice/birth centre, other) 292/362<br><br>While the questionnaire was piloted, this suggests some questions may have been ambiguous to participants i.e., there was poor face validity (Jones and Rattray, 2015). |

4.0 ANALYSIS

| | |
|---|---|
| 5.1 Are the data suitable for analysis? | Yes |
| 5.2 Are the methods appropriate to the data? | Yes<br><br>Other discrete choice experiments use same methods. |
| 5.3 Are any statistics correctly performed and interpreted? | Yes<br><br>Utility functions/formulae stated in the paper. |

5.0 DISCUSSION

| | |
|---|---|
| 6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives? | Yes<br><br>Authors relate findings to other studies that found high rates of satisfaction with OPIOL. They also explore why basic inpatient care may have been preferred by women under obstetric led care and non-English speaking women and question whether respondents may have assumed enhanced inpatient care was associated with an additional cost. |
| 6.2 Is the discussion biased? | Unclear<br><br>Authors do not mention low response to some of the demographic characteristic questions which may have undermined the validity of the findings. |

| | |
|---|---|
| | Unexpected finding explored – that no significant difference in responses between OPRA participants and pregnant volunteers. Authors suggest this may have been because half of the OPRA participants did not undergo IOL in the end. Therefore responses not all experiential.<br><br>Authors also explore why basic inpatient model may have been preferred over enhanced care by women under obstetric led care and non-English speaking women. Suggestions include women may have assumed there was an associated additional cost, or some other unexpected interpretation. The alternative not stated here is that perhaps the question was not well understood. |
| 6.3 Can the results be generalised? | The authors state the findings cannot be generalised to apply to women living in rural settings as ineligible for OPIOL.<br><br>The model of care in Australia is different to UK. A greater proportion of women have private health insurance and give birth in labour ward environments. |

7.0 INTERPRETATION

| | |
|---|---|
| 7.1 Are the authors' conclusions justified by the data? | Unclear<br><br>• The authors conclude that OPIOL slightly preferred over enhanced inpatient care although this is through indirect evidence as no head to head comparison was made (only OPIOL versus basic inpatient, and enhanced inpatient care versus basic inpatient care).<br>• The authors do make clear that women's preferences are mediated by demographic characteristics and that no one setting would be appropriate for all. |
| 7.2 What level of evidence has this paper presented? (using CEBM levels) | Non-randomised experiment.<br><br>1C |

| | |
|---|---|
| 7.3 Does this paper help me answer my problem? | The paper states women's preferences but not women's views and experiences of OPIOL. |

How do you rate this paper now? 6/10

O'Brien *et al.* (2013) – CASP-UK qualitative research checklist (Critical Appraisal Skills Programme, 2013)

| | |
|---|---|
| Was there a clear statement of the aims of the research? | Yes<br><br>Women's experiences and preferences of OPIOL with remote fetal monitoring. |
| Is a qualitative methodology appropriate? | Yes |
| Was the research design appropriate to address the aims of the research | Yes<br><br>Semi-structured interviews used to gain insight into women's views and experiences. |
| Was the recruitment strategy appropriate to the aims of the research? | Yes<br><br>Cohort selection was appropriate i.e., women at low risk of complications were recruited to the OPIOL phase of the study.<br><br>Sister study gave women diaries to complete during IOL process. Following birth when diaries collected, women who had undergone OPIOL were asked whether wished to participate in the in-depth interviews. |
| Was the data collected in a way that addressed the research issue? | Yes<br><br>Audio recordings of interviews were made and then transcribed. |
| Has the relationship between researcher and participants been adequately considered? | Not clearly stated<br><br>The nature of the relationship between the researcher and participants is not explicitly stated. While the correspondence details suggest that the research assistant works at the School of Nursing, Midwifery and Social Work, it cannot be surmised that they were not directly involved in clinical care. This is important to state clearly because women's responses may be influenced depending on their experiences and relationships with the clinician leading care which can undermine the validity of subsequent interview findings (Tod, 2015). |

| | |
|---|---|
| Have ethical issues been taken into consideration? | Yes<br><br>• Consent procedures are not clearly stated but ethical approval was granted for the study which would have demanded these procedures to be clearly outlined.<br>• Similarly, the ethical approval process would have required clarity about the measures the researchers had put in place to ensure consideration was given on preventing harm for instance if the participant was identified as being at risk of self-harm (Tod, 2015).<br>• Participant anonymity was maintained by the allocation of pseudonyms.<br>• It is not clear when the interviews take place, but the ethical review process would have asked the researchers to consider what timeframe after the birth would be appropriate. |
| Was the data analysis sufficiently rigorous? | Yes<br><br>• Systematic, thematic analysis of transcripts by reading and re-reading transcripts, developing codes and collation of overarching themes (Braun and Clarke, 2006).<br>• Interpreter bias reduced by triangulating findings between two researchers.<br>• Audit trail of decision making maintained. |
| Is there a clear statement of findings? | Yes<br><br>15 interviews undertaken.<br><br>Themes identified<br><br>Labour within their comfort zone<br><br>• Physical comforts of familiar surroundings<br>• Emotional and physical relaxation<br>• Carrying on everyday activities<br>• Freedom of movement<br>• Sense of control over environment and movement<br>• Support available<br>• Childcare arrangements<br>• Hospital environment – noise, lack of privacy, limited movement, lack of sleep, busy staff/being a burden |

| | |
|---|---|
| | The next best thing to a normal labour<br><br>• Disappointment that not spontaneous labour<br>• Uncertainty about what to expect<br>• Coping in their own way<br>• Approximating a normal labour experience<br>• Control<br><br>The importance of a virtual presence<br><br>Impressed with technology<br><br>• Better monitoring (constant) versus hospital (intermittent and performed multiple times)<br>• Concern over adequacy of monitoring/confidence in staff<br>• Importance of ongoing communication throughout, especially primiparous women |
| How valuable is the research? | Gives insight into women's experiences of OPIOL in the UK but remote monitoring not currently feasible. |

Oster *et al.* (2011) – CASP-UK qualitative research checklist (Critical Appraisal Skills Programme, 2013)

| | |
|---|---|
| Was there a clear statement of the aims of the research? | Yes<br><br>The aim of the study is clearly explained: to explore and compare women's preferences experiences of their environments while undergoing inpatient and outpatient induction of labour in terms of being a therapeutic landscape.<br><br>The authors support the use of the concept of the therapeutic landscape by defining it and citing relevant literature. They suggest certain locations are imbued with symbolic or social meaning that makes our experience of them more significant. A therapeutic landscape has an impact on health outcomes in terms of psychological and physiological effects, whether positive and negative.<br><br>Qualitative evidence about women's relationships with the location in which induction of labour is conducted is highly relevant as women's experiences are often poor and hospitals associated with illness (Reid et al 2011). |
| Is a qualitative methodology appropriate? | Yes<br><br>Semi-structured interviews were used to gain a deep insight into women's preferences around the most appropriate place to be induced. Transcripts were coded and categorised, and the resultant themes which related to environment were identified and synthesised. |
| Was the research design appropriate to address the aims of the research? | Yes<br><br>The authors also justify the use of this design by stating that only one other study prior to theirs explores women's preferences and experiences about outpatient induction although the study used isosorbide mononitrate as an induction agent rather than vaginal dinoprostone (Reid et al 2010).<br><br>Other studies included in this review generally used questionnaires to obtain quantitative data to compare satisfaction and preferences between outpatient and inpatient |

| | |
|---|---|
| | management (Awartani 1999; Biem; Howard; Turnbull)<br><br>O'Brien et al (2013) included data obtained from 15 semi-structured interviews about experiences of outpatient induction of labour using controlled-release vaginal dinoprostone in tandem with remote fetal monitoring. Rauf (2011) a sister paper to O'Brien asked outpatients to record how they were coping, their comfort and satisfaction levels in semi-structured diary entries at least once every two hours. The diaries included Likert scales and space for free text. While the coping, comfort and satisfaction are excluded from this review as there was no inpatient comparison group, the free text qualitative entries correspond with the findings in O'Brien et al (2013). Diary extracts highlight the themes of the comfort of home countered by women's uncertainty about the induction process and concerns about safety and whether they were being adequately monitored. |
| Was the recruitment strategy appropriate to the aims of the research? | Yes<br><br>The authors selected 16 participants from the OPRA trial who had already undergone induction of labour and given birth. While parity reflected the cohort of the main trial, purposive sampling was used to select participants with a range of different characteristics in terms of age, parity, language, education and type of birth. Nine of the women had undergone inpatient induction of labour and 7 had received outpatient care. Purposive sampling was used to improve the richness of data as it is likely to reveal varying points of view of people from different backgrounds (Hunt and Lathlean 2015). The authors concede, however, that generalisability to other situations may be undermined by recruitment of participants within 45 minutes' drive of the hospital in an urban area. |
| Was the data collected in a way that addressed the research issue? | Yes<br><br>Semi-structured interviews were used. These are an effective way to gather rich data about |

| | |
|---|---|
| | people's experiences about topics of interest to researchers (Tod 2015).<br><br>Over a four-week period, each of the participants were interviewed using a schedule that had already been piloted. The authors are explicit about the method and the themes addressed. Topics included knowledge and experience and information about induction of labour, continuity of care, location of care, time waiting at home or in hospital, access to pain relief and support. Each interview took approximately half an hour, the recording of which was then transcribed verbatim. The authors state data saturation was achieved after 12 interviews (Polit and Beck 2006). However, it was decided to continue with data collection to ensure the views of participants from different socio-economic groups were gathered. The women had given birth between up to 4 months beforehand which may have influenced recall. Furthermore, the authors comment that childcare commitments may have curtailed some of the discussions which may have undermined the validity to a degree. |
| Has the relationship between researcher and participants been adequately considered? | The authors have not made the professional background of the interviewer explicit. It is therefore difficult to establish whether the interviewer may have unintentionally influenced the participants' responses (Tod 2015). The authors do acknowledge that women who may have given less favourable responses about outpatient induction of labour would not have decided to participate in the OPRA trial in the first place. |
| Have ethical issues been taken into consideration? | Yes<br><br>The authors detail appropriate ethical considerations including ethics committee approval, confidentiality and how hospital staff did not have access to the data. |
| Was the data analysis sufficiently rigorous? | Unclear<br><br>The authors do not state they have used investigator triangulation to check the codes and themes identified in the transcriptions. This method is used to improve the credibility |

| | |
|---|---|
| | and trustworthiness of the study (Polit and Beck 2006).<br><br>Excerpts of the transcriptions are included in the paper which add vivid detail and illustrate the identified themes. By including raw data, this enhances the confirmability of the findings (Polit and Beck 2006).<br><br>Is it clear how themes derived from data?<br><br>Yes<br><br>Comfort<br>Being comfortable at home was a major theme. The authors make good use of excerpts to contrast the lights, machines and discomfort of a sterile hospital environment versus the freedom, calming familiarity and social intimacy of being at home surrounded by family and loved ones. The authors note the emphasis on the comfort of home was strong despite the time spent at home being relatively short. One of the women found being in hospital more relaxing, however, as she knew she did not have to worry about childcare commitments. The inclusion of disconfirming evidence enhances the credibility of this study (Polit and Beck 2006).<br><br>The theme of comfort and many of the attributes of the home environment were also identified by the participants in O'Brien et al's (2013) qualitative study of women undergoing outpatient induction of labour with a remote monitoring device. Unlike Oster et al (2011) a sense of feeling more in control in their home environment was also articulated.<br><br>While Oster et al (2011) focussed on the therapeutic landscape only, other themes emerged in the study by O'Brien et al. '*The next best thing to normal labour*' was also key and helped some of the women with either the disappointment of not experiencing that process, or with coming to terms with a previous poor experience of induction.<br><br>The importance of a '*virtual presence*' was also articulated. Some women liked the reassurance of being continuously monitored remotely, especially when there was |

| | |
|---|---|
| | telephone contact from the hospital. Others worried whether they were being monitored adequately, particularly those who did not have telephone contact paradoxically because their fetal heart tracing was of adequate quality and reassuring.<br><br>Safety<br>The theme of safety contradicted that of the comfort of home, however. The participants felt hospital was a place of safety and were apprehensive or afraid of being at home. Access to medical professionals and fear of the unknown or an unexpected emergency were also expressed.<br><br>The authors cite extracts which demonstrate the interplay between different contextual factors which influenced women's preferences. For instance, women who had had a baby before, who had support at home and lived close to the hospital were more likely to express positive views about outpatient induction labour. Furthermore, the authors provide evidence to demonstrate how the participants navigate these contextual factors in relation to birth as a natural or medical event – for instance, lack of support at home was considered less of an issue for someone living close to the hospital. |
| Is there a clear statement of findings? | Yes<br><br>The authors state there was a clear preference for outpatient induction of labour, yet they also note the influence and tension between the opposing cultural ideologies of a 'natural' versus a 'medicalised' birth. The authors relate this wider evidence to their own findings. While outpatient induction of labour affords women with more homely comforts, inpatient induction is associated with greater perceived safety and access to monitoring. |
| How valuable is the research? | Women's preferences around outpatient induction of labour are complex and context-dependent. The authors clearly state the implications for practice which include making the hospital environment more homely and allowing partners to stay, while establishing clear expectations around the minimal nature of professional input and monitoring during |

| | |
|---|---|
| | the induction period. For those going home, the authors state that ensuring telephone support and providing written information is key. The authors suggest further research is needed to determine the transferability of the data to other settings (Polit and Beck 2006). |

Rauf *et al.* (2011) – CASP-UK Cohort Study Checklist (Critical Appraisal Skills Programme, 2013)

| | |
|---|---|
| Did the study address a clearly focused issue? | Yes<br><br>Many clinicians remain concerned about ongoing assessment of fetal wellbeing during OPIOL with vaginal dinoprostone. Study to determine feasibility of remote wireless trans-abdominal fetal monitoring in terms of signal quality, clinical outcomes and women's views, satisfaction and comfort. |
| Was the cohort recruited in an acceptable way? | Unclear how women were approached to participate although ethical approval given for study.<br><br>Cohort selection was appropriate i.e., women at low risk of complications were recruited to the OPIOL phase of the study. |
| Was the exposure accurately measured to minimise bias? | • Feasibility study not a comparison study. Authors acknowledge that a RCT would be needed to compare OPIOL with and without remote fetal monitoring versus inpatient management. However, large sample would be needed to measure significant differences due to rare adverse outcomes.<br>• As feasibility study rather than RCT no blinding of participants/clinicians which can introduce bias.<br>• Potential design bias as research funded by pharmaceutical company and the company supplying the fetal ECG monitor.<br>• 104 women at low risk of complications gave consent to participate, of whom 70 underwent OPIOL.<br>• Eligibility clearly described i.e., low risk pregnancy, intact membranes, Bishop score <6, normal fetal monitoring for 60 minutes after insertion of vaginal dinoprostone pessary, birthing partner at home, access to telephone and transport, living within 60 minutes or less journey time.<br>• Intervention clearly described i.e., 30 minutes of simultaneous standard fetal CTG monitoring with wireless fetal ECG recording, insertion of controlled-release vaginal dinoprostone (10mg) pessary then a further 60 minutes recording prior to removal of standard CTG leaving fetal ECG monitor in situ. |

| | |
|---|---|
| Was the outcome accurately measured to minimise bias? | • Signal loss – measurement bias minimised by using an objective measurement based on the transmission received and recorded by the hospital computer. In addition, targets pre-defined for successful monitoring (>70% of the time during the day and 80% at night).<br>• Qualitative assessment recorded 2 hourly during the OPIOL process – women's ratings recorded on 4 point scale of how well they were coping, comfort and satisfaction. Location preference was also stated at each data entry point. Recording this throughout the process may have reduced recall bias as completed at the time rather than after the event (Jones and Rattray, 2015). It is unclear whether a validated tool was used.<br>• Free-text data was also collected and interpreted using thematic analysis which is an appropriate method. Authors can enhance validity using investigator triangulation i.e., by independently coding the data and resolving any differences by discussion . It is unclear whether this was carried out. |
| Have the authors identified all important confounding factors? List the ones you think might be important that the author missed. | No applicable as no comparison. |
| Have they taken account of the confounding factors in the design and/or analysis? | Not applicable as no comparison. |
| Was the follow up of subjects complete enough? | Yes |
| Was the follow up of subjects long enough? | Yes |
| What are the results of this study | • 62/70 (89%) of women successfully monitored at home<br>• 1 hour 55 mins – 22 hours and 4 minutes range successful recording time (median 10 hours 35 mins)<br>• 86% of total home monitoring time per woman successfully recorded<br>• 6/70 (11%) of women had prolonged episodes of signal loss |

| | |
|---|---|
| | • 3/70 (4%) developed non-reassuring fetal heart rate patterns, 2 born by caesarean section with normal Apgar and arterial cord pH values. The third trace normalised.<br>• 2 cases mild hyperstimulation at home where contractions more than 5:10 minutes. In one case, contractions normalised. The other came to hospital, had a further pessary to replace one which had fallen out. Later vaginal birth with Apgar of 6 at 5 mins and normal arterial cord pH.<br>• 2 cases low Apgar.<br>• Signal strength outcomes<br>• Clinical outcomes<br>• Of 70 women who underwent OPIOL, 51 diaries returned.<br>• 19/51 coped well, 29/51 coped very well. 3/51 coped less well – reporting difficulties with monitoring device or lack of feedback of progress in labour from hospital.<br>• 26/51 felt comfortable, 20/51 felt very comfortable wearing the device.<br>• 21/51 satisfied, 25/51 very satisfied with monitoring – comments suggesting feedback from hospital influenced this.<br>• 47/51 stated home as location preference at each data entry point.<br>• 22/51 expressed some concern at specific time points mainly relating to signs of labour or issues with monitoring.<br>• Expression family support, familiar environment. |
| How precise are the results? | Standard deviation reported for monitoring success rate |
| Do you believe the results? | Yes |
| Can the results be applied to the local population? | Unclear<br><br>Demographic characteristics not stated |
| Do the results of this study fit with other available evidence? | Novel study |
| What are the implications of this study for practice? | Some technical issues faced when using remote monitoring during OPIOL and would require significant investment. Study suggests may be feasible once technology improves. |

Sutton, Harding and Griffin (2016) – survey critical appraisal checklist (Best Evidence Topics, 2018)

How do you rate this paper? 7/10

6.0 OBJECTIVES AND HYPOTHESES

| | |
|---|---|
| 1.1 Are the objectives of the study clear stated? | Yes<br><br>To assess attitudes and opinions towards OPIOL in women undergoing inpatient IOL with vaginal dinoprostone as well as foley catheter balloon. |

7.0 DESIGN

| | |
|---|---|
| 2.1 Is the study design suitable for the objectives? | A prospective survey of women's attitudes and opinions before, during and after IOL as part of a quality improvement project.<br><br>Surveys are also a low cost way of obtaining people's views compared to interviews (Hasson, McKenna and Keeney, 2015) |
| 2.2 Who/what was studied? | Women undergoing IOL between June 2014 and August 2014. |
| 2.3 Was this the right sample to answer the objectives? | Yes, in the absence of women undergoing OPIOL. |
| 2.4 Did the subject represent the full spectrum of the population of interest? | No<br><br>Also included women at high risk of complications whose views may be biased towards inpatient management. |
| 2.5 Is the study large enough to achieve its objectives? Have sample size estimates been performed? | No<br><br>A quality improvement project. |
| 2.6 Were all the subjects accounted for? | No<br><br>• Questionnaires distributed in non-consecutive manner to women undergoing IOL. The authors acknowledge this means there may have been sampling bias in terms of how questionnaires were |

| | |
|---|---|
| | distributed – and not all women would have had an opportunity to take part.<br>• Similarly, some women lost to follow up – with the second and third part of the questionnaire not completed in 44% and 42% of cases respectively. |
| 2.7 Were all appropriate outcomes considered? | Question 2 – attitudes towards OPIOL<br><br>49.1% unhappy versus 33.3% happy at start of process (57 respondents)<br><br>46.9% unhappy vs 25% happy after cervical ripening but before labour (32 respondents)<br><br>45.5% unhappy vs 33.3% happy after birth (33 respondents)<br><br>The others were equivocal<br><br>The question about how calm and stress free women felt about being in hospital is not a relevant outcome as women were undergoing inpatient IOL. It cannot be used to infer how calm and stress free women might feel having OPIOL.<br><br>46.6% reported feeling calm and stress free before IOL<br><br>53.1% after cervical ripening but before labour<br><br>36.4% after birth<br><br>There was a question about whether women's social circumstances would make them worried about OPIOL. 29.5% (15) reported it would. |
| 2.8 Has ethical approval been obtained if appropriate? | Hospital governance approval as quality improvement project. |
| 2.9 What measures were made to contact non-responders? | Not stated |
| 2.10 What was the response rate? | 57/72 questionnaires completed.<br><br>100 of those women completed part A<br><br>56% completed part B<br><br>58% completed part C |

8.0 MEASUREMENT AND OBSERVATION

| | |
|---|---|
| 3.1 Is it clear what was measured, how it was measured and what the outcomes were? | Unclear<br><br>Entire questionnaire not included |
| 3.2 Are the measurements valid? | No<br><br>A visual analogue scale is a good way to quantify views that are more subjective such as satisfaction or pain (Griffiths and Rafferty, 2015). The visual analogue scale has no scale which enhances the validity of the score because the participant is not likely to be influenced by the increments. However, in this study the visual analogue scale had 1cm increments. There is also likely to be additional bias due to the small number of participants meaning the results may not be generalisable elsewhere. |
| 3.3 Are the measurements reliable? | Yes<br><br>A simple questionnaire that is likely to obtain similar results if conducted again (Jones and Rattray, 2015). |
| 3.4 Are the measurements reproducible? | Yes<br><br>The methods and procedure are clearly stated meaning it would be possible to reproduce the same results again. For instance, interpretation of the visual analogue scale was as follows:<br><br>0-3cm (unhappy)<br><br>>3-7cm (equivocal)<br><br>>7cm (happy) |

9.0 PRESENTATION OF RESULTS

| | |
|---|---|
| 4.1 Are the basic data adequately described? | No |

| | |
|---|---|
| | The authors state there were 14 questionnaire items but not all reported in the results.<br><br>Percentages were reported but natural frequencies were not making interpretation of the results difficult in terms of potential bias introduced by the small number of responses received. |
| 4.2 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement? | No |
| 4.3 Are the results internally consistent, i.e., do the numbers add up properly? | Unclear<br><br>As described above. |

10.0 ANALYSIS

| | |
|---|---|
| 5.1 Are the data suitable for analysis? | Yes |
| 5.2 Are the methods appropriate to the data? | Yes |
| 5.3 Are any statistics correctly performed and interpreted? | Yes<br><br>Simple descriptive statistics used. Calculations appear correct. |

11.0 DISCUSSION

| | |
|---|---|
| 6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives? | No<br><br>Authors discuss findings of other research about women's satisfaction with OPIOL using balloon catheters (Henry *et al.*, 2013) or vaginal dinoprostone (Howard *et al.*, 2014).<br><br>It would be helpful to discuss how these findings are similar or contrast with their own findings.<br><br>The authors then discuss a study relating to cost of OPIOL and a study of women's satisfaction with inpatient IOL using balloon |

| | |
|---|---|
| | catheters. Discussion is rather confusing in this respect as study relates to OPIOL. |
| 6.2 Is the discussion biased? | No but this is because the discussion appears not to integrate their own findings in the wider research context.<br><br>The authors do not discuss the relevance of their findings and whether OPIOL is acceptable to women or not. |
| 6.3 Can the results be generalised? | No |

7.0 INTERPRETATION

| | |
|---|---|
| 7.1 Are the authors' conclusions justified by the data? | No<br><br>The conclusion seems to be positive about OPIOL while only a third of women would consider this method of IOL. |
| 7.2 What level of evidence has this paper presented? (using CEBM levels) | 2c outcomes research i.e., audit/evaluation |
| 7.3 Does this paper help me answer my problem? | No – lack of in depth consideration of women's views about OPIOL.<br><br>41/57 (72%) women underwent IOL with catheter balloon<br><br>8/57 (14%) with balloon and vaginal dinoprostone<br><br>2/57 (3.5%) with vaginal dinoprostone only<br><br>This study cannot be readily applied to finding out more about women's views of OPIOL with prostaglandins only. |

How do you rate this paper now? 3/10

Turnbull *et al.* (2013a) – CASP-UK qualitative research checklist (Critical Appraisal Skills Programme, 2013)

| | |
|---|---|
| Was there a clear statement of the aims of the research? | Yes<br><br>The aim of the study is stated clearly: to determine whether outpatient induction of labour increases anxiety or satisfaction levels when compared to inpatient management.<br><br>The authors cite the previous NICE guideline (National Collaborating Centre for Women's and Children's Health, 2008) which emphasises the need for studies which take into account women's views as well as outcomes in terms of safety and efficacy of outpatient management. The authors also highlight the relevance of this kind of research because of the increasing numbers of women undergoing induction of labour. |
| Is a qualitative methodology appropriate? | Yes<br><br>Questionnaires are a relatively inexpensive, quick and convenient way to systematically gather information about people's knowledge, attitudes, behaviour and beliefs (Cluett and Bluff 2006; Jones and Rattray 2015). Questionnaires do have limitations, however, and will not capture the same richness of data that semi-structured interviews will. Participants' recall, desire to give socially desirable responses, and post-hoc information gathering, particularly when those approached had favourable outcomes are all potential sources of bias to consider (Jones and Rattray 2015). |
| Was the research design appropriate to address the aims of the research? | The study involved both an enrolment questionnaire to determine women's anxiety levels at the outset as well as a post-intervention questionnaire given 7 weeks after birth to determine satisfaction, experience and the Edinburgh Postnatal Depression Scale.<br><br>The enrolment questionnaire was used to determine whether there was any difference in anxiety levels between women managed as inpatients and outpatients before the intervention was carried out. Validated scales were used: the Hospital Anxiety and |

| | |
|---|---|
| | Depression Scale, part of the Multiple Affect Adjective Check-list examining anxiety, and a 100mm linear analogue scale. Using previously validated scales may improve the validity of the findings although caution should be exercised when applying a scale developed and validated for use in one setting and applying it in another potentially very different setting (Jones and Rattray 2015).<br><br>No significant difference was found in anxiety levels in the enrolment questionnaire despite the women knowing at that point whether or not they were randomised to the outpatient group.<br><br>The postpartum questionnaire was sent to 819 participants seven weeks after birth including those women who did not actually receive the intervention. The questionnaire was not sent to two women who had had a poor pregnancy outcome. While there were good ethical reasons not to include these women, this is an example of how bias may be introduced when using questionnaires.<br><br>The postpartum questionnaire was adapted from one previously validated for use to assess differences in women's satisfaction about choice, information, decision-making and individualised care differences between midwife-led and obstetric-led care models (Turnbull 1996). As the questions were quite general e.g., '*I feel I get too little information*' it seems appropriate to have adapted this questionnaire. Furthermore, the reliability of the items in the adapted questionnaire was examined again using the Cronbach alpha test in this new context (Rattray and Jones).<br><br>Two of the questions were only relevant to the outpatient group and so it was appropriate that they were asked of only those women who received the intervention: '*I was worried that I would not make it back to hospital in time*' and '*I was worried about how long I should wait at home*'. |
| Was the recruitment strategy appropriate to the aims of the research? | Yes |

| | |
|---|---|
| | The authors explain clearly how the participants were recruited as part of a randomised controlled trial. In addition, they used both the intention to treat and the per protocol participants to analyse their results although do not display both sets of analyses in their paper. |
| Was the data collected in a way that addressed the research issue? | Yes<br><br>Questionnaires are a convenient and effective way to gather lots of data about a large group of people relatively quickly (Jones and Rattray).<br><br>The first questionnaire was given to women at enrolment, and the postpartum one was mailed to participants seven weeks after birth with telephone reminders to non-respondents. This ensured a response rate of 76 per cent which is considered to be good rate (Cluett and Bluff 2006).<br><br>The design of the second postpartum questionnaire was adapted and the items checked for their internal consistency in terms of how well they measured the same concept using the Cronbach alpha test. This statistical method improves the reliability of questionnaires (Jones and Rattray 2015). |
| Has the relationship between researcher and participants been adequately considered. | As with other questionnaires, results can be biased. For instance, participants may struggle to recall events accurately, their answers may be influenced by the outcome or they may give what they perceive to be socially desirable responses (Jones and Rattray 2015). However, the authors purposefully chose both positively and negatively phrased questions to avoid acquiescent response bias (Rattray and Jones 2007). |
| Have ethical issues been taken into consideration? | Yes<br><br>Ethical approval was sought appropriately. Furthermore, the authors state that women with a score of 12 or above on the Edinburgh Postnatal Depression Scale were reviewed by the research midwife and an appropriate referral made if required. |
| Was the data analysis sufficiently rigorous? | Unclear |

| | |
|---|---|
| | While the authors state appropriate statistical methods were used to detect whether there were significant differences between the characteristics of inpatients and outpatients, these are not always clear in the data tables themselves where mainly percentages are illustrated but *p* values to quantify the significance are not.<br><br>The results of the postpartum questionnaire show the differences between the mean score of outpatients and inpatients for each of the psychosocial outcome subscales, as well as standard deviation to show the range of responses. To illustrate the differences between inpatients and outpatients, the authors make appropriate use of the mean difference in values alongside a 95% confidence interval. This makes significance clear, as well as describing the strength or influence of the factor under consideration (Cluett and Bluff 2006).<br><br>The results showed significantly improved scores for outpatients for the following subscales: 'social support', 'self-efficacy', 'readiness', 'stress', 'control', 'information' and 'safety'. 'Environment' and 'general satisfaction' were not significantly different. While the main results appear to be an analysis of the questionnaire findings of the intention to treat participants, the per protocol analysis is not detailed. The authors only comment that the effect size was stronger in general, although they state that 'information' and 'general satisfaction' subscales were not significant, yet the 'environment' subscale presumably was although they do not explicitly say so.<br><br>Women who received the intervention were not concerned about getting back to hospital on time (66%). The authors state that in the main, participants were not worried about how long to stay at home although it could be argued that with 29% unsure or in agreement with that statement, that is a sizeable proportion of participants who did have some uncertainty about being in an outpatient setting. Such an overstatement is a potential source of bias. |

| | |
|---|---|
| Is there a clear statement of findings? | Yes<br><br>The authors clearly state that there was no difference in anxiety levels amongst women randomised to the outpatient group when compared to those in the inpatient group. This reassures the authors that the concept of outpatient induction of labour should not cause women undue anxiety.<br><br>They also state their findings demonstrate a small but significant difference in most of the subscales used to assess satisfaction favouring outpatient induction in line with other research evidence. |
| How valuable is the research? | On balance, the authors perhaps rather over-state that their study demonstrates that women favoured outpatient management. |

Turnbull *et al.* (2013b) – survey critical appraisal checklist (Best Evidence Topics, 2018)

How do you rate this paper? 8/10

12.0 OBJECTIVES AND HYPOTHESES

| | |
|---|---|
| 1.1 Are the objectives of the study clear stated? | Yes<br><br>To determine the extent to which the introduction of OPIOL affected midwives' workload, stress levels and job satisfaction. |

13.0 DESIGN

| | |
|---|---|
| 2.1 Is the study design suitable for the objectives? | No<br><br>I'm not sure work demands, stress and job satisfaction can be adequately be assessed in a questionnaire.<br><br>Questionnaires are a relatively inexpensive, quick and convenient way to systematically gather information about people's knowledge, attitudes, behaviour and beliefs (Cluett and Bluff 2006; Jones and Rattray 2015). Questionnaires do have limitations, however, and will not capture the same richness of data that semi-structured interviews will. Participants' recall, desire to give socially desirable responses, and post-hoc information gathering, particularly when those approached had favourable outcomes are all potential sources of bias to consider (Jones and Rattray 2015). |
| 2.2 Who/what was studied? | Midwives |
| 2.3 Was this the right sample to answer the objectives? | Yes - midwives involved in IOL process or subsequently taking care of women who had undergone OPIOL. |
| 2.4 Did the subject represent the full spectrum of the population of interest? | Not initially – group practice midwives did not receive the pre-trial questionnaire because there was uncertainty at the time whether they would be involved in the trial. They received |

| | |
|---|---|
| | the pre-trial questionnaire 2 months later, and then completed the post-trial questionnaire.<br><br>Midwives worked on the labour ward, midwifery group practice, outpatient assessment service and antenatal ward. |
| 2.5 Is the study large enough to achieve its objectives? Have sample size estimates been performed? | Yes<br><br>87/108 pre-trial questionnaires were completed<br><br>121/156 post-trial questionnaires were completed |
| 2.6 Were all the subjects accounted for? | Yes |
| 2.7 Were all appropriate outcomes considered? | Yes |
| 2.8 Has ethical approval been obtained if appropriate? | Yes |
| 2.9 What measures were made to contact non-responders? | Questionnaires were left in midwives' mailboxes. Midwives were given two to three weeks to respond. |
| 2.10 What was the response rate? | Response rate was 81% for pre-trial questionnaire.<br><br>Response rate was 78% for post-trial questionnaire.<br><br>A response rate of 75 % or more is considered good (Jones and Rattray, 2015). |

14.0 MEASUREMENT AND OBSERVATION

| | |
|---|---|
| 3.1 Is it clear what was measured, how it was measured and what the outcomes were? | Questionnaires were sent to midwives two weeks prior to the start of the trial. The post-trial questionnaire was sent to midwives two years later, near the end of the recruitment period. |
| 3.2 Are the measurements valid? | Derived from existing measures in studies of healthcare workers initially used amongst Dutch staff. Face validity checked by midwife researcher in study, then piloted on small sample of midwives. Modification of |

| | |
|---|---|
| | demographic section – last age category changed from '35+' to 'over 45'. |
| 3.3 Are the measurements reliable? | When designing questionnaires, bias can be reduced by including multi-item scales (Rattray and Jones, 2007). This reduces the likelihood that respondents misunderstand a single question and answer in an unexpected way. It is therefore important to ensure that each subpart of the questionnaire are consistent with, or in other words, truly reflect the concept of interest. This is calculated by splitting the items in half and comparing the scores which should be similar. If there is a discrepancy, this reflects that there is poor internal consistency and that the subparts do not reflect the concept of interest well (Polit and Beck, 2006). Cronbach's alpha is a more sophisticated way of performing this comparison as the subparts of the concept of interest are split in half and compared using every possible permutation. A questionnaire Cronbach alpha of 0.7 or above is thought to have good internal consistency (Rattray and Jones, 2007).<br><br>In the pre-trial questionnaire there were 10 questions related to 'work demands', 5 related to 'autonomy' and 1 question related to 'job satisfaction'. In the post-trial questionnaire there were 7 additional questions relating to satisfaction, stress, workload and 4 relating to midwives' experiences with outpatient induction.<br><br>Cronbach's alpha score for 'work demands' was >0.8. Cronbach's alpha score for 'autonomy' was undermined by two questions which were subsequently excluded leaving a score of 0.79. |
| 3.4 Are the measurements reproducible? | Test-retest reliability measures the stability of the attribute being measured over time when the questionnaire is administered to the same people again at a later date. The higher the test-retest reliability, the more reliable or stable the attribute of interest. Coefficients of 0.70 or above are satisfactory and 0.85 to 0.95 are ideal (Polit and Beck, 2006). The test-retest reliability in this study was at least 0.55. This suggests the test-retest reliability coefficient in |

| | |
|---|---|
| | this study was not satisfactory. However, it is important to note that attitudes towards attributes may change over time or be affected by experiences or moods. |

15.0 PRESENTATION OF RESULTS

| | |
|---|---|
| 4.1 Are the basic data adequately described? | Unclear.<br><br>Response rates, demographics, experience and workplace of the midwives were clearly described.<br><br>51% were over the age of 45 reflecting the ageing workforce.<br><br>A large majority (84%) had 10 or more years of hospital experience.<br><br>61% worked in the labour ward or birth centre.<br><br>Experience with outpatient priming was also clearly described with 69% being 'somewhat experienced' – performing one or fewer outpatient primings every two weeks.<br><br>10% were 'highly experienced'.<br><br>21% were 'not at all experienced'.<br><br>Job satisfaction, autonomy and demand scores were not clearly described. While the narrative describes fairly clearly percentages are not clearly displayed and are spread between the results and discussion section.<br><br>Summarised in results section using words like 'majority' and 'most' with no percentages e.g., Work demands – authors state majority responded they worked 'hard' or 'very hard'.<br><br>Autonomy – majority of responses fell into 'sometimes' to 'often'.<br><br>Satisfaction with job – most agreed or strongly agreed. |

| | |
|---|---|
| | It is not clear in the table how these scores were generated without referring back to the methods section.<br><br>• Work demands were scored between 10-50 with high score reflecting high demand (mean score=38.25 and 37.98 pre and post-trial).<br>• Autonomy was scored between 5 and 25 with a high score reflecting high autonomy (mean score =10.33 and 10.38 pre and post-trial).<br>• Scoring of satisfaction is not described so it is difficult to tell from the table alone how satisfied staff were (mean score=3.76 and 3.85 pre and post-trial). This makes it hard to compare the results in the table with what is described in the narrative.<br><br>Post-trial satisfaction, stress and workload summarised clearly in table 4:<br><br>• 93% of midwives felt outpatient priming had made no difference or improved their satisfaction. 2% decreased a little or a lot.<br>• 89% felt made no difference or decreased stress. 7% increased a little or a lot.<br>• 85% felt made no difference or decreased workload. 12% increased a little or a lot.<br><br>The authors describe that midwives who disagreed were in work areas where outpatient priming was an additional task for them. This data is not summarised in a table.<br><br>I would argue it would be more pertinent to look at outcomes by experience levels of midwives with outpatient priming rather than work area. If those more experienced in outpatient priming/performing them more regularly were critical then this would have more significant. |
| 4.2 Are the results presented clearly, objectively and in sufficient detail to enable readers to make their own judgement? | Yes. While it is difficult to interpret what the scores actually mean, it is clear to see there |

| | |
|---|---|
| | were no significant changes over time between pre and post-trial questionnaires. |
| 4.3 Are the results internally consistent, i.e., do the numbers add up properly? | Unclear. As stated above it would have been valuable to express the distribution of responses on the 5-point Likert scales prior to calculation of the mean and standard deviation. |

16.0 ANALYSIS

| | |
|---|---|
| 5.1 Are the data suitable for analysis? | Yes |
| 5.2 Are the methods appropriate to the data? | Interval measurement allows authors to rank objects within the scale and quantify the difference between items on the scale. This allows further statistical analysis and calculation of the average and is used in many educational and psychological tests (Polit and Beck, 2006). In this way, by applying parametric tests to a Likert scale whose ordinal data has been converted to a score it is argued that it is possible to calculate the average of 'never' 'sometimes' and 'always'. This works best when there is a normal distribution of data and an adequate sample size (Sullivan and Artino, 2013).<br><br>However, others argue it is better to report the frequencies in each category and use non parametric tests for analysis.<br><br>A review by Norman (2010) suggests that the former approach is possible. |
| 5.3 Are any statistics correctly performed and interpreted? | Yes although some midwives left and others joined before the post-trial questionnaire was administered which may have introduced random effects. Using a linear mixed model, it was possible to adjust for changes in demographics and work unit it was possible to interpret the impact of outpatient priming on midwives in terms of their satisfaction, autonomy and work demand. |

17.0 DISCUSSION

| | |
|---|---|
| 6.1 Are the results discussed in relation to existing knowledge on the subject and study objectives? | Yes<br><br>Set in context of other studies that show initial drop in satisfaction with new working practices. Otherwise this research is first to review impact of outpatient priming on midwifery practice. |
| 6.2 Is the discussion biased? | Authors acknowledge no change could be due to 21% who reported not involved in procedure. |
| 6.3 Can the results be generalised? | This study reflects general views of outpatient priming including midwives who do not perform this practice frequently. This means that the findings of this study should not be generalised to other settings in which midwives work exclusively in induction of labour suite. |

7.0 INTERPRETATION

| | |
|---|---|
| 7.1 Are the authors' conclusions justified by the data? | Yes, although it is not explicitly clear how midwives with main responsibility for outpatient priming feel versus the rest of the staff who perform this clinical task less frequently. |
| 7.2 What level of evidence has this paper presented? (using CEBM levels) | Questionnaires are used to make inferences about the wider population but cannot be used to establish cause and effect. In view of this, they are not high in the CEBM hierarchy. |
| 7.3 Does this paper help me answer my problem? | No<br><br>While the study found 97% of midwives were in favour of outpatient priming, it is not explicitly clear how midwives' workload and stress levels were affected as the sample included staff who did not perform the task regularly. More qualitative data is required to explore the discrepancy between attitudes towards |

| | |
|---|---|
| | outpatient priming and how this plays out in clinical practice. |

How do you rate this paper now? 6/10

Survey (including pre-test probabilities) checklist (http://BestBETs.org/ca/pdf/survey.pdf)

# Appendix IX Summary critique of full papers

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| **Awartani, Turnell and Olatunbosun (1999)**<br><br>Prospective non-randomised study to compare birth outcomes of outpatient and inpatient management as well as duration of stay and maternal satisfaction. | • No differences in mode of birth, induction to active labour interval, induction to birth interval and neonatal unit admission between outpatient and inpatient groups.<br>• Women managed as outpatients more likely to require oxytocin augmentation (54% versus 34%; p=0.043).<br>• Length of stay longer for inpatients versus outpatients (3.4 ± 1.2 days versus 2.8 ± 0.9 days; p=0.004)<br>• No women experienced abruption, hyperstimulation or systematic side effects.<br>• Greater patient satisfaction in outpatient group (96% versus 56%; p<0.0001). | Strengths<br><br>• Early evaluation of outpatient induction of labour.<br>• Consideration of patient satisfaction.<br><br>Weaknesses<br><br>• Small study with 100 participants overall.<br>• Outpatients were recruited from one hospital, the inpatients were from another. Authors acknowledge clinical practice may have varied between sites which could have affected outcomes (e.g., around use of oxytocin augmentation).<br>• Although not significant, there were more primigravid women in inpatient group versus outpatient (62% versus 46%). This may have had an impact on need for augmentation and other outcomes as labour tends to be shorter amongst multiparous versus nulliparous women. In addition, it is likely that parity has a bearing on women's experience of labour.<br>• Bishop score of women managed as inpatients significantly less favourable than that of women managed as |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | | outpatients (3.26 ± [1.59] versus 4.22 ± [1.21]; p=0.001). No statistical adjustment for this which means difficult to compare outcomes.<br>• Unclear what tool used to measure patient satisfaction. |
| **Biem *et al.* (2003)**<br><br>A randomised controlled trial to compare birth outcomes of outpatient and inpatient management as well as duration of stay, time avoided in hospital and maternal satisfaction. Controlled-release vaginal dinoprostone pessary (10mg).<br><br>Women undergoing OPIOL had a reassessment 12 hours after the start of the process and were discharged again if appropriate and readmitted after 24 hours. | • No differences in time to labour/birth within 24 hours, epidural, hyperstimulation, oxytocin augmentation, mode of birth and neonatal outcomes between outpatient and inpatient groups.<br>• Rates of tachysystole or hypertonus were 10% in each group.<br>• Significantly higher levels of satisfaction in initial 12 hours amongst outpatient group (56% versus 39%; p=0.008).<br>• No differences in satisfaction overall or median pain in first 12 hours or anxiety in first 12 hours.<br>• Time avoided in hospital by outpatient group = 8 hours (95% CI 6.7 to 9.4) although overall length of stay not significantly different. | Strengths<br><br>• 300 participants randomised increases generalisability of findings.<br>• Randomisation completed after administration of pessary. This reduced drop out of participants and meant the intention to treat analysis was likely to reflect the reality of how the patients were managed.<br>• Define hyperstimulation and hypertonus clearly and differentiate between hyperstimulation both with and without non-reassuring fetal heart rate changes.<br>• During IOL process, satisfaction, pain and anxiety measured 4 hourly using automated computer based interview using telephone keypad to avoid interviewer bias. Woman also recorded score between 0 and 9 in a diary.<br><br>Weaknesses<br><br>• Authors acknowledge difficult to determine whether statistical |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | | differences in satisfaction are clinically significant.<br>• 1 day postpartum, women rated overall satisfaction using visual analogue scale. This is a good way to quantify views that are more subjective such as satisfaction or pain (Griffiths and Rafferty, 2015). Typically, a visual analogue scale has no scale which enhances the validity of the score because the participant is not likely to be influenced by the increments. However, in this study, a 10-point scale is described. |
| **Coates *et al.* (2021)**<br><br>Qualitative study of women's experiences of OPIOL with dinoprostone pessary or balloon catheters using thematic analysis of semi-structured interviews. Transcripts coded and analysed using a thematic framework approach. Part of a wider feasibility study to compare methods of OPIOL. | Two key themes identified – ownership of induction of labour and importance of place.<br><br>**Ownership of induction of labour**<br><br>• Understanding of the induction process was limited<br>• Choice and control in labour and birth – mixed findings. Some felt more in control by deciding to participate, others felt they had no choice about induction.<br>• Experience of method of induction (new sub-theme) – pessary seen as medicalised option, balloon seen as natural option – although women unprepared for having end of balloon catheter left protruding. Future | Strengths<br><br>• Recruitment of 21 participants is appropriate for methodology.<br>• An existing conceptual framework was used to guide coding and analysis of the data. This had been generated by systematic review and thematic synthesis of existing peer-reviewed literature about women's experiences of induction of labour.<br>• Peer review of coding was also conducted by two other authors on a subsample of interviews.<br>• Verbatim excerpts used which increase confirmability of identified themes.<br>• Disconfirming evidence enhances credibility of findings – e.g., some felt they had no choice about |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | preference for balloon in both groups.<br>• Further intervention (new sub-theme) – two thirds of women required oxytocin – seen as inevitable.<br>• Experience of pain management – four of 14 women who received pessary reported rapid onset of very strong contractions.<br><br>**Importance of place**<br><br>• Enduring the hospital – lack of privacy in hospital versus being able to do usual activities at home.<br>• Keeping to established rhythms at home. However, some concerns if pessary or balloon displaced at home or uncertainty about whether pain was 'normal'.<br>• Transition between home and hospital (new) – journey time not a concern as within 30 minutes. Frustrations around parking and admission process. | induction. In addition, women had different experiences of pain during induction and subsequent labour and for some it was bearable.<br><br>Weaknesses<br><br>• Purposive sampling was intended but not used due to low recruitment to the feasibility trial and so all participants were invited to take part in the interviews. The authors acknowledge this could bias the findings as balloon induction was not usually available and so participants may have been motivated to experience that method of induction which could bias findings.<br>• The authors note no new themes were identified in the final interviews and tentatively suggest saturation was reached although this can be difficult to assess rigorously and its usefulness can be overstated (Braun and Clarke, 2019). |
| **Howard *et al.* (2014)**<br><br>Discrete choice experiment to determine women's preferences around setting for induction of labour. Options included own home, basic inpatient care and enhanced inpatient care. Vaginal dinoprostone gel (2mg for nulliparous women, 1mg for multiparous women). | Own home preferred over basic inpatient care by:<br><br>• All women (OR 1.771; 95% CI 1.445 to 2.178; p<0.0001).<br>• Women with university or college degree (OR 1.570; 95% CI 1.150 to 2.155; p=0.0052).<br>• Women in first pregnancy (OR 2.325; 95% CI 1.703 to 3.190; p<0.00001). | Strengths<br><br>• Only retrieved study to assess number of trips and travelling time women prepared to travel to have OPIOL as well as women's preferences.<br><br>Weaknesses |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | • Age (per year) (OR 1.094; 95% CI 1.061 to 1.128; p<0.00001).<br><br>Basic inpatient care over own home preferred by:<br><br>• Non-English speaking background (versus English speaking) (OR 0.145; 95% CI 0.105 to 0.201; p<0.00001)<br>• Previous history of obstetric led care (OR 0.443; 95% CI 0.331 to 0.594; p<0.00001)<br>• Previous experience of induction (OR 0.633; 95% CI 0.465 to 0.865; p-0.0041).<br>Number of trips and travel time<br>• Women willing to accept an extra 1.42 trips to hospital (2.42 trips total) and travel time of 30.6 minutes per trip to have OPIOL. | • Included 260 OPRA participants as part of 7 week postnatal questionnaire. However approximately half did not undergo IOL process which may have influenced responses. Outcome and recall bias at play for those who did undergo IOL.<br>• Study also included 102 pregnant volunteers. Their views found not differ from OPRA participants – perhaps due to hypothetical nature of questions for pregnant participants and half of the OPRA participants not requiring IOL.<br>• Choices of IOL settings may not translate well to other hospitals limiting generalisability of findings (e.g., own home; single room with private bathroom, midwife known to woman, doctor on site; twin room with shared bathroom, midwife not known to woman, doctor not on site) |
| **O'Brien *et al.* (2013)**<br><br>Qualitative study of women's experiences of OPIOL with remote fetal monitoring using thematic analysis of semi-structured interviews. Sibling study to Rauf *et al.* (2011). | Themes identified<br><br>Labour within their comfort zone<br><br>• Physical comforts of familiar surroundings<br>• Emotional and physical relaxation<br>• Carrying on everyday activities<br>• Freedom of movement | Strengths<br><br>• Sample size of 15 appropriate for this methodology.<br>• Systematic, thematic analysis of transcripts by reading and re-reading, developing codes and collation of overarching themes (Braun and Clarke, 2006). |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | • Sense of control over environment and movement<br>• Support available<br>• Childcare arrangements<br>• Hospital environment – noise, lack of privacy, limited movement, lack of sleep, busy staff/being a burden<br><br>The next best thing to a normal labour<br><br>• Disappointment that not spontaneous labour<br>• Uncertainty about what to expect<br>• Coping in their own way<br>• Approximating a normal labour experience<br>• Control<br><br>The importance of a virtual presence<br><br>Impressed with technology<br><br>• Better monitoring (constant) versus hospital (intermittent and performed multiple times)<br>• Concern over adequacy of monitoring/confidence in staff<br>• Importance of ongoing communication throughout, especially nulliparous women | • Interpreter bias reduced by triangulating findings between two researchers to ensure consensus of themes identified.<br>• Audit trail of decision-making maintained.<br><br>Weaknesses<br><br>• Consent procedures are not clearly stated but ethical approval was granted for the study which would have demanded these procedures to be clearly outlined.<br>• Similarly, the ethical approval process would have required clarity about the measures the researchers had put in place to ensure consideration was given on preventing harm for instance if the participant was identified as being at risk of self-harm (Tod, 2015).<br>• It is not clear when the interviews take place, but the ethical review process would have asked the researchers to consider what timeframe after the birth would be appropriate.<br>• The authors acknowledge the potential cognitive bias or 'halo effect' which may have meant women had an enhanced view of the OPIOL experience having returned home in the postnatal period with a healthy baby. |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| **Oster *et al.* (2011)**<br><br>To explore women's preferences and experiences of outpatient and inpatient management. Vaginal dinoprostone gel (2mg for nulliparous women, 1mg for multiparous women). | • Themes identified: comfort and safety and how women balanced these.<br>• Familiarity of home versus more clinical environment in hospital. Greater social support on offer, more relaxing.<br>• Hospital seen as place of safety versus uncertainty about process and apprehension faced at home. Closer to staff, availability of monitoring. Some women found telephone support acceptable.<br>• Balancing tensions between comfort and safety depended on contextual factors e.g., experience of having had baby before, availability of support, distance from hospital, risk status of pregnancy.<br>• Contextual factors impacted how women navigated between birth as natural process versus medicalised one. | Strengths<br><br>• Sample size of 16 appropriate for this methodology – 7 women managed as outpatients and 9 managed as inpatients.<br>• Maximum variation purposive sample to ensure range of views expressed based on age, parity, language, education and type of birth.<br>• State data saturation achieved but not clear how.<br>• Verbatim excerpts used which increase confirmability of identified themes.<br>• Disconfirming evidence enhances credibility of findings – e.g., one woman preferred hospital as helped her avoid childcare commitments and get more rest.<br><br>Weaknesses<br><br>• Interviews 7 weeks to 4 months after birth which may have influenced recall.<br>• Childcare commitments may have curtailed some of the discussions which may have undermined the validity to a degree.<br>• Authors acknowledge views of outpatient management likely to be favourable as taken from sample who accepted this approach. |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | | • Investigator triangulation not used to check the codes and themes identified in the transcriptions which may undermine credibility and trustworthiness of findings. |
| **Rauf *et al.* (2011)**<br><br>Feasibility of OPIOL with remote fetal monitoring which also included evaluation of women's views. Data collected using semi-structured, self-report diary which was completed at least 2-hourly. 51 completed diaries collected. Sibling study to O'Brien *et al.* (2013). | Home monitoring<br><br>• 62/70 (89%) of women successfully monitored at home<br>• Successful remote recording time ranged between 1 hour 55 mins – 22 hours and 4 minutes range (median 10 hours 35 mins)<br>• 86% of total home monitoring time per woman successfully recorded<br>• 6/70 (11%) of women had prolonged episodes of signal loss<br>• 3/70 (4%) developed non-reassuring fetal heart rate patterns, 2 born by caesarean section with normal Apgar and arterial cord pH values. The third trace normalised.<br>• 2 cases mild hyperstimulation at home where contractions more than 5:10 minutes. In one case, contractions normalised. The other came to hospital, had a further pessary to replace one which had fallen out. Later vaginal birth with Apgar of 6 at 5 mins and normal arterial cord pH.<br>• 2 cases low Apgar. | Strengths<br><br>• Qualitative assessment of women's coping, comfort and satisfaction recorded prospectively every 2 hours during the OPIOL process. Location preference was also stated at each data entry point. Recording this throughout the process likely to reflect women's views more accurately as completed at the time rather than after the event which would have introduced recall bias (Jones and Rattray, 2015).<br>• Free-text data was also collected and interpreted using thematic analysis which is an appropriate method.<br>• Signal loss – measurement bias minimised by using an objective measurement based on the transmission received and recorded by the hospital computer. In addition, targets pre-defined for successful monitoring (>70% of the time during the day and 80% at night). |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | Women's views<br><br>• Of 70 women who underwent OPIOL, 51 diaries returned.<br>• 19/51 coped well, 29/51 coped very well. 3/51 coped less well – reporting difficulties with monitoring device or lack of feedback of progress in labour from hospital.<br>• 26/51 felt comfortable, 20/51 felt very comfortable wearing the device.<br>• 21/51 satisfied, 25/51 very satisfied with monitoring – comments suggesting feedback from hospital influenced this.<br>• 47/51 stated home as location preference at each data entry point.<br>• 22/51 expressed some concern at specific time points mainly relating to signs of labour or issues with monitoring.<br>• Over 100 positive comments made. Expression family support, familiar environment, freedom, comfort.<br>• 34 comments made expressing some concerns e.g., lack of direct feedback from hospital about whether monitoring ongoing. | Weaknesses<br><br>• Small sample (70 underwent OPIOL). Larger sample and RCT needed to measure significant differences in rare adverse outcomes.<br>• Comparison study would have enabled comparison of views between OPIOL and inpatient management.<br><br>Weaknesses<br><br>• Demographic characteristics of women not stated so unclear whether findings generalisable in other settings.<br>• It is unclear whether a validated tool was used to measure women's coping, comfort and satisfaction.<br>• Authors can enhance validity using investigator triangulation i.e., by independently coding the data and resolving any differences by discussion (Creswell, 2013). It is unclear whether this was carried out. |
| **Sutton, Harding and Griffin (2016)**<br><br>Prospective questionnaire of women's attitudes and | • 57/72 (79%) response rate to questionnaire.<br>• 41/72 (72%) had foley catheter. | Strength<br><br>• Prospective design. |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| opinions towards outpatient induction of labour with balloon catheter and/or vaginal dinoprostone. Completed prior to commencement of process, after cervical ripening but before ongoing induction, and after birth but prior to discharge from hospital. | • Part A completed prior to commencement of IOL<br>• Completion after removal of foley catheter balloon but before commencement of labour<br>• Part C completed by all after birth<br>• 8/72 (14%) had foley catheter and vaginal dinoprostone.<br>• 2/72 (3.5%) had vaginal dinoprostone only.<br><br>Prior to starting IOL process:<br><br>• 33.3% felt happy about OPIOL.<br>• 46.6% felt calm and stress free.<br><br>When asked after cervical ripening but before commencement of labour:<br><br>• 25% felt happy about OPIOL.<br>• 53.1% felt calm and stress free (foley catheter in situ).<br>• 63% would choose this method again.<br>• 70% would recommend this method to a friend.<br><br>After giving birth:<br><br>• 33.3% felt happy about OPIOL when asked after giving birth.<br>• 36.4% felt calm and stress free.<br>• 45.5% would choose this method again.<br>• 57.6% would recommend this method to a friend.<br><br>• 29.5% felt social circumstances would | Weaknesses<br><br>• Authors acknowledge poor generalisability as single centre study.<br>• Acknowledge unable to generalise to women at low risk of complications as 28.1% being induced for diabetes, and 19.3% for hypertension. 14% being IOL for post-dates pregnancy.<br>• Potential non-responder bias as questionnaires not given to all women undergoing IOL.<br>• Potential bias as completed in hospital – respondents may have felt obliged to give desirable response (Jones and Rattray, 2015). |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | make them worried about OPIOL. | |
| **Turnbull *et al.* (2013a)**<br><br>Questionnaire to evaluate women's psychosocial outcomes of outpatient and inpatient management. Vaginal dinoprostone gel (2mg for nulliparous women, 1mg for multiparous women). | • Enrolment questionnaire showed no differences between OPIOL and inpatient group in anxiety or depression scales following enrolment into the trial i.e., randomisation to OPIOL did not increase anxiety.<br>• No statistical differences in depression scores or infant feeding.<br>• Favourable responses to OPIOL versus inpatient management for seven of nine subscales including social support, self-efficacy, readiness, stress, control, information and safety.<br>• *'I was worried that I would not make it back to hospital in time'* 23/146 respondents who went home agreed or strongly agreed (15.7%).<br>• *'I was worried about how long I should wait at home'* 45/143 respondents who went home agreed or strongly agreed (31.5%). | Strengths<br><br>• High response rate (enrolment questionnaire 99% response rate – 813/819, and postpartum questionnaire sent 7 weeks after birth 76% overall response rate – 620/819)<br>• Comparison of outpatient and inpatient protocol groups on intention to treat basis.<br>• Validated scales used in questionnaire to assess anxiety and depression (Hospital Anxiety Depression Scale, Multiple adjective anxiety checklist, Linear analogue anxiety scale, Edinburgh Postnatal Depression scale).<br>• Questionnaire items generated from previous study of semi-structured interviews of women having IOL.<br>• Cronbach alpha test to assess internal reliability of items in questionnaire addressing satisfaction and experiences of care.<br>• Positively and negatively phrased questions to avoid acquiescent response bias.<br>• Authors state there was onward referral for women with depression.<br><br>Weaknesses |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | | • Questionnaire sent to participants 7 weeks postpartum which may have introduced recall bias.<br>• Unsure whether the observed statistically significant differences between OPIOL and inpatient management are clinically significant.<br>• Limited detail on of impact of per protocol analysis. Authors state that effect size stronger.<br>• Authors state women not concerned about how long to wait at home when in fact 31.5% reported they were worried. |
| **Turnbull *et al.* (2013b)** | • 51% of respondents were over the age of 45 reflecting the ageing workforce.<br>• A large majority (84%) had 10 or more years of hospital experience.<br>• 61% worked in the labour ward or birth centre.<br>• Experience with outpatient priming was also clearly described with 69% being 'somewhat experienced' – performing one or fewer outpatient primings every two weeks.<br>• 10% were 'highly experienced'.<br>• 21% were 'not at all experienced'.<br>• In post-trial questionnaire when asked specifically about impact of OPIOL, most stated it had made no difference or improvement to | Strengths<br>• Only study exploring impact of OPIOL on staff.<br>• Use of existing measures in questionnaire that demonstrate good reliability and validity (Cronbach alpha coefficients equal to or higher than 0.75). Measures used to quantify autonomy, workload and satisfaction. Two questions relating to autonomy had poor reliability removed following testing.<br>• Questionnaire checked for face validity in Australian population as previously measures had been used in Dutch study.<br>• Response rate fairly good (81% - 87/108 for survey one and 78% - 121/156 for survey two). |

| Study and summary of aim | Main findings | Strengths and weaknesses |
|---|---|---|
| | satisfaction, stress and workload:<br>• 93% of midwives felt outpatient priming had made no difference or improved their satisfaction. 2% decreased a little or a lot.<br>• 89% felt made no difference or decreased stress. 7% increased a little or a lot.<br>• 85% felt made no difference or decreased workload. 12% increased a little or a lot.<br>• 97% responded that OPIOL should be offered to eligible women. | Weaknesses<br>• 15% of midwives responded to both surveys, 18% were unsure. This lack of continuity may undermine the reliability of the findings. However, the authors attempt to take staffing changes into account by adjusting for age group and work area.<br>• 21% of midwives had no experience in OPIOL yet post-trial questionnaire included 3 questions about how OPIOL affected midwives' satisfaction, stress and workload, and 4 questions about midwives' experience with OPIOL. This means that the findings of this study should not be generalised to other settings in which midwives work exclusively in induction of labour suite.<br>• Authors acknowledge that changes in midwives' satisfaction, workload and autonomy may not be related to OPIOL but other unrelated changes. |

# Appendix X Alternative philosophical approaches

The section describes alternative philosophical approaches I considered and why they were rejected.

At the outset of the research project, I initially intended to use mixed methods underpinned by a constructivist grounded theory approach described by Charmaz (2014). Charmaz' approach is recognised as a more flexible and pragmatic one than traditional grounded theory of Glaser and Strauss of the 1960s and 70s. Both approaches help researchers generate an over-arching theory based on themes that are 'grounded' or emerge from the collected data (Creswell, 2013 p. 85). However, Glaser in particular had a rigorous positivist background, and recommended that researchers avoid any engagement with background literature entirely prior to the commencement of the research (Holloway and Galvin, 2015b). He argued that by doing this, researchers would remain objective, neutral observers. In contrast, constructivist grounded theory recognises that qualitative research is inevitably interpretive; reflexivity is key as researchers' and participants' actions and decisions inevitably shape the findings of the research. Charmaz is also pragmatic about the realities of 'doing' research – that it is not possible to secure ethical approval without conducting a literature review first, and that such preparation helps researchers '*learn the language*' of the participants and avoid mistakes (Charmaz 2014, p. 60). The other advantage of using Charmaz' approach is its simple approach which makes it ideal for novice researchers. Charmaz also describes step-by-step instructions and provides a clear framework for data collection and analysis.

Following feedback at my upgrade assessment, I was encouraged to consider an alternative philosophical approach more closely aligned with mixed methods than grounded theory and so I considered pragmatism as it is frequently cited by mixed methods researchers (Creswell, 2013). Pragmatism is regarded as a practical, applied research approach that wastes no time with deep, metaphysical concerns about the nature of reality (Creswell and Plano Clark, 2018). Others regard pragmatism as a philosophical approach in its own right; a 'middle road' between positivism, in which there is a single, observable and objective reality, and constructivism, in which there are multiple, subjective realities (Morgan, 2014 p.39; Johnson *et al.*, 2017). From this perspective, pragmatism has a mechanistic ontology which focuses on the cause and effect observed in the interactions between humans and their environment (Biesta, 2010). Human actions have consequences and people have the power to transform the environment. This transaction creates

an experience which is just as real to the individual as the landscape around them, yet individuals may perceive, experience and interpret phenomena differently from one another. For pragmatists, the nature of reality can therefore be understood as a continuum – having both a mechanistic and social constructivist ontology (Biesta, 2010).

This view reflects the early influence of psychology on the development of pragmatism. William James (1842-1910) emphasised that individuals perceive and interpret sensory inputs differently to one another which means their experiences are at once very real but also unique and the meanings drawn from them are subjective. However, James was also open to idea of an objective reality which exists independently of human thought rather than Solipsism which maintains that the only reality is that which the individual perceives (Pernecky, 2016). James argued that the nature of reality includes objective truths or matters of fact, individual subjective perceptions, as well as broader socially constructed shared understanding.

Pragmatism was also heavily influenced by the work of Dewey (1859-1952) and his work is perhaps best known (Hall, 2013; Morgan, 2014; Johnson *et al.*, 2017). Dewey was Peirce's student and shared the ontological view of both a single objective reality and the multiple realities of individuals based on transactions between humans and their environment. He saw these transactions as a process of natural inquiry or problem-solving to enable humans to not only learn about their environment but to adapt to it and even transform it. To describe his stance, Dewey preferred 'instrumentalism', 'radical empiricism', 'humanism', 'naturalism', 'operationalism' to Pragmatism. Dewey described several steps in the process of natural inquiry and how these lead to the creation of new knowledge which he called warranted assertions or warranted beliefs (Morgan, 2014; Johnson *et al.*, 2017):

1. Noticing something is wrong, problem not yet well-defined
2. Formulate a problem or question to be answered
3. Formulate a hypothesis – using facts and theoretical concepts to predict outcomes
4. Refinement of the hypothesis – a conceptual review, highlighting any potential conflicts
5. Action and evaluation leading to a warranted assertion – testing and seeing if the solution fits. Knowledge creation is a near-truth or provisional – the warranted assertion is fallible and subject to further inquiry and refinement.

From an epistemological perspective, pragmatists maintain that human knowledge represents theories or solutions that are workable and hold true for now. In other words, these warranted assertions are provisional truths and potentially fallible, and their value lies in how well they work when applied, and how they align with existing knowledge (Johnson *et al.*, 2017) The process of natural inquiry is iterative in that warranted assertions can be later refined as a result of reflection

and reapplication of the knowledge through what Dewey called intelligent action (Biesta, 2010). That said, pragmatists assert that the real truth or answer may not be apparent until some hypothetical moment years in the future (Teddlie and Johnson, 2009). In this respect, pragmatism takes the focus away from seeking ultimate truths and determining the nature of reality, and shifts the emphasis to problem-solving (Teddlie and Tashakkori, 2009). There is a temporal and contextual element to this knowledge, and it may be refined or acquire further meaning and significance over time following further reflection and intelligent action (Biesta, 2010). Dewey saw social democracy and social improvement being the ultimate goal of the process of natural inquiry (Hall, 2013). Some would criticise this naïve position and would suggest that pragmatism fails to acknowledge or address the conditions which lead to social injustice and inequality. Indeed, Peirce was writing at a time when slavery had not yet been abolished in the US.

Pragmatism emphasises the importance of reflection during the research process to explore assumptions and consider stakeholder perspectives to enhance credibility. Hall (2013) maintains that researchers have a moral obligation to ensure stakeholders voices are heard in the research process which can help address power imbalances. In this sense, pragmatism embraces pluralism and multiple points of view (Teddlie and Johnson, 2009). In contrast, Pawson and Tilley (1997) argue this can lead to 'crowd pleasing' (p. 16) and the focus on answering the question and using a 'what works' approach may mean the research is shaped by wider agendas and corresponding research funding streams, potentially resulting in answers that align with current socio-political consensus.

These criticisms aside, pragmatism could be considered an ideal philosophical approach to underpin mixed methods research about women's and staff views and experiences of outpatient induction of labour. It lends itself well to an iterative and exploratory approach, making it useful for novice researchers and accepts the inevitable fallibility of knowledge and subsequent refinement of theories through further testing (Hall, 2013). However, pragmatism lacks a recognised toolkit which may not suit novice researchers (Allmark and Machaczek, 2018). Some regard pragmatism as mechanistic and reductionist in terms of the cause and effect in the creation of experience resulting from the transaction between individuals and their environment, which ignores the underlying conditions which trigger those events, or not, in the first place (Bhaskar, 1997; Maxwell, 2012). Instead, a critical realist perspective was adopted as this enabled deeper consideration of the underlying factors influencing people's views and experiences about outpatient induction of labour. However, I still lacked a 'toolkit' but following a review of critical realist literature, I found a paper by Sims-Schouten, Riley and Willig (2007) which described their

critical realist discourse analysis approach. The authors combined quantitative data collection which then informed the research interviews to explore factors influencing women's talk of motherhood, childcare and female employment. This approach is described further in Chapter 3.

# Appendix XI Approaches to discourse analysis

## Introduction

Discourse analysis (DA) is the study of 'language in use' and how people create meaning (Wetherell, 2001b p.3). It covers a broad range of approaches to analysing language materials, whether written or spoken, and there is some overlap in methods. Some researchers use DA as an umbrella term to define the analysis of any kind of talk or writing, whereas others consider it to be the study of certain styles and genres of language materials which are situated within and influenced by a particular historical and political context (Potter and Wetherell, 1987). Wetherell breaks down the use of forms of DA into three domains:

- the study of minds, selves and sense-making – for example, through discursive psychology
- understanding social interaction – for example, through conversation analysis
- the study of culture and social relations – for example, Foucauldian discourse analysis, critical discourse analysis

These are now considered in turn to justify the rationale for the method chosen for the research project.

## Discursive psychology

Discursive psychology (DP) focuses on how individuals formulate their accounts of reality, whether real or imagined, in terms of what they are trying to achieve (Te Molder, 2015; Goodman, 2017; Wiggins, 2017). In this sense, DP focuses on in-the-moment interactions and the rhetorical use of language, and departs from more traditional psychological approaches that focus on talk as a window to cognition (Te Molder, 2015; Huma *et al.*, 2020). In other words, meaning is 'talked into being' and managed through the social interaction (Flinkfeldt, 2020 p.373). DP has been influenced by the work of philosopher Wittgenstein who saw language as a toolkit that can be put to use in multiple ways depending on the social situation rather than an abstract system of representation (Potter, 2001). Wittgenstein also recognised the difficulty of accessing people's inner thoughts and feelings and that these are only made accountable by the language people choose to use publicly to describe them (Wiggins, 2017). It is not always clear what people are thinking since talk is situated within social practice. For example, stating that 'it is wet outside' may be an observation that it is raining or it may actually be an indirect request for a lift (Goodman, 2017 p.143). If a lift is then offered, this demonstrates that the listener has orientated

towards the statement as a request. In summary, the interpretation of discourse is very much situated or dependent on the context and sequence of talk (Wiggins and Potter, 2008).

Goodman offers a useful guide to DP for novices and recommends starting with an action-orientated question so for example, rather than just exploring views and experiences, Goodman suggests asking 'how do people justify x' or 'how do people accomplish z' (Goodman, 2017 p.145). The next step is to generate a collection or corpus of data. To explore and analyse talk-in-action, DP promotes a naturalistic approach by studying language 'in the wild' rather than in a contrived way such as interviews or focus groups where findings may say more about the research methods and the interpretations of the researcher (Wiggins and Potter, 2008; Te Molder, 2015; Wiggins, 2017; Huma *et al.*, 2020 p.317). That said, even a naturalistic approach may be biased, and talk is likely to be influenced by the presence of an audio device or video camera (Wiggins, 2017). Furthermore, practical considerations such as time, resources and the experience of the researcher are also likely to influence what is practical and achievable (Wiggins, 2017). Goodman (2017) argues there is no right or wrong answer in this debate and recommends articulating the rationale for the chosen approach.

Next, accounts are transcribed, and this is usually done in great detail, often using the Jeffersonian notation system in order to highlight overlapping speech, the duration of pauses, as well as laughter, stutters, sighs, changing intonation and other idiosyncratic aspects of speech. Non-verbal gestures and background noises are also noted (Goodman, 2017). This detailed approach is referred to as naturalised transcription but it can be time-consuming to produce and difficult for novices to read (Oliver, Serovich and Mason, 2005; Goodman, 2017; Huma *et al.*, 2020). Proponents have also faced some criticism for not knowing when to stop. Indicating all the utterances and gestures may crowd out what is being said, their relevance may be questionable and they may make analysis more difficult (Ochs, 2006; Gibson, 2010). That said, proponents argue that including as much detail as possible is a moral and ethical decision by 'giving voice' to participants (Huma *et al.*, 2020 p.321). However, researchers acknowledge that transcription is inevitably selective and will not capture every minute gesture, sigh or eye movement, and aspects of participant talk and action may be open to misinterpretation (Oliver, Serovich and Mason, 2005). With this in mind, researchers need to be reflexive in their approach to acknowledge potential bias (Ten Have, 1990). By reading the detailed transcripts, researchers can begin to explore the action-orientation of individuals and how they position themselves by the linguistic building blocks they use – the words, idioms, categories of 'them' and 'us' – as well as rhetorical strategies deployed (Wiggins and Potter, 2008). Individuals may also use anecdotes, widely available repertoires or 'out there' concepts and tropes to add further legitimacy and impact to their accounts. (Goodman, 2017 p.148). Furthermore, talk may highlight fluidity in how people

construct their identities and present themselves to others as well as how tensions between competing ideologies are navigated discursively to ward off criticism (Goodman, 2017; Wiggins, 2017).

## Conversation analysis

While discursive psychology examines how individuals deploy language as a tool for action, conversation analysis (CA) tends to focus more on the structural aspects of exchanges between individuals such as genre and turn taking (Te Molder, 2015; Wiggins, 2017). In other words, CA tends to focus more on 'just the talk' (Ten Have, 1990; Heritage, 2001; Wetherell, 2001a p.390). So, for example, different conversational styles will be heard in a doctor-patient discussion, a media interview or a meal-time conversation and studying these in detail, alongside the fallout of any transgressions, gives a rich insight into social norms (Wiggins, 2017). In his seminal paper, Ten Have (1990) describes the systematic approach adopted by researchers to examine in detail the exchanges between individuals and how meaning is negotiated. As with DP, naturalised transcription is advocated and some studies also handle speech in an empirical way by quantifying different aspects of interactions such as the number of interruptions between speakers. By adopting a systematic and detailed approach, the researcher aims to be as objective as possible, focusing on the data in its own right rather than examining the influence of wider discourses and social structures (Ten Have, 1990).

CA has faced criticism for failing to address the wider, extra-discursive aspects that shape exchanges between individuals. For instance, age, ethnicity or job role influence the way people interact and talk to one another. However, Ten Have argues this criticism actually provides further justification to use CA in order to observe the naturally occurring interactions as they happen, and record how these non-discursive aspects are 'talked into being' (Ten Have, 1990 p.36).

Criticisms aside, CA is helpful in highlighting multiple discursive strategies people adopt to achieve their aims. They may use rhetorical or persuasive devices such as extreme cases or contrasts to make a point, counterclaims are used to ward off or inoculate against potential criticism and talk is peppered with hesitations and hedges (Silverman, 2001; Riley, 2002; Jingree and Finlay, 2008). CA techniques are therefore frequently adopted in discursive psychology as well as other dialectical approaches to analysing discourse (Wetherell, 2001c; Riley, 2002; Wiggins, 2017). However, Wetherell questions whether it is right just to focus on the immediate exchange between individuals as CA does and suggests wider social meanings and context are woven through interactions like threads through cloth:

> *'Utterances are threads in this respect: they connect with other utterances and other conversations, texts and documents'*
>
> (Wetherell, 2001a p.389)

In other words, there is no clear line that demarcates where talk stops and the rest of social life begins. These contextual or 'extra-discursive' factors mediate the way people feel, express themselves and behave. While meaning is constructed through language, the accounts people give reflect and are co-constituted by their wider social and physical reality (Sims-Schouten, Riley and Willig, 2007; Cromby and Harper, 2009; Wiggins and Riley, 2010; Adams, McCreanor and Braun, 2013).

## Foucauldian discourse analysis

While conversation analysis and discursive psychology examine how people adopt different discursive strategies to achieve their aims, Foucauldian discourse analysis examines the *relationships* between discursive practice and the wider physical and social reality (Hall, 2001; Wetherell, 2001a; Fairclough, 2003). Foucault was a social constructionist who did not deny the existence of reality. For him, meaning or knowledge about an object is constructed in the discourse and social practices that accompany it. In other words, discourse provides a way of conceptualising physical and social reality, and also influences social action. Furthermore, discourse refers to the way language is used to represent knowledge about a subject at a particular point in time and is regulated by rules and practices (Wiggins and Riley, 2010). Moreover, the intelligibility and acceptability of certain discourses and changes over time (Hall, 2001; Alcoff, 2013).

As an example, in his book Madness and Civilisation, Foucault charts observations of hysteria in the discourse of medicine. In the seventeenth century, hysteria was seen as an affliction of women distracted by love or loss and symptomatised as a fiery heat in the heart, heaviness of the blood or on the contrary, blood becoming too fluid. Various causes were cited from 'malign vapours', 'nervous fluids', the fibres of the body becoming too humid, fermentation causing irritation of the digestion and nervous system, or the displacement of the uterus. Eventually by the eighteenth century, hysteria was attributed to 'weak nerves' and medical discourse started to focus on 'nervous conditions' (Foucault, 1988 p.154). These constructions guided subsequent medical recommendations and treatments such as taking cold baths and even institutional confinement, and later influenced the development of psychiatry in the nineteenth century. Meanwhile, discourse around hysteria influenced wider society too. Novel-reading, theatre trips and an overindulgence in education were seen as potential irritants to female nerves and such

activities were therefore discouraged. In this sense, Foucault argued that discourse not only governs how people talk about a topic, it also produces knowledge because it provides people with a way of conceptualising those ideas and influences their attitudes, actions and behaviour (Hall, 1992; Wiggins and Riley, 2010).

Similarly, in his seminal account, 'The West and the Rest', Stuart Hall charts the emergence and use of the term 'The West' and how it is used to represent 'a society that is developed, industrialised, urbanised, capitalist, secular and modern' and how this creates a conceptual contrast and an evaluative scale by which other countries, 'The Rest', are inevitably compared (Hall 1992, p.57). He argues that it also presents a homogenised view of what westernised means when in fact the countries may have strong national identifies and are diverse in culture, language and history. Furthermore, it is clear that people have a range of different views and attitudes internally, towards other parts of their society, as well as externally, towards other western countries.

Fundamentally, Foucault was interested in how discourse is not neutral but reflects institutional interests or ideology. What is foregrounded in that discursive formation and what is conveniently ignored reflects an overarching 'regime of truth', for example, whether someone is labelled a 'terrorist' or 'freedom fighter', or discourse around single parents and delinquency (Hall, 1992 p.76; Hall, 2001). In this way, falsehoods and 'alternative facts' can become true in the sense that they are adopted conceptually and influence people's beliefs and actions (Hendricks and Vestergaard, 2019). But while Marxists focus on the relationship between knowledge and power relationships and the role of discourse in oppression and class struggle, Foucault argued that examining discourse through the lens of a 'class war' or the 'ruling elite' was far too limiting. Instead, discourses surround many aspects of social life other than class alone, such as race, gender and sexuality, health and motherhood. In this respect, Foucault did not see power as one-directional or top-down, but localised and circulating between groups (Hall, 2001).

## Critical discourse analysis

While Foucault has been criticised for underplaying individual agency of the subject as well as the impact of wider structural and economic issues on discourse, proponents of critical discourse analysis (CDA) take an overt and critical socio-political stance to examine the role discourse plays in sustaining inequality and existing power relationships in more detail:

> *'There cannot be an aloof, let alone a 'neutral', position of critical scholars. Critical scholars should not worry about the interests or perspectives of those in power, who are*

> *best placed to take care of their own interests anyway. Most male or white scholars have been shown to despise or discredit such partisanship, and thereby show how partisan they are in the first place, e.g., by ignoring, mitigating, excluding or denying inequality. They condemn mixing scholarship with 'politics', and thereby they do precisely that. Some, even more cynically and more directly, collude with dominance, e.g., by 'expert' advice, support and legitimation of the (western, middle-class, white, male, heterosexual, etc.) power elites.'*
>
> (Van Dijk, 1993 p.253-4)

While examining top-down power relations, CDA also considers how discourse and ideology sustain a wider hegemony, a term widely used to CDA to refer to the tolerance, acquiescence, acceptance and even legitimation and institutionalisation of inequality (Van Dijk, 1993). Furthermore, restriction in access to discourse sustains and reproduces inequalities. For example, the voices of shop floor workers are seldom heard in boardroom meetings, ethnic minorities are less well represented on committees and men are more likely to talk over any women present. Similarly, discourse constructions about 'them' and 'us' can incite further distancing, suspicion and blame. Van Dijk gives the example of racist views being predominant in the socioeconomic context of white poverty. Furthermore, this kind of polemic has fuelled Brexit and is exemplified in the language used by the Leave campaign and mainstream media about Muslims, refugees and asylum seekers 'swamping' the UK, talk of 'closing the floodgates' and immigration 'spiralling out of control' in a debate that pitted those who wanted to 'take back control' against a 'treacherously liberal' elite intent on ruining the country (Tornberg and Tornberg, 2016; Cooper *et al.*, 2017; Elsayed, 2018 p.2398; Valluvan and Kalra, 2019; Vlad, 2019).

Norman Fairclough's seminal text on CDA highlights the causal effects and transformative power language can have in both written and spoken forms. Citing the work of critical realist, Roy Bhaskar, Fairclough shares a realist ontology where both concrete and more abstract social structures have the potential to have causal effects in the empirical realm – events which are experienced by individuals and are observable and measurable. In this way, reality is stratified or made up of multiple layers. Firstly, the potentiality of mechanisms lies in the domain of the real and when triggered or enacted by certain conditions, these events lie in the domain of the actual. Finally, the experience of that event, or what is observable or can be measured, lies in the empirical domain. Similarly, Fairclough argues that discourse is read or heard in the empirical domain. In other words, what is actually presented is inevitably partial and selective. This is because socio-political context has the potential to shape the content of the discourse event that follows. Furthermore, the discourse setting, such as a political chamber, a newspaper or a

doctor's surgery will shape the genre of that discourse event, such as a political speech, a newspaper article or a doctor-patient interaction, with accompanying expectations and limitations around style and acceptability of things that can be said.

Fairclough promotes CDA as a way to analyse the discursive strategies used by individuals or groups to engage and influence others or even justify, sustain or challenge existing power relations. His main research focus is what he calls 'the language of New Capitalism' (Fairclough, 2003 p.4). For example, Fairclough examined the speeches of Tony Blair and language of 'New Labour' and how this set the party apart from 'old Labour'. Blair also promoted the idea that through political leadership, globalisation would be a 'force for good' in terms of wealth creation and the opportunities it would create 'for the many' (Blair 2001, cited by Fairclough 2003 p.175).

Not only has CDA been used to explore power relationships and political change, it has also been used in a variety of other settings to reveal how opinions can be shaped, stances legitimated and change affected not only in social and political terms but also in commercial settings as well. CDA is used widely in organisational studies (Leitch and Palmer, 2010), for example, the way companies use strategy reports to engage stakeholders (Higgins and Coffey, 2016) and the discourse used in company initial public offering statements (Nam, 2020). Similarly, CDA has been used to examine how different groups are represented in the media. For example, pregnant women are depicted as high-consuming, 'yummy mummies' (Thomas and Lupton, 2016 p.502) and breast cancer survivors are portrayed as young, heterosexual and vibrant 'she-ros' within 'pink ribbon' culture which encourages charitable investment in science and technology and the unwavering certainty that the eradication of cancer will follow (McGannon *et al.*, 2016 p.199). Reporting of maternal deaths in the US is examined using CDA to analyse a PBS news report which portrayed the death of pregnant nurse Lauren Bloomstein, 'the last person you would expect to die in childbirth' (Allen and Benedetti, 2019 p.685). Neatly side-stepping any criticism of her care and maternity care failings in the wider US healthcare system, the report focusses on the dangers of pre-eclampsia. CDA is also used to inform health promotion by asking groups to talk about their health (e.g., Caddick *et al.* (2017) on lorry drivers), to reveal the negative framing of mental health in police policy (Boyd and Kerr, 2016), energy poverty discourse (Listo, 2018) and discourse around complex case management in children's services and the illusion of predictability and control (Hood, 2016)

While CDA has been used to explore the action orientation of discourse and how it may be used to affect change in people's views and behaviour, or even to control others and legitimate social inequality, this approach has been criticised for down-playing extra-discursive factors that shape

discourse (Wetherell, 2001a; Sims-Schouten, Riley and Willig, 2007). In other words, it is not just wider structural factors such as the media or government policies and strategies that have an impact on discourse; personal factors shape discourse too. For example, material factors such as socioeconomic background, education, living circumstances and the availability of family or social support networks as well as more personal factors such as ethnicity, gender and health status may influence experiences, perspectives and discourse (Sims-Schouten, Riley and Willig, 2007). Similarly, both CDA and Foucauldian discourse analysis have been criticised for losing sight of the subject and the agency they have. Archer (2003) argues that:

> *'Our subjectively defined concerns, and especially our ultimate concerns, act as a sounding board for our reception of and response to the objective situations that we confront.'*
>
> (Archer, 2003 p.139)

In other words, in discourse analysis it is important to recognise individual agency and reflexivity as interactions unfold as well as the influence of the wider social and political context (Archer, 2003). However, Archer acknowledges that this does not mean people are always free to articulate themselves as they please as social structure and hierarchy mediate discourse, particularly if people are anxious about speaking out of turn. She also recognises that the voices of some people are seldom heard if in distress or disenfranchised.

## Critical discursive psychology

This approach adopts a broader view than DP and CA, and considers the influence of the wider social, cultural and historical context (Wiggins, 2017). By integrating aspects of Foucauldian discourse analysis with DP, critical discursive psychology (CDP) adopts a more critical approach and this enables researchers to consider the cultural influences that mediate how interactions play out. In addition, it provides an opportunity to examine how individuals incorporate wider social meanings in their talk to bolster their claims and achieve their aims (Wiggins, 2017). These interpretations and socially constructed meanings are often presented as social facts and may feature in talk in similar ways as discursive repertoires. That said, they can be adopted flexibly and people may offer opposing repertoires as ideological dilemmas in their talk to present themselves in a favourable light or to test the water before settling on a particular argument, depending on the situation they find themselves in. Furthermore, discursive repertoires wax and wane over time and there are seismic shifts in social discourse between one generation and the next. For instance, in their talk nowadays, individuals are likely to orientate rather differently towards cultural issues such as racism, gender and sexuality compared to their parents or grandparents 50 years ago.

As with DP, rather than focusing on the views and experiences of participants, the researcher engages in reflexive interpretation of the discursive strategies used and the effects these have during interactions. However, there is a possibility the resultant analyses will be considered strange by the participants themselves (Hammersley, 2014; McMullen, 2018). This presents an ethical dilemma as the participant may see the interpretation as invalid. It also has the potential to cause harm to participants as it could make them feel they have been misunderstood, causing anger or upset. There is greater emphasis on participant involvement in research design and analyses in other forms of qualitative research so that research is *with* rather than *on* participants (Hammersley, 2014). This has challenges for both DP and CDP since it is likely to make people self-conscious about the way they express themselves during interviews, meaning discursive practices might be self-edited in order to present themselves in a better light (McMullen, 2018). Member checking is used to enhance credibility in other qualitative research but this is not commonly done in DP or CDP. Typically, credibility is demonstrated by providing several extracts alongside an interpretation to establish the coherence of the analysis. McMullen concludes that researchers should try not to self-censor but should continue to be reflexive about the interpretations and decisions made during analysis and writing up. Hammersley (2014) argues there is a need for a more detailed discussion at the outset to ensure participants are aware of how their data is interpreted.

## Critical realist discourse analysis

Critical realist discourse analysis (CRDA) addresses some of the limitations of other approaches to discourse analysis by combining discursive psychology and Foucauldian discourse analysis, and by recognising the mediating effect of extra-discursive factors on what people think, do and say. For example, institutional factors such as government policy influence individual talk as well as wider social discourses (Sims-Schouten, Riley and Willig, 2007; Stevens, 2019). Similarly, material factors such as education and employment status may also have an effect on sense-making. CRDA also considers personal embodiment, and how this features in interactions. Lupton (2012) defines embodiment as 'complex and dynamic admixtures of cultural, social and biological processes' p.330. In this sense, embodiment considers the person as a whole, not only in a biological sense, but also emotionally, culturally and socially (Anastas, 2019). For example, stress and anxiety may affect how people express themselves and may also have an impact on an interaction.

Sims-Schouten, Riley and Willig (2007) used CRDA to examine how women talk about motherhood and decision-making around their childcare arrangements. They approached this in a systematic way by performing an initial literature review to help identify the potential extra-

discursive factors that could have an impact on the lives of their study participants. These included factors associated with women's personal embodiment such as their age or the number of children, material conditions such as income, accommodation and the availability of childcare facilities, and institutional factors in terms of prevailing government policies towards childcare. The second step of their research was to examine these extra-discursive factors within the research setting to understand the material and social context within which their participants lived and worked. Finally, participants were interviewed, and the transcriptions were then coded for recurring themes to determine how individuals orientated towards wider discourses and extra-discursive factors, if at all, in their decision-making. Participants' talk was analysed in three distinct ways as follows:

1. Discursive practice – influenced by conversation analysis and discursive psychology to highlight the discursive strategies individuals adopt to achieve their aims in an interaction in order to understand the action orientation of speech.
2. Foucauldian discourse analysis – to highlight the wider discourses which feature in participants' talk, and how participants orientate themselves towards those.
3. Critical realist level of analysis – the influence of the extra-discursive factors on discourse including social and political institutions as well as those relating to an individual's personal embodiment and their material resources.

This approach enabled Sims-Schouten et al to highlight potential extra-discursive factors that influenced decision-making about childcare arrangements and return to work such as the availability of informal childcare and government policies supporting the provision of formal childcare. They argue this approach respects participants as individuals and acknowledges their unique set of circumstances – material, institutional and embodied factors – that mediate their decision-making. They describe these extra-discursive elements as

> *'a kind of scaffolding milieu – the conditions of possibility – from which it makes sense for a participant to account for themselves in particular ways and not others.'*
>
> (Sims-Schouten and Riley, 2014 p.52)

In terms of exploring factors influencing views and decisions about outpatient induction of labour, a synthetic CRDA approach as described by Sims-Schouten, Riley and Willig (2007) was considered a good fit for a number of reasons. Firstly, in maternity care and other aspects of healthcare, risk management influences the way health professionals make and justify their decisions, interact and talk with each other and patients. As a midwife, the researcher is very aware that risk management and a 'culture of fear' is embedded within maternity culture and reflected in professionals' views and discourse as 'risk talk' (Scamell and Alaszewski, 2012; Coxon, 2014; Bisits,

2016; Coxon *et al.*, 2016 p.2; Scamell and Alaszewski, 2016; Ferndale *et al.*, 2017; Healy, Humphreys and Kennedy, 2017). This influences decision-making and ultimately the experiences of pregnant women. Secondly, extra-discursive factors such as health status, medication, the availability of social support, as well as care setting, institutional frameworks, policies and guidelines mediate decision-making. Amongst professionals, these factors typically articulated during transactional encounters when sharing information in the workplace, for instance, when requesting action, during procedural and directive discourse or when discussing and evaluating decisions (Koester 2006). Thirdly, carrying out interviews with individuals and then closely examining their discursive practices and formulations enables an in-depth exploration of midwives' views and decision-making about outpatient induction of labour as well as providing an opportunity to scrutinise the wider discourses in maternity care and how participants orientate towards them. This approach recognises the agency individuals have and how their views and actions are produced through their own experiences and 'reflexive deliberation' (Archer, 2003 p.141).

## Summary

This section has justified my approach to analysing participant talk about OPIOL. A critical realist discourse analysis (CRDA) approach combines realist ontology with social constructionist epistemology. Participant talk is not just a reflection or representation of individual conceptual models and thought processes (Riley, 2002; Te Molder, 2015). Instead, talk is mediated and co-constituted by an individual's wider social and physical reality, and the extra-discursive factors at play are like scaffolding or threads woven through cloth (Wetherell, 2001a; Sims-Schouten, Riley and Willig, 2007; Sims-Schouten and Riley, 2019). Factors relating to personal embodiment and materiality influence talk, as do wider institutional factors such as government policy or organisational guidelines (Sims-Schouten, Riley and Willig, 2007). In addition, people may incorporate widely understood tropes in their talk and orientate towards particular discourses that suit their agenda or situation, and use these in talk to influence the views and actions of others (Hall, 1992; Goodman, 2017). In this sense, discourse is both constructed by context in which people find themselves and yet it is also constructive or action-orientated with real-life consequences (Fairclough, 2003).

# Appendix XII REC approval with conditions met

Health Research Authority

East Midlands - Leicester Central Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

**Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval**

02 January 2019

Ms Lisa Smith
14 Wilton Road
Southampton
SO15 5LB

Dear Ms Smith

| | |
|---|---|
| **Study title:** | **Views and experiences of women and staff of outpatient induction of labour (OPIOL): a mixed methods study.** |
| **REC reference:** | **18/EM/0334** |
| **Protocol number:** | **31461** |
| **IRAS project ID:** | **240694** |

Thank you for your letter of 23 December 2018. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 18 December 2018

**Documents received**

The documents received were as follows:

| *Document* | *Version* | *Date* |
|---|---|---|
| Other [Participant information - staff] | v0.5 | 20 December 2018 |
| Other [Recruitment poster staff] | v0.4 | 25 November 2018 |
| Other [Covering letter 20.12.18] | v1 | 20 December 2018 |

**Approved documents**

The final list of approved documentation for the study is therefore as follows:

| *Document* | *Version* | *Date* |
|---|---|---|
| Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [Response from HRA and Trust information governance manager] | v0.1 | 25 July 2018 |
| Copies of advertisement materials for research participants [Recruitment poster - women] | v0.4 | 25 November 2018 |
| Covering letter on headed paper [Covering letter] | v0.1 | 09 September 2018 |
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Completed insurance letter v0.1 25.7.18] | v0.1 | 25 July 2018 |
| Interview schedules or topic guides for participants [Semi-structured interview prompts] | From protocol v0.12 | 25 November 2018 |
| IRAS Application Form [IRAS_Form_09102018] | | 09 October 2018 |
| IRAS Checklist XML [Checklist_23122018] | | 23 December 2018 |
| Letter from sponsor [Sponsor_Letter2018-09-06__13_45] | v0.1 | 09 September 2018 |
| Other [Supervisor 2 CV October 2017 v0.2] | v0.2 | 11 December 2017 |
| Other [Covering letter 16.10.18] | v1 | 16 October 2018 |
| Other [Staff awareness campaign Theme of the Week] | v0.5 | 25 November 2018 |
| Other [Staff awareness campaign Maternity Mail article] | v0.4 | 25 November 2018 |
| Other [Social media post - women] | v0.4 | 25 November 2018 |
| Other [Covering letter 25.11.18] | v1 | 25 November 2018 |
| Other [Consent form - staff] | v0.3 | 25 November 2018 |
| Other [Participant information - staff] | v0.5 | 20 December 2018 |
| Other [Recruitment poster staff] | v0.4 | 25 November 2018 |
| Other [Covering letter 20.12.18] | v1 | 20 December 2018 |
| Participant consent form [Consent form - women] | v0.3 | 25 November 2018 |
| Participant information sheet (PIS) [Participant information sheet - women] | v0.6 | 25 November 2018 |
| Referee's report or other scientific critique report [PR1RevR v0.1 13.05.18] | v0.1 | 13 May 2018 |
| Research protocol or project proposal [Protocol] | v0.12 | 25 November 2018 |
| Summary CV for Chief Investigator (CI) [Lisa Smith CV] | v0.1 | 13 May 2018 |
| Summary CV for student [Lisa Smith CV] | v0.1 | 13 May 2018 |
| Summary CV for supervisor (student research) [Dr ER Cluett CV for res ethics] | v0.1 | 19 December 2017 |
| Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flowchart summary of protocol v0.2 15.09.18] | v0.2 | 15 September 2018 |

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

| | |
|---|---|
| **18/EM/0334** | **Please quote this number on all correspondence** |

Yours sincerely,

**Rebecca Morledge**
**REC Manager**

E-mail: nrescommittee.eastmidlands-leicestercentral@nhs.net

*Copy to:* *Ms Lisa Smith*
*Dr Mikayala King, University Hospital Southampton NHS Foundation Trust*

# Appendix XIII HRA approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Ms Lisa Smith
Consultant Midwife
University Hospital Southampton NHS Foundation Trust
14 Wilton Road
Southampton
SO15 5LB

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

02 January 2019

Dear Ms Smith

**HRA and Health and Care Research Wales (HCRW) Approval Letter**

| | |
|---|---|
| **Study title:** | **Views and experiences of women and staff of outpatient induction of labour (OPIOL): a mixed methods study.** |
| **IRAS project ID:** | **240694** |
| **Protocol number:** | **31461** |
| **REC reference:** | **18/EM/0334** |
| **Sponsor** | **University of Southampton** |

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

**How should I continue to work with participating NHS organisations in England and Wales?**
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should **formally confirm** their capacity and capability to undertake the study. How this will be confirmed is detailed in the "*summary of assessment*" section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a 'green light' email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.).

| IRAS project ID | 240694 |
|---|---|

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

**How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?**
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

**How should I work with participating non-NHS organisations?**
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

**What are my notification responsibilities during the study?**
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

**I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?**
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Dr Ferdousi Chowdhury
Tel: 02380 595058
Email: rgoinfo@soton.ac.uk

**Who should I contact for further information?**
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **240694**. Please quote this on all correspondence.

| IRAS project ID | 240694 |
|---|---|

Yours sincerely

Andrea Bell
Assessor

Email: hra.approval@nhs.net

*Copy to:* *Dr Ferdousi Chowdhury – Sponsor contact*
*Dr Mikayala King, University Hospital Southampton NHS Foundation Trust – Lead NHS R&D contact*

## Appendix XIV NHS Trust guideline

Note this guideline was incorporated into the main induction of labour guideline in 2020

# Outpatient Induction of Labour Guideline

Version: 1.0

Issued: September 4th 2015

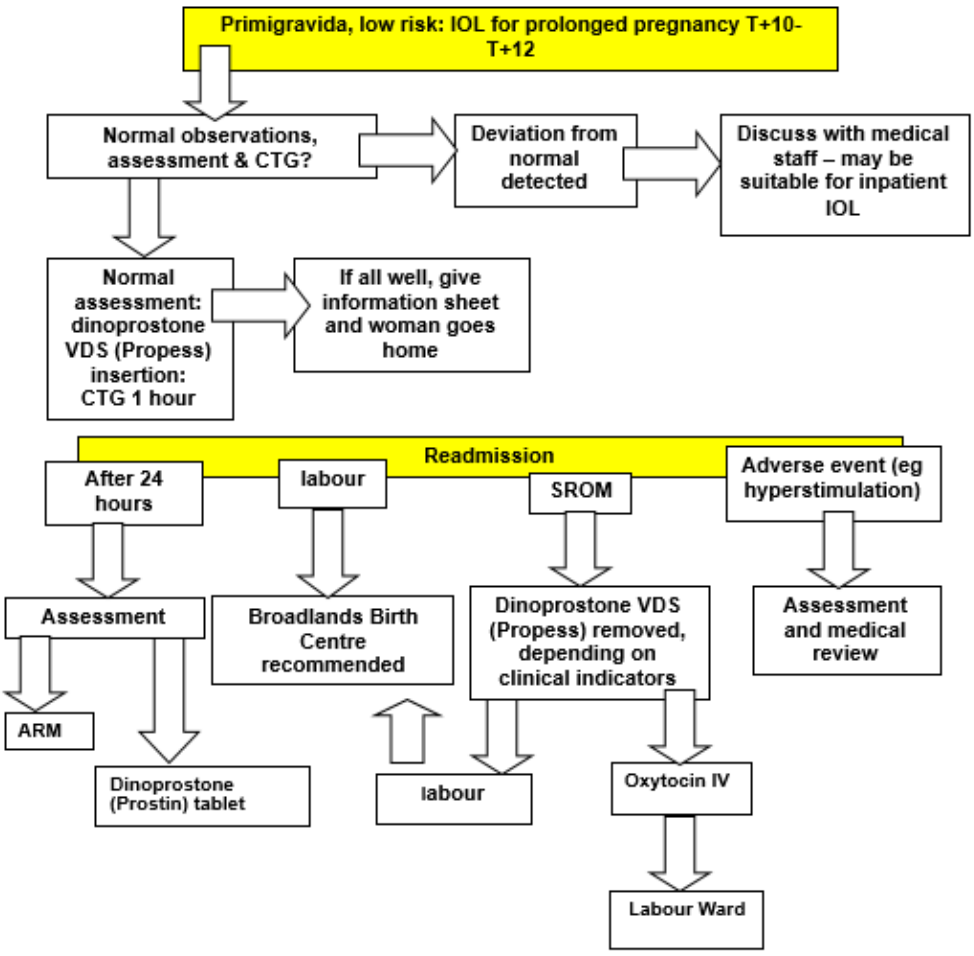
Review date: September 2018

Author:

## Executive Summary

Outpatient induction at [NHS TRUST] is only recommended for primigravid women whose pregnancies are "low risk" and whose length of gestation is 40+10- 40+12; or if induction is being carried out for social reasons or pelvic girdle pain (PGP). There should therefore be a thorough risk assessment prior to insertion of [dinoprostone pessary]. The period between assessments in hospital is 24 hours, during which time the women are recommended to be at home and to seek midwifery advice if labour starts.

## Flow chart




## Introduction

Induction of labour (IOL) is an intervention designed to artificially initiate uterine contractions leading to progressive dilatation and effacement of the cervix and birth of the baby. Women who are expecting their first baby and whose pregnancies are low risk (see Clinical Risk Assessment in

Labour [NHS TRUST] Guideline) and who are between 40+10 and 40+12 weeks gestation are suitable for outpatient IOL (OPIOL). Women whose pregnancies are beyond 38 weeks gestation who are having labour induced for social reasons or for PGP are also suitable.

Theoretical benefits of outpatient induction of labour (OPIOL) include shorter in-patient stay, higher patient satisfaction rates, decreased staff workload and resulting economic savings; these benefits as applicable to our local setting are yet to be backed up by good quality evidence. There are large cohort studies that show no serious complications associated with OP IOL; to date randomised trials are not adequately powered to demonstrate safety data due to the very low incidence of adverse outcomes in a low risk population. Continuous audit will be carried out as per NICE Guidance (NICE, 2008).

The process for booking OPIOL is detailed in The [NHS TRUST] Induction of Labour guideline on Staffnet. Please identify suitability for OPIOL.

## 2. Definitions

OPIOL = outpatient induction of labour

IOL = Induction of labour

ARM = artificial rupture of membranes

PGP = pelvic girdle pain

Favourable [cervix] = effaced

Uterine hyperstimulation = contractions occurring > 5 every 10 minutes

(S)ROM = (spontaneous) rupture of membranes

Senior obstetrician = ST6/7 or above

VDS = vaginal delivery system

## 3. Related Trust Documents

- [NHS TRUST] Induction of Labour guideline
- [NHS TRUST] Fetal Monitoring in labour guideline
- [NHS TRUST] Latent Phase of Labour guideline
- [NHS TRUST] Use of Oxytocin guideline

## 4. Assessment and documentation prior to induction

- Confirm low risk status (see Clinical Risk Assessment in Labour [NHS TRUST] Guideline), reason for induction: pregnancy between 40+10 - 40+12; social reasons; or PGP
- Primigravida
- Single vertex pregnancy
- Booking BMI <40
- Maternal age <35
- Intact membranes, not contracting
- Women with a favourable cervix (>2cm) are still eligible for this pathway if they are not contracting. An ARM may be done instead if it is relatively easy and this should be the examiner's decision together with the woman
- the woman has a phone, will not be travelling more than 30 minutes away from the hospital and has transport available
- Maternal temperature, pulse, respiratory rate, blood pressure, urine analysis
- Abdominal palpation: minimum – symphysis-fundal height, presentation, engagement, contractions
- Vaginal examination (including Bishop score)
- CTG immediately prior to administration of dinoprostone vaginal delivery system for a minimum of 20-30mins

An information leaflet on Induction of Labour should be given to support the discussion between healthcare professionals and the woman

*Contra-indications/exclusions to OPIOL*

- CTG – any non-reassuring feature
- Presenting part above the pelvic inlet
- Hb <100g/l
- Fibroids >5cms size
- Reduced fetal movements

.

## 5. Dinoprostone [pessary] insertion

- Insert dinoprostone [pessary] high into the posterior fornix using Aquagel NOT Hibitane.
- The pessary should lie transversely in the posterior fornix.
- After dinoprostone [pessary] has been inserted the withdrawal tape may be cut, but ensure that there is sufficient tape outside the vagina to allow removal
- The woman should remain semi-recumbent for 20 minutes following the insertion to allow moisture absorption and swelling of the pessary

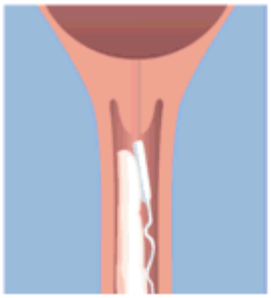


Figure a.

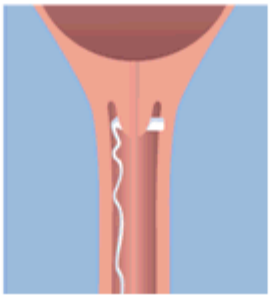


Figure b.

Figure c.

## 6. Post Dinoprostone [pessary] insertion

- Continue CTG for one hour.
- Note any adverse effects: nausea, vomiting, tachycardia, hypotension, fever, vaginal irritation, abdominal pain, vaginal bleeding, hypertonic uterine activity,

abnormal CTG and if any are evident the woman should be reviewed by an obstetrician.

- If all is well the woman can go home having been given the information sheet and instructions to return to IOL unit 24 hours later if all remains well.
- The midwife undertaking dinoprostone [pessary] inductions should e-mail the Labour Line with the names of women who have undergone the procedure.
- The Labour Line midwife will phone the women who have had OPIOL between 6 and 8 hours post dinoprostone [pessary] to check how they are
- The woman will be instructed to ring the Labour Line if:

  - Contractions become distressing or regular (every 5 minutes or more frequent)
  - There is bleeding
  - Membranes rupture
  - Fetal movements are reduced from the normal movements felt
  - Other adverse effects such as pyrexia or diarrhoea
  - Dinoprostone [pessary] falls out or drops lower in the vagina- advise patient to bring the dinoprostone [pessary] in a clean bag for re-insertion

The Labour Line midwife may ask the woman to remove the pessary herself. Instructions on how to do this will be given before the woman goes home.

## 7. Removal of Dinoprostone [pessary]

Remove dinoprostone [pessary] in the following circumstances:

- 24 hours after insertion
- Established labour (effaced Cervix >4cm dilated and regular painful contractions)
- Spontaneous rupture of membranes with favourable Bishop score (>7)
- Significant vaginal bleeding
- Suspected fetal compromise
- Uterine hyperstimulation
- Maternal adverse effect

It is possible to do a vaginal examination with dinoprostone [pessary] in situ. If not in established labour do not remove dinoprostone [pessary] before 24 hours.

## 8. Labour within 24 hours of Dinoprostone [pessary] insertion

Women should be encouraged to labour and give birth in Broadlands Birth Centre. No CTG is required for labour.

## 9. Spontaneous rupture of membranes (SROM) with Dinoprostone [pessary] in the vagina:

- Commence CTG
- Assess strength of contractions
- SROM confirmed by speculum if liquor not visible
- If contractions are > 4 in 10 minutes remove dinoprostone [pessary] and transfer to Birth Centre or Labour Ward
- If there are no contractions do a vaginal examination:
    - if the cervix is ≥ 3cm dilated and fully effaced then dinoprostone [pessary] should be removed and consideration of oxytocin after 30 minutes
    - If the cervix is <3cm dilated and not fully effaced may be left in place until oxytocin commenced at the next opportunity (oxytocin should not be started within 30 minutes of removal of dinoprostone [pessary]).

## 10. Re-admission to the IOL unit 24 hours post-insertion

- Maternal observations should be documented (BP, Pulse, Temperature, urinalysis)
- Palpation and CTG (at least 20 minutes)
- Perform a vaginal examination: assess for suitability for ARM +/ - oxytocin (Syntocinon)
- Remove dinoprostone [pessary]

- If possible to perform at ARM at this stage, transfer to Labour Ward for this to be done. If ARM not possible then discuss management with Senior SpR/Consultant

## 11. Management of unsuccessful Dinoprostone [pessary] (If cervix is closed):

This will be discussed with a senior member of staff (Consultant or ST 6/7)

Options:

- Dinoprostone (Prostin) 3mg tablet and subsequent management as an inpatient
- Abandon induction and try again at a later date. However, for most women there will be limited options at this stage.
- Deliver by Caesarean section if labour does not establish and the cervix remains unfavourable

## 12. Pain relief during induction of labour

Women should be offered appropriate pain relief as per Latent Phase of Labour guideline

## 13. Uterine hyperstimulation

Tocolysis should be considered if uterine hyperstimulation occurs during induction of labour. See the [NHS TRUST] Use of Oxytocin guideline

## 14. References

1. Biem SR, Turnell RW, Olatunbosun O, Tauh M, Biem HJ. A randomized controlled trial of outpatient versus inpatient labour induction with vaginal controlled-release prostaglandin-E2: Effectiveness and satisfaction. *J Obstet Gynaecol Can*. 2003;25(1):23-31.

2. O'Brien E, Rauf Z, Alfirevic Z, Lavender T. Women's experiences of outpatient induction of labour with remote continuous monitoring. *Midwifery*. 2012.

3. Kelly AJ, Alfirevic Z, Ghosh A. Outpatient versus inpatient induction of labour for improving birth outcomes. *status and date: New search for studies and content updated (conclusions changed), published in*. 2013(11).

4. Adelson PL, Wedlock GR, Wilkinson CS, Howard K, Bryce RL, Turnbull DA. A cost analysis of inpatient compared with outpatient prostaglandin E2 cervical priming for induction of labour: Results from the OPRA trial. *Australian Health Review*. 2013;37(4):467-473.

5. Ramsey PS, Meyer L, Walkes BA, et al. Cardiotocographic abnormalities associated with dinoprostone and misoprostol cervical ripening. *Obstetrics & Gynecology*. 2005;105(1):85-90.

6. Salvador SC, Simpson ML, Cundiff GW. Dinoprostone vaginal insert for labour induction: A comparison of outpatient and inpatient settings. *J Obstet Gynaecol Can*. 2009;31(11):1028-1034.

7. Dowswell T, Kelly AJ, Livio S, Norman JE, Alfirevic Z. Different methods for the induction of labour in outpatient settings. *The Cochrane Library*. 2010.

8. National Institute for health and Care Excellence Reviewed 2008 Induction of labour. http://www.nice.org.uk/guidance/cg70

*With thanks to Barts Health NHS Trust*

# Appendix XV Data collection tool

| Characteristic | Drop down options if relevant | Data source |
|---|---|---|
| All women undergoing IOL | | |
| Parity | Nulliparous<br>Parous | Maternity database |
| Gestation at commencement of induction of labour | Weeks + days | Maternity database |
| Indication for induction of labour | Antepartum haemorrhage<br>Abruption<br>Cholestasis<br>Diabetes<br>Fetal abnormality<br>Gynaecological history<br>HELLP (haemolysis, elevated liver enzymes, low platelets)<br>Intrauterine death<br>Maternal request<br>Multiple pregnancy<br>No information<br>Obstetric history<br>Other<br>Preeclampsia<br>Pregnancy induced hypertension | Maternity database |

| Characteristic | Drop down options if relevant | Data source |
|---|---|---|
| | Prolonged rupture of membranes<br><br>Post-term<br><br>Symphysis pubis dysfunction<br><br>Suspected Rhesus iso-immunisation<br><br>Suspected chorioamnionitis<br><br>Suspected fetal compromise | |
| Use maternity database and obstetric electronic diary system to identify eligible nulliparous women at low risk of complications being induced at 41 plus 3 to 5 days. This will include:<br>• Women who are eligible but decline OPIOL<br>• Women who are eligible and consent to OPIOL<br>• Women eligible and consent to OPIOL who are subsequently not discharged home due to the development of newly arising complications | | |
| Age | | Maternity database |
| Gravida | | Maternity database |
| Parity | | Maternity database |
| Body mass index | | Maternity database |
| Education status | Primary school<br><br>Secondary school<br><br>College<br><br>Undergraduate<br><br>Graduate<br><br>Postgraduate | Maternity database |
| Employment status | Full-time<br><br>In education | Maternity database |

| Characteristic | Drop down options if relevant | Data source |
|---|---|---|
| | No pain employment<br>Not specified<br>Part-time | |
| Requires interpreter | Yes/No | Maternity database |
| Smoker | Never smoked<br>10-20 a day<br>>20 a day<br>Stopped more than a year ago<br>Stopped in last year<br>Stopped when pregnancy confirmed<br>Up to 10 a day | Maternity database |
| Ethnic group | African<br>Asian other<br>Bangladeshi<br>Black other<br>Caribbean<br>Chinese<br>Ethnic other<br>Indian<br>Mixed other<br>Mixed white and Asian | Maternity database |

| Characteristic | Drop down options if relevant | Data source |
|---|---|---|
| | Mixed white and black African<br><br>Mixed white and black Caribbean<br><br>Not asked<br><br>Not stated<br><br>Pakistani<br><br>White British<br><br>White Irish<br><br>White other | |
| Nulliparous women at low risk of complications being induced at 41 weeks and 3 to 5 days who are ineligible due to the following reasons | Live >30 minutes' drive from hospital<br><br>No phone<br><br>No transport | Maternity records<br><br>Maternity database |
| Nulliparous women at low risk of complications being induced at 41 weeks and 3 to 5 days eligible for OPIOL after initial assessment but who decline | Yes/No | |
| Nulliparous women at low risk of complications being induced at 41 weeks and 3 to 5 days eligible for OPIOL after initial assessment | Yes/No:<br><br>Contractions<br><br>Spontaneous rupture of membranes<br><br>Hypertension<br><br>Pyrexia | Maternity records<br><br>Maternity database |

| Characteristic | Drop down options if relevant | Data source |
|---|---|---|
| | Maternal tachycardia<br>Reduced fetal movements<br>Antepartum haemorrhage<br>Hyperstimulation[11]<br>Hypertonus[12]<br>Other adverse maternal effect<br>Abnormal presentation or lie<br>Presenting part above the pelvic inlet<br>Suspected fetal growth restriction<br>Anhydramnios, oligohydramnios or polyhydramnios suspected on palpation<br>Abnormal fetal heart recording | |
| For those eligible for OPIOL to record the following: | | |
| Bishop score at commencement of induction of labour | 0-12 | Maternity database |
| Time of administration of dinoprostone pessary | Date/time | Maternity database<br>Electronic prescribing database<br>Maternity records |

[11] Defined here as tachysystole >5 in 10 minutes with or without fetal heart changes
[12] Defined here as contraction >2 minutes in duration with or without fetal heart changes

| Characteristic | Drop down options if relevant | Data source |
|---|---|---|
| Time of discharge home | Date/time | Maternity records<br>eCamis |
| Time of readmission to hospital | Date/time | Maternity records<br>eCamis |
| Primary reason for readmission following OPIOL | Suspected labour<br>Suspected rupture of membranes<br>Bleeding<br>Reduced fetal movements<br>Suspected hyperstimulation<br>Suspected hypertonus<br>Suspected abnormal maternal observations<br>Anxiety<br>Other<br>Readmission for ongoing IOL | Maternity records<br>Maternity database |
| Bishop score on readmission | 0-12 | Maternity database<br>Maternity records |
| Cervical dilatation on readmission | 0-10 | Maternity database<br>Maternity records |
| Oxytocin augmentation required | Yes/no | Maternity database |
| Mode of birth | Spontaneous vaginal birth | Maternity database |

| Characteristic | Drop down options if relevant | Data source |
|---|---|---|
| | Instrumental birth<br>Ventouse<br>Neville-Barnes Forceps<br>Keilland's Forceps<br>Indication for instrumental birth<br>Slow progress<br>Suspected fetal compromise<br>Other<br>Emergency caesarean section not in labour<br>Unsuccessful IOL<br>Suspected fetal compromise<br>Other<br>Emergency caesarean section in labour<br>Slow progress<br>Failed instrumental<br>Suspected fetal compromise<br>Other | Maternity records |
| Place of birth | Home planned | |

| Characteristic | Drop down options if relevant | Data source |
|---|---|---|
| | Home unplanned<br>Freestanding birth centre<br>Alongside birth centre<br>Labour ward<br>Theatre<br>Other | |
| Time of birth | Date/time | Maternity database |
| Apgar score at 5 minutes | 0-10 | Maternity database |
| Neonatal unit admission within first 24 hours | Yes/No | Maternity database<br>Neonate's electronic records |

# Appendix XVI Inclusion criteria – women

| Inclusion criteria | Justification |
|---|---|
| • Nulliparous<br>• Singleton, cephalic pregnancy<br>• Intact membranes<br>• Postmaturity as primary indication for induction at T+10-12<br>• Low-risk pregnancy defined as woman with no pre-existing medical, obstetric or social risk factors requiring obstetric-led care<br>• Booking body mass index <40<br>• Maternal age <35<br>• Haemoglobin ≥100g/l<br>• Women perceive normal fetal movements<br>• *Newly arising* clinical features on admission that make OPIOL inappropriate e.g., spontaneous rupture of membranes, contractions<br>• *Newly arising* clinical risk factors following admission that make OPIOL inappropriate e.g.,<br>  ○ Hypertension<br>  ○ Pyrexia<br>  ○ Maternal tachycardia<br>  ○ Reduced fetal movements<br>  ○ Antepartum haemorrhage<br>  ○ Hyperstimulation<br>  ○ Other adverse maternal effect<br>  ○ Abnormal presentation or lie | • Clinical characteristics of women included and excluded by OPIOL guideline.<br>• Women with newly arising clinical features or risk factors on the day of admission for OPIOL will be invited to participate in the study to obtain a wide range of views.<br>• Non-English speaking women excluded as per OPIOL guideline to avoid delays in readmission in the event of an adverse reaction.<br>• Most 16 to 18 year olds are usually competent to consent to treatment and making decisions about participation in research (Health Research Authority, 2021). However, under 18s were excluded because the risk of perinatal death is highest amongst young people when compared to the reference group of women aged 30-34 (MBRRACE-UK, 2021). |

| Inclusion criteria | Justification |
|---|---|
| ○ Presenting part above the pelvic inlet<br>○ Suspected fetal growth restriction, anhydramnios, oligohydramnios or polyhydramnios based on abdominal palpation<br>○ Abnormal fetal heart recording<br>• English-speaking<br>• ≥18 years of age | |
| • Women eligible for OPIOL who went home<br>• Women eligible for OPIOL who did not go home<br>• Women who declined OPIOL | • To obtain a range of views from women about OPIOL whether they underwent the procedure or not. |
| • Well baby, living with mother | • To avoid causing distress to participant in the event of baby being unwell. |

# Appendix XVII Recruitment poster – clinicians

## Are you involved in giving information about or caring for women undergoing outpatient induction of labour?

We are looking for staff to participate in research about their views and experiences of outpatient induction of labour.

**What is in it for you?**

- An opportunity to improve care for women undergoing induction of labour in future
- Learn more about research
- Reflect on your clinical practice
- Contribute to research

**Staff involved in giving information to or caring for women undergoing outpatient induction are invited to take part:**

- Community midwives
- Midwives caring for women undergoing induction
- Labour Line midwives
- Obstetricians

**What's involved?**

- A confidential 30-60 minute interview in which we explore your views and experiences of caring for women undergoing outpatient induction of labour
- This can take place in a location convenient to you such as your home, [Location 1] or [Location 2]

## To find out more please contact lisa.smith@[NHS Trust].nhs.uk

Data collection taking place between February 2019 and January 2020

Project title: Views and experiences of women and staff of outpatient induction of labour: a mixed methods study
IRAS ID: 240694 ERGO ID: 31461
Poster take down date: February 2020
Document version: v0.4 Date: 25.11.18

# Appendix XVIII 'Maternity Mail' article

**Recruiting now for outpatient induction of labour study**

Women and staff will be asked about their views and experiences of outpatient induction of labour in a new study at [NHS Trust]. Around 18 per cent of 164 UK Trusts who responded to a recent survey have introduced outpatient induction but little is known about what women or staff think about this option. Lisa Smith is recruiting participants now.

The study will include women:

- Who were discharged home
- Who declined outpatient induction of labour
- Who were not actually discharged on the day due to complications

Staff involved in explaining outpatient induction to women, booking induction appointments or caring for women undergoing outpatient induction of labour are invited to take part.

You may be any one of the following:

- A midwife working in the midwifery-led pathway who provides antenatal care and books induction of labour appointments for women
- A midwife working in the induction of labour suite providing care to women commencing outpatient induction of labour
- A midwife caring for women who having outpatient induction of labour who return in labour or come back to continue the induction process
- An obstetrician involved in the care of women who are undergoing or have had outpatient induction of labour

The research will involve an interview of 30-60 minutes long to find out more about your experiences. Participant recruitment and interviews will take place between February 2019 and January 2020.

The research will be mixed methods in design and will also look at other induction of labour activity as well as women's outcomes.

If you would like to find out more, please get in touch with Lisa Smith (lisa.smith@[NHS Trust].nhs.uk). There is no obligation to take part and you can withdraw from the study at any time.

IRAS ID: 240694 ERGO ID: 31461
Document version: v0.4
Date: 25.11.18

# Appendix XIX ‘Theme of the week’

## Theme of the Week

### Researching women's and staff views and experiences of outpatient IOL

**Study title:** Views and experiences of women and staff of outpatient induction of labour: a mixed methods study
**Researcher:** Lisa Smith (PhD student and midwife)
**IRAS ID:** 240694 **ERGO ID:** 31461
Document version: v0.5 Date: 25.11.18

**Women booked for outpatient induction will be invited to take part in semi-structured interviews about their experiences. Recruitment and interviews between February 2019 and January 2020.**

**This will include women:**

- **Who were discharged home**
- **Who declined outpatient induction**
- **Who were not actually discharged home on the day due to complications**

**Staff involved in giving information to or caring for women undergoing outpatient induction are also invited to take part:**

- **Community midwives**
- **Midwives caring for women undergoing induction**
- **Labour Line midwives**
- **Obstetricians**

**For more information please email lisa.smith@[NHS Trust].nhs.uk**

# Appendix XX Participant information – clinicians

**Participant Information sheet**

**Study title**: Views and experiences of women and staff of outpatient induction of labour: a mixed methods study

Researcher: Lisa Smith (PhD student and Consultant Midwife)

IRAS ID: 240694 ERGO ID: 31461

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

**What is the research about?**

In 2015, [NHS Trust] launched an outpatient induction of labour service for women having their first baby who are at low risk of complications. Women are invited into hospital between 10 and 12 days past their due date and following a check-up, a controlled-release dinoprostone vaginal pessary is inserted. Providing the check-up is normal, women are then discharged home for 24 hours after they have been given advice about when to contact the service again. The pessary stays in place until labour starts, waters break or it is removed by a member of staff.

There is little evidence about what women and staff think about women returning home during this time and so this research aims to find out more about women's and staff views and experiences of outpatient induction of labour.

Participant recruitment and data collection will take place between February 2019 and January 2020.

**Who is conducting the study?**

Lisa Smith is conducting the research as part of a PhD at the University of Southampton. She is also a Consultant Midwife at [NHS Trust].

Document version: v0.5
Date: 20.12.18

**Why have I been asked to participate?**

You are eligible to take part in this research because:

- You are a midwife at [NHS TRUST] working in the midwifery led pathway and talk to women about outpatient induction of labour
- You are a midwife supporting women undergoing outpatient induction of labour
- You are a midwife working within the Labour Line telephone triage service
- You are an obstetrician involved in the care of women undergoing outpatient induction of labour

The researcher is aiming to recruit up to 12 members of staff and 12 women.

**What will happen to me if I take part?**

If you decide to take part this will involve having an interview lasting about 30-60 minutes with the researcher. You can choose whether you would like the researcher to come to your home, [Location 1] or [Location 2]. Parking and mileage expenses will not be reimbursed, however there are no parking charges at [Location 2]. On the day of the interview you will be asked to read and sign a consent form prior to being asked some questions about your views and experiences of talking to women about or caring for women undergoing outpatient induction of labour.

**Are there any benefits in my taking part?**

There may not be any direct benefits to you in taking part but it may increase your understanding of how research is undertaken. We hope the findings of the study may help improve care for women undergoing induction of labour.

**Are there any risks of taking part?**

There are no risks involved in taking part in the interview. In the unlikely event you feel upset during the interview, you will have the opportunity to stop at any time if you do not wish to continue. Similarly, the researcher may decide to stop the interview if you appear to be distressed. The researcher can direct you to sources of support such as the Trust's Employee Assistance Programme or your Professional Midwifery Advocate.

**What data will be collected?**

In line with the EU General Data Protection Regulation (GDPR) it is important that the researcher is fair and transparent about how data about you is collected and processed.

Data will be collected during the interview about your views and experiences of talking to women about or caring for women undergoing outpatient induction of labour. If you give consent, this will be in the form of an audio recording. If you decline the interview being recorded, the researcher may ask to make notes.

Some personal data is defined as special category data by the Data Protection Act (1998). This includes information on ethnicity, sexual orientation, gender identity, religious beliefs, genetic data or biometric data from which you can be uniquely identified and health data. Information of this nature disclosed during the interview will be anonymised.

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

At the beginning of the interview you will be given a unique participant code to act as a pseudonym to protect your confidentiality. During the research process it is important to be able to link your participant code with your personal data (your name and telephone number). An example of when this would be required would be if you wish to withdraw from the study. In this example, being able to link your participant code with your personal data would enable the researcher to retrieve and then destroy the correct interview data. However, to protect your confidentiality, the data file which contains both your personal information and your participant code would be stored securely in a separate password protected file to the interview data.

Only the researcher and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

If you give consent to the interview being audio-recorded, the device will be transported securely then the recording will be transcribed. The data file of the transcription will be stored securely in a password protected folder within the University of Southampton computer network and the original audio recording will then be deleted.

Your data will only be accessed by the researcher and will be stored securely and destroyed after 10 years following University guidelines.

Short quotes from your interview may be included in publications but by using a unique participant code to act as a pseudonym you would not be identifiable by others.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part.

**Making a decision to take part in the research study**

If you decide you would like to take part, or if you would like some more information before making a decision, please email Lisa Smith (lisa.smith@[NHS Trust].nhs.uk) to arrange a no-obligation discussion. Following this, if you decide you would like to take part in the research study, an appointment will be made for a 30-60 minute interview at a mutually convenient time. You will have a further opportunity to ask any questions about the research study before the interview and will be asked to read and sign a consent form to confirm you have agreed to take part.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. You can contact the researcher or the project supervisors. If you withdraw from the study, any data collected about you, such as your interview transcript, will be deleted.

**What will happen to the results of the research study?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

The findings of the research will be submitted for publication in academic journals. If you would like a copy of any findings please let the researcher know.

**Protecting women's health**

The researcher has a professional responsibility to challenge any poor practice identified during data collection in accordance with the NMC Code. This would involve a discussion to explore any learning from the incident as well as observing Trust risk management procedures. This may include submitting an adverse incident form and a wider Trust review of what happened.

**Where can I get more information?**

Please email lisa.smith@[NHS Trust].nhs.uk if you would like to take part or learn more about the research.

**Researcher**
Lisa Smith
[NHS Trust]
lisa.smith@[NHS Trust].nhs.uk
ls1r15@soton.ac.uk

**Supervisor**
Dr Elizabeth Cluett
Lead Midwife for Education
Director of Practice Projects
Building 67
Faculty of Health Sciences
University of Southampton
Southampton
SO17 1BJ
e.cluett@soton.ac.uk

**Supervisor**
Dr Julie Cullen
Head of Nursing Midwifery and Health, Faculty of Health Sciences
Building 67
Faculty of Health Sciences
University of Southampton
Southampton
SO17 1BJ
*j.cullen@soton.ac.uk*

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researcher who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

If you have a complaint about any aspect of your employment which has not been resolved by your line manager or the Director of Midwifery and Professional Lead for Neonatal Service, please contact Human Resources on 023 8120 4446 or your Trade Union Representative.

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

Appendix XX

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information linking you with the unique participant code given to you for 10 years after the study has finished after which time any link between you and your information will be removed. This identifiable information can only be accessed by the researcher.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

**Who has reviewed this research?**

The study has been approved by the NHS ethics committee and the University of Southampton.

**Who is organising and funding the research?**

PhD fees funded by Health Education Wessex as part of the Trainee Consultant Practitioner Programme 2015-18.

**Thank you for taking the time to read this information sheet.**

# Appendix XXI Social media post – women

## What are your views and experiences of outpatient induction of labour?

Starting labour artificially can take a while and some women prefer to spend time at home while they are being induced rather than waiting in hospital for their labour to start.

We are looking for women to take part in research about their views and experiences of outpatient induction of labour at [NHS Trust]. You can take part if:

- You have undergone outpatient induction of labour at [NHS TRUST] recently
- You declined outpatient induction of labour at [NHS TRUST]
- You were planning to have outpatient induction of labour at [NHS TRUST] but you developed complications that made this option inappropriate

Hearing about your experiences will help us improve care for women having induction of labour in future. Recruitment and data collection is taking place between February 2019 and January 2020.

**To find out more or if you would like to take part, please email lisa.smith@[NHS Trust].nhs.uk**

IRAS ID: 240694
ERGO ID: 31461
Document version: v0.4
Date: 25.11.18

# Appendix XXII Recruitment poster – women

## Are you having outpatient induction of labour?

**Background**

Starting labour artificially can take a while and it is appropriate for some women to spend time at home while they are being induced rather than waiting in hospital for their labour to start.

We are looking for women to take part in research about their views and/or experiences of outpatient induction of labour. You can take part if:

- You are undergoing outpatient induction of labour
- You declined outpatient induction of labour
- You were planning to have outpatient induction of labour but when you came to the hospital you were found to have developed complications that made this option inappropriate

Hearing what you think about outpatient induction of labour will help us improve care for women in future.

**What's involved?**

- A confidential 30-60 minute interview in which we explore your views and/or experiences of outpatient induction of labour a few weeks after your baby is born
- This can take place in a location convenient to you such as your home, [Location 1] or [Location 2]

**To find out more or if you would like to take part, please email**
**lisa.smith@[NHS Trust].nhs.uk**

Data collection taking place between February 2019 and January 2020

Project title: Views and experiences of women and staff of outpatient induction of labour: a mixed methods study
IRAS ID: 240694 ERGO ID: 31461
Poster take down date: February 2020
Document version v0.4 Date: 25.11.18

# Appendix XXIII Participant information leaflet – women

## Participant information sheet

**Study title**: Views and experiences of women and staff of outpatient induction of labour: a mixed methods study

Researcher: Lisa Smith (PhD student and Consultant Midwife)

IRAS ID: 240694 ERGO ID: 31461

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

**What is the research about?**

In 2015, [NHS Trust] launched an outpatient induction of labour service for women having their first baby who are at low risk of complications. Women are invited into hospital between 10 and 12 days past their due date and following a check-up, a controlled-release dinoprostone vaginal pessary is inserted. Providing the check-up is normal, women are then discharged home for 24 hours after they have been given advice about when to contact the service again. The pessary stays in place until labour starts, waters break or it is removed by a member of staff.

There is little evidence about what women and staff think about women returning home during this time and so this research aims to find out more about women's and staff views and experiences of outpatient induction of labour.

Recruitment and data collection will take place between February 2019 and January 2020.

**Who is conducting the study?**

Lisa Smith is conducting the research as part of a PhD at the University of Southampton. She is also a Consultant Midwife at [NHS Trust].

**Why have I been asked to participate?**

You have been chosen to take part in this research because

- You are having or have recently had outpatient induction of labour
- You chose not to have outpatient induction of labour
- You have had an uncomplicated pregnancy but after a check-up when you came into hospital, the staff decided outpatient induction of labour was not an appropriate option for you.

The researcher is aiming to recruit up to 12 women and 12 members of staff.

**What will happen to me if I take part?**

If you decide to take part this will involve having an interview lasting about 30-60 minutes with the researcher. You can choose whether you would like the researcher to come to your home, [Location 1] or [Location 2]. Parking and mileage expenses will not be reimbursed, however there are no parking charges at the [Location 2]. On the day of the interview you will be asked to read and sign a consent form prior to being asked some questions about your views and/or experiences of outpatient induction of labour.

**Are there any benefits in my taking part?**

There are no direct benefits to taking part but we hope the findings may help improve care for others undergoing induction of labour. Women who wish to ask questions about their birth experience will be directed towards the Birth Afterthoughts debrief service.

**Are there any risks of taking part?**

There are no risks involved in taking part in the interview. However, if you are affected by your birth experience, the researcher may decide to stop the interview if you appear to be distressed. Similarly, you may decide to stop the interview yourself at any time if you do not wish to continue. If there are concerns about your emotional wellbeing, as a registered midwife, the researcher would stop the interview and discuss this with you further. She would be able to refer you for further assessment with your GP, Improving Access to Psychological Therapies Service (IAPT) or the local Perinatal Mental Health Team as appropriate. The researcher can also direct you to the Birth Afterthoughts debrief service for further support if this would be helpful.

**What data will be collected?**

In line with the EU General Data Protection Regulation (GDPR) it is important that the researcher is fair and transparent about how data about you is collected and processed.

Data will be collected during the interview about your views and experiences outpatient induction of labour. If you give consent, this will be in the form of an audio recording. If you decline the interview being recorded, the researcher may ask to make notes.

Some personal data is defined as special category data by the Data Protection Act (1998). This includes information on ethnicity, sexual orientation, gender identity, religious beliefs, genetic data or biometric data from which you can be uniquely identified and health data. Information of this nature disclosed during the interview will be anonymised.

**Will my participation be confidential?**

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

At the beginning of the interview you will be given a unique participant code to act as a pseudonym to protect your confidentiality. During the research process it is important to be able to link your participant code with your personal data (your name and telephone number). An example of when this would be required would be if you wish to withdraw from the study. In this example, being able to link your participant code with your personal data would enable the researcher to retrieve and then destroy the correct interview data. However, to protect your confidentiality, the data file which contains both your personal information and your participant code would be stored securely in a separate password protected file to the interview data.

Only the researcher and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

If you give consent to the interview being audio-recorded, the device will be transported securely then the recording will be transcribed. The data file of the transcription will be stored securely in a password protected file within the University of Southampton computer network and the original audio recording will then be deleted.

Your data will only be accessed by the researcher and will be stored securely and destroyed after 10 years following University guidelines.

Short quotes from your interview may be included in publications but by using a unique participant code to act as a pseudonym you would not be identifiable by others.

**Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part.

**Making a decision to take part in the research study**

If you decide you would like to take part, or if you would like some more information before making a decision, please complete the expression of interest form attached, or email Lisa Smith (lisa.smith@[NHS Trust].nhs.uk) to arrange a no-obligation discussion. Following this, if you decide you would like to take part in the research study, an appointment will be made for a 30-60 minute interview at a mutually convenient time. This will take place approximately 6-12 weeks after the birth to allow you some time to recover. You will have a further opportunity to ask any questions about the research study before the interview and will be asked to read and sign a consent form to confirm you have agreed to take part.

**What happens if I change my mind?**

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. You can contact the researcher or the project supervisors. If you withdraw from the study, any data collected about you, such as your interview transcript, will be deleted.

**What will happen to the results of the research study?**

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

The findings of the research will be submitted for publication in academic journals. If you would like a copy of any findings please let the researcher know.

**Adult and child safeguarding**

As a registered midwife, the researcher has a professional responsibility to safeguard children and vulnerable adults. If the researcher has any concerns that you, your child or other household members are a risk of harm, the interview will be terminated. The researcher will then discuss her concerns with you and seek your consent for information sharing with other agencies who may be able to help. If you, your child or another household member is at risk of significant harm, the Data Protection Act 2018 makes a provision that referral may be made without your consent if gaining consent puts you, your child or other household member at additional risk.

**Where can I get more information?**

Please email lisa.smith@[NHS Trust].nhs.uk if you would like to take part or learn more about the research.

**Researcher**
Lisa Smith
Consultant Midwife
[NHS Trust]
lisa.smith@[NHS Trust].nhs.uk
ls1r15@soton.ac.uk

**Supervisor**
Dr Elizabeth Cluett
Lead Midwife for Education
Director of Practice Projects
Building 67
Faculty of Health Sciences
University of Southampton
Southampton
SO17 1BJ
e.cluett@soton.ac.uk

**Supervisor**
Dr Julie Cullen
Head of Nursing Midwifery and Health, Faculty of Health Sciences
Building 67
Faculty of Health Sciences
University of Southampton
Southampton
SO17 1BJ
*j.cullen@soton.ac.uk*

**What happens if there is a problem?**

If you have a concern about any aspect of this study, you should speak to the researcher who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

If you have a complaint about any aspect of your care which has not been resolved by the Ward Lead Midwife or Matron for Inpatient Services, please contact

Patient Support Services
[NHS Trust]

Telephone: [Trust telephone number]
Email: patientsupportservices@[NHS Trust].nhs.uk

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information linking you with the pseudonym you chose for 10 years after the study has finished after which time any link between you and your information will be removed. This identifiable information can only be accessed by the researcher.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

**Who has reviewed this research?**

The study has been approved by the NHS ethics committee and the University of Southampton.

**Who is organising and funding the research?**

PhD fees funded by Health Education Wessex as part of the Trainee Consultant Practitioner Programme 2015-18.

**Thank you for taking the time to read this information sheet.**

**(Continued)**

**Expression of interest**

**Study title**: Views and experiences of women and staff of outpatient induction of labour: a mixed methods study

Researcher: Lisa Smith (PhD student and Consultant Midwife)

IRAS ID: 240694 ERGO ID: 31461

Thank you for reading the information sheet about this research. If you would like to find out more or are interested in taking part and would be happy for the researcher, Lisa Smith, to contact you, please email lisa.smith@[NHS Trust].nhs.uk or complete your details below and give to your midwife. Filling out this form does not mean you have to take part.

Name ……..

Email address ……..

Telephone number ……..

Address ……..

……..

……..

……..

**Alternatively, please return to:**

Lisa Smith
[NHS Trust]

# Appendix XXIV Consent form – clinicians

**Views and experiences of women and staff of outpatient induction of labour: a mixed methods study**

**Consent form for staff**

Researcher: Lisa Smith
IRAS ID: 240694 ERGO ID: 31461

| Please initial the boxes if you agree with the statements | Participant initials |
|---|---|
| 1. I confirm that I have read and understand the information sheet dated …… version number …… for the above study and have had the opportunity to ask questions which have been answered satisfactorily. I have been given a copy of the information sheet to keep. | |
| 2. I agree to take part in this research project and agree for my data to be used for the purpose of this study and educational purposes. | |
| 3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. | |
| 4. I understand that relevant sections of data collected by the researcher may be looked at by responsible individuals from [NHS TRUST] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to these records. | |
| 5. I agree to the researcher making an audio recording of my interview. | |
| 6. I agree to the researcher taking notes during the interview. | |
| 7. I understand that the researcher may use direct quotes I make in publications about the research, but that I will not be able to be identified through these quotes. | |

| …….. | …….. | …….. |
|---|---|---|
| Name of participant | Date | Signature |
| …….. | …….. | …….. |
| Name of researcher | Date | Signature |

**ENQUIRIES:**
Lisa Smith
Email: lisa.smith@[NHS Trust].nhs.uk

□ Original in researcher's file
□ Copy to participant

Document version: v0.3

Date: 26.11.18

# Appendix XXV Consent form – women

**Views and experiences of women and staff of outpatient induction of labour: a mixed methods study**

**Consent form for women**

Researcher: Lisa Smith

IRAS ID: 240694 ERGO ID: 31461

| Please initial the boxes if you agree with the statements | Participant initials |
|---|---|
| 1. I confirm that I have read and understand the information sheet dated …… version number …… for the above study and have had the opportunity to ask questions which have been answered satisfactorily. I have been given a copy of the information sheet to keep. | |
| 2. I agree to take part in this research project and agree for my data to be used for the purpose of this study and educational purposes. Data will be stored on a password protected computer. | |
| 3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. | |
| 4. I understand that relevant sections of my medical records and those of my baby as well as relevant sections of data collected by the researcher may be looked at by responsible individuals from [NHS TRUST] or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to these records. | |
| 5. I agree to the researcher making an audio recording of my interview. | |
| 6. I agree to the researcher taking notes during the interview. | |
| 7. I understand that the researcher may use direct quotes I make in publications about the research, but that I will not be able to be identified through these quotes. | |

| …… | ……. | ……. |
|---|---|---|
| Name of participant | Date | Signature |
| …… | ……. | …….. |
| Name of researcher | Date | Signature |

**ENQUIRIES:**
Lisa Smith
Email: lisa.smith@[NHS Trust].nhs.uk

□ Original in researcher's file
□ Copy to participant
□ Copy in participant's electronic medical records

Document version: v0.3

Date: 25.11.18

# Appendix XXVI Interview checklist and prompts

- Welcome participant and show University and Trust identification badge
- Offer participant refreshments and ensure they are comfortable (depending on where interview is taking place)
- Explain purpose of the interview
- Clarification of topic under discussion
- Explain the format of the interview and that there will be opportunity to ask questions about care at the end
- Approximate length of the interview
- Assurance of confidentiality
- Purpose of digital recorder – ask permission to use. Explain who will listen to the recording
- Assure participant that he or she may seek clarification of questions
- Assure participant that he or she can decline to answer a question
- Assure participant that he or she can withdraw from the study at any stage
- Assure participant that there will be an opportunity during the interview to ask questions
- Explain the purpose of note taking during the interview
- In line with Good Clinical Practice guidelines, if the participant is service user, explain that documentation of the consent process in the patient's health records is required
- Sign the consent form
- Does the participant wish to be notified about the results and how would they like this to happen (e.g., email, letter, SMS)? Contact details would be kept separate from research data and stored securely in a password protected file.

*Prompt questions for women*

Can you tell me about how OPIOL was explained to you?

If you went home, can you tell me about your experience?

If you declined OPIOL, can you explain the reasons that led to your decision?

From protocol v0.12 25.11.18

If you stayed in hospital for another reason, can you tell me about your experience?

What contact did you have with professionals during the induction process and what was your experience of this?

What support was your birth partner able to give you during the induction process?

What contact and support were your friends and family able to give you during the induction process?

If you went home, can you tell me more about how you knew when to come back to hospital?

If you went home, can you tell me more about your journey back to hospital?

*Prompt questions for clinicians*

Can you tell me about your experience talking to women about OPIOL?

Can you tell me about your experience of supporting women undergoing OPIOL?

Can you tell me more about how OPIOL affects your workload?

# Appendix XXVII Induction of labour activity July 2015 to June 2018

| | n | % |
|---|---|---|
| **Number of women induced** | 4402 | |
| **Parity** | | |
| Nulliparous | 2306 | 52.39 |
| Multiparous | 2096 | 47.61 |
| **Median gestation at birth (interquartile range)** | 40 | ($38^{+5}$ – $41^{+4}$) |
| **Number of reasons cited for induction (total)** | 4826 | |
| 0 | 41 | 0.8 |
| 1 | 3911 | 81.0 |
| 2 | 413 | 8.6 |
| 3 | 33 | 0.7 |

# Appendix XXVIII Outcomes of women not discharged due to fetal concerns following administration of dinoprostone pessary

| Summary (n=11) | Birth outcome | Pessary to birth interval (hh:mm) | Apgar score at 5 mins | Admission to neonatal unit |
|---|---|---|---|---|
| Very active baby noted. Transferred to antenatal ward for further fetal monitoring in the evening. | Forceps birth | 22:05 | 10 | No |
| Very active baby noted. Transferred to antenatal ward for further fetal monitoring in the evening. | Ventouse birth – suspected fetal compromise | 49:58 | 8 | No |
| CTG baseline rate 158bpm. Some episodes of fetal tachycardia. Transferred to antenatal ward for further fetal monitoring in the evening. | Unplanned caesarean – suspected fetal compromise | 51:06 | 9 | No |
| One concerning deceleration. Narrative states likely to be positional as woman lying flat. Continued CTG and transferred to antenatal ward. | Unplanned caesarean – unsuccessful induction | 45:51 | 10 | No |
| Initial CTG baseline rate 160bpm. Normal CTG prior to transfer to antenatal ward. | Unplanned caesarean – slow progress | 49:15 | 10 | No |
| Initial CTG had deceleration lasting 2 minutes. Normal CTG prior to transfer to antenatal ward. | Unplanned caesarean – suspected fetal compromise | 12:33 | 8 | No |

| Summary (n=11) | Birth outcome | Pessary to birth interval (hh:mm) | Apgar score at 5 mins | Admission to neonatal unit |
|---|---|---|---|---|
| One non-concerning deceleration in otherwise normal CTG. Narrative states in context of baby measuring small for dates (symphysis fundal height of 36cm at 41+5 weeks of gestation), decision made to transfer to antenatal ward. | Unplanned caesarean – suspected fetal compromise | 20:13 | 10 | No |
| Prolonged deceleration, CTG normalised and decision made to transfer to antenatal ward. | Unplanned caesarean – suspected fetal compromise | 11:06 | 10 | No |
| Fetal bradycardia for 6 minutes. CTG subsequently categorised as normal and later it was discontinued and the woman was able to mobilise. | Emergency caesarean due to suspected fetal compromise | 40:08 | 10 | No |
| Narrative states shallow decelerations noted in sleep phase. CTG normalised and transfer to antenatal ward. | Forceps birth | 44:51 | 7 | No |
| CTG initially graded as suspicious with one non-concerning decelerations and three shallow decelerations then normalised. CTG repeated 2 hours later, frequent uterine contractions (6 in 10 minutes) and CTG graded as suspicious. Doctor review and pessary removed. | Emergency caesarean – suspected fetal compromise | 25:29 | 10 | No |

# Appendix XXIX Clinical governance and the evolution of maternity safety strategy

Clinical governance was introduced in the NHS in response to falling public opinion in the 1990s following high profile scandals such as the inquiry into child cardiac surgery at Bristol Royal Infirmary and failures of the UK cervical screening programme (Halligan and Donaldson, 2001; Scamell, 2016). In 1997, the UK Labour Government published their white paper, the New NHS: Modern and Dependable which laid out a strategy to increase both quality and efficiency (Department of Health, 1997). Clinical governance was highlighted in the paper as a means to help restore public confidence by ensuring the delivery of evidence-based practice, embedding a culture of audit and service improvement and ensuring that adverse incidents were investigated, and learning put into practice quickly. While quality improvement initiatives were nothing new, the white paper addressed it explicitly and the 1999 Health Act which followed placed a statutory duty of quality on NHS and Primary Care Trusts. The 1997 white paper also announced the creation of the National Institute for Clinical Excellence (NICE) which was established to develop national standards and guidelines. National Service Frameworks were also implemented which described standards and pathways for improving priority health areas, alongside responsibilities and agreed time scales for implementation.

The evolution of the clinical governance framework in the NHS also aimed to combat rising litigation costs driven by legal reforms which have had a significant impact on legal markets over the past 25 years (National Audit Office, 2017). In 1995, the Courts and Legal Services Act 1990 came into force which introduced ‘no-win-no-fee’ arrangements and the same year, the NHS Litigation Authority (NHSLA) was established and this aimed to reduce NHS costs by managing and defending unjustified claims robustly and working with trusts to improve risk management and patient safety. NHSLA also established the Clinical Negligence Scheme for Trusts (CNST), a pay-as-you-go scheme covering clinical negligence claims for incidents which have occurred on or after 1st April 1995 (NHS Resolution, 2018). Despite these changes, legal claims have continued to rise faster than increases in NHS funding (National Audit Office, 2017; Tingle, 2021).

A key watershed was reached in maternity services in 2015 and a number of landmark announcements and strategies gave further momentum to the maternity safety agenda. From January 2015, the Royal College of Obstetricians and Gynaecologists commenced data collection for their Each Baby Counts strategy and every trust and health board in the UK was required to submit data via a secure online platform about adverse intrapartum and neonatal events involving term babies at 37 weeks of gestation or more. The eligibility criteria were defined as

intrapartum stillbirth, early neonatal death and severe brain injury diagnosed within the first week of life (Royal College of Obstetricians and Gynaecologists, 2016).

Maternity services were in the media spotlight again in March 2015. Firstly, the Morecambe Bay Report was published in March 2015 following maternity and neonatal care failings at Furness General Hospital between January 2004 and June 2013. Key themes included poor clinical competence, insufficient recognition of risk, an inappropriate pursuit of normal childbirth and poor team working. The report also identified inadequate clinical governance arrangements and lack of board oversight as well as failures in external scrutiny (Kirkup, 2015). Despite this, the media focussed on the arrogance of a group of 'Musketeer midwives' and dysfunctional working relationships (Malone, 2015).

The Montgomery v Lanarkshire Health Board [2015] judgment was made the same month at the Supreme Court in London. Nadine Montgomery was a woman with diabetes and had a large fetus and yet the risk of shoulder dystocia and its potential implications were not discussed, and neither was the alternative option of planned caesarean birth. After the birth in 1999 was delayed due to shoulder dystocia, her son sustained a hypoxic brain injury and developed cerebral palsy. Despite criticisms that the judgment disregarded national guidance and evidence, this high-profile case was widely reported in the media at the time and continues to have a significant impact on informed decision-making and discussions between health care professionals and patients (Montgomery and Montgomery, 2016). It represented a shift away from a patriarchal 'doctor knows best' model to one in which health care professionals are expected to explore what matters to the patient, take reasonable care to any material risks of intervention or treatment, and provide information about alternative options. There were concerns about possible implications of the judgment, that it risked overwhelming patients with information and that a further increase in defensive practices would ensue. It also signalled a significant shift towards giving patients greater autonomy which some feared could undermine professional expertise and more nuanced negotiation about benefits and risks (Montgomery and Montgomery, 2016; Chan *et al.*, 2017b; Chervenak and McCullough, 2017). However, the legal principles have become embedded in GMC guidance on decision-making and consent, replacing the previous Bolam test, which asked whether a doctor's conduct would be supported by a responsible body of medical opinion and instead determining what a reasonable patient would expect to know (General Medical Council, 2020). Furthermore, analysis of NHS 'failure to inform' claims identified a four-fold increase since the judgement in 2015 (Wald, Bestwick and Kelly, 2020).

Lastly, a national review of maternity services was commissioned in March 2015 by NHS England to embed learning from the Morecambe Bay report and to consider how tariff-based NHS funding could support women's choices as recommended in the wider Five Year Forward View (NHS England, 2014). The terms of reference included reviewing safe and efficient models of maternity care, including service delivery in isolated rural areas. The recommendations in *Better Births* which were published in February 2016 emphasised the importance of delivering safe and personalised care, by providing continuity of carer, improved multiprofessional working and better access to perinatal mental health services. It also emphasised the importance of developing a safety culture as well as ensuring Trust board level focus on maternity safety and quality (National Maternity Review, 2016).

At this time, the stillbirth rate in the UK was 4.7 per 1000 live births and when late stillbirths from 28 weeks' gestation were compared, the UK ranked 24$^{th}$ out of 49 high-income countries. As a result, the Secretary of State for Health announced a national ambition in November 2015 to halve the rates of stillbirths, neonatal and maternal deaths and intrapartum brain injuries by 2030, a target that was later brought forward to 2025 (Department of Health, 2015).

The maternity safety agenda gained further momentum the following year following the publication of Spotlight on Maternity in March 2016 – a collaborative publication by NHS England, the Department of Health, Monitor, NHS Trust Development Authority, NHSLA and the CQC. This report recommended the development of bespoke safety improvement plans with board level oversight within each Trust. Multiprofessional working was emphasised and regular safety briefings and huddles were recommended as ways to build an effective safety culture within organisations. Improved access to perinatal mental health services were also highlighted (Sign Up to Safety, 2016).

Later the same month, the Saving Babies Lives Care Bundle was launched which focussed on reducing smoking in pregnancy, detection of fetal growth restriction, management of reduced fetal movements and improving fetal monitoring in labour (NHS England, 2016). While it was not possible to determine whether changes were directly attributable to the care bundle itself, retrospective data from 19 Trusts showed a significant reduction in the stillbirth rate in participating Trusts from 4.2 to 3.4 per 1000 over a four-year period (RR 0.80; 95% CI 0.70-0.90) (Widdows *et al.*, 2021). However, there were also significant increases in induction of labour (19.4 per cent) and both planned (19.5 per cent) and unplanned caesarean birth (9.5 per cent). The number of ultrasound scans increased from 3.5 per pregnancy to 4.3 per pregnancy in the 8 Trusts providing complete data. Furthermore, antenatal detection of small for gestational age infants increased from 33.8 to 53.7 per cent. The evaluation also identified increases in preterm birth,

neonatal unit admission and therapeutic cooling of 6.5, 17.1 and 27.7 per cent respectively since implementation (Widdows *et al.*, 2018), and version two of the Saving Babies' Lives Care Bundle added a fifth element focussing on the reduction of preterm birth (NHS England, 2019b).

The Maternity and Neonatal Health Safety Collaborative was launched in February 2017 to work with all trusts to build quality improvement capability and support the development of a safety culture as part of a three-year programme (NHS England, 2017d). Key national drivers were identified to focus improvement activities, including increasing the number of smoke-free pregnancies, improvements to screening and management of diabetes, optimisation and stabilisation of the very preterm infant, detection and management of neonatal hypoglycaemia and improving the early recognition and management of deterioration during labour and early postpartum period. Teams from individual Trusts were invited to participate in the collaborative in a series of three waves and share their improvement projects.

NHSLA was renamed in April 2017 as NHS Resolution (NHSR) signalling a move towards a more proactive approach. Due to ongoing concerns about high value claims in maternity, the 2017/18 Maternity Incentive Scheme was launched, which offered trusts up to a 10 per cent discount on their insurance contributions by demonstrating achievement of strategic safety actions. However, in September 2017, a National Audit Office report called for urgent government action due to continuing rising costs of litigation (National Audit Office, 2017). NHSR was called to provide evidence to the Public Accounts Committee in November that year due to the worrying trajectory of annual claims which was forecast to be £3.2 billion by 2020 (House of Commons Committee of Public Accounts, 2017).

Subsequently, NHSR extended the Maternity Incentive Scheme in 2018/19 and 2019/20 (extended due to Covid-19) to include additional key safety actions including those of other national safety strategies such as Avoiding Term Admissions into Neonatal Units and the Saving Babies' Lives Care Bundle (NHS England, 2016; Battersby *et al.*, 2017). NHSR also launched the Early Notification Scheme in April 2017 which requires Trusts to notify NHSR of all cases of possible severe neonatal brain injury within 30 days where there is a possibility of a high value claim exceeding £500,000. The Early Notification Scheme commences a preliminary investigation to identify early learning and also ensures records and other evidence are preserved which may be required in the event of a future claims.

In August 2017, the Royal College of Midwives came under heavy scrutiny for removing references to its Campaign for Normal Birth from its website having made the decision three

years previously to align their campaign activity with the *Better Births* agenda. This fuelled an outpouring of criticism in both the press and on social media of midwives akin to a 'contemporary witch-hunt' (Schiller, 2017). Baby deaths were blamed on the 'cult of normal birth' despite randomised controlled trial evidence that women receiving midwife-led continuity of care are 16 per cent less likely to experience a stillbirth or neonatal death (Sandall *et al.*, 2016b; Downe, 2017; Schiller, 2017).

The NHSR report, *Five Years of Cerebral Palsy Claims*, followed in September 2017 and found errors in fetal heart rate monitoring, breech birth, inadequate quality assurance around staff competency and training and poor quality investigations at local level as well as lack of family involvement (NHS Resolution, 2017). Jeremy Hunt, then Secretary of State for Health, announced the launch of *Safer Maternity Care* in November 2017 – a refreshed maternity safety strategy which brought forward the target date to halve rates of stillbirths, neonatal and maternal deaths and intrapartum brain injuries from 2030 to 2025 (Department of Health, 2017). An independent NHS safety investigator, the Healthcare Safety Investigation Branch, was also established to improve the rigour and quality of investigations. HSIB became operational in April 2018 and has since published a number of national learning reports and recommendations following thematic analysis of maternity incidents (Healthcare Safety Investigation Branch, 2020).

Despite the strategic focus on the maternity safety agenda and investment in embedding quality improvement within Trusts, further maternity scandals have been reported in the media following the Morecambe Bay Report. After a series of maternal and neonatal deaths at Shrewsbury and Telford NHS Trust an independent review was announced in April 2017, although the review was delayed as further family members came forward. Interim findings were reported in December 2020 which included seven immediate and essential safety actions for all NHS Trusts following clinical review of 250 cases (Ockenden, 2020). Similarly, in February 2020 an independent review of East Kent maternity services led was announced in Parliament (Kirkup, 2021). Further reviews have been undertaken at Cwm Taf Morgannwg University Health Board and Nottingham (Care Quality Commission, 2020; Independent Maternity Services Oversight Panel, 2021)

Latest figures suggest there has been some progress towards achieving the mandated national ambition to halve stillbirths and neonatal deaths in England by 2025 from 2010. In 2020, stillbirths in England and Wales were the lowest on record at 3.8 per 1000 (Office for National Statistics, 2021a). However, neonatal deaths in the first 28 days of life have remained static over the past few years at 2.8 per 1000 (Office for National Statistics, 2021b). Furthermore, there has been a statistically non-significant increase in the overall maternal death rate in the UK between 2013-15 and 2016-18 from 9.16 to 9.7 per 100,000. Mortality rates are higher amongst older women,

those with pre-existing medical conditions, women living in the most deprived areas and amongst women with Black, Asian and mixed ethnic backgrounds and improvements in care may have made a difference to the outcome for 51 per cent of women who died (MBRRACE-UK, 2020). Despite differences in maternal and perinatal mortality associated with ethnicity having been reported in preceding MBRRACE reports for many years previously, the Covid-19 pandemic highlighted differences in mortality more widely across the NHS (Public Health England, 2020a). Achieving equity in outcomes for women of Black, Asian and minority ethnic backgrounds was formally included in national maternity strategy and key actions include delivery of continuity of care and improving uptake of Healthy Start vouchers and immunisation programmes (NHS England, 2020; Public Health England, 2020b).

# Appendix XXX  List of accompanying materials

The dataset supporting this doctoral thesis is available at:

https://doi.org/10.5258/SOTON/D2321