Perineal re-suturing versus expectant management following vaginal delivery complicated by a dehisced wound 'The PREVIEW Study'

Thesis submitted in accordance with the requirements of

Staffordshire University for the award of the degree of

Doctor of Philosophy

by

Lynn Dudley

(RN, RM, BSc, Supervisor of Midwives)

November 2014

Faculty of Health Sciences Staffordshire University

ABSTRACT

TITLE OF THE STUDY: Perineal re-suturing versus expectant management following vaginal delivery complicated by a dehisced wound (PREVIEW): A mixed methods study, incorporating a pilot and feasibility randomised controlled trial.

BACKGROUND: Each year approximately 350,000 women in the United Kingdom (UK) experience perineal suturing following childbirth. For those women whose perineal wound dehisces, the management will vary according to individual practitioner's preferences. For most women the wound will be managed expectantly (healing by secondary intention) whereas others may be offered re-suturing. However, there is limited scientific evidence and no clear guidelines to inform best practice.

DESIGN: PREVIEW was a four-phase study, using a sequential range of quantitative and qualitative paradigms including:

- A Cochrane systematic review (phase 1)
- A comparative retrospective case note audit (phase 2)
- A national electronic survey (phase 3)
- A multi-centre pilot and feasibility randomised controlled trial (RCT) (phase 4, part 1) and semi-structured interviews with women who participated in the RCT (phase 4, part 2). Phase four was the main component of the study.

AIMS AND OBJECTIVES:

Phase 1:

- Evidence synthesis for the therapeutic effectiveness of secondary suturing of dehisced perineal wounds following childbirth compared to non-suturing.

Phase 2:

- Explore risk factors associated with perineal wound dehiscence, with the use of a logistic regression model.

Phase 3:

- Survey current practice relating to the current management of dehisced perineal wounds from a representative cohort of RCOG members.

Phase 4:

- Establish the feasibility of conducting a definitive RCT comparing re-suturing of dehisced perineal wounds versus expectant management.
- Provide preliminary evidence of the effectiveness of re-suturing versus expectant management for dehisced perineal wounds following childbirth.
- Explore women's experiences of living with a dehisced perineal wound.

METHODS:

Phase 1: A systematic review of RCTs investigating re-suturing versus expectancy for dehisced perineal wounds following childbirth. This was conducted in accordance with Cochrane guidance.

Phase 2: Case notes from women with perineal wound dehiscence (n=100) were compared with case notes from women with no dehiscence (n=100) using an audit tool developed in accordance with NHS Litigation Authority guidance.

Phase 3: National electronic survey of **m**embers of the Royal College of Obstetricians and Gynaecologists.

Phase 4: A mixed methods study where participants with a dehisced perineal wound were recruited to one of ten participating centres and randomised to either re-suturing or expectant management. The primary outcome for the RCT was time taken to heal. The secondary outcomes were: pain, dyspareunia, women's satisfaction with the aesthetic results of healing and breast feeding. A purposive sample of women who participated in the RCT were interviewed for the qualitative study.

RESULTS:

Phase 1: The Cochrane systematic review (2 studies n=52 women) recommended that there was an urgent need for a robust randomised trial to fully evaluate the comparative effects of both treatment options.

Phase 2: The audit (n=200 case notes) revealed that episiotomy was an increased risk factor for perineal wound dehiscence.

Phase 3: The national survey (n=53 respondents) confirmed the lack of evidence based guidelines to support clinical practice.

Phase 4: The mixed methods study revealed a number of feasibility issues, particularly relating to a strong patient preference for a treatment option and researcher/clinician engagement at recruiting centres which would need careful consideration before proceeding to a definitive study. Thirty four women were

randomised in the pilot RCT (17 in each arm). A further 95 women were eligible but not randomised. Data from 33 women were analysed on an intention to treat analysis. There was a trend for increased wound healing at 2 weeks following randomisation, Odds Ratio (OR) 20.00 95% Confidence Interval (CI) (2.04, 196.37) *P* = 0.004 but no difference at 6 weeks. Findings from the interviews (n=6) revealed 4 emerging themes: physical impact, psychosocial impact, sexual impact, satisfaction with healing and an 'a priori' theme participating in the RCT.

CONCLUSIONS:

This study has contributed to the paucity of literature surrounding perineal wound dehiscence. The results of the RCT should be interpreted with some caution due to the relatively small numbers included in the final analysis, mostly due to patient preference for a treatment option. However, there was a significant trend to favour re-suturing for the primary outcome measure of wound healing and the overall findings of phase four show that a further study is feasible. Furthermore, data from this study will be included in future updates of the Cochrane review published in 2013 and presented in chapter three of this thesis.

THE RESEARCH TEAM

The author of this thesis, Lynn Dudley conducted the whole of the research for her doctoral studies and was the lead midwife and trial co-ordinator for the PREVIEW randomised controlled trial.

Lynn Dudley in collaboration with Professor Emerita C Kettle conceived the original idea for the research.

The PREVIEW research team consisted of the following members:

- Professor Emerita C Kettle, Professor in Women's Health, Staffordshire University, UK (primary doctoral research supervisor)
- Professor KMK Ismail, Professor of Obstetrics and Gynaecology, The Birmingham centre of Women's and Children's Health, College of Medical and Dental Sciences, University of Birmingham, UK (Chief Investigator for the study and secondary doctoral research supervisor)
- Professor P Thomas, Director (Methodology) Bournemouth University Clinical Research Unit and Consultant for the NIHR Research Design Service (statistical support for the study)
- Dr P Carter, Research Fellow (User Involvement) Arthritis Research UK Primary Care Centre , Keele University , UK (November 2009, to February 2012) and Dr J Waterfield, Senior Lecturer, School of Health and Rehabilitation, Keele University, UK (qualitative research guidance and support).

Professor Kettle and Professor Ismail are experts in the field of perineal assessment, management and repair and have collaborated on previous research studies of a similar phenomenon with Professor Thomas.

Principle Investigators (PIs) and lead research midwives were identified at each recruiting site.

DEDICATION

This work is dedicated to the memory of my parents Peter and Andrea Dudley.

I know you would be immensely proud of my achievements.

Mrs Andrea Dudley (11.09.1942 - 02.04-1988)

Mr Peter Dudley (06.03.1942 - 26-05-2013)

Also to my dear, courageous friend and fellow midwife Pat who was going to proof read this thesis; your unrelenting support and humour despite your pain will never be forgotten.

Mrs Patricia Hampton (08.12.1963 - 01.05-2014)

ACKNOWLEDGEMENTS

My passion and enthusiasm for evidence based midwifery practice has been the driving force behind conducting this research, however there have been some very challenging times. Completing the study and this thesis would not have been possible without the encouragement and support of several people whom I would personally like to thank for allowing me this incredible opportunity.

Firstly, I would like to thank my principle research supervisor Professor Emerita Christine Kettle who has not only been a constant source of support and advice but has also encouraged me to use various methods of investigating the phenomena of interest, thereby widening my academic skills, knowledge and experience. Professor Kettle it has been an absolute privilege to work alongside you over the years both clinically and academically, you are a constant source of inspiration for many midwives throughout the world.

Secondly, I would like to thank my additional research supervisor Professor Khaled Ismail. I am extremely grateful for your continual encouragement, advice, support and constant belief in my academic abilities.

I would like to express my immense gratitude to Professor Peter Thomas and Dr Zoe Sheppard for your expert statistical support and guidance. Your time and patience with me in an area that I found particularly challenging was very much appreciated. Also Dr Pam Carter and Dr Jackie Waterfield, thank you so much for your time and support with the qualitative study. I was a novice to qualitative research but with your expertise, advice and words of encouragement and positivity, I need not have worried about being out of my comfort zone.

Other individuals who have assisted me on this journey that I wish to thank are Dr Frank Lally. I am so grateful for your time and remarkable patience assisting me with end note, statistical analysis, formatting the thesis and your frequent phone calls to make sure I was coping. Dr Darren Clement and the research & development team at the University Hospital of North Staffordshire (UHNS) for their constant support relating to research governance and funding applications. The research design service team at Keele University for their expertise and support in preparing the Research for Patient Benefit (RfPB) grant application and Mr Ian Bailey for your efficient management of the RfPB funding.

I would particularly like to thank my special friends, midwifery, medical and managerial colleagues at the UHNS too numerous to mention individually. Thank you all for your persistent belief in my abilities and unwavering support over the last six years.

I am extremely grateful to the research teams, midwives and doctors at all the recruiting sites for their commitment to the study. Thank you so much to you all for your continual efforts to increase recruitment despite your heavy workloads. I personally have gained so much from working with all of you.

I deeply express my immense gratitude to all the women for taking part in the RCT and interviews, without you this study would not have been possible.

Funding is extremely competitive for research so I am gratefully indebted to the Smith and Nephew Foundation who believed in the study from the outset and awarded me a Doctoral Nursing Fellowship in 2008 (the financial commitment was subsequently continued by Research into Ageing when the charitable side of the Smith and Nephew Foundation dissolved). Also to the National Institute for Health Research, for their RfPB award in 2010 which enabled the successful completion of the study.

My final thank you must go to my partner Andrew, and my brother and sister, Mark and Lavelle. Thank you for being there for me and for sharing in my frustrations and successes. Mum and Dad would be so proud of us all.

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CHAPTER ONE: INTRODUCTION

1.1 Background to the study

A review of the literature indicates that perineal trauma associated with vaginal delivery affects a vast amount of women throughout the world. Following childbirth approximately 85% of women in the United Kingdom (UK) alone will sustain some degree of perineal trauma and more than 70% will need stitches to facilitate healing of a spontaneous tear or episiotomy (Health and Social Care Information Centre, 2012a; Kettle and Tohill, 2008; McCandlish *et al*, 1998; Sleep *et al*, 1984).

Given that the postpartum management of perineal trauma, including the prevention of wound infection and assessing wound healing are core components of routine maternity care (Bick, 2009; National Institute for Health and Care Excellence, 2006; National Collaborating Centre for Women's and Children's Health, 2007; Steen, 2007), there is limited research evidence available on the management and consequences of perineal wound infection and dehiscence.

For those women whose perineal wound dehisces, the management will vary according to individual clinician preference. In the majority of cases, the wound will be managed expectantly whereas others may be offered re-suturing. Healing by expectancy may take up to 16 weeks and can lead to protracted periods of morbidity leaving the new mother feeling very traumatised (Hankins *et al*, 1990; Ramin *et al*, 1992; Uygur *et al*, 2004). Some of these women may even request that the mode of delivery for subsequent pregnancies will be via caesarean section to avoid further perineal damage. Moreover, in the eighth confidential enquiry into maternal mortality, sepsis was identified as the leading cause of

maternal mortality in England and Wales (Centre for Maternal and Child Enquiries, 2011) and wound dehiscence is commonly associated with infection.

Several retrospective studies (Arona *et al*, 1995; Hankins *et al*, 1990; Ramin *et al*, 1992; Uygur *et al*, 2004) and two small randomised controlled trials (Christensen *et al*, 1994; Monberg and Hammen, 1987) have suggested that secondary perineal repair is an alternative to expectant management for dehisced perineal wounds even in the presence of infection. However previous studies have demonstrated considerable methodological weaknesses. Hence there was an urgent need for a comprehensive clinical trial to identify the best management strategy for dehisced perineal wounds following primary repair of the initial trauma.

Appendix 1 provides a timeline for the components of the PREVIEW study, presented in this thesis.

1.2 Classification of perineal trauma

Perineal wounds may occur spontaneously during childbirth and are classified as first, second, third or fourth degree trauma. The current classification of perineal trauma, presented in table 1, was proposed by Sultan (1999) and has been adopted by national clinical guidelines (National Collaborating Centre for Women's and Children's Health, 2007; Royal College of Obstetricians and Gynaecologists, 2007) and the International Consultation on Incontinence (Norton *et al*, 2002).

Table 1: Classification of perineal trauma wounds

Classification of perineal trauma wounds (Sultan, 1999)	
First degree	Injury to the skin only
Second degree	Injury to the perineum involving the perineal muscles but not involving the anal sphincter
Third degree	Injury to the perineum involving the anal sphincter complex. **3a** <50% of the external anal sphincter (EAS) thickness torn **3b** >50% of the EAS torn **3c** Internal anal sphincter (IAS) torn
Fourth degree	Injury to the perineum involving the anal sphincter complex EAS and/or IAS and the anal epithelium
Third and fourth degree tears are commonly referred to as OASIS	

Spontaneous third and fourth degree perineal trauma is now commonly referred to as OASIS an acronym for Obstetric Anal Sphincter Injuries. Unless specified, where studies that have included OASIS are referred to in this thesis, this acronym will indicate either third or fourth degree trauma or both.

A perineal wound may also be caused by performing an episiotomy which is a surgical incision to increase the diameter of the vaginal outlet to facilitate the baby's birth (Kettle *et al*, 2012). An episiotomy involves the same structures as a second degree tear.

1.3 Aetiology and risk factors of perineal wound dehiscence

Perineal wound dehiscence is associated with infection, haematoma formation and sub-optimal care such as poor suturing techniques. Numerous risk factors for delayed wound healing have been identified in the literature. In addition to infection, these include: poor nutrition, obesity, smoking, stress, tissue hypoxia, poor hygiene, medical conditions and therapies. Whilst predisposing factors for perineal wound dehiscence following childbirth are reported in several retrospective studies as being: operative vaginal delivery (forceps or vacuum delivery), episiotomy, prolonged second stage, birth weight, third and fourth degree tears and meconium liquor.

1.4 The purpose of the research study

Worldwide, there is currently no robust evidence as to whether early re-suturing or expectant management is associated with better outcomes for women. The majority of dehisced perineal wounds are currently managed by expectancy which is also referred to as healing by secondary intention. To retain consistency of nomenclature throughout this thesis the term expectancy will be used where appropriate.

The whole of the study presented in this thesis was called 'PREVIEW' which is an acronym for '**P**erineal **re**-suturing **v**ersus expectant management following vaginal delivery complicated by a deh**i**sc**e**d **w**ound'. PREVIEW was conducted in 4 phases by the author of this thesis and was designed to provide the most comprehensive world-wide evidence relating to the management of dehisced perineal wounds to date.

Phase one of PREVIEW was dedicated to completing a Cochrane systematic review of the literature 'Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth', conducted by the author in collaboration with her research colleagues (Dudley *et al*, 2013a).

Phase two of PREVIEW was a local retrospective comparative case note audit, conducted to determine risk factors associated with perineal wound dehiscence and to collect baseline data to inform the development of standards against which future care is provided and measured.

Phase three focused upon a national electronic survey of members of the Royal College of Obstetricians and Gynaecologists, carried out to establish the current management of dehisced perineal wounds. To the best of the author's knowledge this is the first time a comparative case note audit and a national survey of the current practice of dehisced perineal wounds have been conducted in the UK.

Phase four was the major component of PREVIEW, conducted in two parts using sequential range of both quantitative and qualitative paradigms commonly referred to as mixed methods research.

Part one was a multi-centre, pilot and feasibility RCT designed to assess the feasibility of conducting a definitive trial comparing the effectiveness of re-suturing dehisced perineal wounds versus expectant management. As both a pilot and feasibility RCT, this timely research aimed to test out multiple components of the study and estimate crucial parameters that would be used to inform the design of a larger definitive trial. Preliminary evidence relating to the effectiveness of treatment options has been provided.

Part two was a qualitative study, which involved conducting in-depth semi-structured interviews with a small number of women who had participated in the RCT. The purpose of this qualitative study was to capture information relating to the personal physical and psychosocial experiences of perineal wound dehiscence following childbirth. This is an aspect of childbirth that again to the best of the author's knowledge, has previously never been explored. Conducting the interviews also allowed for an assessment of how acceptable the research plan was for the participants.

The complete findings of PREVIEW address an area of clinical research that has been extremely neglected and have the potential of making a significant world-wide impact on women's health and well-being**.** The research focuses upon outcomes that are of prime concern to women themselves following perineal trauma. However, the qualitative component of PREVIEW also made additional attempts to establish if researchers have in fact addressed concerns that are unique to this particular group of women.

1.5 Chapters presented in the thesis

In this thesis, complex questions relating to the management of dehisced perineal wounds culminating in the findings of the whole of the PREVIEW study are addressed in chapter's two to seven. A brief outline of each chapter is provided below.

Chapter two provides an in-depth review of both the quantitative and qualitative literature and demonstrates the considerable gaps in both clinical practice and research.

Chapter three presents the Cochrane systematic review of the literature 'Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth'(Dudley *et al*, 2013a).

Chapter four is presented in two parts. Part one presents the methodology, results and discussion of a local retrospective comparative case note audit. Whilst part two presents the methodology, results and discussion of a national electronic survey of members of the Royal College of Obstetricians and Gynaecologists.

Chapter five discusses both the rationale for the mixed methods research design, and the theoretical framework to underpin phase four of the PREVIEW study. Methods used for both the quantitative and qualitative paradigms are addressed in full. Ethical considerations and research governance procedures at all recruiting sites are also detailed in this chapter.

Chapter six presents the findings from the mixed methods research, of phase four of PREVIEW adhering to both the Consolidated Standards of Reporting Trials (CONSORT) (Moher *et al*, 2010) and the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidance (Tong *et al*, 2007).

Chapter seven discusses the main research findings of phase four of PREVIEW, the pilot and feasibility mixed methods study. The results are interpreted in consideration of existing evidence from both research paradigms and the research methodology is evaluated. The limitations of phase four of the study and implications for both practice and future research are presented.

Chapter eight provides a conclusion to the whole of the PREVIEW study with a summary of the innovations for each phase of the research. Plans for the dissemination of the study are outlined. References to the papers that have been published to date by the author in collaboration with her research colleagues as a direct consequence of the study are also presented.

1.6 Caveats

The author of this thesis would like to point out that following the completion of her research, the National Collaborating Centre for Women's and Children's Health (2007) clinical guideline number 55, Intrapartum care: care of healthy women and their babies during childbirth, referred to throughout this thesis was replaced in December 2014 with clinical guideline number 190, Intrapartum care: care of healthy women and their babies during childbirth (National Institute for Health and Care Excellence, 2014). The guidance referred to in this thesis remains unchanged in the updated 2014 guideline.

Similarly, the Eighth Report on Confidential Enquiries into Maternal Deaths in the United Kingdom (Centre for Maternal and Child Enquiries, 2011) again referred to throughout this thesis, has recently been replaced by the MBRRACE-UK report: Saving Lives, Improving Mothers' Care - Lessons learned to inform future maternity care from the UK and Ireland Confidential Enquiries into Maternal Deaths and Morbidity 2009–12 (Knight *et al*, 2014). The author of this thesis wishes to acknowledge that whilst sepsis referred to in this current chapter and subsequent chapters (two, four and seven) remains a prominent cause of maternal mortality, thrombosis and thromboembolism is once again the leading cause of direct maternal death.

1.7 Conclusion

This chapter has presented a brief overview of the phenomena being investigated which has provided the context for this timely research. Chapter two will now proceed with an evaluation of the current literature in relation to perineal wound dehiscence following childbirth.

CHAPTER TWO: LITERATURE REVIEW

A literature review… *"the use of ideas in the literature to justify the particular approach to the topic, the selection of methods and demonstration that this research contributes something new" (Hart, 1988, p. 1).*

2.1 Introduction

This systematic and critical review of literature will set the context for the research study presented in this thesis and in light of the existing body of literature will provide the rationale for addressing the research questions for the PREVIEW study. The literature review will establish what evidence already exists and will identify gaps in both knowledge and practice where further research is needed.

2.2 Search strategy

The search for relevant literature was underpinned by the following research questions:

1. What is the evidence relating to re-suturing of dehisced perineal wounds versus expectant management?
2. What is the physiology of wound healing?
3. What are the risk factors for wound infection and dehiscence?
4. What is the morbidity associated with dehisced perineal wounds?
5. What are women's experiences of a dehisced perineal wound?

The literature search was conducted prior to commencing the study and continued at regular six monthly intervals between September 2008 and May 2014. An extensive search of relevant electronic databases was conducted. Journals, national

and local clinical guidelines, books and the proceedings of major conferences were also searched both electronically and manually.

The following terms and combination of terms were used to search the literature using keywords (free text): Wounds, wound classification, wound healing, postnatal, perineal trauma, classification of perineal trauma, episiotomy, suturing materials, suturing methods, dehisced wounds, risk factors, morbidity, pain, dyspareunia, sexual health, infection, sepsis, mortality, risk factors, secondary re-suturing, expectancy, secondary intention, women's experiences.

All papers relevant to the research questions including: systematic reviews, meta-analysis RCTs, case control studies, literature reviews, qualitative studies, dissertations and thesis were reviewed and provide the context for the research presented in this thesis.

The literature review revealed little robust quantitative evidence relating to the management of dehisced perineal wounds and was either based on retrospective audit or case review, included small numbers of participants or was subject to bias.
It was also evident that no primary qualitative research had been conducted to explore women's experience of perineal wound dehiscence; therefore the literature search was expanded to include perineal morbidity following childbirth. However, even despite this, there remained a noticeable gap of women's knowledge, experiences and views related to this phenomenon.

A thorough understanding of the classification of wounds and the pathophysiology of the wound healing trajectory is fundamental if health care practitioners are to provide crucial advice in relation to wound healing (Steen, 2007; Vuolo, 2006). This chapter will therefore commence with a section dedicated to the classification of

wounds, how wounds heal and factors that can compromise wound healing. The remainder of the chapter is then devoted to a detailed review of perineal wound infection and dehiscence, the associated morbidity and the current management of this unfortunate complication of childbirth.

2.3 Classification of wounds

Enoch and Price (2004) define a wound as a break in the epithelial integrity of the skin, which may extend to the dermis, subcutaneous fat, fascia, muscle or even the bone. Two broad categories exist for the classification of wounds: acute and chronic (Monaco and Lawrence, 2003). Dependent upon the aetiology of the wound, the type of wound patients present with will vary from one clinical setting to another and will include acute surgical wounds, traumatic wounds such as those that occur following an accident, burn wounds, or chronic wounds such as leg and pressure ulcers (Monaco and Lawrence, 2003; Patel, 2007). Wounds may also be classified as infected or dehisced (broken down) (Vuolo, 2006). Irrespective of the type of wound, the skin is the largest organ of the body and when intact has a major function of protection against infection and external noxious agents (Boyle, 2006; Enoch and Price, 2004; Richardson, 2003). When this barrier becomes disrupted, it is therefore vital to restore its integrity as soon as possible (Enoch and Price, 2004).

Wounds are commonly seen in obstetrics, resulting from a caesarean section and as a consequence of perineal trauma. The caesarean section rate in England during 2012-2013 was 25.5% (Health and Social Care Information Centre, 2013). In comparison, the vast majority of women who have a vaginal delivery, sustain a degree of perineal trauma either spontaneously or through an episiotomy (chapter one, table 1). Whilst an episiotomy wound usually involves the same tissue damage

as a second degree tear, spontaneous trauma may also occur concurrently resulting in a more complex OASIS (Kettle and Fenner, 2009).

Fortunately, most perineal trauma wounds heal without complications, however for some women their sutured wound may dehisce, a term also referred to as rupture or breakdown. Wound dehiscence in general is a medical word used to describe the separation of a surgical wound to reveal a cavity that was originally closed with sutures, staples, or adhesive paper strips (Dealey, 2005). This can either be a partial dehiscence and may only involve the superficial layers of the skin, or a complete dehiscence, involving deeper tissues.

Wound dehiscence following primary repair, (initial wound closure immediately following childbirth) of a perineal tear or episiotomy can be partially or completely dehisced. The dehisced area may involve separation of the vaginal mucosa, the superficial perineal muscles (bulbospongiosus and transverse perinei) and sometimes the deeper perineal muscle (pubococcygeus). If an OASIS is sustained, the external anal sphincter (EAS) and the internal anal sphincter (IAS) may also dehisce due to infection. Variable rates of perineal wound dehiscence are quoted in the literature with figures of 0.59% to 13.5% being suggested (Bharathi *et al*, 2013; Glazener, 1999; Goldaber *et al*, 1993; Kaltreider and Dixon, 1948; Kettle *et al*, 2010; McGuinness and Norr, 1991). Further discussion surrounding the possible reasons for this wide disparity of data are presented in section 2.7.2.1 of this current chapter.

Despite considerable efforts and advances in maternity care over recent decades, the number of women with childbirth related perineal trauma is unlikely to decline significantly in the near future (Boyle, 2001; Kettle and Fenner, 2009). In contrast, there is evidence to suggest that the rates of OASIS are actually increasing. Indeed,

Gurol-Urganci *et al* (2013) recently reported a three-fold increase in the rates of OASIS in England in primiparous women, from 1.8% to 5.9% over a 12-year period (2000-2012). The authors also revealed that over the same time period, episiotomy rates were 30-36%. This suggests that despite robust evidence recommending restrictive episiotomy policies (Carroli and Mignini, 2009), these figures are not declining.

It is therefore imperative that midwives and doctors who are at the forefront of care delivery have a thorough knowledge base and understanding of tissue trauma, types of wounds and the pathophysiology of wound healing (Steen, 2007). In relation to perineal wounds the purpose of this knowledge base is crucial towards correctly identifying the degree of trauma requiring repair, achieving haemostasis, initiating appropriate measures to promote healing, restoring both structure and function to the traumatised tissues and towards preventing complications such as infection and or dehiscence (Gould, 2007; National Collaborating Centre for Women's and Children's Health, 2007).

2.4 Pathophysiology of wound healing

2.4.1 Phases of wound healing

The literature maintains that all phases involved in wound healing, which will depend upon the type of injury sustained, are regulated by a highly complex series of sequential, yet overlapping and interdependent chemical reactions which initiate, control or inhibit various factors (Boyle, 2006; Enoch and Price, 2004; Steen, 2007). Whilst there is some disparity of opinions regarding the terminology, the phases involved in complete wound healing are commonly described as: haemostasis (not considered as a phase by some authors), inflammation, proliferation and remodelling (maturation). This whole process is orchestrated immediately after

injury by the release of various growth factors and cytokines (small proteins), which are secreted by platelets, lymphocytes and macrophages within the wound area (Cole-King and Harding, 2001; Werner and Grose, 2003). Cytokines are crucial for optimum wound healing; they help to protect against infection and prepare injured tissue for repair by enhancing the recruitment and activation of phagocytes, whilst also contributing to the regulation of re-epithelialisation, tissue re-modelling and angiogenesis (the formation of a network of new blood vessels) (Werner and Grose, 2003).

2.4.1.1 Haemostasis/vascular response

Tissue damage such as that sustained to the perineum during vaginal delivery will initiate several processes, activating the release of various cells and cellular elements and large numbers of chemical mediators and cytokines (Steen, 2007). Ruptured blood vessels immediately result in bleeding which initiates the emergency response of clot formation. A damaged vessel wall, platelets and coagulation factors are the three elements that interact to enable clot formation (Flanagan, 1996; Li *et al*, 2007; Steen, 2007). Vasoconstriction occurs which will lead to a rapid reduction in bleeding. The corresponding release of plasma proteins forms a platelet clot which elicits a coagulation cascade to create a fibrin clot thereby promoting good haemostasis (Flanagan, 1996; Steen, 2007). A prostaglandin encourages this process and a regulated clotting mechanism commences; calcium ions and phospholipids are necessary for the clotting process (Steen, 2007). Wounds usually produce copious amounts of blood or serous fluid at this stage which will assist natural cleansing (Flanagan, 1996).

2.4.1.2 Inflammatory phase

The inflammatory phase which is a crucial component of the body's initial reaction to injury (Li *et al*, 2007; Steen, 2007) occurs in response to tissue damage, the activation of clotting factors and exposure to bacteria (Flanagan, 1996; Li *et al*, 2007; Steen, 2007). This consequently causes the release of various vasoactive substances, such as prostaglandins and histamine, leading to increased vasodilation and permeability of the blood vessels as well as stimulation of pain fibres (Flanagan, 1996; Steen, 2007). An acute inflammatory response occurs within hours after delivery and its effects can last for 5 to 7 days (Boyle, 2006), normally leading to tissue repair and restoration of function (Li *et al*, 2007). The inflammatory phase may be prolonged if the wound site becomes infected or the tissues become irritated, for example by the presence of suture material (Steen, 2007).

Inflammatory cells occupy the wound tissue; the fibrin clot attracts leucocytes and within the first 24 hours, particularly neutrophils whose primary role is phagocytosis, which is the removal and destruction of bacteria and other foreign bodies (Boyle, 2006; Werner and Grose, 2003). As neutrophil infiltration slows, monocytes appear and once in the tissues are called macrophages (Boyle, 2006). Macrophages have an important role in most phases of wound healing, not only in clearing the wound site but also in producing growth factors, cytokines and prostaglandins which promote healing by attracting the cells needed for the angiogenesis and most importantly in the formation of the collagen (Boyle, 2006; Werner and Grose, 2003). Vasodilation not only enables neutrophils and monocytes to be easily delivered to the wound site, but also results in the production of exudate which may lead to oedema (Boyle, 2006). The presence of exudate in the wound bed during the healing process is normal and its role should not be underestimated (Oldfield, 2010). Normal healing requires growth factors, nutrients and bacterial activity all of which are present in this inflammatory exudate (Cameron, 2006). However, too

much or too little exudate will hinder the wound healing process (Oldfield, 2010). Excessively high exudate may indicate an infection, sinus or fistula; whilst excessively low levels are often associated with ischemia or dehydration (Oldfield, 2010).

Normal inflammation may be characterised by the following signs which can be observed clinically and are important in the assessment of wounds and wound healing: erythema, possibly oedema, some pain and a slight increase in local temperature (Boyle, 2006; Flanagan, 1996; Steen, 2007). Any exaggeration of these signs may indicate infection or the formation of a haematoma and would trigger an immediate review of the woman.

2.4.1.3 Proliferative phase

Three processes characterise this phase whereby the wound is filled with new connective tissue: granulation, contraction and epithelialisation (Flanagan, 1996; Steen, 2007).

Granulation

Granulation involves the establishment of a network of new blood vessels (angiogenesis) in a collagen matrix (Flanagan, 1996; Li *et al*, 2007; Steen, 2007). This process, stimulated by tissue hypoxia resulting from disruption of blood flow at the time of injury, is crucial as no new tissue can be developed without new blood vessels supplying oxygen and nutrients (Boyle, 2006; Flanagan, 1996). Angiogenic growth factors secreted by macrophages stimulate the endothelium to divide and organise the growth of new blood vessels (Boyle, 2006). Intact vessels around the wound, attach to new vessels which migrate throughout the wound and proliferate (Boyle, 2006). Increases in the numbers of macrophages also attract fibroblasts,

cells that produce a primary protein of connective tissue, an essential component for wound strength (Boyle, 2006).

Fibroblasts multiply from about 2 to 4 days after injury creating a matrix of collagen around the new vessels (Boyle, 2006). They are stimulated to produce collagen by lactate and ascorbate (a form of ascorbic acid), which are present in the hypoxic wound bed (Doughty, 1992). The fibroblasts move over the matrix; granulation tissue which at this time includes fibroblasts, collagen, new blood vessels and macrophages proliferates and epithelialisation ensues (Boyle, 2006; Iocono *et al*, 1998).

The granulation process is more visible in wounds that heal by secondary intention (Vuolo, 2006). On observation, healthy granulation tissue appears bright red, moist, shiny, does not bleed easily and is often a good indicator of the process of wound healing (Flanagan, 1996). Over granulation tissue however also appears to be associated with healing by secondary intention (Stephen-Haynes and Hampton, 2010). Over granulation tissue is defined as “an excess of granulation tissue which is in excess of required granulation tissue needed to replace the tissue deficit which often results in a peduncle (raised mass) above the wound” (Stephen-Haynes and Hampton, 2010, p. 4). The raised tissue over a perineal wound site will increase the susceptibility to rubbing and friction from clothing (McGrath, 2011). Over granulation tissue can be treated with the application of silver nitrate (repeated applications are often required) which may cause the woman to experience additional minor discomfort both during the procedure and for a short period following the treatment.

In wounds that heal by primary intention, collagen production usually peaks at approximately 6-7 days, although will actually continue for some time after this (Flanagan, 1996).

Contraction

Contraction is responsible for minimising the size of the wound and starts around the 5th or 6th day (Steen, 2007). Little of this process can be seen in wounds that heal by primary intention as it is unnecessary because they require minimal collagen synthesis and little epidermal cell migration to cover the deficit (Boyle, 2006). Contraction, which can significantly decrease the surface area to be covered by the epithelium, is a gradual process and will only commence after the wound bed has been occupied with healthy granulation tissue (Flanagan, 1996; Steen, 2007).

Epithelialisation

The process of epithelialisation covers the wound with epithelium and following acute trauma, reconstruction of injured epithelium is crucial for re-establishment of the barrier functions of the skin (Monaco and Lawrence, 2003). Epithelial cells are not able to migrate over a dry surface or necrotic wound so an open wound healing by secondary intention needs to be full of granulation tissue before epithelialisation can take place (Boyle, 2006; Flanagan, 1996; Steen, 2007). New epithelial cells originate either from the wound edges or from the remnants of hair follicles or sebaceous or sweat glands (Flanagan, 1996). They migrate along the surface of the granulation tissue until they form a continuous layer of cells and close the wound (Boyle, 2006; Flanagan, 1996; Steen, 2007). Newly formed epithelial cells have a translucent appearance and are usually whitish-pink, they can often be seen on the surface of open, clean granulating wounds at the wound margin and/or as small islands on the wound surface (Flanagan, 1996).

2.4.1.4 Maturation (remodelling) phase

This final phase begins after the wound has been closed by connective tissue and epithelialisation and centres around remodelling of the wound site (Flanagan, 1996; Steen, 2007). During this process the macrophages and fibroblasts become less concentrated, angiogenesis ceases and both blood flow and metabolic activity are reduced (Boyle, 2006; Steen, 2007). Excess collagen is removed and the original collagen is replaced with stronger and more highly organised lattice structure (Boyle, 2006; Traversa and Sussman, 2001).

Remodelling commences at varying times (commonly around 20 days) within different areas of the wound and may continue for up to a year or even longer (Boyle, 2006). Complete wound healing will result in the formation of tissue which is structurally and functionally satisfactory, however the outcome will not be identical to non-wounded tissue (Li *et al*, 2007). Remodelled tissue is never as strong as the original with reports suggesting 80% of the strength when compared to non-wounded tissue even in the healthiest of patients (Doughty, 1992; Monaco and Lawrence, 2003).

2.4.1.5 Scars

The remodelling of granulation tissue may be the most important contributor towards morbidity developing from scarring (Boyle, 2006). During remodelling the density of the scar is dissimilar to that of normal skin and is thicker in comparison to undamaged skin. (Boyle, 2006). The dermis of a healed wound is also different, as the arrangement of the organised collagen fibres may be altered (Boyle, 2006). The healed quality of the scar can vary in terms of appearance, size and whether full function is restored (Boyle, 2006). A perineal scar needs to be flat and pliable to maximise comfort and minimise the potential for on-going morbidity (Boyle, 2006) such as dyspareunia (painful sexual intercourse) discussed later in this chapter.

Any alterations that disrupt the complex pathophysiological processes described above would as Li *et al* (2007) acknowledge extend tissue damage and prolong the wound healing process.

2.5 Types of wound healing

2.5.1 Primary Intention

Wounds can heal by primary intention, which occurs when the wound edges are approximated by suturing, described in section 2.6. There is close approximation of the tissues and no 'dead space' and healing occurs without (or with minimal) granulation tissue, contraction also has a minor role (Boyle, 2006; Koopmann, 1995; Steen, 2007). The epithelium will migrate over the suture line and healing is primarily by connective tissue deposition (Boyle, 2006). The wound will heal with minimal scaring (Majid and Kingsnorth, 1998).

2.5.2 Secondary intention

A wound that involves some degree of tissue loss, where there is a degree of gaping or dead space between the wound edges, heals by secondary intention (Boyle, 2006). Granulation tissue fills the area, which gradually contracts to bring the wound edges together. This is a protracted process that can prolong healing times (Majid and Kingsnorth, 1998; Oldfield, 2010), increase the potential for infection and scarring and have a higher rate of complications than wounds that heal by primary intention (Boyle, 2006; Steen, 2007). Excessive collagen is produced when healing is delayed, which may result in wound contracture, causing tightness and restrictive movement dependent upon the site of the original injury (Majid and Kingsnorth, 1998).

An example of delayed wound healing in obstetrics is a surgical wound such as an episiotomy or spontaneous perineal trauma which has dehisced (broken down) following primary repair and is not re-sutured. The dehisced wound then heals by secondary intention also referred to as expectant management.

2.5.3 Tertiary intention (delayed primary closure)

Healing by tertiary intention occurs when wounds are left open for several days to allow for oedema and or infection to resolve and for exudate to drain prior to primary closure (Boyle, 2006; Vuolo, 2006). After several days the wound is then debrided (devitalised tissue removed) and surgically closed (Vuolo, 2006). The tissue viability team throughout acute, primary and secondary care NHS organisations are a crucial part of multi-disciplinary team when managing wounds that are left to heal by tertiary intention.

2.6 Primary repair of perineal trauma wounds

It has already been established that the majority of women will need suturing of their perineal trauma following childbirth. Trained midwives repair the majority of perineal wounds in the UK. Repair of OASIS however are outside most midwives scope of professional practice. This type of trauma is repaired in theatre under regional or general anaesthesia by appropriately trained practitioners (Royal College of Obstetricians and Gynaecologists, 2007). Clear recommendations for the choice of suture methods and materials for primary repair of OASIS are provided in a clinical guideline, ‘The management of third and fourth degree perineal tears’ (Royal College of Obstetricians and Gynaecologists, 2007).

First and second degree tears and episiotomies are the type of wounds experienced by the majority of women following childbirth and were included in the research conducted for this thesis (second degree tears and episiotomies) presented in

chapters five to seven respectively. The literature relating to primary perineal repair of these types of wounds will therefore now be discussed in more detail.

Guidance from the National Institute for Health and Care Excellence which advises upon the level care that all women giving birth in the National Health Service (NHS) in England and Wales should expect to receive, recommends that all perineal trauma should be sutured to improve healing outcomes (National Collaborating Centre for Women's and Children's Health, 2007). Their guidance also applies to first degree trauma unless the skin edges are well opposed.

Methods for primary repair of first and second degree tears and episiotomies

Historically perineal trauma has principally been repaired in 3 layers described by Kettle (2002) as being a continuous locking stitch which is inserted to close the vaginal trauma, commencing at the apex of the wound and finishing at the level of the fourchette with a loop knot. The perineal muscles are then re-approximated with three or four interrupted sutures and finally, the perineal skin is closed by inserting interrupted transcutaneous stitches (Kettle, 2002). This method has been used for many years despite the fact that there have been numerous arguments in favour of a non-locking continuous technique, in terms of reducing pain in the postnatal period (Kettle and Fenner, 2009).

There is now however, high level evidence from meta-analysis and systematic reviews to recommend that primary perineal repair of second degree tears and episiotomies (chapter one, table 1) should be undertaken using a continuous non-locked suturing technique for the vaginal wall and muscle layer (Kettle *et al*, 2012; Kettle *et al*, 2002; National Collaborating Centre for Women's and Children's Health, 2007). Where the skin does require suturing, this should also be undertaken using a continuous subcuticular technique (Kettle *et al*, 2002; National Collaborating

Centre for Women's and Children's Health, 2007). A meta-analysis included in a recently updated systematic review demonstrated that continuous suture techniques compared with interrupted sutures for perineal closure (all layers or perineal skin only) are associated with less pain for up to 10 days postpartum (risk ratio (RR) 0.76; 95% CI 0.66 to 0.88) (Kettle *et al*, 2012). There was an overall reduction in analgesia use associated with the continuous subcutaneous technique versus interrupted stitches for repair of perineal skin, (RR 0.70; 95% CI 0.59 to 0.84) (Kettle *et al*, 2012).

The authors provide a clear rationale for the continuous technique to reduce pain in that the tension is transferred throughout the whole length of the single suture, whilst the skin sutures are inserted well below the skin surface, thus avoiding the nerve endings (Kettle *et al*, 2012). The same review also reported a reduction in suture removal in the continuous suturing groups versus interrupted (RR 0.56; 95% CI 0.32 to 0.98), but no significant differences were seen in the need for re-suturing of wounds or long-term pain, although the review authors acknowledged that the numbers were too small to draw reliable conclusions (Kettle *et al*, 2012). Suture removal following primary perineal repair can be an extremely distressing experience for some women.

Materials for the primary of first and second degree tears and episiotomies

Similarly, the choice of suture material may not only influence the amount of perineal pain women experience following primary repair, it also has the potential to compromise wound healing. Historically, until the beginning of this century, a catgut suture has been used worldwide for millions of surgical procedures including perineal repair. Chromic catgut sutures were actually the suture material of choice at a local maternity unit with over 6000 deliveries per annum until 2001. However the characteristic nature of the material's processing and composition makes this

type of suture material less than ideal when compared to the newer, synthetic absorbable sutures available present day (Greenberg and Clark, 2009). Surgical catgut is available in two preparations: plain and chromic and both are manufactured from collagen derived from the intestines of healthy mammals (sheep and cows). If the catgut suture is then further coated in a bath of chromium trioxide, it is then called to chromic catgut (Greenberg and Clark, 2009). The chromium treatment delays the absorption of the chromic catgut suture and consequently protracts its tensile strength for longer periods (Greenberg and Clark, 2009). Sutures that remain in the tissues for prolonged periods have the potential to act as a foreign body and may stimulate a significant inflammatory response that consequently lowers the body's defence mechanism against infection (Kettle, 2005). This increases the potential for impaired wound healing and dehiscence, ultimately leading to inferior wound strength due to excessive scar tissue formation (Greenberg and Clark, 2009). Catgut is reported to cause an inflammatory response in the tissues due to the fact that it is broken down by proteolytic enzymes and phagocytosis (Greenberg and Clark, 2009; Irvin, 1981). Moreover, a catgut suture elicits the greatest tissue reaction of all suture material (Greenberg and Clark, 2009) and is a very unstable and unpredictable material in terms of time taken to be absorbed, especially if there is wound infection or malnutrition (Kettle *et al*, 2010). Catgut suture material is actually no longer available in the UK although it is still used in other non-European countries and was recently the subject of a comparative RCT conducted in India (Bharathi *et al*, 2013).

A meta-analysis by Kettle and colleagues revealed that compared with catgut, standard synthetic sutures were associated with less pain up to three days after delivery (RR 0.83, 95% CI 0.76, 0.90); and less analgesia up to ten days postpartum (RR 0.71, 95% CI 0.59 to 0.87) (Kettle *et al*, 2010). Comparing standard synthetic with rapidly absorbing sutures, short and long term pain were similar,

although in one trial (Kettle *et al*, 2002) fewer women with rapidly absorbing sutures reported using analgesics at 10 days (RR 0.57, 95% CI 0.43, 0.77) (Kettle *et al*, 2010). More women in the standard synthetic suture group required suture removal compared with those in the rapidly absorbed group (RR 0.24, 95% CI 0.15, 0.36) (Kettle *et al*, 2010). There was no evidence of significant differences between groups for long-term pain (three months after delivery) (Kettle *et al*, 2010). Not surprisingly given the nature of catgut sutures, secondary re-suturing also occurred more frequently in women who had primary repair with catgut sutures (15/1201) compared with synthetic sutures (3/1201) (RR 0.25, 95% CI 0.08, 0.74, four trials, 1402 women) (Kettle *et al*, 2010).

Overall despite the evidence in favour of using standard synthetic materials and rapidly absorbing synthetic material for suturing perineal trauma (episiotomies and second degree spontaneous trauma) the authors acknowledged variable degrees of heterogeneity among the studies included in the review. They remarked that due to heterogeneity they could not exclude the possibility that the effect would be the same in a single study, suggesting that further research is needed to explain the causes of such between study heterogeneity (Kettle *et al*, 2010).

The use of a rapidly absorbing suture material for example, Vicryl Rapide® is nonetheless currently the material of choice recommended by national guidance for perineal repair of spontaneous first and second degree perineal trauma and episiotomies in UK maternity units (National Collaborating Centre for Women's and Children's Health, 2007).

Ismail *et al* (2013) in a more recent RCT have demonstrated how crucial the provision of evidence based perineal management is upon improving outcomes that are important to women. The collaborative team conducted a matched-pair cluster

RCT, Perineal Assessment and Repair Longitudinal Study (PEARLS) that enrolled women (n=3861) who had sustained second degree perineal trauma. Participating units were randomised to receive an interactive multi-professional educational package (the intervention) either early or late into the study. The intervention consisted of a PEARLS DVD covering anatomy, basic surgical skills and assessment and repair of perineal trauma; copies of national guidelines for perineal trauma management (referred to in the previous two sections above: methods and material for perineal repair), self-directed reading material and perineal care information leaflets for women. Participating units that received early intervention of the multi-professional training program revealed significant improvements in adherence to evidence based repair with statistically significant reductions in average reported rates of wound infection (*P* = 0.03) and need for suture removal (*P* = 0.03) (Ismail *et al*, 2013). Infection is a considerable cause of maternal morbidity and in the UK cases of mortality associated with genital tract sepsis are increasing as the following sections clearly reveal.

2.7 Complications of perineal wounds following primary repair

2.7.1 Infection

All wounds, including perineal trauma sustained during childbirth, are at risk of infection because colonisation of the wound by bacteria occurs (Arianpour *et al*, 2009; Steen, 2007). Wound infection prolongs the inflammatory phase of healing and contributes to delayed wound healing with an increase in granulation tissue and scar formation (Boyle, 2006; Flanagan, 1996; Greenberg and Clark, 2009; Quick *et al*, 2000; Tharpe, 2008), frequently causing additional morbidity for the woman. Steen (2007) suggests that wounds that are left open such as dehisced perineum's which are allowed to heal by secondary intention (managed expectantly) are potentially more at risk of infection.

2.7.1.1 Defining perineal wound infection

Despite the definitive criteria for the classification of surgically infected wounds (National Institute for Health and Clinical Excellence, 2008) there remains no standardised universal classification for postpartum perineal wound infections following childbirth. Consequently, there has been a distinct lack of robust data of women experiencing perineal wound infection.

According to the Centre for Disease Control/ National Healthcare Safety Network (CDC/NHSN) (Horan *et al*, 2008) the criteria for diagnosing an infected episiotomy are:

- Purulent drainage from the episiotomy
- Episiotomy abscess.

Whilst episiotomy is clearly referred to by the CDC/NHSN they do not consider it an operative procedure and there is no reference made to infected spontaneous trauma. Equally, there is no validated universal system designed specifically to aid the assessment and management of all surgical wounds. The most commonly used CDC definition, employs stringent criteria to classify infection. A single, standard definition of a surgical wound infection is needed so that comparisons over time and between departments and institutions are valid, accurate and useful (Petrica *et al*, 2009).

Features of perineal infection commonly include localised pain, erythema, exudate, (purulent discharge) odour, oedema and pyrexia with or without wound dehiscence (Johnson *et al*, 2012; Thakar and Sultan, 2009).

2.7.1.2 Prevalence of perineal wound infection

True epidemiological data relating to the prevalence of perineal wound infection with or without dehiscence world-wide is limited. In the UK perineal wound healing is currently monitored in both primary and secondary care settings by midwives, doctors, the woman's general practitioner (GP) and health visitors. If there are any concerns with wound healing new mothers access a variety health centres and clinics such as the labour ward, maternity triage, postnatal wards, perineal care clinics, health centres, accident and emergency units and private obstetric clinics (Johnson *et al*, 2012).

Retrospective case note studies, clinical audits and prospective studies world-wide discussed in more detail below, have all revealed variable rates of perineal wound infection using various clinical markers. Some reports provide infection rates of perineal trauma wounds (0.3%-10%) whilst others provide rates of infection associated with wound dehiscence (39-79%).

Hankins *et al* (1990) reviewed the case notes of women n=31 with early secondary repair of episiotomy dehiscence, some of whom had also sustained an OASIS n=26. Infection was reported as being present in 12/31 women (39%). Most of the women were delivered by operative vaginal delivery n=26 with the remainder delivering spontaneously n=5. No reference relating to the parity of the women was provided by the authors.

Similarly Ramin *et al* (1992) reviewed the case notes of women n=34 with early secondary repair of episiotomy. All but one of the women had experienced their first vaginal delivery. All women had received an episiotomy and 27/34 (79%) women also sustained an OASIS. Infection, was detailed as a cause of dehiscence in 27/34 (79%) of all cases, based on the presence of fever or purulent discharge. Out of all women, common features were pain n=22 (65%), purulent discharge n=22 (65%)

and fever n=15 (44%). Wound dehiscence was the only symptom reported by three women. It is not clear if wound swabs were obtained as no bacteriology results were either detailed or referred to. Operative vaginal delivery was reported in 23 (68%) women whilst spontaneous vaginal delivery was achieved by 11 women (32%).

A retrospective case control study conducted using the surgical site infection definition by the Centres for Disease Control and Prevention's National Nosocomial Infection Surveillance system (Horan *et al*, 1992), suggested that 0.3% of all women who experienced a vaginal delivery (n = 2301) developed episiotomy infections (Yokoe *et al*, 2001). They too acknowledged the difficulties of infection surveillance experienced in the UK as most postnatal infections occur after hospital discharge, adding that the decreasing lengths of hospital stays following childbirth may further compromise detection of these infections. Unfortunately, the study does not reveal any data relating to women who had wound dehiscence as a result of the episiotomy infection. Neither do they refer to women who have sustained spontaneous trauma.

Similar to other studies investigating early secondary repair of episiotomy dehiscence, Uygur *et al* (2004) conducted a prospective study of women n=37 with episiotomy dehiscence, 14/37 (38%) also sustained an OASIS. Their study compared secondary repair with expectant management in which women were allocated management options of re-suturing n=25 or expectancy n=12, according to the clinicians individual preference. Infection, diagnosed in the presence of purulent discharge or fever was present in 25/37 (68%) women. Perineal wound swabs were obtained but unfortunately the authors were unable to locate any microbiology results. The majority of the women in this study delivered spontaneously n=35 compared to operative vaginal delivery n=2.

Concern for a reported increase in both perineal and abdominal wound infections led to a clinical audit being conducted in women who gave birth in a national maternity unit in Dublin (Fox, 2011a; Fox, 2011b). These women were offered postnatal care in the community as part of an early transfer home project (ETHP). In 2005-6 out of 1,538 women in the ETHP, 956 had perineal wounds, 89 (9.3%) had a perineal wound infection (Fox, 2011a). In women who sustained a second degree tear n= 220 infection was reported in 13 (5.9%) of those women; OASIS n=16 infection was reported in 1 woman (6.3%) and following episiotomy n=334 there were 68 (20.4%) women with a perineal infection (Fox, 2011a). The remaining infections were following first degree tears either sutured or unsutured.

Anaerobic streptococci and staphylococcus aureus were the common pathogens noted (Fox, 2011b). Infection rates were increased with an instrumental delivery, 25 infections (19.4%) compared to 64 (5.6%) following spontaneous vaginal delivery (Fox, 2011a). A second audit using data from 2007-2008 included 1206 women with perineal wounds in the ETHP, 42 of those women subsequently had an infected perineal wound (Fox, 2011a). In women who sustained a second degree tear n=284 there were 11 (3.9%) reported cases of infection; no infections following a third degree tear n=19 and in 515 women who had an episiotomy there were 30 (5.8%) women with a perineal infection (Fox, 2011a). Reductions in infection rates were attributed to the following (Fox, 2011b):

- Additional education and training for staff in hand hygiene and wound management
- Regular hygiene audits
- Introducing regulated referral systems
- Incident reporting to monitor re-admission rates secondary to infection

- Advising women to avoid the use of tea tree oil baths and regular douches as there is no scientific evidence to support this routine practice.

The ETHP care for only approximately 12% of the national maternity hospitals caseload and therefore may not be totally representative of the total population, a limitation of the audit findings that the author herself acknowledges. In addition the ETHP team usually transfer women to the public health nurse and GP on day five postnatal and Fox (2011b) accepts that there could be a potentially higher proportion of women who require referral after this time.

A recent 3-month prospective audit in the UK which involved 409 women who sustained sutured perineal tears, (first, second, third and fourth degree tears and episiotomies were included) demonstrated that one in ten women who sustained a perineal tear at vaginal delivery that required suturing developed a perineal wound infection (Johnson *et al*, 2012). Wound infection was defined by the authors as the presence of any two of the following three markers: perineal pain, wound dehiscence or purulent vaginal discharge (Johnson *et al*, 2012). The latter marker is also used by the CDC/NHSN criteria of infection albeit defined as purulent discharge from the episiotomy site (section 2.7.1.1).

A total of 341 (83%) women were contacted by telephone 21 days post-delivery and asked about self-reported markers for perineal wound infection and antibiotic use. Of the women contacted, 39 (11%) had a perineal wound infection based on the criteria of any two infection markers and 16 (5%) women had all three markers of wound infection. Prolonged rupture of membranes and instrumental delivery were significant risk factors for women with two and three markers of wound infection (Johnson *et al*, 2012). The assessment of wound infection was based entirely on the personal experiences of the women alone; neither formal clinical assessment of the

wounds was made or microbiology results from wound swabs included. However, the crucial findings with this study are that 1 in 10 women had developed a perineal wound infection following vaginal delivery in a hospital environment. The authors themselves refer to the studies limitations whilst highlighting the need for a prospective study involving a thorough clinical assessment of perineal healing (Johnson *et al*, 2012).

Bharathi *et al* (2013) in their prospective randomised study carried out in India compared two different types of absorbable suture material for primary repair of episiotomies. The authors revealed a wound infection rate of 3.5% in the 200 women who were sutured with chromic catgut and no infections in the 200 women who were sutured with Vicryl Rapide®. Wound infection was assessed clinically with the following markers: throbbing pain in the perineum, a local rise in temperature, swelling and discharge from the wound. As with previous studies no reference was made to bacteriology markers.

2.7.1.3 Aetiology of perineal wound infection

The source of a perineal infection is considered to be either endogenous (vaginal flora) or exogenous (clinicians, visitors, equipment or the healthcare environment) (Horan *et al*, 2008; Steen, 2007). Wound haematomas, which may present in the vulval, vaginal or sub-peritoneal areas in addition to being a cause of wound dehiscence on their own, can provide an ideal medium for bacteria to colonise and multiply (Bick, 2009; Oldfield, 2010; Pudner and Ramsden, 2000).

2.7.1.4 Common pathogens

In the UK, the most common pathogen identified among women's deaths in the eighth triennial maternal mortality report was b-haemolytic streptococcus Lancefield Group A (Streptococcus pyogenes), of which there were 13 cases (Centre for

Maternal and Child Enquiries, 2011). There were five cases of Escherichia coli, one of which also grew Enterococcus faecalis; three cases of Staphylococcus aureus, one of which also grew mixed coliforms; and one case each of Streptococcus pneumoniae, Morganella morganii and Clostridium septicum. Similar pathogens have been reported in research studies world-wide (Arianpour *et al*, 2009; Christensen *et al*, 1994; Fox, 2011b).

Although maternal mortality associated with perineal trauma is extremely rare in developed countries, an infected perineal wound is a potential route for systemic infection whereby sepsis and septic shock may ensue (Lewis, 2007). Further discussion of sepsis particularly in relationship to perineal wounds is therefore included in this thesis.

2.7.1.5 Sepsis

Definition

Sepsis is a systemic, toxic response to infection leading to severe sepsis and septic shock (severe sepsis plus hypotension not reversed with fluid resuscitation) (Dellinger *et al*, 2013).

Sepsis has been most recently defined as: the presence (probable or documented) of infection together with systemic manifestations of infection. Severe sepsis is defined as: “sepsis plus sepsis induced organ dysfunction or tissue hypoperfusion” (Dellinger *et al*, 2013 p.583).

Sepsis is often insidious in onset and may not reveal itself for several days postpartum, when most women will be at home, especially with routine early discharge now encouraged. Whilst sepsis following perineal trauma is extremely

rare, current evidence revealed in the following section confirmed that for a small minority of women this can prove fatal.

2.7.1.6 Maternal mortality and sepsis associated with perineal wound infection

A review of the eighth confidential enquiry into maternal deaths in the UK, published in 2011 alarmingly revealed that sepsis was the leading cause of mortality (Centre for Maternal and Child Enquiries, 2011). The report included the vignette below clearly illustrating how a fit, healthy woman with an uncomplicated pregnancy and delivery can become critically ill and die in a very short time.

"A woman with a second-degree tear felt feverish a few days after delivery and then developed severe lower abdominal pain and diarrhoea. She was accurately and quickly assessed as having sepsis by her community midwife and GP and rapidly transferred to the Emergency Department, whose staff as well as the maternity team had been alerted in advance. She was extremely ill on admission to hospital, and her condition deteriorated despite appropriate treatment including triple antibiotic therapy. Despite maximum support in intensive care, she died a few hours later. Blood cultures and perineal swabs grew b-haemolytic streptococcus Lancefield Group A (GAS)" (Harper, 2011 p.89).

GAS was the most common pathogen identified in relation to sepsis, it is a typically community based with 5-30% of the population asymptomatic carriers on the skin or throat (Health Protection Agency, 2004). It is very rapidly spread by person to person contact or by droplet from an infected individual (Harper, 2011) and reinforces how crucial the advice is we give to women relating to hand and personal hygiene.

Necrotising Fasciitis also reported in the literature is a rare but exceedingly serious infection of soft tissues associated with a high incidence of maternal mortality

ranging from 13% to 48% in affected women (Tharpe, 2008). A retrospective study in the USA of necrotising fasciitis by Gallop *et al* (2002) included 3 infections that were associated with OASIS and 3 that were associated with a caesarean section. Five of the six women required narcotic analgesia for pain relief; one required a temporary colostomy and one died from an overwhelming sepsis. Barkdull and Wittich (2004) also reported a case review from the United States of America (USA) of the death of a young 19 year old from necrotising fasciitis, 4 days postnatal following episiotomy dehiscence. Similarly necrotising fasciitis due to the virulence of Extended Spectrum Beta Lactamases (ESBL) E. coli (faecal flora) has also recently been identified as the cause of death in England of a woman who had experienced a traumatic vaginal delivery whereby a perineal tear developed into a recto-vaginal fistula (Centre for Maternal and Child Enquiries, 2011).

Lynch *et al* (1997) stress that necrotising fasciitis should be included in a differential diagnosis of postpartum women who present clinically with signs and symptoms of wound infection such as those detailed previously (Horan *et al*, 2008; Johnson *et al*, 2012; Thakar and Sultan, 2009).

2.7.2 Perineal wound dehiscence and epidemiological data

Dehisced perineal wounds, are frequently reported to be associated with infection (Gould, 2007; Hankins *et al*, 1990; Tharpe, 2008; Goldaber *et al*, 1993). If left untreated or managed inappropriately this complication of childbirth may lead to major physical, psychological and social problems and increase the potential for a medico-legal claim.

2.7.2.1 Prevalence

Anecdotal evidence suggests that the number of women reporting perineal wound dehiscence and infection in the community is increasing. The majority of these

wounds will dehisce in the first 7-14 days following childbirth (Hankins *et al*, 1990; Ramin *et al*, 1992; Uygur *et al*, 2004) commonly in the first week. However robust systems to track wound dehiscence following hospital discharge are lacking. Meaningful epidemiological data is therefore as equally challenging as perineal infection rates and has led to the wide disparity of prevalence from 0.59% (Ajibade *et al*, 2013) to 13.5% (Bharathi *et al*, 2013). The majority of studies report this phenomenon as secondary outcome data and most focus upon dehiscence following episiotomy and OASIS.

The disparity of definitions relating to perineal wound dehiscence provided by clinicians and researchers compounds the difficulties of obtaining true epidemiological data. Researchers conducting retrospective and prospective studies have defined perineal wound dehiscence as separation of the episiotomy repair (Ramin *et al*, 1992; Uygur *et al*, 2004) or complete separation of the vaginal mucosa of at least 50% of the length of the repair and or deeper separation of the perineal body (Williams and Chames, 2006).

Perineal wound dehiscence was reported back in 1948 in the United States of America (USA) by Kaltreider and Dixon (1948) in their survey of 707 women who experienced mid-line episiotomies complicated by OASIS. They reported that 15 women (2.11%) had perineal wound dehiscence to the level of but not involving the anal sphincter complex.

Some 45 years later a retrospective case review conducted by Goldaber and colleagues of 390 fourth degree tears in a hospital in Texas USA, revealed that wound dehiscence with an infection was present in n=11 (2.8%) women, whilst dehiscence alone occurred in n=7 (1.8%) of women (Goldaber *et al*, 1993).

A comparative, stratified survey by McGuinness and Norr (1991) compared perineal healing between 181 women with episiotomies and 186 women without episiotomies, at one to two weeks after delivery. Women were from a medically indigent low-risk population who had normal spontaneous vaginal deliveries at the same tertiary-care hospital. Overall, there was a 4.9% (n=18) incidence of delayed perineal healing due to wound separation or clinical infection. In the episiotomy group, 7.7% of the women experienced delayed perineal healing compared with 2.2% in the no-episiotomy group. The results were statistically significant using Pearson chi-square analysis. This evidence also suggests that women without episiotomies exhibit better perineal healing compared to women with episiotomies (McGuinness and Norr, 1991).

A larger survey by Glazener in the Grampian Scotland, involving 707 women who either had a spontaneous vaginal delivery or an assisted vaginal delivery, revealed that 5.5% had significant perineal wound dehiscence following primary repair of either an episiotomy or tear (Glazener, 1999). Whilst a further case-control study including 14,124 women in Michigan, USA, between 1995 and 2005 identified 0.4% (n=59) women with perineal wound dehiscence (Williams and Chames, 2006). This study was primarily conducted to establish risk factors for wound dehiscence and is discussed in more detail in section 2.7.2.3.

More recently, Bharathi and colleagues in their comparative study recently reported wound dehiscence as high as 13.5% out of 200 women (sutured with chromic catgut) and 4% out of 200 women (sutured with Vicryl Rapide®) (Bharathi *et al*, 2013).

The most current evidence of wound dehiscence rates in the UK however is provided from an audit conducted in Reading which revealed that 19 out of 3218 (0.59%) women presented with perineal wound dehiscence (Ajibade *et al*, 2013).

Whilst the rates of perineal wound dehiscence on the whole are undoubtedly small, the available literature to date reveals that wound dehiscence following primary repair of all types of perineal trauma does occur. Lack of a formal reporting process, unrepresentative sample populations and a lack of an agreed definition of perineal wound dehiscence will continue to prevent the true extent of this problem being realised. The literature does suggest however that several factors appear to increase the risk of wound dehiscence and these are discussed in more detail in the following section.

2.7.2.2 Aetiology of perineal wound dehiscence

In addition to infection which appears to the main factor associated with perineal wound dehiscence, retrospective case note studies, clinical audit and two Cochrane systematic reviews have revealed various risk factors that may predispose women to perineal wound dehiscence (Ajibade *et al*, 2013; Goldaber *et al*, 1993; Kettle *et al*, 2010; Kettle *et al*, 2012; Williams and Chames, 2006).

2.7.2.3 Risk factors for perineal wound dehiscence

In the earlier case control by Goldaber *et al* (1993) referred to in the previous section, women were more likely to have experienced shoulder dystocia, endometritis and postpartum pyrexia.

Published at a later date, a comparative retrospective case-control study conducted in the USA to identify risk factors that are associated with the breakdown of the initial perineal repair, included 59 women with various degrees of perineal trauma

(Williams and Chames, 2006). Second degree tears n = 38 (64%), 3rd degree tears n = 17 (28.8%) and 4th degree tears n = 4 (6.8%) were included in this study. Half of the women had received an episiotomy n = 31 (52%). The authors revealed that 28 cases (47.5%) had no complication other than the wound breakdown and 24 cases (40.7%) were associated with infection. Infectious morbidities included perineal abscess n=17 or cellulitis n=7 (Williams and Chames, 2006). A control group n= 118 matched to cases with a 2:1 design were identified as having significant perineal trauma but without evidence of dehiscence. Significant risk factors for perineal wound dehiscence were identified as: prolonged second stage of labour (*P* = 0.001); operative vaginal delivery (OR 3.6, 95% CI 1.8, 7.3); episiotomy (OR 6.9, 95% CI 2.6, 18.7); third or fourth-degree tear (OR 3.1, 95% CI 1.5, 6.4) and meconium-stained liquor (OR 3.0, 95% CI 1.1, 7.9). Logistic regression analysis revealed the most significant factor being an interaction between operative vaginal delivery and episiotomy (OR 6.36, 95% CI 2.18, 18.57) (Williams and Chames, 2006). The study is retrospective and as the authors acknowledge themselves is therefore limited by ascertainment bias. They also accepted that women who required operative repair or debridement had a high capture rate, which may have biased the number of cases towards those who needed operative repair. Additionally, women who did not have a symptomatic dehiscence, for example infection, pain, or discharge may have been missed because the dehiscence had healed by secondary intention by the 6 week postpartum visit (Williams and Chames, 2006). The predominately white population investigated also limited the authors drawing any conclusions about race as a risk factor in perineal wound dehiscence. Future studies with a more diverse population were recommended by the authors to adequately answer the question of race as a risk factor.

A small 12 month retrospective case note audit of 19 women with perineal wound dehiscence also revealed that medio-lateral episiotomy n = 13 (68%) was a common finding in addition to operative vaginal delivery n = 11 (57%), OASIS n = 4 (21%) and meconium stained amniotic liquor n = 1 (5%) respectively. A total of 8 (42%) cases had episiotomy in conjunction with operative vaginal delivery (Ajibade *et al*, 2013).

Randomised controlled trials, systematic reviews and meta-analysis referred to earlier (Bharathi *et al*, 2013; Ismail *et al*, 2013; Kettle *et al*, 2010; Kettle *et al*, 2012) have also demonstrated that the choice of materials and suture techniques used for perineal repair may have the potential to contribute towards wound dehiscence.

A systematic review which included a meta-analysis of 'continuous versus interrupted absorbable sutures for repair of episiotomy and second-degree perineal tears following childbirth', revealed small differences of wound dehiscence but no real statistical evidence between the two groups (Kettle *et al*, 2012). Where small differences were found the authors, two of whom are experts in the assessment and management of perineal repair revealed that there was considerable heterogeneity between the findings from the studies contributing data.

Bharathi *et al* (2013) in their recent prospective, randomised study compared two different suture materials Vicryl Rapide® with chromic catgut. Similar results to those revealed in the Cochrane review (Kettle *et al*, 2010) were reported. Women in the Vicryl Rapide® group had less wound dehiscence at 3-5 days (4%) compared to 13.5% in the chromic catgut group, which was statistically significant at $P < 0.05$. No details of how the authors defined wound dehiscence were provided and only women who received an episiotomy were included, all perineal tears and extensions of episiotomies were excluded. Spontaneous delivery and assisted delivery rates in

both groups were however comparable 95% and 5% (Vicryl Rapide® group) and 92.5% and 7.5% (chromic catgut group) (Bharathi *et al*, 2013).

Although the study population were from a homogenous group of women, the study conducted in India (Bharathi *et al*, 2013) does demonstrate that wound dehiscence following primary repair of perineal trauma is a global issue for a growing minority of women. A caveat to note is that all the episiotomies were repaired by a standard three-step approach. The vaginal mucosa was sutured by using a continuous interlocking suture and the perineal muscle was sutured by using an intermittent suture. The skin closure was repaired using a mattress suture. This method of suturing is in complete contrast to the continuous suturing techniques for perineal closure referred to previously, that have been recommended in the UK (National Collaborating Centre for Women's and Children's Health, 2007) and a recently updated Cochrane review (Kettle *et al*, 2012). Indeed failure to adhere to this high level of evidence in clinical practice can increase the rates of perineal wound infection (Ismail *et al*, 2013) and the potential for wound dehiscence.

2.8 Factors that compromise wound healing following primary repair of perineal trauma

In addition to infection, an overall review of the literature suggests that numerous physiological and psychological factors are thought to compromise effective wound healing with the potential for a complete or partial wound dehiscence. These are synonymous with the obstetric population, are applicable to new mothers and include: poor nutrition, obesity and smoking, lack of sleep, stress, tissue hypoxia, low albumin levels, medical conditions, certain drug therapies and sub-optimal care. Whilst these factors are discussed in more detail below, some of these complexities have only recently been realised.

2.8.1 Poor nutrition

The literature clearly illustrates that a poor nutritional status can lead to reduced strength of the wound, increased susceptibility to infection, increased wound dehiscence and poor-quality scarring (Boyle, 2006; Gray and Cooper, 2001; Johnston, 2007; McLaren, 1992). Specific nutrient deficiencies can have a long lasting effect on wound healing. Amino acids the building blocks of protein are necessary for cell synthesis and division, crucial for wound healing (Boyle, 2006). A lack of protein leads to a decrease in angiogenesis, reduced proliferation of fibroblasts and endothelial cells in addition to reduced collagen synthesis and remodelling (Boyle, 2006). Albumin is the body's predominant serum-binding protein tissue; oedema which can occur as the result of hypoalbuminemia (low albumin levels) can also result in decreased oxygen delivery as diffusion distances are increased (Burns *et al*, 2003). Zinc deficiency can reduce rates of epithelialisation, reduce collagen synthesis and therefore reduce wound strength (Boyle, 2006). Vitamin A is important in cell differentiation and epithelial keratinisation and a deficiency will lead to collagen deficiency and delayed epithelialisation (Boyle, 2006; MacKay and Miller, 2003). Moreover, vitamin A deficiency will increase the woman’s susceptibility to infection and consequently increase her risk of morbidity and mortality (Azais-Braesco and Pascal, 2000). Similarly, vitamin C is also essential for efficient wound healing and is fundamental towards the synthesis of collagen; deficiencies reduce tensile strength, impair angiogenesis and increase capillary fragility (Boyle, 2006; MacKay and Miller, 2003). Several B vitamins are also necessary for collagen reactions and bacterial resistance, whilst iron, zinc, copper and manganese all make significant contributions in the healing process (Boyle, 2006).

2.8.2 Obesity

Obesity which is increasing in women of childbearing age (Department Of Health, 2002), is reported to be a risk factor for infection and successful wound healing (National Institute for Health and Care Excellence, 2010). Adipose tissue is poorly vascularised and the consequential effects on oxygenation of the tissues and functioning immune response is thought to increase the risk of surgical site infections (National Institute for Health and Clinical Excellence, 2008). A comparison of maternal outcomes based on a pre-pregnancy weight reported an increase in the incidence of caesarean wound infections and episiotomy infections in women who were moderately and severely obese (Robinson *et al*, 2005).

2.8.3 Smoking

Nicotine and carbon monoxide are known to have a damaging influence on wound healing by the vasoconstrictive effects and reduced oxygen carrying capacity of blood associated with smoking cigarettes (Bale *et al*, 2000; National Institute for Health and Clinical Excellence, 2008). Even limited smoking can reduce peripheral blood flow to the wound but also decreases vitamins B, B6, B12 and C, essential for tissue regeneration (Flanagan, 1997).

2.8.4 Lack of sleep

Sleep disturbances (experienced by virtually every new mother) may inhibit wound healing. Sleep encourages anabolism (the synthesis of complex molecules from simple ones) and wound healing includes anabolic processes (Boyle, 2006).

2.8.5 Stress

It is believed that anxiety and stress can affect the immune system and thereby inhibit wound healing (Bale *et al*, 2000). A systematic review (22 studies) and meta-analysis (12/22 studies) demonstrated that psychological stress across a variation of wound types and in both clinical and experimental settings was associated with impaired healing or dysregulation of a biomarker associated with wound healing (RR 0.37, 95% CI 0.51, 0.32) *P* = <0.01 (Walburn *et al*, 2009).

Childbirth itself is considered an immense life stressor for many women. Additional stresses caused by pain, fear and sometimes narcosis and the resulting secretion of hormones (particularly norepinephrine) can lead to vascular changes that result in a reduction in oxygen levels in the tissues (Bryant, 1992). Increased secretion of corticosteroids can inhibit the production and function of leucocytes (Workman, 1995). Stress may also contribute to lower levels of pro-inflammatory cytokines in wound fluid following surgery (Upton, 2011). Recognition of risk factors and good support from clinicians may help towards alleviating some of the stresses associated with childbirth. Consequently this will also make an important contribution towards the promotion of good wound healing. Upton (2011) recently argued that clinicians must continue to recognise the importance of the psychological variables in wound care to improve both short and long term outcomes. Of particular relevance to current maternity services, he also acknowledged the pressures of modern day heath care by adding that this must not hinder the appreciation of these variables within everyday clinical practice (Upton, 2011).

2.8.6 Tissue hypoxia

Hypovolaemia, hypothermia and vasoconstriction can all limit the oxygen carrying capacity to the tissues and may occur in the woman who has had a traumatic labour experience, for instance a major postpartum haemorrhage. However, tissue hypoxia can be difficult to quantify because it can occur before the measurable clinical parameters of blood pressure, pulse, temperature, respirations or urinary output alter and when partial pressures of arterial oxygen are adequate (Bryant, 1992). A health care professional with skills underpinned by good knowledge base of wound healing can as Boyle (2006) points out, anticipate and prevent the potential problem by ensuring that the woman is well hydrated, warm, pain free and nutritionally maintained, as well as psychologically supported. In addition when suturing perineal trauma, midwives and obstetricians should avoid the inappropriate insertion of tight sutures as this too may cause tissue hypoxia and delay healing (Kettle and Fenner, 2009).

2.8.7 Medical conditions and therapies

A variety of medical conditions experienced by the general population which result in additional co-morbidities for women of childbearing age can potentially influence their wound healing ability. Low haemoglobin levels may affect the healing process (Oldfield and Burton, 2009). Anaemia in pregnancy for instance, defined as less than 110 g/L (World Health Organization, 2011), can impair wound healing, as red blood cells are necessary to transport oxygen to the tissues. Immunocompromised women due to sepsis or malnutrition, specific disease processes such as acquired immune deficiency syndrome (AIDS), renal or hepatic disease or drugs such as corticosteroids, can all result in a reduced ability to regulate growth factors and inflammatory and proliferative cells, necessary for wound repair (Boyle, 2006).

2.8.8 Suboptimal care

Unidentified perineal trauma, inadequate repair and failing to assess wound healing effectively, leading to inappropriate wound management, all have the potential to contribute towards poor outcomes for newly delivered mothers (Premkumar, 2005; Vuolo, 2006). Incorrect identification of perineal injuries may result in primary or secondary postpartum haemorrhage with the potential for hypovolaemic shock, vulvovaginal haematoma, faecal and flatus incontinence, recto-vaginal fistula and wound infection with the potential for sepsis (Keighley *et al*, 2000).

Retained swabs following a vaginal delivery are a preventable source of maternal morbidity, including pyrexia, infection (with the potential for wound dehiscence), pain, secondary postpartum haemorrhage and psychological problems (National Patient Safety Agency, 2010).

Sub-optimal care and current provision of postnatal maternity care

In the postnatal period, national guidance in the UK recommends that at each postpartum contact women should be asked whether they have concerns about the healing process of any perineal wound (National Institute for Health and Care Excellence, 2006). However, it could be argued that the perineum should be visually inspected, with the woman's consent, not simply enquired about at each postpartum contact. Reflecting upon her own midwifery career Deery acknowledged that examining the woman's perineum on a daily basis was part of the routine care plan (Deery, 2011). What providers of maternity services certainly have not been good at, is prioritising wound care and treatment (Bryson and Deery, 2010). There are valid criticisms that this has almost become 'unimportant' in a culture where midwives are inundated often on a daily basis by the immediate process driven demands of NHS organisations (Bryson and Deery, 2010). These criticisms echo the anxieties of many health care practitioners who feel overwhelmed by the

endless paperwork and the continual pressure to achieve clinical and financial targets that currently seem to control the delivery of the art and science of midwifery (Bryson and Deery, 2010).

Standards for postnatal care from the Department of Health (2004) included the early identification of morbidity and the promotion of a longer duration of contact as required by either the woman or determined by the midwife. Assessors for the Centre for Maternal and Child Enquiries (CMACE) during the period of 2006-2008 however, expressed their concerns relating to morbidity, in particular that of neglected perineal pain in the puerperium. In their chapter 'back to basics' they clearly stress that if a woman complains of perineal pain after delivery, her perineum should be examined (Oates *et al*, 2011). They also recommend that if there has been significant perineal trauma, for example multiple vaginal lacerations or third degree tears, then the perineum should be inspected daily until satisfactory healing has taken place (Oates *et al*, 2011). Whilst no-one would disagree with the latter recommendation of daily inspection, in reality with early transfer home from hospital and fewer postnatal home visits than ever before this is rarely achievable. Indeed, a survey by the Care Quality Commission in 2010 revealed that there had been a decrease in the total number of midwife visits reported by women since 2007 (Care Quality Commission, 2010). The survey confirmed a decrease in the proportion of women who saw a midwife five times or more (37% in 2007 down to 25% in 2010). Over three quarters (76%) of the women who took part in the 2010 survey did report seeing a midwife between one and four times, (an increase from 63% in 2007). However 22% of women reported having had only 1-2 visits from their community midwife. These are concerning statistics, given that over two thirds of direct maternal deaths occurred in the postnatal period.

It is widely acknowledge in the literature that obstetrics is a specialty that is associated with high risk of litigation. Maternity service purchasers, providers and all clinicians, particularly those at the forefront of care delivery must therefore continually strive to put measures in place to prevent sub-optimal care and the potentially catastrophic consequences for new mothers and their families. Effective seamless communication, sensitive to the needs of women, team working, documentation, robust education and training and risk management strategies can help improve patient care and outcomes and reduce the rising level of medico-legal claims (Chandraharan and Arulkumaran, 2006). Complications of episiotomies and perineal tears, including infection, dehiscence, incontinence, fistulae and dyspareunia, have all been cited as potential causes for medico-legal problems in obstetrics (Chandraharan and Arulkumaran, 2006).

2.9 Maternal morbidity and perineal wound dehiscence

It is evident from the literature that maternal morbidity following perineal injury is a major health problem worldwide for many women. It is not surprising therefore that perineal wound infection, dehiscence and the consequences of poor healing are feared by many pregnant and recently delivered women (Al-Mufti *et al*, 1997; Clements, 2001; Perkins *et al*, 2008).

Members of a collaborative research team conducted a two iteration Delphi study in Staffordshire and a traditional consumer survey in Reading, of women who previously sustained perineal trauma (Perkins *et al*, 2008). The purpose of the study was to establish outcomes that were important for women in preparation for the Perineal Assessment and Repair Longitudinal Study (PEARLS) (Ismail *et al*, 2013). The findings demonstrated that the most important outcome for women is avoiding perineal wound infection and delays in wound healing, both at one week and two to four weeks postnatal. The research team felt that the responses were possibly

related to the growing concerns throughout the UK of the escalating numbers of community and hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA) infection. People in the UK are aware that MRSA is an emerging problem which may present as skin and soft tissue infection or sepsis with the potential of septic shock (Lewis, 2007). However, the Delphi study was repeated in Brazil where it was also found that perineal wound infection and wound healing were the main concerns of the women even though MRSA was not so widely publicised there as in the UK. Hence the findings of the Delphi study confirmed that postnatal wound infection and anxieties surrounding healing are not only isolated to the UK but are a true cross-cultural fear for many women. Despite this, the major sources of perineal morbidity following childbirth have on the whole been relatively neglected by researchers. Bick, clearly acknowledges this by arguing that: “the identification and management of perineal morbidity including pain, dyspareunia and wound infection have not been a high priority” (Bick, 2009 p.113). Whilst others have equally argued that, “the prevailing method of managing disease and conducting research is based on a biomedical model that targets organic causation of disease” (Lal, 2009 p. 2). Emphasising the need for adapting a biopsychosocial model to both clinical practice and research in obstetrics and gynaecology was the key message from the paper by Lal (2009), which clarified both the scope and clinical importance of psychosomatic approaches in this particular discipline.

The literature appears to support both of these arguments in that the prevalence and underlying aetiology surrounding morbidity in the postnatal period frequently referred to as the ‘Cinderella’ of maternity care is mostly anecdotal and in the main limited by its methodology (Glazener, 1997). The evidence to support clinical practice has focused upon epidemiological research and case control studies, with clinical trials and qualitative studies in the extreme minority. Historically there has been a tendency to regard the puerperium as a low-risk period compared with

pregnancy and delivery despite the fact that significant problems can develop during this time. Undeniably, morbidity associated with the breakdown of perineal repair particularly in the presence of an infection, can and does pose a serious threat to the general biopsychosocial wellbeing and quality of life of the mother. In the extreme, infection and perineal wound dehiscence can be a catastrophic event even fatal for the woman as previously illustrated.

The extent of morbidity with the added complication of wound dehiscence will depend upon the severity of the initial trauma and the full extent of the wound dehiscence. For many women morbidity will centre around the following: infection, persistent pain and discomfort at the perineal wound site; urinary retention and defecation problems including faecal incontinence, sexual morbidity, dyspareunia and psychological and psychosexual issues from embarrassment and altered body image (Ramin *et al*, 1992; Ramin and Gilstrap, 1994; Steen, 2007; Steen, 2010; Uygur *et al*, 2004; Williams *et al*, 2005). The relationship with her newborn baby may become affected and also the ability to breast feed may also be prevented due to the distress cause by perineal problems (Sleep, 1991). The morbidity experienced may also have the potential to have a negative impact on the woman's relationship with her partner and other family members, subsequently this may lead to relationship or marriage breakdown.

Despite the paucity of literature relating to maternal morbidity associated with perineal wound dehiscence, the following sections acknowledge both the quantitative and qualitative studies that have made some attempts to address the experience of perineal pain and sexual morbidity which are prominent outcomes and findings from both research paradigms. However the distinct lack of literature relating to these outcomes and wound dehiscence is clearly evident.

2.9.1 Pain and perineal wound dehiscence

2.9.1.1 Definition of pain

Pain has been defined as: an unpleasant sensory and emotional experience associated with either actual or potential tissue damage, or described in terms of such damage (International Association for the Study of Pain, 2012). Whilst Upton (2011) refers to wound pain as a biopsychosocial phenomenon, influenced not only by the extent of the injury and its subsequent management, but equally if not more so by the emotional factors of anxiety, worry and depression.

2.9.1.2 Prevalence of perineal pain and wound dehiscence

Perineal pain, irrespective of any additional co-morbidity, such as infection or dehiscence is one of the most commonly reported symptoms following vaginal delivery (Thakar and Sultan, 2009). The severity of the pain experienced is thought to be directly proportional to the severity of the perineal trauma (Albers *et al*, 1999; Macarthur and Macarthur, 2004). Although pain is also often reported in the absence of perineal trauma, possibly as a consequence of soft tissue injury (Thakar and Sultan, 2009; Wylie, 2000). In the UK almost 44% of women will continue to report perineal pain and discomfort for up to 10 days following childbirth (Kettle *et al*, 2002) and whilst 10% will endure longer term pain up to 18 months postnatal; this can increase to 30% for women following assisted vaginal delivery (Glazener *et al*, 1995). For some women, the experience of perineal pain and trauma can impact on their longer-term recovery from childbirth (McCandlish *et al*, 1998).

The literature relating to the extent and duration of perineal pain following wound dehiscence is extremely sparse and at best is assessed as an outcome measure following secondary repair, despite the predominance for expectant management.

Several studies that have investigated secondary perineal repair have focused upon discharge home times with no reference to pain as an outcome measure (Christensen *et al*, 1994; Monberg and Hammen, 1987; Uygur *et al*, 2004). Whilst others have focused upon rates of incontinence, a particularly significant outcome measure, relevant to the population being studied, as the majority of women included, underwent early secondary repair of a dehisced OASIS (Arona *et al*, 1995; Hankins *et al*, 1990).

Hankins *et al* (1990) study of 31 women did reveal that 78% of women with a complete dehiscence of an OASIS (n=4), or episiotomy without OASIS (n=5) reported pain and tenderness as a main symptom of their dehiscence prior to secondary repair. They added that incontinence of faeces and flatus was the primary complaint in 73% of women (n=22) with a completely dehisced episiotomy and OASIS, which included the recto vaginal septum, anal sphincter and rectal mucosa in 17 women (Hankins *et al*, 1990).

Although no actual data were provided by Arona *et al* (1995) in their retrospective case study of 23 women with OASIS they also revealed that pain in addition to incontinence of faeces and flatus was the main complaint with wound dehiscence.

A retrospective study by Ramin *et al* (1992) was an exception in that pain prior to and following secondary repair was reported on. Thirty-four women with a dehisced episiotomy wound (28 also sustained OASIS) underwent secondary perineal repair. Out of the 27 who presented with an infection 22 (81%) reported increased pain prior to re-suturing. Follow-up at 1 and 2 weeks was obtained in 29 women out of 34 (85%). Remarkably, none of the women complained of perineal pain, numbness, incontinence of flatus or stool, in addition the authors revealed that most wounds had healed completely in 2 to 3 weeks (Ramin *et al*, 1992).

Although direct comparisons cannot be made to secondary perineal repair, several studies that have investigated suturing versus no suturing for the primary repair of perineal trauma have assessed perineal pain as an outcome measure (Langley *et al*, 2006; Lundquist *et al*, 2000; Metcalfe *et al*, 2006). All of the studies concluded that there were no significant differences between the two groups for perineal pain at pre-specified time points.

2.9.1.3 Aetiology of perineal pain associated with wound dehiscence

It is recognised that perineal pain can be increased if there is an associated inflammatory process, which can range from mild inflammation, cellulitis and more extensive inflammation with wound infection, abscess formation and dehiscence (Steen, 2007; Thakar and Sultan, 2009). Indeed most of the studies referred to in the previous section (2.7.1.2) reported pain in association with infection.

The literature suggests that longer term pain may lead to the major sequale of physical, psychosexual and social problems if left, (Glazener, 2005) either as a result of not being reported, not recognised or not treated. This may have implications for the mother's relationship not only with her partner but has the potential to have far reaching consequences on the family unit as a whole (Glazener, 1997; Royal College of Obstetricians and Gynaecologists, 2004; Sleep, 1991; Steen, 2010). In addition, protracted pain and complications of perineal trauma such as dehiscence may affect the mode of delivery woman choose in subsequent pregnancies (Wagner, 2000) or even their decision to contemplate future pregnancies.

It is crucial therefore that any perineal problems such as wound dehiscence are identified quickly and managed appropriately to both limit the extent of the morbidity experienced and to prevent any additional complications arising.

2.9.2 Sexual morbidity and dyspareunia associated with perineal wound dehiscence

2.9.2.1 Definition of sexual morbidity

Sexual morbidity is defined as having at least one index of reported sexually related morbidity: vagina too lax, vagina too tight, pain on penetration, pain on deep penetration, lack of lubrication, unwanted leakage of flatus, urine or faeces during sexual intercourse, lack of sensation (numbness during sexual intercourse) (Williams *et al*, 2007b). Whilst women may experience a temporary reduction in libido following childbirth, pain during intercourse should not be expected unless this was a problem prior to pregnancy (Kettle *et al*, 2005).

2.9.2.2 Definition of dyspareunia

Dyspareunia can be defined as any pain or soreness that occurs during sexual intercourse (Kettle *et al*, 2005)**.** Whilst Bick (2005) extends the definition to include pain experienced before, during or following sexual intercourse, which is most likely to be caused by perineal pain (Glazener, 1997). Dyspareunia can be further classified as primary dyspareunia whereby women have always experienced pain during intercourse or secondary dyspareunia where it occurs following a period of pain free intercourse, typically following childbirth (Kettle *et al*, 2005). Superficial dyspareunia where women will commonly experience pain or discomfort around the introitus or vulva or urethral areas and deep dyspareunia which has a tendency to occur secondary to gynaecological problems, are further sub-classifications referred to in the literature (Kettle *et al*, 2005).

2.9.2.3 Prevalence of dyspareunia associated with perineal wound dehiscence

Data surrounding the prevalence of sexual morbidity in the literature is highly variable. Sexual health problems following childbirth have been reported to be between 17% and 83%. (Barrett *et al*, 2000; Glazener, 1997; Greenshields and Hulme, 1993; Solana-Arellano *et al*, 2008). Dyspareunia is most commonly cited amongst the literature on postnatal sexual morbidity, but as Bick (2005) emphasises, existing data surrounding dyspareunia tends to have been obtained from observational studies and clinical trials of varying perineal management regimes. Where dyspareunia has been reported upon this has largely been in response to questionnaire surveys where women are asked to recall when intercourse was resumed, which may in itself be subject to recall bias (Bick, 2005). In addition some studies exclude spontaneous trauma with a focus upon episiotomy or OASIS whilst others focus upon primiparous women. This is particularly apparent in the paucity of literature relating to perineal wound dehiscence and dyspareunia, most of which relates to secondary repair with an OASIS. The results therefore cannot be generalised to women in subsequent pregnancies or indeed to women experiencing the whole range of perineal trauma.

Rates of dyspareunia were reported in two retrospective studies investigating early repair of episiotomy dehiscence with OASIS referred to throughout this chapter (Arona *et al*, 1995; Hankins *et al*, 1990). Arona *et al* (1995) reviewed 17/23 women at 3 months and out fifteen women who had resumed sexual intercourse, only one woman complained of dyspareunia. In comparison Hankins *et al* (1990) reported rates of dyspareunia following episiotomy with 4th degree tear as 4/22 (18%) at 3 months, 3/21 (14.3%) and 2/19 (10.5%) at 9 and 12 months. Rates of dyspareunia were also reported at the same time points for the four women with an episiotomy and 3rd degree tear and the five women with an episiotomy not complicated by an

OASIS. Only one woman complained of dyspareunia reported as occasional coital discomfort just over 2 years following childbirth.

Data relating to the rates of dyspareunia from Monberg and Hammen (1987) is the subject of a Cochrane review and is presented in chapter three.

2.9.2.4 Aetiology of dyspareunia and its association with perineal wound dehiscence

A case study conducted in a hospital in Acapulco revealed that physical complications of an episiotomy such as an infection, dehiscence and a constricted introitus may result in long term dyspareunia (Solana-Arellano *et al*, 2008). Whilst others add that superficial dyspareunia can be secondary to scar tissue formation, poor anatomical reconstruction during perineal repair, vaginal dryness or haemorrhoids (Kettle *et al*, 2005; Sayasneh and Pandeva, 2010). Wounds that are allowed to heal by secondary intention such as dehisced perineal wounds which delays the healing process are potentially more at risk of increased scar formation.

Psychological dyspareunia may occur as a result of a traumatic birth experience and can be associated with anxiety or depression (Kettle *et al*, 2005). Whilst altered body image as a result of poor perineal healing also has the potential to become an immense source of anxiety for women.

2.10 Women's experiences of perineal wound dehiscence

There is no primary qualitative literature devoted to women's experiences of perineal wound dehiscence. Even the literature exploring women's experiences of living with perineal trauma is sparse. However there is encouraging evidence which builds upon earlier qualitative research (Herron-Marx *et al*, 2007; Salmon, 1999; Williams *et al*, 2005) with the publication of more recent papers (Priddis *et al*, 2012; Priddis *et al*, 2014; Way, 2012) suggesting a renewed interest in this phenomena.

Following a review of these qualitative studies it was not apparent that any of the women had experienced perineal wound dehiscence. Three of the papers also focused primarily upon women's experiences of perineal trauma following OASIS (Priddis *et al*, 2012; Priddis *et al*, 2014; Williams *et al*, 2005). The paper by Priddis *et al* (2012) was a meta-ethnographic synthesis of women's experiences following OASIS and included several of the studies referred to above (Herron-Marx *et al*, 2007; Salmon, 1999; Williams *et al*, 2005). However further discussion presented below, suggests that the commonalities of both the physical and psychosocial findings of these studies have the potential to be applicable to women who sustain perineal wound dehiscence. Reading the women's unique accounts of living with the consequences of perineal trauma, clearly demonstrates the magnitude of physical, psychosocial and sexual morbidity they have experienced both in the short and long term. Issues around poor communication (including both content and timing of discussions with midwives, obstetricians and GPs), lack of service provision and poor emotional support from health care professionals and family members and unresolved anxieties in partners were also key themes identified in all of the qualitative studies referred to above.

Salmon (1999) conducted a feminist study using unstructured interviews, with broad questions, to explore women's experiences of recovering from perineal trauma in the first weeks of motherhood. Feminist research is conducted by women and is highly applicable to midwifery (Donovan, 2006). The principles aim to empower women and give them a voice to speak about unique experiences from their perspective (Sarantakos, 2005; Webb, 1993). Although as Donovan (2006) acknowledges women researching women can potentially lead to bias.

Salmon (1999) used a 'snow ball' sampling technique to recruit six women, all of whom had experienced some degree of perineal trauma following childbirth in the previous five years. Snowball sampling is often used in qualitative research (Chaim, 2008) and occurs when a participant refers someone they know to the researcher with the same condition (Bowling, 2009), which was perineal trauma in this instance. This is considered an appropriate sampling method particularly when the phenomena under investigation is rare (Cluett and Bluff, 2006). The weakness of this method are debated by Biernacki and Waldorf (1981) and Bowling (2009) who contend that participants will often suggest others from the same network, who share similar characteristics or the same viewpoint as themselves and that there are inherent ethical problems with confirming the eligibility of potential participants. There is therefore, the potential for an element of bias in the findings. Salmon herself acknowledged the criticisms, however she maintained that the interviews revealed a range of personal and subjective experiences from the women who took part (Salmon, 1999). Experiences of social support and interpersonal relationships during the healing process and feelings associated with coming to terms with perineal trauma were emergent themes from the taped accounts of the interviews (Salmon, 1999). Women reported the intensity of their perineal pain, their concerns about infection and the healing process, their fears and anxieties resuming sexual intercourse and that they were simply not being listened to (Salmon, 1999). Perineal

pain, which as previously acknowledged, may be increased in the presence of wound infection and dehiscence was perceived as the women's inability to cope, with what health care professionals (midwives and doctors) believed to be the normal healing process (Salmon, 1999). Feeling unheard and the normalisation of pain by health care professionals had a considerable impact upon their recovery from childbirth. Indeed one woman who had persistently been reviewed by a male doctor was 18 months postnatal when she was referred for re-suturing and re-fashioning of her perineum by a female locum (Salmon, 1999). Not surprisingly, listening to women was one of the key recommendations of Salmon (1999) feminist research as being fundamental to responsive care.

Participants in the study by Williams *et al* (2005) also revealed accounts of how they struggled with health care professionals to have their thoughts and feelings of concern heard. In comparison to the one-one interview, Williams *et al* (2005) used two focus groups to explore the views and experiences with a purposive sample of 10 women who had sustained OASIS. The strength of purposive sampling commonly used in qualitative research is that it selects individuals who will have rich knowledge of the phenomena concerned (Clifford, 1997; Patton, 2002). One group (n = 6) had repair of OASIS following recent childbirth and the second group (n = 4) had a subsequent pregnancy after OASIS. The authors provide a rational for using focus groups as opposed to interviews in that women who sustain OASIS may not feel so isolated in their experience and therefore would be more willing to share their thoughts and feelings with others (Williams *et al*, 2005). In support of their rationale Webb and Kevern (2001) agree that interaction with participants in a group setting has the potential to generate meaningful data that may not emerge using other methods. Careful thought though, must be given to using focus groups where sensitive topics are discussed as some women would feel less comfortable discussing their experiences with others in a more public setting (Barbour, 2008).

Although Morgan and Kreuger (1993) have previously pointed out that in reality people quite readily talk about sensitive, emotive and personal topics. Moreover despite women being upset as they reflected upon their experiences Williams *et al* (2005) acknowledged that women found the focus groups therapeutic, adding that the level of information gained, confirmed that they were the most appropriate method of collecting the data. The authors provided examples about women's apprehension surrounding the consequences of the injury and for future childbirth; altered body image and being petrified as a result of inappropriate comments from midwives (Williams *et al*, 2005).

Herron-Marx *et al* (2007) conducted a Q methodology study which combines the strengths of both qualitative and quantitative methods (Shabila *et al*, 2014) with 20 women who had either sustained varying degrees of spontaneous trauma, received an episiotomy, had intact an perineum or delivered by caesarean section. Women were self-identified as part of their previous involvement in a cross-sectional community survey of enduring postnatal and pelvic floor morbidity (Williams *et al*, 2007a). Q methodology is considered to be particularly suitable for identifying both commonality and diversity and can provide a powerful opportunity for thematic identification and analysis (Shinebourne, 2009).

In the Q method, participants are asked to sort a set of statements representing a wide range of opinions and perspectives on the phenomenon (perineal morbidity) being investigated (Shinebourne, 2009). Items for the Q set can be gathered from a variety of sources (Shinebourne, 2009) and in the study by Herron-Marx *et al* (2007) this came from the themes from the interviews which were then reduced to a list of statements. Respondents, (women interviewed) are then called the P-set and are asked to sort the statements (Q sorting) from their individual perspective, according to some preference, judgment or feeling about them (Shabila *et al*, 2014). By Q-

sorting, people give their subjective meaning to the statements, and by doing so reveal their subjective viewpoint (Shabila *et al*, 2014). Fourteen out of the 20 women interviewed in the study (Herron-Marx *et al*, 2007) completed the Q sort. Several factors were then identified and included: perineal morbidity of minor inconvenience, insufficient support services, the 'taboo' of perineal morbidity, normalising perineal morbidity and the isolation of perineal morbidity (Herron-Marx *et al*, 2007). Q-studies are exploratory and consequently are not meant to be generalisable (Shabila *et al*, 2014; Shinebourne, 2009) although sadly the findings reported by Herron-Marx *et al* (2007) and the earlier qualitative studies referred to were to be replicated several years later (Way, 2012).

Way (2012) explored the feelings, experiences and perceptions of eleven women using grounded theory in relation to their perineum following childbirth. Women were recruited into the study using a theoretical sampling technique, 4 women sustained perineal trauma of varying degrees, 3 women received an episiotomy and interestingly 4 had an intact perineum. Purposeful sampling guided the initial recruitment, however this was soon replaced by theoretical sampling, to allow for the development of theory (Way, 1996). In theoretical sampling as Charmaz (2006) states, "you conduct sampling by sampling to develop the properties of your categories until no new properties emerge" (p. 96). This required recruitment of women to continue in response to the analysis of data which was collected using diaries and interviews. Key findings from this research were that women strive for normality but often face the unexpected and have to adjust to the reality of perineal pain; pain when feeding their newborn or even themselves, pain when passing urine and fear of tearing their stitches (Way, 2012). Implications for practice were that midwives and doctors must listen to women appropriately, meaning at the time of when the reality of what they are experiencing becomes evident and not trivialise the amount of pain that women experience simply because from their personal

perspective this may be normal (Way, 2012). The findings also suggest that whilst women may have experienced a 'normal' birthing process, women themselves may not view the subsequent pain and discomfort as normal. Way (2012) acknowledged the limitations of the study, revealing that all the women were of Caucasian origin and recruited from an area with a low ethnic prevalence. The inclusion of a more heterogeneous population may have elicited additional themes applicable to a diverse group of women (Way, 2012).

Priddis *et al* (2014) provide the most current research of women's experiences of perineal trauma. Using an interpretive feminist approach, they interviewed 12 women, recruited using the 'snow balling technique' who had sustained OASIS. The time since the OASIS was between 7 weeks and 12 years. Similar to the previous studies discussed (Salmon, 1999; Way, 2012; Williams *et al*, 2005) the authors also revealed traumatic accounts of women feeling vulnerable and disempowered as a direct result of the actions (or lack of in some circumstances) of health care professionals (Priddis *et al*, 2014). Moreover, for many women their 'fairy tale was fractured,' (a main theme of the study) the reality of childbirth and the weeks and months, years even in some circumstances did not match their expectations (Priddis *et al*, 2014). Women relayed intense and moving accounts of on-going pain, urinary and faecal incontinence, and the social isolation resulting from embarrassment and not feeling clean, echoing the sentiments of women in previous studies (Salmon, 1999; Way, 2012; Williams *et al*, 2005). These distressing examples of morbidity were referred to by Priddis *et al* (2014), as a 'broken body,' a 'contaminated uncontrolled body' (sub-themes of the fractured fairy tale).

Various methodological approaches have been used by the researchers in these qualitative studies, the findings of which suggest that women's concerns, fears and anxieties about intimate areas of their body, areas which they are extremely knowledgeable about, are simply still not being heard. Not surprisingly all authors concluded that health care professionals must listen carefully to women to ensure that the care provided is responsive, sensitive and timely to their individual needs. Further reference to these qualitative studies in relation to the findings of the qualitative component of the research presented in this thesis will be provided in chapters five, six and seven.

Premkumar rightly states that "in order to encourage women to consider vaginal delivery more positively, adverse outcomes need to be minimised and the management needs to be based on the best available evidence possible" (Premkumar, 2005 p. 32). Despite repeated acknowledgement that further research into the management of perineal wound infection and dehiscence is needed (Arona *et al*, 1995; Bick, 2005; Boyle, 2006; Thakar and Sultan, 2009) the following section confirms that there is no robust evidence to support best clinical practice.

2.11 The management of dehisced perineal wounds

2.11.1 Diversity of practice

Once more anecdotal evidence postulates that the management of dehisced perineal wounds varies from one organisation to another and even from one clinician to another. Historically, managing dehisced perineal wounds by expectancy or delaying closure thereby allowing the wound to heal by secondary intention, stems from an era without modern suture materials and antibiotics and the scientific evidence to support this long held practice is weak (Arona *et al*, 1995).

Over half a century ago two obstetricians reported that the management of perineal wound dehiscence could be managed by early secondary repair once any infection had been treated (Kaltreider and Dixon, 1948). Surprisingly it took some 40 years following their suggestions for clinicians to feel confident in their beliefs that early closure of dehisced perineal wounds could be both a feasible and safe option. Some believe that this approach should be attempted in order to maintain perineal integrity and reduce both short and long term morbidity (American College of Obstetricians and Gynecologists, 2006; Arona *et al*, 1995; Christensen *et al*, 1994; Hankins *et al*, 1990; Monberg and Hammen, 1987; Ramin *et al*, 1992; Uygur *et al*, 2004). Others even add that forcing new mothers to wait three to four months before repairing dehisced wounds maybe both cruel and unnecessary and can lead to prolonged suffering, social embarrassment and temporary loss of sexual function (Arona *et al*, 1995).

Promising results of secondary re-suturing in women with even the most complex of perineal trauma and in the presence of infection have been reported in the prospective and retrospective case note studies referred to previously (Arona *et al*, 1995; Hankins *et al*, 1990; Ramin *et al*, 1992; Uygur *et al*, 2004). The prospective study by Uygur *et al* (2004) followed up 21/25 women who had secondary re-suturing and revealed complete healing in 18/21 women with 3/21 having superficial separation of the skin edges. Out of the 12 women who received expectancy 2 were lost to follow-up, time take to complete healing was not provided for this group although the authors acknowledged that healing continued without complication (Uygur *et al*, 2004).

Despite evidence of some methodological weaknesses, two small randomised controlled studies of 17 and 35 women respectively, demonstrated that it is possible to manage infected dehisced episiotomy wounds by the administration of

intravenous antibiotics and early re-suturing (Christensen *et al*, 1994; Monberg and Hammen, 1987). These studies were included in a recent Cochrane systematic review and are discussed in detail in chapter three.

2.11.2 Diversity of suture methods and materials for secondary perineal repair

Due to the paucity of research relating to the management of dehisced wounds there is a consequent lack of evidence to suggest the most appropriate choice of suture material and methods for women undergoing secondary perineal repair. Only the studies by Ramin *et al* (1992) and Uygur *et al* (2004) refer to the methods and materials used for the repair of the vaginal mucosa, perineal muscles and skin. Hankins *et al* (1990) and Arona *et al* (1995) both provide information relating to the repair of the OASIS but then refer the reader to a standard obstetric book (Williams Obstetrics) for the remainder of the repair. All cases of perineal wound dehiscence in the study by Ramin *et al* (1992) were repaired in layers with either chromic catgut or Vicryl suture, additional details relating to the method used were not provided. Whilst, Uygur *et al* (2004) revealed that a Vicryl suture was the material of choice in their study and that all layers were repaired using an interrupted technique for women undergoing secondary repair. No rational for the choice of methods or materials were provided by the authors, although low cost, was the rationale for the use of a catgut suture for the primary repair (Uygur *et al*, 2004).

Debridement of infected and necrotic tissue was a common procedure with secondary repairs that were conducted in the operating theatre, using either intravenous analgesia or spinal anaesthesia (Arona *et al*, 1995; Hankins *et al*, 1990; Ramin *et al*, 1992; Uygur *et al*, 2004). Granulation tissue where present was also debrided and tissues dissected to enable good approximation and most women

received either intravenous and or oral antibiotics (Arona *et al*, 1995; Hankins *et al*, 1990; Ramin *et al*, 1992; Uygur *et al*, 2004).

2.12 Summary of the literature review

It is clear from a review of the literature that the protracted morbidity of perineal wound infection and dehiscence and its on-going sequale is a real world wide problem experienced by a significant number of women. In terms of prevalence it is difficult to quantify the true extent of the problem due to the fact that this data is not routinely collated by individual maternity centres or GP practices. It is imperative that before a true estimate of the problem can be fully realised, that standardised criteria for diagnosing perineal wound infections and dehiscence are established. At the same time it is crucial that we determine best practice guidance with scientific evidence from a robust RCT which takes into consideration women's views and experiences when treating dehisced perineal wounds. As yet there remains no scientific evidence to support best clinical practice and inform local, national and international guidelines. In reality, current management varies widely between individual practitioners and institutions, a fact confirmed in a national survey of obstetricians and gynaecologists conducted as part of this thesis which is presented in chapter four.

2.13 Introduction to chapter three

The following chapter details a Cochrane Systematic Review completed by the author as part of this thesis. The results confirmed the urgent need for a robust randomised trial to fully evaluate the comparative effects of both treatment options.

CHAPTER THREE:
A COCHRANE SYSTEMATIC REVIEW

"By removing uncertainties in science and research, systematic reviews ensure that only the most effective and best value interventions are adopted by the NHS and social care providers" (Davies, 2010 p. 1).

3.1 Introduction

The Cochrane collaboration is a world-wide organisation whose overarching principle is to assist users and providers of health services to make well-informed decisions about health care by preparing, maintaining and promoting the accessibility of systematic reviews of the evidence that underpins them (Green *et al*, 2011).

Phase one of PREVIEW was a Cochrane Systematic Review of the literature conducted by the author of this thesis and her research colleagues, Professor C Kettle (CK) and Professor KMK Ismail (KMKI). Using both the guidance from the Cochrane Collaboration (Higgins and Green, 2011) and the PRISMA statement (Preferred Reporting Items for Systematic reviews and Meta-Analyses) (Moher *et al*, 2009), this current chapter will present in detail the background, objectives, methodology and results of the Cochrane review 'Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth' (Dudley *et al*, 2013a). The chapter will conclude with the implications for future practice and research.

The key characteristics of a systematic review which are clearly outlined by (Green *et al*, 2011) are demonstrated throughout this chapter and include:

- A clearly stated set of objectives with pre-defined eligibility criteria for studies
- An explicit, reproducible methodology
- A systematic search that attempts to identify all studies that would meet the eligibility criteria
- An assessment of the validity of the findings of the included studies, for example through the assessment of risk of bias
- A systematic presentation, and synthesis, of the characteristics and findings of the included studies.

As well as setting out what we know about a particular intervention, systematic reviews can also demonstrate where knowledge is lacking (Petticrew and Roberts, 2006). The paucity of scientific evidence from Randomised Controlled Trials (RCT) persistently considered as the gold standard for evidence based research and synonymous with the systematic review was clearly apparent in the review presented in this chapter. Moreover, as Brown *et al* (2006) suggest, this then became a significant contributory factor towards conducting phase four of PREVIEW (the RCT and qualitative study), influencing both the trial design and protocol.

3.2 Background

Currently there is wide variation in how practitioners manage perineal wound dehiscence. This variation is a result of the lack of robust evidence, including the absence of a Cochrane systematic review to support any management strategy. Whilst the evidence in the previous chapter acknowledged that mortality from perineal wound dehiscence is extremely rare, it clearly demonstrated that the

morbidity associated with this complication can have a significant impact upon the lives of women and their families.

This systematic review was therefore conducted to increase the level of evidence to guide clinical practice by evaluating the effectiveness of the management options currently offered to women who present with childbirth related perineal wound dehiscence. In addition it is postulated that the review will identify gaps in knowledge that necessitate further robust investigation.

3.3 Description of the condition

For the purpose of the review a dehisced perineal wound was defined as: separation of sutured perineal skin, vaginal mucosa or the underlying perineal muscles.

3.4 Description of the intervention

The intervention was described as: re-suturing of the dehisced perineal wound compared with leaving the wound to heal by expectant management (secondary intention).

3.5 How the intervention might work

Traditionally dehisced perineal wounds are managed expectantly, thereby allowing the wound to heal by secondary intention. This approach can result in a protracted period of significant morbidity for women. In comparison, some clinicians advocate secondary suturing and have reported that early repair of perineal wound dehiscence is safe, effective and abolishes the prolonged period of disability and distress inherent with healing by secondary intention (Hankins 1990; Ramin 1992; Uygur 2004).

3.6 Objectives for the review

The objective for the review was to evaluate the therapeutic effectiveness of secondary suturing of dehisced perineal wounds following childbirth compared to non-suturing (healing by secondary intention, expectancy).

3.7 Review methods

As this was a new review, all collaborating authors agreed and registered a review title with the editor of the Pregnancy and Childbirth Group of the Cochrane Collaboration 'Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth.'

Conducting this Cochrane review was a two stage process involving the development of a protocol for the review, followed by the actual review. The protocol and the review were subject to strict methodological criteria and were prepared using Review Manager (RevMan) software, supplied by the Cochrane Collaboration. Both the protocol and review were expertly peer reviewed and following final approval by the editorial board were published on the Cochrane Database of Systematic Reviews (Dudley *et al*, 2013a).

3.7.1 Criteria for considering studies for the review

3.7.1.1 Types of studies

All randomised controlled trials investigating re-suturing versus expectancy for the management of dehisced perineal wounds following primary repair of second, third and fourth-degree tears and episiotomies sustained during childbirth were included in the review (chapter 1, table 1, provides the classification of perineal trauma).

Non-randomised, quasi-randomised, cluster-randomised, and crossover trial designs were excluded.

3.7.1.2 Types of participants

All women with a dehisced perineal wound following primary repair of a spontaneous second, third, or fourth degree tear or episiotomy, within the first two weeks following childbirth were included in the review.

3.7.1.3 Types of interventions

Any secondary suturing of dehisced perineal wounds (second, third, or fourth degree tear or episiotomy), following wound debridement and the removal of any remaining suture material within the first six weeks following childbirth compared with non-suturing.

All re-sutured perineal wounds were included irrespective of suture material.

3.7.1.4 Types of outcome measures

Primary outcomes:

- The main outcome measure for the review was perineal wound healing at 6-8 weeks.

Secondary outcomes:

- Pain at six weeks, three months and six months
- Resumed intercourse within two months
- Resumed intercourse by six months
- Dyspareunia at three to six months
- Women's satisfaction with the aesthetic results of the perineal wound

- Rates of breast feeding (at six weeks and at six months)
- Rates of exclusive breast feeding (at six weeks and six months)
- Maternal depression
- Maternal anxiety.

3.7.1.5 Definition of wound healing

A commonly used definition of wound healing was detailed in the review; defined as the physiological processes by which the body both replaces and restores function to the damaged tissues (Flanagan, 1996; Tortora and Grabowski, 1996).

3.7.1.6 Assessment of wound healing

For the purpose of the review, wound healing was taken as that described by the study investigator.

3.8 Search methods for the identification of studies

3.8.1 Electronic searches

The authors utilised the expertise of the trials search co-ordinator who searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31st July 2013). The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the trials search co-ordinator and contains trials identified from:

1. Monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL)
2. Weekly searches of MEDLINE a Medical Literature Analysis and Retrieval System Online (U.S. National Library of Medicine's life science database)
3. Weekly searches of the Excerpta Medica Database commonly referred to as EMBASE

4. Hand searches of 30 journals and the proceedings of major conferences
5. Weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The trials search co-ordinator searched the register for the review using the topic list rather than keywords.

3.8.2 Searching other resources

Reference lists of retrieved studies, national and international guidelines and other publications identified were also searched when preparing the review. Language restrictions were not applied and where applicable the translation services offered by the Cochrane Pregnancy and Childbirth Group were utilised.

3.9 Data collection and analysis

3.9.1 Selection of studies

Three review authors Lynn Dudley (LD), Christine Kettle (CK) and Khaled MK Ismail (KMKI) independently assessed and selected trials for inclusion in the review. It was not possible for the review authors to assess the relevance of the trials blinded because the authors' names, institution, journal of publication and results were known when the inclusion criteria was applied. Disagreements were resolved by discussion until a consensus was reached. Reasons for exclusion of studies were documented. See appendix 2 for characteristics of included and excluded studies.

3.9.2 Data extraction and management

A bespoke data extraction form was designed by adapting an example supplied by the Cochrane Pregnancy and Childbirth Group. For eligible studies, two reviewers (LD and CK) independently extracted the data. Discrepancies were resolved by discussion or, if required, by consulting a third reviewer (KMKI). Data entry and analysis was undertaken using Review Manager software (RevMan) (RevMan, 2011). All three review authors checked for the accuracy of data entered.

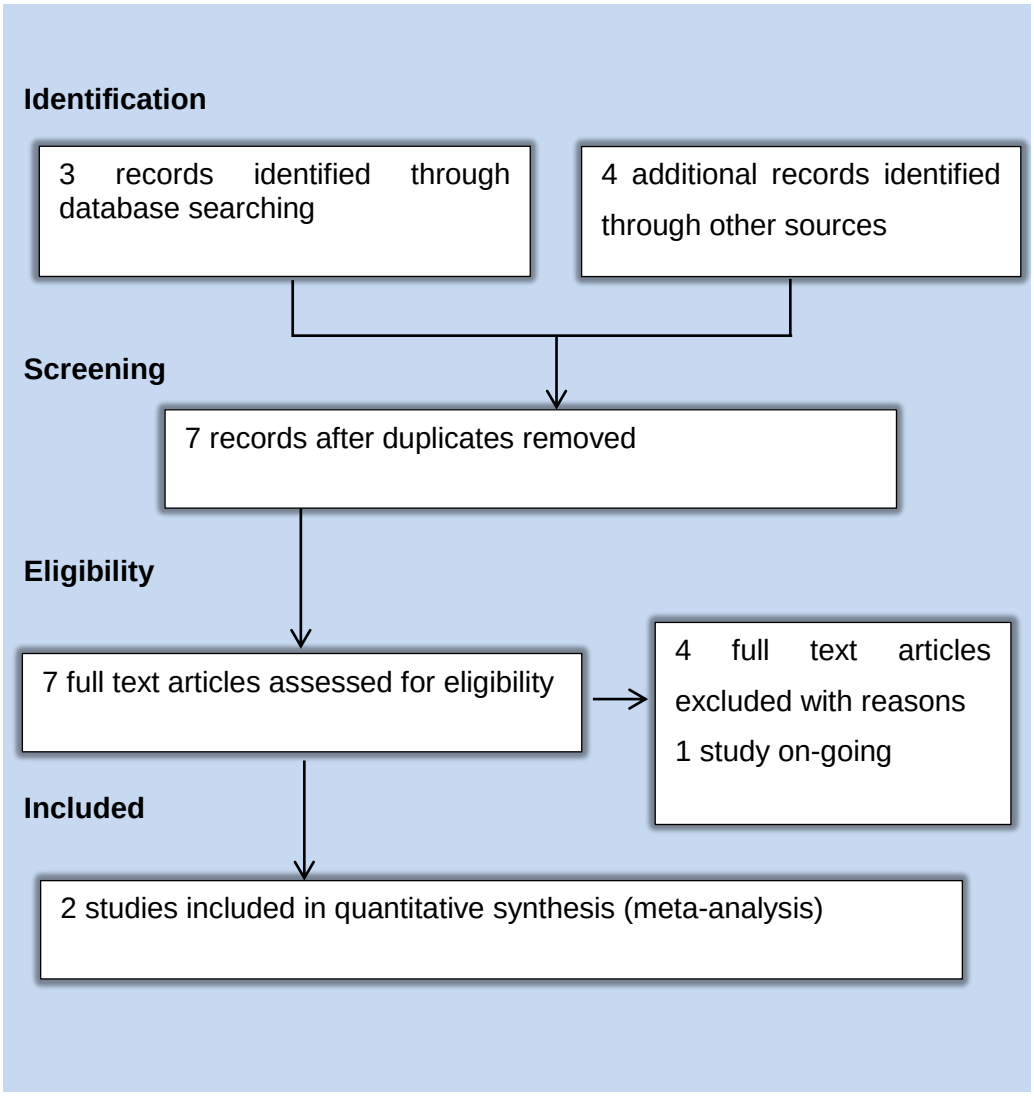
3.9.3 Assessment of risk of bias in included studies

Two review authors (LD and CK) independently assessed risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, 2011). Any disagreements were resolved by discussion or by involving the third review author (KMKI).

3.9.4 Results of the search

The search strategy identified seven reports in total (three from the Cochrane Pregnancy and Childbirth Group's Trials Register and four from other sources). See Figure 1 study selection flow diagram.

Figure 1: Study selection flow diagram



3.9.5 Included studies and excluded studies

Two studies were included by the review authors involving 52 women with a dehisced and or an infected episiotomy wound at point of study entry (Christensen *et al*, 1994; Monberg and Hammen, 1987).

Four studies were excluded from the review; in all cases the reason for exclusion being that they were not randomised controlled trials (Arona *et al*, 1995; Hankins *et al*, 1990; Ramin *et al*, 1992; Uygur *et al*, 2004). See appendix 2 for characteristics of included and excluded studies.

3.9.6 Settings

Both studies were conducted within individual hospital settings in Denmark, over a period of 24 months (Monberg and Hammen, 1987) and 31 months (Christensen *et al*, 1994).

3.9.7 Participants

The sample size for both studies was small and ranged between 17 (Christensen *et al*, 1994) and 35 (Monberg and Hammen, 1987); all women had received an episiotomy with primary repair of the perineal trauma. The mean number of days from delivery to the confirmation of perineal wound breakdown in the trial by Monberg and Hammen (1987) was 4.8 to 5.5 for both the intervention and the control respectively. No data were provided in the later study (Christensen *et al*, 1994) regarding time from delivery to confirmation of perineal wound breakdown.

3.9.8 Interventions

Both trials compared secondary suturing versus non-suturing. In one trial (Monberg and Hammen, 1987) all women presented with a broken down perineal wound referred to as 'ruptured episiotomy'. All 35 women were then allocated into either group A the experimental intervention or group B spontaneous healing. Group A the experimental intervention women were treated with Clindamycin and secondary suturing referred to as 'primary re-suturing'. Clindamycin was administered 2 hours prior to suturing and continuously for 5 days (300 mg TDS). In the spontaneous healing group; women were treated according to the routine management of the department, which was detailed as cleansing the wound with chlorine and saline. In comparison, in the study by Christensen *et al* (1994) 17 women presented with an infected episiotomy wound, however six of the 17 women presented with wound infection that required incision and drainage. The remaining 11 women had wound breakdown referred to as 'with rupture'. Women were allocated into two groups;

either the experimental intervention of incision, curettage and suture, also described as 'primary suture' under antibiotic cover (Clindamycin), or the conventional treatment of incision and drainage. Of the 11 women presenting with a wound infection and wound breakdown, seven were allocated to the experimental intervention and four were allocated the conventional treatment. Of the six women who presented with wound infection but no wound breakdown, one woman was allocated into the experimental intervention and five allocated the conventional treatment.

3.9.9 Outcomes measured

In relation to the pre-specified primary outcome of wound healing, measurement of the initial episiotomy was provided in one study (Monberg and Hammen, 1987), but no reference was provided in relation to wound healing or how healing was assessed. Whereas Christensen *et al* (1994) referred to outcome measures of both primary and secondary healing, detailed as less than four weeks for primary healing and greater than 4 weeks for secondary healing respectively.

One of the studies included in this review (Monberg and Hammen, 1987) reported figures on the resumption of sexual intercourse in both groups at two and six months and dyspareunia at two and six months. This study also referred to the continuation of lactation and although no actual figures were provided, lactation continued in both groups.

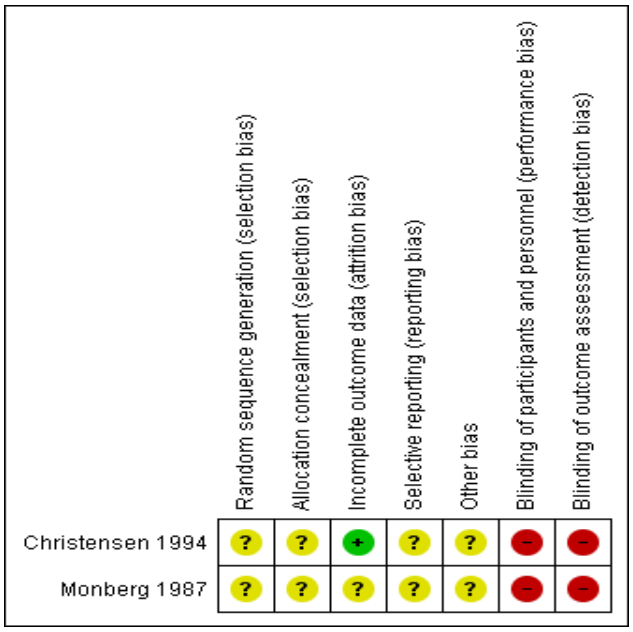
Perineal pain, women's satisfaction with the aesthetic results of the perineal wound, maternal depression and maternal anxiety were not reported in either study.

Both studies did identify length of hospital in-patient times which was not a pre-specified outcome measure for the review. Christensen *et al* (1994) revealing the total number of women discharged from hospital less than and more than 48 hours following the operative procedure and Monberg and Hammen (1987) revealing the number of days following complications until discharge in both the intervention and control group.

3.9.10 Risk of bias in included studies

The methodological qualities of the two trials included in the systematic review did reveal some inconsistencies. It is not clear if antibiotics were used in the expectant management group in either study. Traditionally, antibiotics are used during expectant management; however, if antibiotics were not used in the control arms, this co-intervention could be a serious source for bias particularly in the absence of blinding. A risk of bias summary is provided in figure 2.

Figure 2: Risk of bias summary: review authors' judgements about each risk of bias item for each included study



Low risk of bias

Unclear risk of bias

High risk of bias

Allocation

Both Christensen *et al* (1994) and Monberg and Hammen (1987) revealed that treatment was by randomisation however neither trial described the methods used.

Blinding

No details were provided by Christensen *et al* (1994) or Monberg and Hammen (1987) in relation to blinding of the interventions to either the clinicians or the participants. However, blinding of the outcome assessments would not have been feasible in either trial due to the obvious differences in the treatment groups. The difficulties of blinding clinicians to treatment allocations can be a considered a potential source of bias when assessing outcome measures, particularly when

women are assessed by the researchers themselves. All women in the trial by Monberg and Hammen (1987) were examined by one of the authors with further control if necessary by the general practitioner and/or in the outpatient clinic.

Incomplete outcome data

Attrition was low in the in the trial by Christensen *et al* (1994), 20 women were asked to participate; 17 women were randomised and three withdrew before being allocated to a treatment group. One participant was reported as being unable to attend for the four week review appointment. Outcome data were reported for all women included in the trial with the exception of one participant who was allocated the conventional treatment. There were missing outcome data in the trial by Monberg and Hammen (1987) for dyspareunia, particularly at the two-month assessment; no details were provided in relation to the missing data. Data were however complete for resuming sexual intercourse.

Selective reporting

There is an unclear risk of reporting bias for both included trials (Christensen *et al*, 1994; Monberg and Hammen, 1987). Lactation was reported to have continued in both the intervention and control groups by Monberg and Hammen (1987), however no reference was made to the length of time women continued to breast feed.

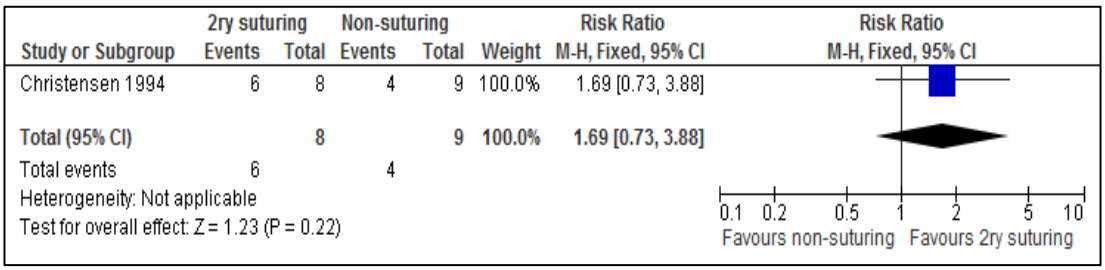
Other potential sources of bias

Only Monberg and Hammen (1987) revealed the technique and material used for the secondary repair, detailed as Vicryl 2/0 into the intradermal and subcuticular layer. Inclusion criteria was not specified in either study whilst only Christensen *et al* (1994) described exclusion criteria specified as Crohn's disease, ulcerative colitis and immunosuppressive treatment.

3.9.11 Effects of interventions: Primary outcome, the proportion of women with a healed perineal wound at six to eight weeks

Only the trial by Christensen *et al* (1994) presented data in a suitable format for inclusion in this analysis. Data were provided in relation to wound healing at less than four weeks although no reference was made on how healing was measured. This small trial demonstrated that there was a trend to reduce healing times in the secondary suturing group, however, this difference was not statistically significant, (risk ratio (RR) 1.69, 95% confidence interval (CI) 0.73, 3.88, one study, 17 women; figure 3).

Figure 3: Comparing wound healing at 4 weeks between suturing versus non-suturing for perineal wound dehiscence



3.9.12 Effects of interventions: Secondary outcomes

Pain, resumption of sexual intercourse, dyspareunia, satisfaction with the aesthetic results of wound healing, rates of breast feeding and rates of anxiety and depression were analysed.

3.9.12.1 Pain at six weeks, three months and six months

Neither of the trials included data in relation to pain at any time interval.

3.9.12.2 Resumption of sexual intercourse (none pre-specified outcome measure)

One of the trials included in the review presented data on the resumption of sexual intercourse in both groups at two and six months (Monberg and Hammen, 1987). This was not an outcome pre-specified in the protocol but one that the review authors felt was relevant to include in the analysis. At two months, significantly more women in the secondary suturing group reported resuming sexual intercourse in comparison to the non-suturing group, (RR 1.78, 95% CI 1.10, 2.89, one study, 35 women; figure 4). However there was no significant difference between groups at the six-month assessment. All women resumed intercourse by six months in the secondary suturing group and all but one woman resumed intercourse at six months in the non-suturing group, the last woman after six months, (RR 1.08, 95% CI 0.9, 1.28, one study, 35 women; figure 5).

Figure 4: A comparison of women who resumed intercourse by two months postnatal between suturing versus non-suturing for perineal wound dehiscence

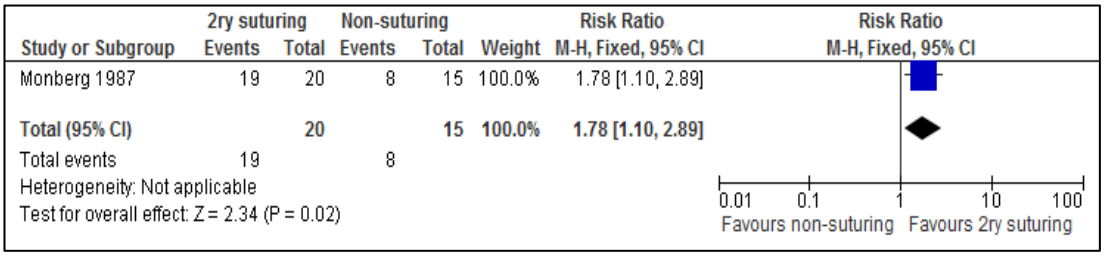
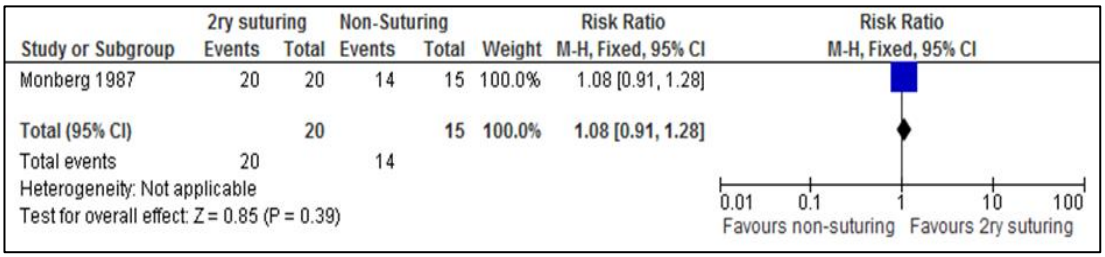


Figure 5: A comparison of women who resumed intercourse by six months postnatal between suturing versus non-suturing for perineal wound dehiscence



3.9.12.3 Dyspareunia at three to six months

Only one trial presented data relating to dyspareunia, assessed at two months and six months (Monberg and Hammen, 1987). At two and six months, dyspareunia was reported less frequently by women allocated to the secondary suturing group in comparison to women in the non-suturing group, however, these differences were not statistically significant, (at two months RR 0.44, 95% CI 0.18, 1.11, one study, 26 women; figure 6), (at six months RR 0.39, 95% CI 0.04, 3.87, one study, 32 women; figure 7).

Figure 6: A comparison of women who experienced dyspareunia at 2 months postnatal between suturing versus non-suturing for perineal wound dehiscence

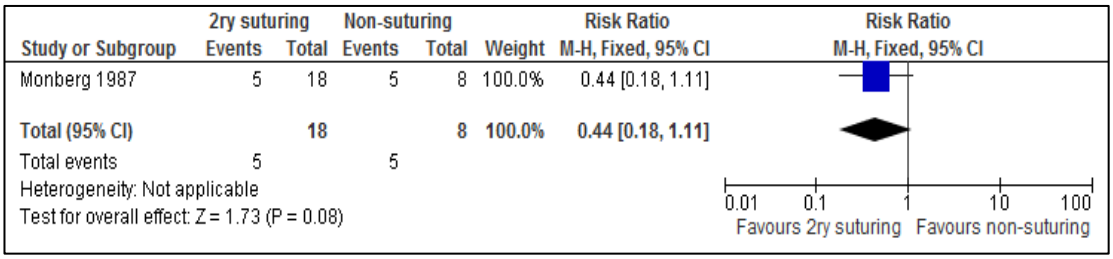
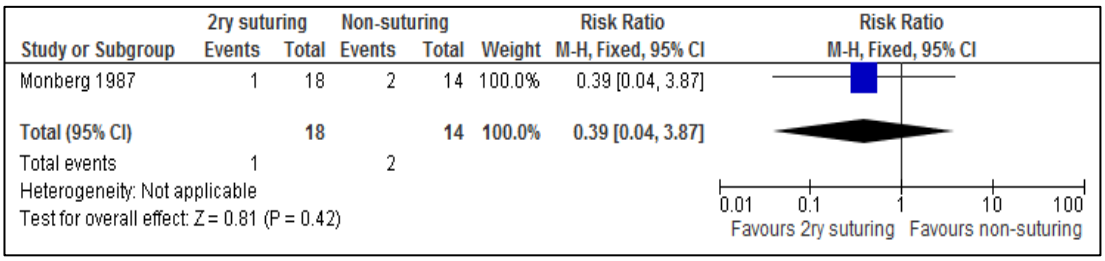


Figure 7: A comparison of women who experienced dyspareunia at 6 months postnatal between suturing versus non-suturing for perineal wound dehiscence



3.9.12.4 Women's satisfaction with the aesthetic results of the perineal wound

Neither of the trials reported upon the woman's satisfaction with the aesthetic results of the perineal wound.

3.9.12.5 Rates of breast feeding (at six weeks and at six months) and rates of exclusive breast feeding (at six weeks and six months)

Only the trial by Monberg and Hammen (1987) commented upon breast feeding, no data were provided regarding rates of breast feeding, although it was stated that lactation continued in both groups.

3.9.12.6 Maternal depression

Neither of the trials included data relating to maternal depression.

3.9.12.7 Maternal anxiety

Neither of the trials included data relating to maternal anxiety.

3.10 Discussion

The evidence from the two randomised trials included in the review demonstrated that when compared with non-suturing of broken down perineal wounds, secondary suturing is a feasible alternative treatment option. However the authors were unable to provide definitive evidence of benefits and risks associated with secondary suturing compared with non-suturing for broken down perineal wounds based on only two studies (Christensen *et al*, 1994; Monberg and Hammen, 1987), particularly due to the methodological inconsistencies and outcome measures assessed. It was not clear if antibiotics were used in the expectant management group in either of the studies. Traditionally, antibiotics are used during expectant management, however if antibiotics were not used in the control arms, this co-intervention could be considered a serious source for bias particularly in the absence of blinding.

The key issue is whether secondary suturing reduces the time taken to heal and only one study assessed this as an outcome measure (Christensen *et al*, 1994). Secondary outcomes of pain; women's satisfaction with the aesthetic results of wound healing and maternal depression were not assessed as outcome measures by either study. Only Monberg and Hammen (1987) assessed rates of dyspareunia at two months and six months.

3.11 Conclusions

3.11.1 Implications for practice

The authors concluded that there is currently insufficient evidence to assess the benefits and risks of secondary suturing for broken down perineal wounds compared with non-suturing. They stressed that there is an urgent need for a robust randomised trial to fully evaluate the comparative effects of both treatment options.

3.11.2 Implications for research

The systematic review highlighted the following areas that need further evaluation to guide the future clinical management of broken down perineal wounds:

- A robust randomised controlled trial to evaluate the effectiveness of secondary suturing compared to non-suturing for broken down perineal wounds which addresses outcome measures that are important to women. In addition to reducing healing times, these include pain, resuming sexual intercourse, dyspareunia, satisfaction with the aesthetic results of healing and the continuation of breast feeding in both the short and long term.
- Research into women's personal experiences of perineal wound breakdown and the impact of this complication of childbirth upon themselves as a new mother and that of their newborn and families.

3.12 Funding and support to conduct the review

A Doctoral Nursing Studentship award from the Smith and Nephew Foundation and Research into Ageing (RIA) UK awarded to the author of this thesis provided the funding to prepare the Cochrane review as a pre-specified phase of the PREVIEW study.

The lead author of the review (LD) attended two Cochrane workshops 'Developing a Protocol for Review' and 'Introduction to Analysis' provided for by the Cochrane collaboration, specifically for review authors. All three review authors acknowledged the support and guidance provided by the Pregnancy and Childbirth Group during the preparation of the review.

CHAPTER FOUR: PART ONE
A RETROSPECTIVE CASE NOTE AUDIT

Exploring risk factors for perineal wound dehiscence

"Clinical audit is an established and crucial tool for upholding standards and achieving improved care" (Cheshire, 2010 p.4).

4.1 Introduction

The literature review presented in this thesis confirms a now widely acknowledged fact, that the majority of women who experience a vaginal delivery will need primary repair of varying degrees of perineal trauma. Fortunately for the majority of these new mothers, their perineal wound will heal with no long-term morbidity. The rates of perineal wound infection and dehiscence however are less clear with variable rates reported. Similarly, with the exception of the retrospective case control study conducted in the USA by Williams and Chames (2006) of 59 women (112 controls) and the small UK based audit of 19 women (Ajibade *et al*, 2013) referred to in the literature review, there remains a relative paucity of data surrounding risk factors for perineal wound dehiscence. The most logical reason for this is that perineal wound dehiscence is perceived to be a relatively rare outcome. Nonetheless, the morbidity experienced by women with this unfortunate complication of childbirth is without doubt very real.

Promoting wound healing and reducing identifiable risk factors that are associated with wound infection and dehiscence are an absolute priority for all healthcare professionals. Concerns about the quality of NHS care both past and present have attracted national publicity, public inquiries and a focus on failure (Francis,

2013; Hine and Rawlins, 2002). Astonishingly, the results of a ten year review of claims (National Health Service Litigation Authority, 2012) revealed an estimate of some £31 million from 441 claims relating to perineal trauma alone. Health care professionals therefore cannot afford to underestimate the true potential for perineal wound dehiscence and the morbidity associated with poor healing to contribute towards these escalating costs. Focusing upon improving the management of risks associated with maternity care and reducing both the financial and human costs of maternity claims, must continue to be at the forefront of clinical practice for all health care professionals (National Health Service Litigation Authority, 2012).

The clinical audit cycle provides a particular framework for all midwives, nurses and doctors to improve the quality of patient care (National Institute for Clinical Excellence, 2002). It is a systematic process that when carried out in accordance with best practice standards provides assurance of compliance with clinical standards; identifies and minimises risk, waste and inefficiencies and improves both the quality of care and patient outcomes (Healthcare Quality Improvement Partnership, 2013). The National Institute for Health and Care Excellence proposed the following universally accepted definition of clinical audit:

“Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the review of change. Aspects of the structure, process and outcome of care are selected and systematically evaluated against explicit criteria. Where indicated changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery” (National Institute for Clinical Excellence, 2002 p.1).

4.1.1 Study design

In response to the paucity of data, a comparative retrospective case-control audit led by the author of this thesis was conducted as phase two of PREVIEW. The medical notes of women who experienced perineal wound dehiscence following vaginal delivery between February 2004 and February 2010 were reviewed for inclusion in the audit. Women without wound dehiscence during the same time period were also identified for audit, consequently increasing its superiority in comparison to a case series (Hess, 2004). Section 4.1.7 provides details of how women were identified for the audit.

The audit design and content was guided by a standard template as detailed in the Maternity Clinical Risk Management Standards, Clinical Audit Report Template (Clinical Risk Negligence Scheme for Trusts, 2012) and Principles for Best Practice in Clinical Audit (National Institute for Clinical Excellence, 2002).

Whilst some sections of this audit reflected recommendations from national guidelines, the audit was developed as a baseline upon which to conduct future audits and to facilitate the establishment of local criteria and standards. This will enable aspects of substandard practice to be recognised and identify where areas for improvement can be made. In contrast, it also provides an opportunity to demonstrate clinical achievements that can also be disseminated within the department.

4.1.2 Ethical approval

In accordance with 'Governance arrangements for research ethics committees: a harmonised edition' (Department of Health, 2011), ethical approval to conduct this clinical audit was not required. The audit was however registered with the Directorate Clinical Audit lead at the maternity unit where the data were collected.

4.1.3 The audit project team

The multi-disciplinary audit team listed below consisted of specialists in the field of perineal trauma recognition and repair with a wealth of clinical knowledge and expertise both locally and world-wide. The Obstetrics and Gynaecology Directorate Clinical Audit lead and the statistician on the audit team had also both been involved in numerous audits and research projects relating to the repair of perineal trauma. The author of this thesis also conducted this audit as an educational project (supervised by the audit team) to complement the doctoral research presented in this thesis and to increase the level of evidence based information surrounding perineal wound dehiscence.

A multi-professional project team with the right level of expertise and skills; clear leadership, with well-defined roles and responsibilities is crucial for successful clinical audit (Dixon and Pearse, 2011). In many cases, changes as a result of audit findings will require support and assistance from the whole management team. There is clear evidence that change in practice is greatly facilitated when clinicians and managers work together (Potter *et al*, 2010). Creating a sense of local ownership with the results of the audit was a fundamental concept prior to commencing this audit. In addition to the audit project team identified below, both managers (within the Obstetric Directorate where data were collected and the wider Trust) and clinicians (midwives and obstetricians) alike were aware that the audit was taking place.

Audit project leads:

- L Dudley, Midwife, audit lead and PhD student, Staffordshire University (author of this thesis)
- Professor Emeritus C Kettle, Professor of Women's Health, Staffordshire University
- Directorate Clinical Auditor, Obstetrics and Gynaecology at the maternity unit where the data were collected
- Professor P Thomas, Director (Methodology) Bournemouth University Clinical Research Unit and Consultant for the NIHR Research Design Service
- Professor K Ismail, Professor of Obstetrics and Gynaecology, The Birmingham centre of Women's and Children's Health, College of Medical and Dental Sciences, University of Birmingham, UK. (Previously UHNS and Keele University).

4.1.4 Aim and objectives of the audit

The primary aim for conducting this audit was to:

- Determine the risk factors associated with perineal wound dehiscence, with the use of a logistic regression model.

The objectives for conducting this audit were to:

- Collect baseline data to inform the development of standards against which future care is provided and measured
- Highlight the need for specificity of criteria to improve data reliability.
- Identify if there are any areas for improvement
- Establish the need for any changes in clinical practice
- Establish the need for additional education and training.

4.1.5 Setting for the audit

The audit was conducted at a maternity unit with approximately 6000-6500 deliveries per annum. Perineal wound dehiscence had not previously been the subject of clinical audit at the unit. The audit was conducted in full collaboration with Directorate Clinical Auditor, Obstetrics and Gynaecology, in the unit where data were collected.

4.1.6 Local and National Guidelines considered for the audit

Poor compliance with evidence based clinical guidelines has the potential to increase the women's risk of developing a perineal wound infection and dehiscence. Key recommendations for clinical practice, located within several local and national guidelines were considered applicable to this audit and were therefore reflected in the data set. The relevant information from these guidelines is outlined in 4.1.6.1 to 4.1.6.3 respectively.

4.1.6.1 Intrapartum Care: length of second stage of labour

Prolonged second stage of labour in conjunction with operative vaginal delivery and an episiotomy have the potential to increase the risk for perineal wound dehiscence (Williams and Chames, 2006). Clear definitions detailed below for the second stage of labour in both nulliparous (women having had no previous births) and parous women (women having experienced at least one previous birth) are provided in both national and local guidance (National Collaborating Centre for Women's and Children's Health, 2007).

Passive second stage of labour:

The passive second stage of labour is defined as: full dilatation of the cervix, prior to or in the absence of involuntary expulsive contractions.

Active second stage:

The active second stage of labour is defined as: the baby being visible or full dilatation of cervix accompanied by the woman experiencing expulsive contractions. In the absence of expulsive contractions the active second stage of labour is also defined as active maternal effort following confirmation of full dilatation of the cervix.

Further recommendations detailed below are also provided regarding the duration and definition of delay in the second stage of labour (National Collaborating Centre for Women's and Children's Health, 2007).

Recommendations on the duration and definition of delay in the second stage of labour (National Collaborating Centre for Women's and Children's Health, 2007).

Nulliparous women:

- Birth of the baby would be expected to take place within 3 hours of the start of the active second stage in most women
- A diagnosis of delay in the active second stage should be made when it has lasted 2 hours and women should be referred to a healthcare professional trained to undertake an operative vaginal delivery if the delivery is not imminent.

In a woman having her first baby, her second stage of labour should therefore not exceed 3 hours from the start of the active phase.

Parous women:

- Delivery of the baby would be expected to take place within 2 hours of the start of the active second stage in most women
- A diagnosis of delay in the active second stage should be made when it has lasted 1 hour and women should be referred to a healthcare professional trained to undertake an operative vaginal delivery if the delivery is not imminent.

In a woman having her second and subsequent vaginal delivery her second stage of labour should therefore not exceed 2 hours from the start of the active phase.

Whilst midwives and obstetricians are encouraged to document the timings of the passive and active second stage of labour in the unit where data were collected, the exact timings are not a requirement of either current or previous birth notes. A pilot of the data collection form demonstrated that passive and active stages of labour are not clearly detailed in the birth records. For the purpose of this audit the total length of the second stage of labour was recorded.

Recording the timings of the active and passive second stages of labour will help to ensure the timely intervention of an operative vaginal delivery for inadequate progress. As previously referred to, operative vaginal delivery is considered a risk factor for perineal wound dehiscence. The recently updated Royal College of Obstetricians and Gynaecologists guideline 'Operative Vaginal Delivery' (Royal College of Obstetricians and Gynaecologists, 2011) provides clear indications based on the active and passive second stage of labour timings as detailed in the National Institute for Health and Clinical Excellence, Intrapartum Care guideline (National Collaborating Centre for Women's and Children's Health, 2007) for the use of this intervention in childbirth. They also acknowledge that these are not

absolute and that the overall clinical situation should be assessed on an individual basis.

Inadequate progress in the second stage of labour for nulliparous women:

- Lack of continuing progress for 3 hours (total of active and passive second-stage labour) with regional anaesthesia, or 2 hours without regional anaesthesia (National Collaborating Centre for Women's and Children's Health, 2007).

Inadequate progress in the second stage of labour for parous women:

- Lack of continuing progress for 2 hours (total of active and passive second-stage labour) with regional anaesthesia, or 1 hour without regional anaesthesia
- Maternal fatigue/exhaustion (National Collaborating Centre for Women's and Children's Health, 2007).

4.1.6.2 Intrapartum care: time from completion of third stage of labour to the suturing of perineal trauma

The third stage of labour is defined by the National Collaborating Centre for Women's and Children's Health (2007), in their Intrapartum Care guideline as: the time from the birth of the baby to the expulsion of the placenta, cord and membranes. This particular guideline does not provide specific timings related to the repair of perineal trauma following the completion of the third stage of labour. It does however provide a clear recommendation that this should be undertaken as soon as possible to minimise the risk of infection and blood loss (National Collaborating Centre for Women's and Children's Health, 2007). Conversely, National Standards for Maternity Care: Maternity Audit Indicators (Royal College of Obstetricians and Gynaecologists *et al*, 2008) detail the percentage of women with an episiotomy or tear sutured within 1 hour as an auditable standard (Standard 12 Intrapartum Care). Clinical guidance at the maternity unit where data were collected

for the timing of perineal repair following spontaneous perineal trauma (second, third and fourth degree tears) and episiotomies currently reflects the NICE Intrapartum care guideline (National Collaborating Centre for Women's and Children's Health, 2007).

4.1.6.3 Intrapartum care: perineal repair, suture methods and material

In the unit where data were collected, clear criteria for the management of perineal repair including the methods and material to be used, reflects that detailed in national guidance (National Collaborating Centre for Women's and Children's Health, 2007). A summary of the guidance which is aimed at achieving haemostasis, promoting healing by primary intention and minimising infection and wound dehiscence is provided below.

Suturing of perineal trauma

Currently and at the time of the audit the maternity unit where the data were collected has a policy to suture all second, third and fourth degree tears and episiotomies. The policy details that first degree tears may be left un-sutured at the midwife or doctor's discretion, but that informed consent must always be sought and documented in the woman's medical records.

Suture methods

Perineal repair should be undertaken using a continuous non-locked suturing technique for the vaginal wall, perineal muscle and skin (National Collaborating Centre for Women's and Children's Health, 2007).

Suture material

An absorbable synthetic suture material should be used to suture the perineum (National Collaborating Centre for Women's and Children's Health, 2007).

Repair of obstetric anal sphincter injuries (OASIS)

National guidelines, adhered to in the unit where data were collected for the repair of OASIS, also provide clear recommendations for the methods and materials used for OASIS including the location of repair and the administration of antibiotic prophylaxis (Royal College of Obstetricians and Gynaecologists, 2007).

4.1.7 Methodology

4.1.7.1 Inclusion criteria for the case group

In the unit where data were collected, women were identified for inclusion in the audit from hard copies of the perineal care clinic listings from February 2004 to February 2010 where the reason detailed for review was perineal wound dehiscence. Retrospective case notes were identified from all women (just over one hundred) who had been referred to the perineal care clinic from 2004 to 2010 with perineal wound dehiscence following primary repair of spontaneous perineal trauma and episiotomies. Referrals to the perineal care clinic had also been received from other NHS organisations. It was not clear from the hard copies of the clinic listings what maternity unit the woman had delivered in until documentation of the clinical review was obtained. Data from one hundred women were collected and included in the final analysis.

4.1.7.2 Exclusion criteria for the case group

Women who had been referred to the perineal care clinic from additional maternity centres were not included in the audit as the data was not available to the study team to support the audit.

It was outside the remit of this study to conduct an extensive audit of the management of OASIS. Data relating to OASIS are analysed as part of cyclical

criterion audit at the unit where the data were collected and are available to all clinicians within the organisation.

4.1.7.3 Control group

A comparison group of 100 (1:1 ratio) women who did not have a perineal wound dehiscence following primary perineal repair of spontaneous trauma and episiotomy were also identified for audit.

4.1.7.4 Inclusion criteria for control group

Women included in the control group were identified from the intrapartum birth registers. All archived birth registers were requested from the records manager at the unit where data were collected. The following sampling technique was used to select the woman for inclusion into the control group:

- Women with perineal wound dehiscence, included in the audit, were identified in the birth register
- The next woman with a documented perineal repair, following spontaneous trauma or an episiotomy, entered immediately below in the register was included in the control group
- Case notes from women included in the control group were cross-checked either manually or electronically to ensure that they had not been previously referred to the perineal care clinic with a wound dehiscence.

See table 2 for a fictitious example of the sampling technique

Table 2: An example of the sampling technique conducted by the audit lead to establish the control group obtained from the birth registers 2004-2010

Name	Mode of delivery	Birth weight	Perineum	Audit
Francis Little	Spontaneous vertex	3600	2nd degree tear sutured	Already included as case
Amanda Green	Spontaneous vertex	2780	Intact	Not applicable
Nadia Hussain	Caesarean section	4100	Intact	Not applicable
Chloe Needham	KIWI	3500	Episiotomy sutured	Identified for control

4.1.7.5 Exclusion criteria for control group

Women were excluded from the control group if there was documented evidence of referral to the perineal care clinic with a wound dehiscence. Women were also excluded from the control group if the perineal trauma was documented as first degree (table 1, chapter 1 provides classification of perineal trauma).

4.1.7.6 Design of the data collection form

The overall design of the data collection form included information from the following sources:

- National and local guidelines
- Evidence from previous audits referred to in section 4.1
- Knowledge and expertise from members of the audit team.

The initial draft was developed by the author of this thesis and revised several times in collaboration with the audit team. Obstetricians were also consulted on the data collection set to ensure that the information collected would fulfil the aims and objectives of conducting the audit and produce meaningful results in the clinical setting.

Questions asked were provided in a logical sequence and free text comments were kept to a minimum. Where appropriate, the inclusion of free text annotations can help to ensure that the question is answered, particularly if the response is not detailed in the list of variables (Dixon and Pearce, 2010).

The data collection form (appendix 3) was piloted by the author of this thesis (the primary data collector) using 5 sets of notes and small amendments made in collaboration with members of the audit team. This is considered good practice to ensure that any issues are identified and corrected prior to commencing the full scale audit (National Institute for Clinical Excellence, 2002).

Consideration was also given to collecting data that would facilitate electronic input using the Statistical Package for the Social Sciences (SPSS); a typical example was the length of the second stage of labour. The draft data collection form asked for length of labour in hours and minutes, this was then amended to length of labour in minutes. The project team also re-grouped some of the data to reflect current national guidance prior to full analysis of the data. Body Mass Index (BMI) was re-grouped in accordance with NICE guidance (National Institute for Health and Care Excellence, 2010); perineal repair techniques was re-grouped into recommended and non-recommended methods (National Collaborating Centre for Women's and Children's Health, 2007) and haemoglobin (Hb) was re-grouped in accordance with the World Health Organisation (WHO) definition of anaemia in pregnancy as a haemoglobin concentration of <110 g/L (World Health Organisation, 2001).

4.1.7.7 Caveats: Issues identified during piloting of the data collection form

A pilot of the data collection form revealed the following:

- Documentation in the second stage of labour did not clearly differentiate between the passive and active second stages of labour. Therefore for the purpose of this audit the total length of the second stage of labour documented was recorded.
- Documentation of perineal repair by both midwives and obstetricians was also not consistent throughout records. For the purpose of this audit, data were recorded verbatim. Data were entered into SPSS as follows: method of repair to vaginal mucosa, perineal muscle and skin and coded according to methods documented. This was then re-grouped into recommended and non-recommended methods as referred to above.
- In relation to antepartum characteristics, audit data for cases and controls, reflected percentages of women who had experienced their first delivery and subsequent vaginal deliveries. For example, if a woman had delivered her first baby by caesarean section and her second baby by vaginal delivery, thereby achieving a vaginal delivery after caesarean section (VBAC) then she would be included in the figures relating to first vaginal delivery.[1]

4.1.7.8 Requesting notes for data collection

Notes for audit were requested in accordance with clinical records guidance and tracked electronically when received, detailing the requesters name and location.

Notes were tracked back out once completed, again detailing the name of the person returning the notes and destination location.

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[1]NICE (2007) do not differentiate between women having their first vaginal delivery and women experiencing a trial of VBAC in their second stage guidance.

4.1.7.9 Data collection

Following a discussion between the author of this thesis and the Obstetrics Directorate Clinical Auditor at the unit where data were collected, a decision was made not to collect the data electronically or use the scanning facilities available. This was mainly due to time and the fact that the study was an educational project for the audit lead. The author of this thesis was responsible for collecting the majority of the data for audit, and entering all the data into SPSS (version 21), with the support from members of the audit team. Research colleagues assisted with data collection, when time allowed. The data for audit (appendix 3) were obtained from a combination of the following sources:

- The woman's individual maternity notes
- Birth note booklets
- Birth registers
- Electronic sources of clinical data.

Validation

A random sample of notes (10 from each group) was obtained. Two independent reviewers verified information recorded on the data collection forms for accuracy in accordance with clinical audit departmental guidelines at the unit where data were collected. The data collection forms were then verified with SPSS to ensure accuracy of electronic data. The random number sample was obtained using the facilities of SPSS. Where responses to variables were missing hospital records both hard and scanned copies and electronic information systems were checked in attempts to ensure data were as complete as possible in both groups. Two data collection forms were amended, one had miscalculated the BMI and one had not recorded the most recent haemoglobin, both amended values however remained in the same grouping variable.

4.1.7.10 Data analysis and statistical tests used

Statistical analysis was conducted using SPSS software version 21. The author of this thesis analysed the data under the supervision of Professor Thomas and Dr Sheppard and in collaboration with the audit team.

Data were analysed using a range of statistical tests such as simple descriptive tests including percentages, the mean and standard deviation for categorical data and the median and inter-quartile range for continuous data. The Chi-squared test, the Fishers Exact, the t-test and the Mann-Whitney U test were used to compare the cases with the controls to determine which factors were associated with wound dehiscence. The Chi-squared test was used to analyse categorical variables where the expected frequencies were greater than five. However where the expected frequencies were highlighted as being too low, for instance less than five, the Fishers Exact test was used. Fishers Exact test is a way of computing the exact probability of the difference between proportions when the sample sizes are small (Field, 2013). The *t*-test, a parametric test for continuous data assumes a normal distribution and was used to analyse continuous variables. Where the variables looked skewed the Mann-Whitney U test, a non-parametric equivalent of the *t*-test for continuous data, was used (Field, 2013).

In addition to comparing the two groups, one variable at a time (bivariate analysis), logistic regression analysis in SPSS was also used. The purpose of logistic regression is to "determine the impact of multiple independent variables presented simultaneously to predict membership of one or other of the two dependent variable categories" (Burns and Burns, 2008, p. 569). In the context of the audit presented in this chapter the multiple independent variables are presented in tables 3 and 4 and the dependent category is the perineal wound, a dichotomous outcome of wound dehiscence or no wound dehiscence.

The process commenced by adding all variables to the model, preliminary analyses identified that there were no variables with large numbers of missing cases. The next stage involved finding a parsimonious model defined as: “One that explains the most variance in the dependent variable containing the fewest number of independent variables” (Miles and Shevlin, 2001, p. 38). The parsimonious model decided upon for this analysis involved the inclusion of variables that revealed statistical significance ($P \leq 0.05$). As Field (2013) suggests, those variables not making a statistically significant contribution towards predicting the outcome variable were then removed from the equation. Variables with a P value of > 0.05 were not included in the model. The final parsimonious model included variables that were statistically significant in the logistic regression ($P \leq 0.05$).

Antepartum characteristics were entered as block 1 and intrapartum characteristics as block 2. Blocks 1 and 2 were then entered into the model together. Further regression analysis was then conducted using a parsimonious model whereby only the significant variables with a P value of ≤ 0.05 were entered into the model.

The Hosmer and Lemeshow’s goodness of fit statistical test was used to test whether the model fits the data. The purpose of any overall goodness-of-fit test is to determine whether the fitted model adequately describes the observed outcome experience in the data (Hosmer and Lemeshow, 2000). A model fits if the differences between the observed and fitted values are small and if there is no systematic contribution of the differences to the error structure of the model (Archer and Lemeshow, 2006). A significance measure of more than $P = 0.05$ indicates that the model used fits the data (Burns and Burns, 2008). Nagelkerke’s R square (R^2) value reported on in SPSS is also an assessment of how good the model fits the data and has been defined as “the proportion of variance 'explained' by the regression model, which makes it useful as a measure of success of predicting the

dependent variable from the independent variables" (Nagelkerke, 1991, p. 691). As with the Hosmer and Lemeshow's statistic, higher values suggest a better fit (Ho, 2013). The values for both the Hosmer and Lemeshow's and Nagelkerke's R square are presented in the following section.

4.1.8 Results

All 200 case notes identified for the audit were reviewed. All dehisced perineal wounds were allowed to heal by secondary intention (expectancy). Bivariate analysis revealed that cases and control groups were similar in most ante-partum characteristics. The main difference between the two groups were the percentages of women who had not experienced a previous vaginal delivery, 81% in the cases and 56% in the control group $P = <0.001$ and women who had experienced a previous wound dehiscence 23.1% in the cases and none in the control $P = 0.022$ (table 3).

Table 3: Bivariate analysis conducted in SPSS by the audit lead to compare the antepartum characteristics of both the cases (n=100) and control group (n=100) included in the audit 2004-2010

Antepartum characteristics	Non-dehisced n (%)	Dehisced n (%)	P value
Age (years)			0.630[CT]
15-19	10 (10.0%)	9 (9.0%)	
20-24	21 (21.0%)	22 (22.0%)	
25-29	26 (26.0%)	35 (35.0%)	
30-34	27 (27.0%)	20 (20.0%)	
35 and over	16 (16.0%)	14 (14.0%)	
Ethnicity			0.308[C]
White	83 (83.0%)	89 (89.0%)	
Non-white	17 (17.0%)	11 (11.0%)	
Body Mass Index (BMI) (KG M^2)			0.802[C]
BMI <30 (%)	75 (78.1%)	79 (80.6%)	
BMI >30 (%)	21 (21.9%)	19 (19.4%)	
Recent Haemaglobin (Hb)(gL)			0.921[C]
>110 (%)	66 (66.7%)	66 (66.0%)	
<110 (%)	33 (33.3%)	34 (34.0%)	
Medical conditions	19 (19.0%)	20 (20.0%)	
Smoking			0.298[C]
No	80 (80.0%)	72 (72.7%)	
Yes	20 (20.0%)	27 (27.3%)	
Previous perineal trauma (only those with previous vaginal delivery included) n=62			0.187[F]
No previous trauma	3 (7.0%)	4 (21.1%)	
Previous trauma	40 (93.0%)	15 (78.9%)	
First vaginal delivery			<0.001[C]
Yes	56 (56.0%)	81 (81.0%)	
No	44 (44.0%)	19 (19.0%)	
Previous dehisced wound			0.022[F]
Yes	0 (0.0%)	3 (23.1%)	
No	0 (0.0%)	97 (67.9%)	

n = notes out of 100 where variable included (except previous perineal trauma)
BMI greater than or equal to 30 kg/m² = obesity (NICE, 2010)
Hb < 110 gL = anaemia (WHO, 2001)
C = Chi squared test **CT =** Chi squared test for trend **F =** Fishers exact test
Medical conditions: Diabetes (Gestational diet n=2 in cases and n=1 in control and gestational insulin n=1 in cases), asthma, epilepsy, underactive thyroid, schizophrenia, crohn's disease, factor 5 Leiden, raised blood pressure, von Willebrand, Group B streptococcus (HVS or MSU), hepatitis B positive, irregular heart beat

Table 4 demonstrates that bivariate analysis of intrapartum characteristics for both the cases and controls were also similar.

Table 4: Bivariate analysis of the intrapartum characteristics conducted in SPSS by the audit lead to compare both the cases (n=100) and control group (n=100) included in the audit 2004-2010

Intrapartum characteristics	Non-dehisced	Dehisced	P value
Duration of 2nd stage (minutes) median (IQR)	49 (119)	102 (128)	0.001[M]
Ruptured membranes >24 hours n (%)	11 (11.0%)	14 (14.0%)	0.649[C]
Estimated Blood Loss			0.839[C]
> 500mLs (%)	13 (13.0%)	15 (15.0%)	
Onset of labour n (%)			0.243[C]
Spontaneous	67 (67.0%)	58 (58.0%)	
Induction of labour	33 (33.0%)	42 (42.0%)	
Analgesia used in labour n (%)			
Entonox	87 (87.9%)	81 (81.8%)	0.322[C]
Epidural	26 (26.3%)	34 (34.3%)	0.279[C]
Mode of vaginal delivery n (%)			0.002[C]
Normal	71 (71.0%)	49 (49.0%)	
Other	29 (29.0%)	51 (51.0%)	
Birth weight ≥ 4Kg n (%)	10 (10.0%)	21 (21.0%)	0.032[C]
Meconium presentation n (%)	18 (18.0%)	24 (24.0%)	0.365[C]
Perineal trauma n (%)			
2nd degree tear	60 (60.0%)	21 (21.0%)	<0.001[C]
Episiotomy*	34 (34.0%)	68 (68.0%)	<0.001[C]
OASIS (3rd or 4th degree tear)	6 (6.0%)	11 (11.0%)	0.310[C]
Delay in repair of trauma n (%)			0.138[C]
(more than 30 minutes)	37 (37.8%)	26 (26.8%)	
Clinician performing the perineal repair n (%)			0.001[C]
Midwife	54 (54.5%)	31 (31.0%)	
Doctor	45 (45.5%)	69 (69.0%)	
Method of perineal repair n (%)			
Vaginal mucosa			0.483[F]
Recommended	89 (96.7%)	80 (94.1%)	
Non-recommended	3 (3.3%)	5 (5.9%)	
Muscle layer			0.500[C]
Recommended	87 (93.5%)	78 (89.7%)	
Non-recommended	6 (6.5%)	9 (10.3%)	
Skin layer			0.002[C]
Recommended	89 (96.7%)	72 (80.9%)	
Non-recommended	3 (3.3%)	17 (19.1%)	
Materials used for repair of episiotomy or 2nd degree tear n (%)			0.343[F]
Vicryl Rapide®	81(96.4%)	94 (98.9%)	
Vicryl	3 (3.6%)	1 (1.1%)	
Antibiotics in labour n (%)	8 (8.0%)	3 (3.0%)	0.215[C]
Location of the perineal repair n (%)			0.363[C]
Delivery room	85 (85.9%)	80 (80.0%)	
Theatre	14 (14.1%)	20 (20.0%)	

n = notes out of 100 where variable included
C = chi squared test **F** = Fishers exact test **M =** Mann- Whitney U test
*****An OASIS with an episiotomy not included as OASIS analysed separately (OASIS with an episiotomy n=5 in cases and n=4 in control)

Intrapartum variables that were found significantly different by group were: the total duration of the second stage of labour (minutes), which in the cases was more than double that of the control group (*P* = 0.001); episiotomy, with 50% more women in the cases receiving an episiotomy than in the control (overall *P* = <0.001), second degree tear 60% in the control, group and 21% in the cases (*P* = <0.001) and mode of delivery which revealed that nearly 25% more women in the cases receiving an operative vaginal delivery than compared to the control group (*P* = 0.002). Birth weights of 4 kg and over were also statistically significant with just over 50% more women in the cases delivering a baby of 4 kg and over (*P* = 0.032) and the clinician performing the initial perineal repair was highly significant in bivariate analysis (*P* = 0.001).

Repairing the skin layer of the episiotomy or spontaneous trauma using either interrupted sutures or mattress sutures which are non-recommended methods of repair (National Collaborating Centre for Women's and Children's Health, 2007) demonstrated a highly significant difference between the two groups (*P* = 0.002), 17 women in the cases were sutured by non-recommended methods compared to only 3 in the control.

Certain characteristics that appeared significant in bivariate analysis were not however significant when other characteristics were controlled for in the logistic regression model (table 5). All variables for both groups in the bivariate analysis tables 3 and 4 were entered into the regression model.

The Hosmer and Lemeshow's *(H-L)* goodness of fit statistical test for the audit persistently had *p*-values of greater than 0.05 which indicated that the model used had predicted values that were not significantly different from what were observed and therefore the chosen model fitted the data at acceptable levels (Burns and

Burns, 2008). Whilst, Nagelkerke R^2 reported in the audit data analysis was 0.180 for block 1 and 0.317 for block 2. Based on an example provided by Verma (2012) this explains 18% and 32% variability of dependent variable by the independent variable respectively, also suggesting that the model used did contribute towards the prediction of risk factors for perineal wound dehiscence.

Table 5 reveals that the most highly significant variable for wound dehiscence was an episiotomy, (odds ratio (OR) 4.34, 95% Confidence Interval (CI) 2.37, 7.94) *P* value <0.001.

Table 5: Logistic regression analysis conducted in SPSS using a parsimonious model including the significant variables (p = ≤ 0.05) only, from audit data of women referred to the perineal care clinic 2004-2010 with dehisced perineal wounds compared to women with no wound dehiscence

Logistic regression analysis		
Variable	**OR (CI)**	**P value**
Ref 2nd degree tear		<0.001
Episiotomy	OR 4.34, 95% CI (2.37, 7.94)	
Nagelkerke R^2 = 0.180 for block 1 and 0.317 for block 2		

Additional descriptive analysis of the women with perineal wound dehiscence revealed that the majority of wounds (almost 70%) dehisced within the first postnatal week (table 6).

Table 6: Postnatal day of wound dehiscence, documented in 85 obstetric records out of the 100 women who were reviewed in the perineal care clinic 2004-2010

Postnatal day of wound dehiscence (information available n = 85)	**% (cumulative %)**
1 – 2	14.1% (14.1%)
3 – 7	55.3% (69.4%)
8 – 14	28.2% (97.5%)
15 days and over (up to 21 days)	2.4% (100%)

Microbiology results were only available in 45 out of the 100 women who were included in the audit and are presented in table 7. A review of the written documentation in the medical and the women's hand held notes in addition to electronic reports, suggested that swabs were not taken in all cases. It is feasible that a number of wound swabs were taken by the women's GP, the results of which were not electronically accessible to the audit team.

Table 7: Microbiology results from dehisced perineal wound swabs documented in 45 obstetric records out of the 100 women who were reviewed in the perineal care clinic 2004-2010

Microbiology result	%
Mixed bacterial growth	35.6%
Streptococcus A/B/C/F/G or microaerophilic streptococcus with other organisms but not Staphylococcus aureus	22.2%
Staphylococcus aureus only	17.8%
No growth or skin flora	8.9%
Gram Negative Bacillus (pure growth only)	6.7%
Staphylococcus aureus with any other organism (aerobic/anaerobic)	4.4%
Anaerobes (mixed or pure growth) only	2.2%
Any species other than S. aureus/Gram Negative Bacillus, in pure growth only	2.2%

All dehisced wounds in the audit healed by secondary intention (expectancy). Wound healing data documented in the number of weeks postnatal were available in 97% of the notes reviewed and the results are presented in table 8. Whilst data revealed that 65% of dehisced perineal wounds had healed at 6-8 weeks postnatal, a further 35% took between 9 and 24 weeks to achieve complete healing.

Table 8: Dehisced perineal wound healing times, assessed in weeks postnatal and documented in 95 obstetric records out of the 100 women who were reviewed at the perineal care clinic 2004-2010

Wound healed (weeks postnatal) Information available n = 97	% (cumulative %)
4 – 5 weeks	16.5% (16.5%)
6 – 8 weeks	48.5% (65.0%)
9 – 12 weeks	23.7% (88.7%)
13 - 16 weeks	9.3% (98.0%)
17 weeks and over (up to 24 weeks)	2.0% (100%)

Information relating to discharge from the perineal care clinic in the number of weeks postnatal was also available for 97 out of the 100 written case notes and electronic records reviewed (table 9). Less than 45% of women were discharged by 6-8 weeks postnatal, with the remaining women being discharged between 9 and 17 weeks postnatal, even longer in some circumstances due to morbidity associated with perineal wound healing.

Table 9: Discharge times assessed in weeks postnatal and documented in 97 obstetric records out of the 100 women who were reviewed at the perineal care clinic with dehisced perineal wounds 2004-2010

Discharge from the perineal care clinic (weeks postnatal) Information available n = 97	% (cumulative %)
4 – 5 weeks	8.2% (8.2%)
6 – 8 weeks	36.1% (44.3%)
9 – 12 weeks	26.8% (71.1%)
13 - 16 weeks	14.5% (85.6%)
17 weeks and over (up to 48 weeks)	14.4% (100%)

The main reasons documented for continual appointments at the perineal care clinic following wound healing were over granulation tissue n=25, v-shaped defects at the introitus n = 20 and scar tissue (wide and tight bands of scar tissue several divided under local anaesthetic) n = 8. Additional reasons included: fissure in ano, anterior vaginal wall prolapse, weak pelvic floor muscles and superficial dyspareunia.

4.1.9 Discussion

The author of this thesis is not aware of other comparative, retrospective case control studies conducted to establish risk factors for perineal wound dehiscence in the UK. The principal aims of conducting this audit were to produce information to inform the delivery of best care and to determine the risk factors associated with perineal wound dehiscence. The most significant risk factor for perineal wound dehiscence identified by the logistic regression model was an episiotomy.

Whilst additional risk factors in bivariate analysis were not significant in the above model, the overall findings of this local audit support results reported in previous studies that suggested prolonged second stage of labour, operative vaginal delivery and oasis as risk factors for perineal wound dehiscence (Ajibade *et al*, 2013; Williams and Chames, 2006).

Although the profession of the clinician conducting the primary repair was significant in this audit, (obstetrician in 69% of the cases, compared to 45.5% in the controls), this is likely to be attributed to the fact that more women in the cases received an operative vaginal delivery. In the maternity unit where the audit was conducted, this mode of delivery is always performed by obstetricians and women often receive an episiotomy to facilitate the delivery of the baby to avoid complex perineal trauma. In addition all OASIS are repaired by obstetricians in theatre and almost 50% more women in the cases sustained an OASIS than in the control group.

Although the available data from retrospective studies and audit reveal individual risk factors for perineal wound dehiscence, clinicians need to be aware that multiple confounding factors may increase the woman's overall risk of this unfortunate complication of childbirth. Helping to reduce any one of those risk factors can play a crucial role towards reducing the short and long term morbidity for these women.

An important message for midwives and obstetricians from this audit is that in comparison to second degree perineal trauma, episiotomy has the potential to significantly increase the woman's risk for perineal wound dehiscence (OR 4.34, 95% CI 2.37, 7.94) *P* value <0.001. Clinicians must therefore ensure that clinical practice is informed by the best available evidence and that a rationale for performing an episiotomy is clearly documented in the woman's records.

Whilst there is robust evidence from a Cochrane review to recommend that episiotomy should not be a routine procedure (Carroli and Mignini, 2009), there does appear to be some conflict of opinions surrounding episiotomy for operative vaginal delivery. Carroli and Mignini (2009) acknowledge that further research needs to be conducted to establish the indications for the restrictive use of episiotomy at an operative vaginal delivery, or when the delivery of a macrosomic baby (over 4.5 kg) is anticipated (Carroli and Mignini, 2009).

NICE guidance suggests that there is an increased risk of OASIS with forceps delivery when compared to Ventouse delivery (National Collaborating Centre for Women's and Children's Health, 2007). In comparison RCOG guidance 'operative vaginal delivery' (Royal College of Obstetricians and Gynaecologists, 2011) refers to a prospective study of 1360 women conducted in the UK, which reveals that episiotomy does not offer protection against OASIS (294 women (21.6%) did not receive an episiotomy) (Macleod *et al*, 2008). They recognise the lack of robust evidence to support the routine use of episiotomy in operative vaginal delivery and support the operator's individual clinical judgement regarding the restrictive use of episiotomy (Royal College of Obstetricians and Gynaecologists, 2011). Similarly, they also advise that routine use of an episiotomy is not recommended in the event of a shoulder dystocia, frequently associated with a macrosomic baby and should only be performed if the clinician's whole hand cannot be inserted into the vagina to

facilitate internal manoeuvres (Royal College of Obstetricians and Gynaecologists, 2012b).

More recent data based on a cohort of 1,035,253 primiparous women who had a singleton, term, cephalic, vaginal delivery however revealed that rates of OASIS had tripled from 1.8 to 5.9% in a 12 year period (2000-2012) (Gurol-Urganci *et al*, 2013). They reported a higher risk of OASIS with operative vaginal delivery including forceps and Ventouse (particularly without an episiotomy), higher birth weight, and shoulder dystocia (Gurol-Urganci *et al*, 2013). Although the authors do offer a potential explanation for this, in that they acknowledge both the improvements in recognition of OASIS and the standardisation of the classification of perineal trauma.

Conducting this audit highlighted the need for on-going education and training for both midwives and obstetricians particularly in relation to documentation and the methods used for perineal repair. This will ensure the delivery of best care, help to prevent complications such as infection and perineal wound dehiscence and reduce the potential for complaints and litigation. The audit also demonstrated that a number of dehisced perineal wounds did have a positive microbiology result and that many women experience multiple out-patient appointments due to the length of time the wound takes to heal by secondary intention (tables 7, 8 and 9 respectively).

4.1.9.1 Record keeping and learning points from the audit

The National Health Service Litigation Authority (2013) stipulates that maternity care services must have approved documentation for the repair of perineal trauma. Methods and materials used remain part of the pre-specified data set that must be recorded as an absolute minimum (National Health Service Litigation Authority, 2013). In some notes audited during the time period this information was not

recorded or had not been recorded in full. Out of the 200 notes audited the materials used were documented in 89.5% of all notes; methods used for repair of the vaginal mucosa were documented in 89% of all notes, muscle layer 90% and the skin layer in 90% of all notes. Consideration also needs to be given to ensure that intrapartum documentation of the passive and active phase of the second stage of labour reflect local and national guidance, to ensure that interventions such as operative vaginal delivery and episiotomy are conducted in a timely manner.

4.1.9.2 Methods used for perineal repair and learning points from the audit

National guidance recommends that all layers involved in a second degree tear and episiotomy (vaginal mucosa, perineal muscle and skin) are sutured with a continual suture (National Collaborating Centre for Women's and Children's Health, 2007). Whilst locally, the methods used for the repair of the vaginal mucosa and the muscle layer were in accordance with national guidelines, nearly 25% of all women included in the audit had the skin layer sutured by non-recommended methods. Indeed, 17 women with a dehisced wound had the skin layer repaired by an interrupted or mattress technique. Repairing the perineum by non-recommended suturing methods may result in wound dehiscence, which is a potential consequence of too tight sutures which result in tissue hypoxia, more common with an interrupted or mattress technique when compared to a continual suture (Kettle *et al*, 2012).

Whilst the data presented in this audit is a reflection of clinical practice in one maternity unit, a recent UK survey of midwifery practice by Bick *et al* (2012) reported concerning figures of midwives who were not using evidence based guidance to support their clinical practice. Out of 338 midwives who met the inclusion criteria to complete the survey only 6% were using the continual suturing technique to repair all layers of perineal trauma (Bick et al, 2012). This survey

clearly demonstrates that there are substantial barriers towards implementing even the most robust clinical evidence in practice. The consequences of failing to completely adhere to national guidance were clearly evident in the PEARLS study referred to earlier in this thesis, with increases in infection rates and a protracted period of morbidity for the new mother (Ismail *et al*, 2013). The authors also concluded by acknowledging that even where improvements in compliance and clinical outcomes for women were made, regular education and training programmes are fundamental towards achieving sustainable quality in perineal management.

4.1.9.3 Perineal wound dehiscence and positive microbiology

Data from this audit have revealed that the majority of perineal wounds will dehisce in the first week following childbirth. Perineal wounds that dehisce during the first 24-48 hours are most likely to be as a consequence of poor suturing technique. However, wounds that subsequently dehisce may be associated with infection (personal communication Kettle, 2013). Unfortunately swab reports were only available in 45 out of the 100 dehisced wounds that were included in this audit; 55.5% had a positive microbiology result, mixed bacterial growth 35.6% and no growth or normal vaginal flora 8.9%. Results such as this will only add to the debate relating to the administration of antibiotics in the absence of a positive microbiology result.

Microbiological assessment alone though is not a reliable method for diagnosing wound infection and a full, holistic assessment of the patient is also required (Cooper, 2005). Moreover, it is argued that routine wound swabbing in the absence of evidence of clinical indicators infection is neither helpful nor cost-effective (Patten, 2010). Clinical signs of infection, including wound dehiscence or delayed

wound healing (compared with normal rates for site and condition) are however considered an indication to swab a wound (Cutting *et al*, 2005).

Cooper (2005) revealed that since the late nineteenth century it has been accepted that the principal pathogens associated with wound infections are Staphylococcus aureus, (also an example of normal body flora) Streptococcus species, anaerobes and Pseudomonas aeruginosa. Superficial flora, with the exception of Staphylococcus aureus do not necessarily represent the flora deep inside a wound and cultures should be interpreted with care (Public Health England, 2014). Streptococcus species, Staphylococcus aureus, Gram Negative Bacillus, Anaerobes and mixed bacterial growth, were the documented pathogens from dehisced wound swabs in the audit presented in this thesis (table 7). Similar pathogens have also been reported previously, where infection and or wound dehiscence have been the subject of clinical audit (Ajibade *et al*, 2013; Arianpour *et al*, 2009; Centre for Maternal and Child Enquiries, 2011; Fox, 2011b).

The 2006-2008 confidential enquiry into maternal deaths in the UK revealed sepsis as the leading cause of maternal mortality and included the death of a woman following infected perineal trauma (Centre for Maternal and Child Enquiries, 2011). Perhaps now is the time to give careful consideration towards the administration of antibiotics to women who have multiple risk factors for perineal wound dehiscence.

The administration of prophylactic antibiotics following the repair of OASIS (third and fourth degree tears), are recommended in national guidelines which are adhered to locally for the prevention of wound infection and dehiscence following complex trauma (Royal College of Obstetricians and Gynaecologists, 2007). A randomised controlled trial (Duggal *et al*, 2008) of prophylactic antibiotics compared to a placebo following OASIS (n = 147), revealed that women in the placebo group

experienced increased rates of purulent discharge (17.2%) and wound dehiscence (20.7%) compared to rates of 4.1% and 8.2% respectively in the women who received prophylactic antibiotics. Wound complications overall were increased in the placebo group (24.1%) compared with the administration of antibiotics (8.2%) (Duggal *et al*, 2008).

A randomised controlled trial to assess the efficacy of antibiotic prophylaxis in women with multiple risk factors for wound dehiscence must now be conducted as a matter of urgency. A collaborative research team have recently received a Health Technology Association award to fund the ANODE trial (Prophylactic a**n**tibiotics for the prevention of infection following **o**perative **de**livery. Women having an operative vaginal delivery will be randomised to receiving antibiotic prophylaxis or placebo (Ismail 2014, Personal communication). The primary outcome for ANODE is maternal sepsis in general and perineal wound dehiscence is secondary outcome measure.

4.1.9.4 Increased out-patient visits

The data in both this audit and the USA based study (Williams and Chames, 2006) also referred to in the literature review, chapter two of this thesis, revealed that cases reviewed had increased outpatient visits that were related to the wound dehiscence. Williams and Chames (2006) reported an average of 4.05 visits although this did include the routine postnatal visit (range, 1-13 visits). In addition some of the women in their audit also experienced wound debridement and secondary repair, whilst other dehisced wounds were allowed to heal by secondary intention. Actual figures relating to additional operative procedures were not provided although there were 17 reported cases of a perineal abscess (which potentially may have been incised and drained), one case of a perirectal abscess and one case of both a perineal and a perirectal abscess (Williams and Chames,

2006). In comparison, all women with dehisced perineal wounds experienced healing by expectancy (secondary intention) at the maternity unit where data were collected for the audit presented in this chapter. The reasons documented for additional appointments clearly demonstrate the sequale of on-going morbidity for new mothers, the incidences of which are likely to be increased when wounds heal by secondary intention. Five women were referred to physiotherapists, five women were referred to urogynaecology (one woman had a Fenton's procedure) and one woman was referred to the colorectal surgeons. Increased number of hospital outpatient appointments at a precious and often vulnerable time for a new mother and her family has the potential to increase the levels of anxiety and stress experienced.

The findings in relation to wound healing and time to discharge in the women where data were collected for the audit presented in this chapter, highlights the length of time wounds take to heal by secondary intention. However, the data provided is an estimate of wound healing compared to the more precise measurement that would be conducted within a clinical trial. More accurate assessment of wound healing and discharge times would necessitate weekly visits to the perineal care clinic which in the current climate is neither organisationally feasible, nor acceptable to the majority of new mothers caring for their babies.

Prior to completing this current audit, gaps in record keeping have been addressed as a result of on-going audit of a local guideline and considerable improvements have been achieved. Birth notes currently in use have also improved upon earlier versions and the use of specific tick boxes and free text annotation have assisted clinicians to record perineal repair more comprehensively. However there remains a need to consider updating pre-specified documentation criteria to ensure that records are as clear and as concise as possible. In future this will improve both data

reliability, further inform the development of standards against which future care is provided and measured and assist healthcare professionals to continually identify any areas for improvement.

The results of this recent audit have implications for both clinical practice and future research. The current findings will contribute to the level of evidence available both nationally and internationally relating to perineal wound dehiscence.

4.1.10 Limitations of the audit

Data for the audit were limited to women with dehisced wounds who were reviewed in the perineal care clinic, therefore information from women who were managed by the community midwife and GP were not included. As previously discussed in the literature review, it is difficult to determine definitive rates of wound dehiscence due to women accessing treatment via different health centres and GP surgeries. Unless electronic data systems between the acute and primary care sectors can improve upon this in the future, this will continually affect the level of information available to audit and potentially contribute to ascertainment bias.

The inconsistencies and even omissions in records from the notes reviewed as part of this audit could be considered an additional limitation of this audit study. Retrospective audits in particular rely upon the accuracy of the written documentation (Hess, 2004). Cross referencing written documentation with electronic patient records, particularly those that necessitated mandatory completion helped to rectify some of the omissions from several written records.

Despite the multi-disciplinary approach to this audit, the project team also acknowledge that service users were not involved in the planning and design stages. Every effort will be made to ensure that this is addressed in future audits including dissemination of the findings and implementing any changes as a result of audit.

4.1.11 Implications for clinical practice

Clinicians need to be aware of the increased risk of a wound dehiscence in women who have multiple risk factors for perineal wound dehiscence: first vaginal delivery, prolonged second stage of labour, episiotomy, operative vaginal delivery and birth weights of ≥ 4 kg, these are common findings from several audits to date.

Whilst operative vaginal delivery should not be an absolute indication for an episiotomy and according to current guidance should be based on the clinical discretion of the operator, this must also be balanced with the risk of an OASIS and the considerable morbidity associated with this complication of childbirth.

The methods and materials used for perineal repair must be based on the most current evidence available and the procedure clearly documented with explanations of any deviations from current local and national based guidance. This is not only a requisite for best practice it can assist future case reviews, audits and research and is crucial in the event of a medico-legal claim.

Completion of an adverse incident report for all women who present with a perineal wound dehiscence is recommend to ensure the timely follow-up of any practice issues and assist towards a more accurate assessment of the rates of this complication of childbirth.

4.1.12 Implications for future audits and research

4.1.12.1 Future audit

A key objective for conducting this audit was to collect baseline data to inform the development of standards against which future care is provided and measured. In light of this current and previous audit, clinicians and service users now need to consider developing a set of standards against which future care is provided and measured. Standards such as those suggested below, could be incorporated in to either a pre-existing audit or be developed as a stand-alone audit.

Dehisced perineal wounds, recommended standards to be considered for inclusion in audit:

- Percentage of records where the length of the second stage has been documented
- Percentage of records where the passive and active second stages of labour have been documented
- Percentage of records that document the reasons for performing an episiotomy
- Percentage of records that document the length of time from delivery of the placenta until repair of the perineal trauma
- Percentage of records where the materials used for the perineal repair have been completed in full
- Percentage of records where the methods used have been recorded correctly for the vaginal mucosa, the muscle layer and the skin; for example: continuous non-locking suture for the vaginal mucosa and muscle layer and continuous sub-cuticular suture for the skin
- Percentage of records where any deviations from recommended practice have been clearly documented including the reasons why

- Completion of an adverse incident reporting form for all women who are referred back to the hospital with perineal wound dehiscence and or problems associated perineal repair
- Percentage of records where a perineal wound swab has been obtained and recorded
- Percentage of women managed by re-suturing and percentage of women managed by expectancy
- Percentage of women with a clear rationale for management of the dehisced perineal wound.

4.1.12.2 Future research

Infection is the leading cause of maternal mortality in the UK and further research is needed as a matter of urgency to establish the efficacy of administrating prophylactic antibiotic therapy to women who experience multiple risk factors associated with perineal wound dehiscence presented in this audit and previous audits.

Future clinical trials need to consider how to monitor more precise measurements of the wound healing times in collaboration with all stakeholders. Full involvement of service users will be crucial in the planning phase to ensure successful completion of the study.

4.1.13 Dissemination of the results of the audit

The results of this audit will be disseminated by the author of this thesis in full collaboration with the audit team both locally and nationally using multi-faceted methods. Approaches to dissemination will include publications in professional journals, conference and or poster presentations, local seminar presentations including maternity services liaison committees, electronic sources, hospital directorate forums and newsletters.

The author of this thesis is currently preparing a paper for publication of the results of the audit, in collaboration with Professor Emerita C Kettle, Professor K Ismail, Professor P Thomas, Dr Z Sheppard and the Obstetrics and Gynaecology Directorate Auditor in unit where the data were collected.

CHAPTER FOUR: PART TWO
A REVIEW OF PRACTICE

A UK survey to establish the current management of dehisced perineal wounds

"Surveys need to be seen as an important partner with experiments in the pursuit of knowledge" (Thompson, 2003, p. 188).

4.2 Introduction

A review of the literature and personal experience would lead both researcher and clinician to the premise that the management of dehisced perineal wounds is not based on robust clinical evidence. Historically, as referred to in the previous chapters of this thesis, clinical practice varies widely between organisations and individual clinicians. Moreover, the referral and review process for these women is equally fragmented. Women often attend a variety of care settings including their general practitioner; maternity triage at their local hospital, accident units and perineal care clinics.

The decision to re-suture the dehisced wound or simply allowing it to heal by secondary intention is outside the midwives scope of practice and is largely made by obstetricians, with an assumption that personal opinion and experience forms a large part of this decision making process. As part of the background to this thesis the author, in collaboration with her research supervisors, conducted a descriptive, cross sectional survey of Clinical Directors in Obstetrics and Gynaecology who were registered with the Royal College of Obstetricians and Gynaecologists (RCOG).

4.2.1 Aim and objectives of the survey

Aim of the survey

The aim of the survey which was conducted as phase three of PREVIEW was to obtain baseline national data relating to the current management of dehisced perineal wounds from a representative cohort of Clinical Directors in Obstetrics and Gynaecology.

Objectives of the survey

The objectives of the survey were to:

- Determine the availability of local clinical practice guidelines
- Establish current management of dehisced perineal wounds
- Identify what methods and materials are used for the secondary repair of dehisced perineal wounds
- Determine antibiotic use with perineal wound dehiscence
- Identify if individual maternity units have designated perineal care clinics.

4.2.2 Methods

Surveys offer an effective way of collecting data which is useful when auditing clinical practice as well as obtaining new research data (Cluett and Bluff, 2006). For the purpose of this study, an electronic questionnaire survey (appendix 4) was designed to address the principle objectives using a 'survey monkey' and the software services of http://www.surveymonkey.com available without cost (conditions applied).

To the best of the author's knowledge this is the first survey conducted in the United Kingdom (UK) to determine the current management of dehisced perineal wounds.

Careful consideration of the design of the questionnaire from the outset enabled the author of this thesis as Thompson (2003) suggests, to improve the quality of the evidence obtained from the survey.

The standardised questionnaire consisted of 10 closed questions with additional space allocated in various sections for free text comments. Additional questions would have involved upgrading the package with financial implications. Closed ended questions are often a cause of frustration for respondents particularly where researchers have not considered all potential responses (Houtkoop-Steenstra, 2000). With this in mind the free text annotation incorporated into the design added richness to the pre-specified responses (Boynton and Greenhalgh, 2004) and would assist with the future design of any subsequent surveys. Attempts were made throughout the questionnaire to ensure that questions carefully reflected the phenomena being investigated. Moreover, a key concept in the design of a valid survey questionnaire is that the questions should be phrased in such a way that the respondents clearly understand the objective of the question (Ng, 2006). To ensure this, obstetricians in a maternity unit, local to the author of this thesis, were invited to comment on the survey and minor amendments were made to the design and layout of the questions.

An outline of the survey was added to the monthly RCOG bulletin administered to all Clinical Directors along with an invitation to participate and details of the survey link. Responses were collected from the 10th October 2012 until the 10th December 2012

4.2.3 Consideration of ethical approval

The survey was anonymous and voluntary, therefore ethical approval was not required as RCOG members demonstrated their consent by accessing the link to the survey website and completing the questionnaire.

4.2.4 Results of the survey

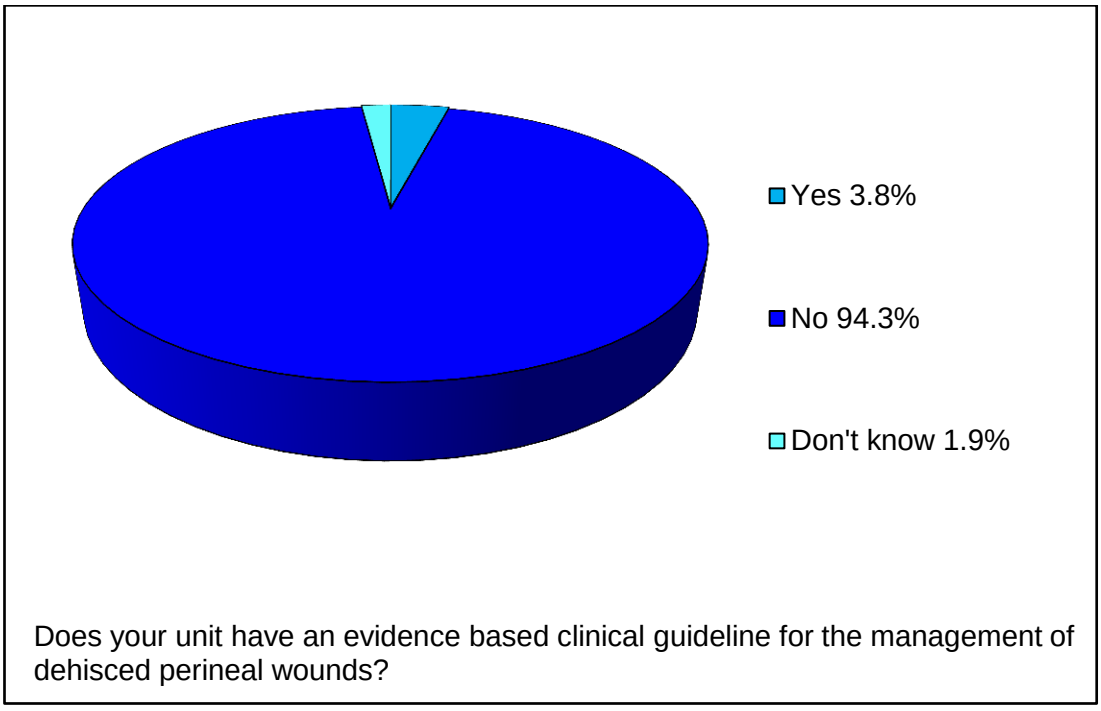
A total of 216 RCOG Clinical Directors were sent an internet link to the survey via the email addresses detailed in the RCOG database.

Of these, 53 (24.5%) Clinical Directors participated in the survey; the responses to each of the questions are provided below.

4.2.4.1 Question 1: Does your unit have an evidenced based clinical guideline for the management of dehisced perineal wounds?

All participants (n=53) completed the first question and not surprisingly figure 8 demonstrates that less than 4% of respondents were able to refer to a clinical practice guideline for the management of dehisced perineal wounds.

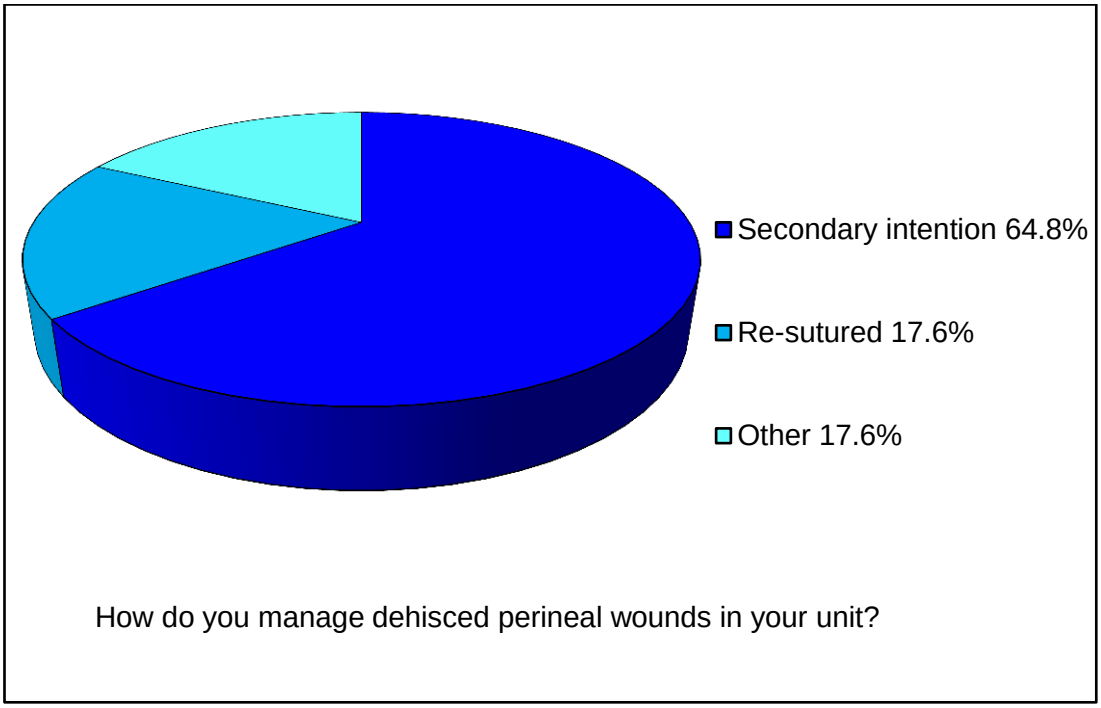
Figure 8: Does your unit have an evidenced based clinical guideline for the management of dehisced perineal wounds? (Respondents n = 53)



4.2.4.2 Question 2: How do you manage dehisced perineal wounds in your unit?

There were 51 respondents to this question (figure 9). Healing by secondary intention was the most common management n = 33 (64.8%) compared to re-suturing n = 9 (17.6%).

Figure 9: How do you manage dehisced perineal wounds in your unit? (Respondents n = 51)



Where respondents had detailed other n = 9 (17.6%), free text comments included the following responses:

"Decision dependent upon the extent of dehiscence and the presence of infection, occasionally re-sutured." (2 responses)

"Depends on how soon after primary repair the dehiscence happens and whether or not there are signs of infection."

"Dependent upon the individual doctor reviewing the patient and the clinical findings."

"Cases are individualised; if infected they are allowed to heal by secondary intention, if clean and early may re-suture."

"Mostly secondary intention, but if severe dehiscence and no infection, sometimes re-suture."

"Decision depends upon the degree of sepsis and HIV status of patient. May be left to heal by secondary intention."

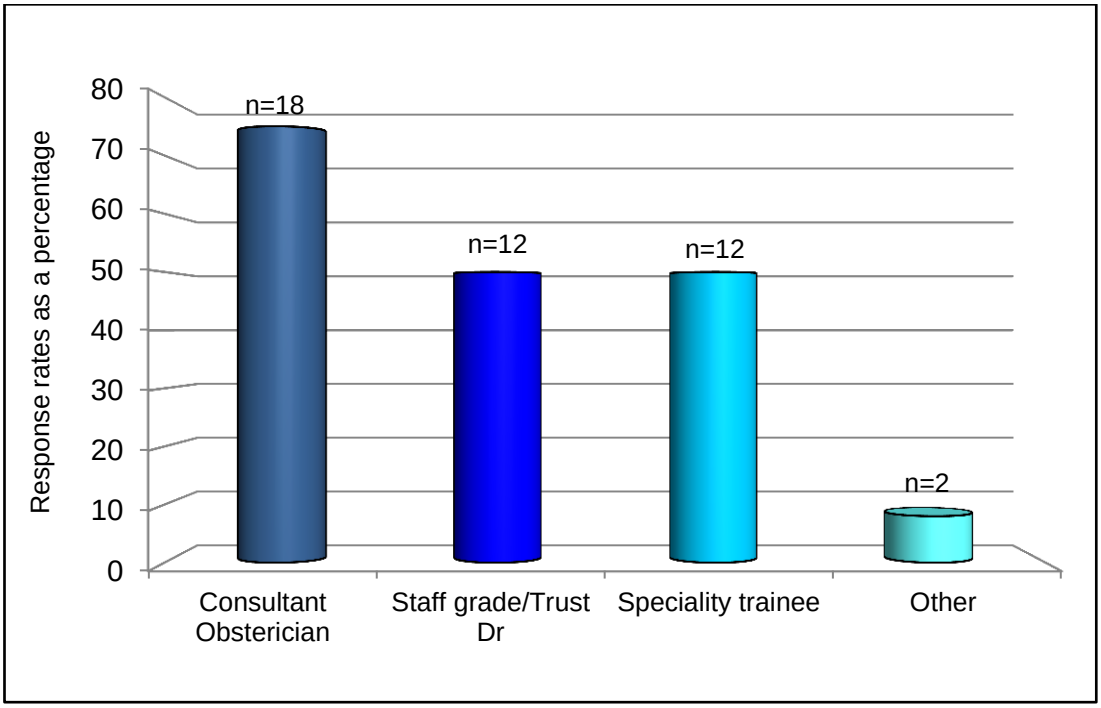
"Some wound dehiscence less than 48 hours following delivery are re-sutured, whilst some of them follow secondary intention after 48 hours; opinions are quite varied."

"Rarely re-sutured depends on how extensive the dehiscence is."

4.2.4.3 Question 3: If the dehisced perineal wound is re-sutured who performs the secondary repair?

Participants were asked to tick all applicable responses: Consultant Obstetrician n = 18 (75%), staff grade/Trust Dr n = 12 (50%) and specialist trainee n = 12 (50%) were the replies respectively from 24 respondents (figure 10). If wounds were left to heal by secondary intention, a filter question directed participants to question number 7.

Figure 10: If the dehisced perineal wound is re-sutured who performs the secondary repair? (Respondents n = 24 were asked to tick all that applied)



Additional free text responses to other (figure 10) n = 2 were:

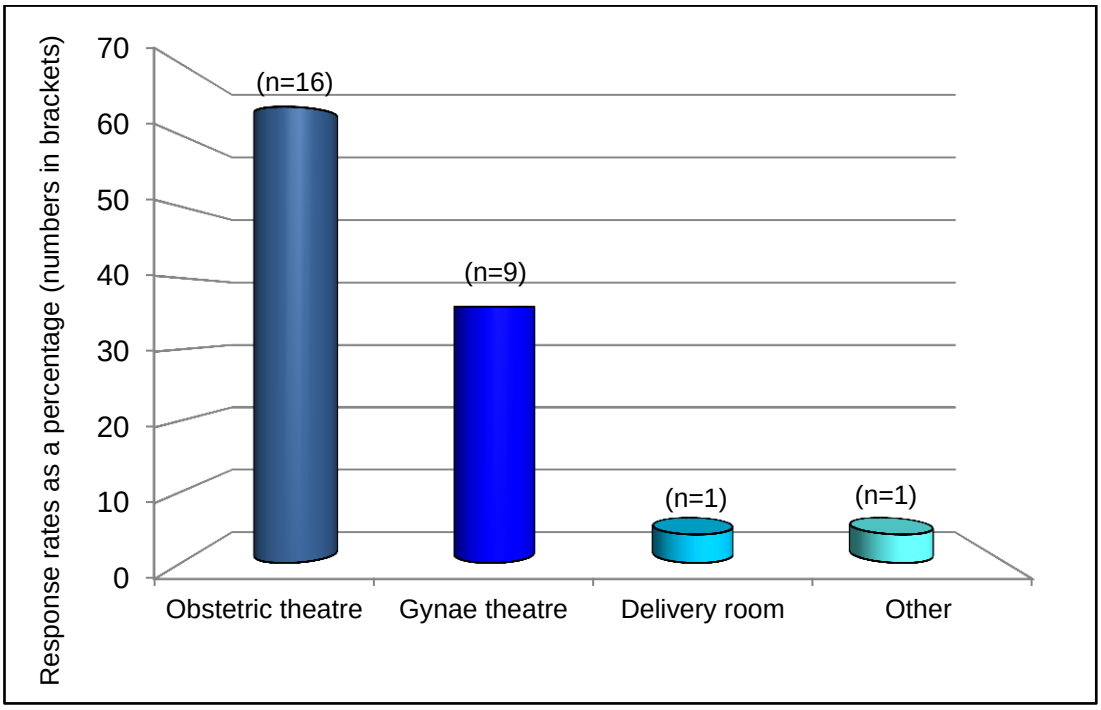
"Variable, grade depending on experience."

"Variable grade depending on experience specialist trainee ST3 or above or consultant."

4.2.4.4 Question 4: Where is the secondary repair performed in your unit?

There were 25 respondents to question 4, which asked participants to tick all applicable options. Most of the secondary repairs n =16 (64%) were re-sutured in an obstetric theatre; n = 9 (36 %) were sutured in a gynaecology theatre and n = 1 (4%) in the delivery room (figure 11).

Figure 11: Where is the secondary repair performed in your unit? Please mark all that apply (Respondents n = 25 were asked to tick all that applied)



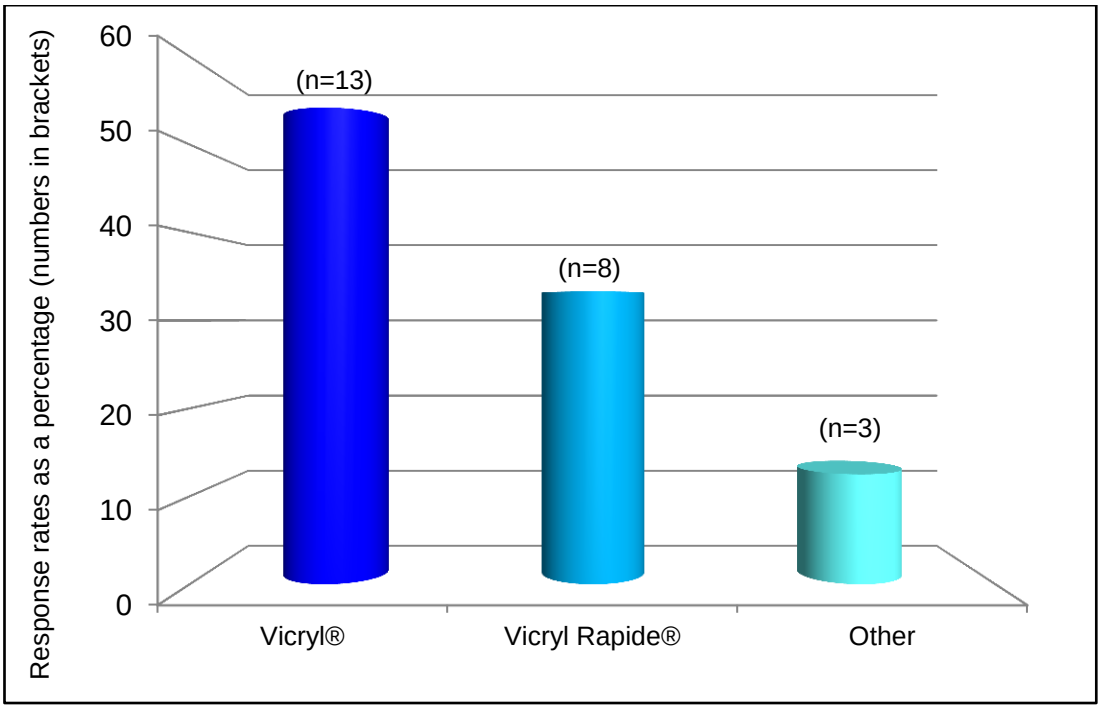
Additional free text responses to other (n =1) were:

"Usually repaired in obstetric theatre but may also be gynaecology theatre."

4.2.4.5 Question 5: What suture material is used for secondary repair in your unit?

Standard polyglycolic acid (Vicryl®) was the suture material of choice used by 13 (54.2%) of the 24 respondents, with rapidly absorbable polyglycolic acid (Vicryl Rapide®) used by 8 (33.3%) of the respondents with the remaining 3 (12.5% respondents detailing other (figure 12).

Figure 12: What suture material is used for secondary repair in your unit? (Respondents n=24)



Free text responses to other (n = 3) were:

"Varies - operator dependent, standard Vicryl for the muscle."

"PDS."™ (Polydioxone suture)

"Nylon, assuming there may be a time delay and a tendency to infection before or after discharge from hospital and time delay."

4.2.4.6 Question 6: What is your preferred method of repair (continuous or interrupted) in each of the following: vagina, muscle and skin?

There were 24 respondents to question number six (table 10).

Vagina: A continuous suture was the preferred method of repair to the vaginal mucosa for the majority of participants n =21 (87.5%) when compared to using interrupted sutures interrupted n =3 (12.5%).

Muscle: Responses relating to the preferred method of repair to the muscle layer were more divided. The continuous suture was the preferred method in just over one-third of participants n = 9 (37.5%), with the remaining participants indicating a preference for interrupted sutures n= 15 (62.5%). One respondent also added that whilst they had a preference for interrupted sutures, the hospital recommended a continuous suture technique.

Skin: Just over half of the participants responses to the preferred method of repair for the skin layer were interrupted n =13 (53.2%); compared with n =9 (37.5%) who favoured a subcuticular approach. At the discretion of clinician n =1 and early dehiscence Vicryl Rapide® and tied together, with careful follow-up n =1 were two additional responses.

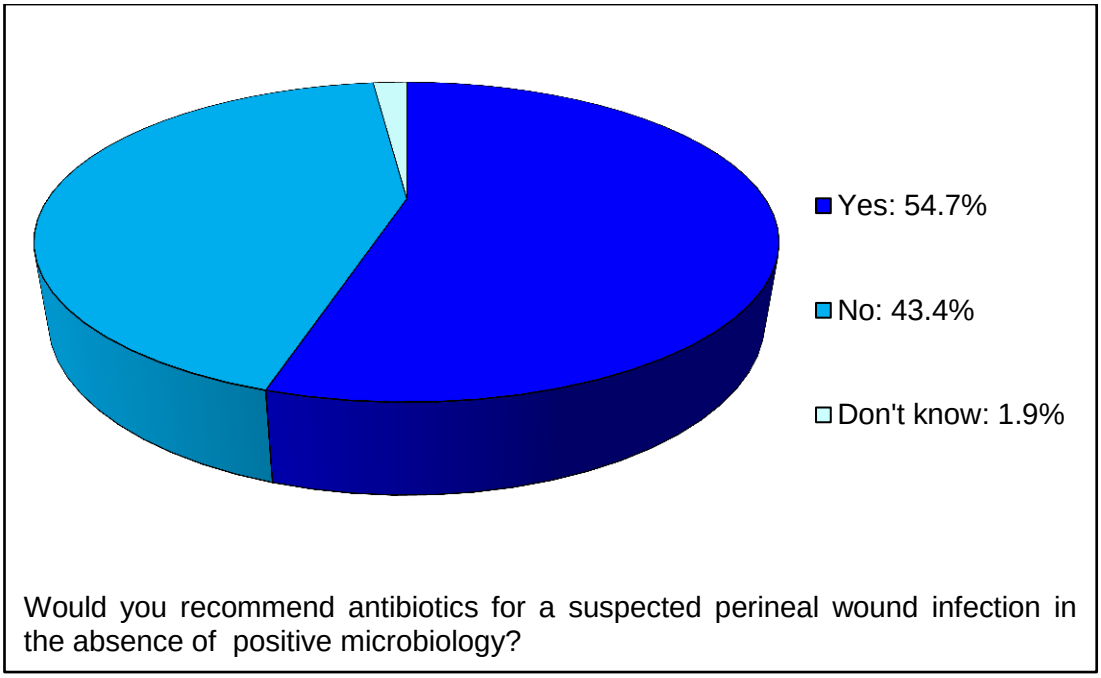
Table 10: What is your preferred method of perineal repair (continuous or interrupted) in each of the following: vaginal mucosa, muscle layer, perineal skin? (Respondents n=24)

Preferred method of repair	Respondents n (%)
Vaginal mucosa	
Continuous	21 (87.5%)
Interrupted	3 (12.5%)
Muscle layer	
Continuous	9 (37.5%)
Interrupted	15 (62.5%)
Perineal skin	
Interrupted	13 (54.2%)
Continuous subcuticular	9 (37.5%)
Other	2 (8.3%)

4.2.4.7 Question 7: In your unit would you recommend commencing antibiotics for a suspected wound infection in the absence of a wound swab confirmation?

All participants replied to this question and figure 13 demonstrates that just over half indicated that antibiotics would be commenced in the absence of microbiology results n = 29 (54.7%). The remaining participants n = 23 (43.4%) indicated that they would not recommend commencing antibiotics in the absence of a positive microbiology result. One participant responded “don’t know”.

Figure 13: In the absence of positive microbiology, from a perineal wound swab, would you recommend commencing antibiotics for a suspected infection? (Respondents n = 53)



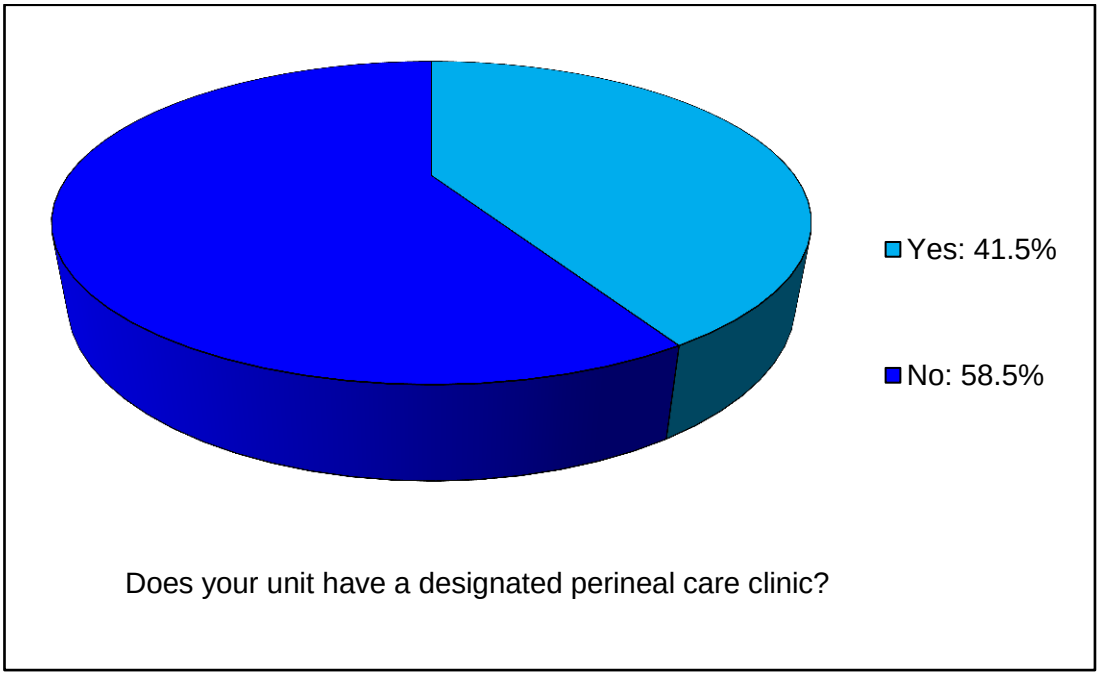
If participants answered yes to antibiotics they were asked to detail what antibiotics they would you prescribe, what dose and for how long? (Respondents n =21). The antibiotics prescribed for women with a dehisced perineal wound were Co-amoxiclav 625mgs or 375mgs administered for 5 or 7 days n = 9 (42.8%) and Cephalexin 250mg 8hrly together with Metronidazole 400mg 8hrly for 7 days n = 8 (38.1%). Other choices were Co-amoxiclav and Metronidazole for 5 days,

Amoxicillin and Metronidazole for 5 days, Erythromycin and Ampiclox 500 mg for 5 days n = 4 (19.1%).

4.2.4.8 Question 8: Does your unit have a designated perineal care clinic?

Out of the total participants responding to this question n=53, figure 14 reveals that less than half 41.5% (n = 22) had a designated perineal care clinic.

Figure 14: Does your unit have a designated perineal care clinic? (Responses n = 53)



If the participants answered yes to a designated perineal care clinic, they were asked to provide additional information relating to how often the clinic is held. Their responses are summarised below.

How often is the perineal care clinic held? (Responses n = 8/22). Where units had a designated perineal care clinic these were held weekly (n = 2) every two weeks (n = 3) and monthly (n = 3). Three respondents also commented that these clinics were

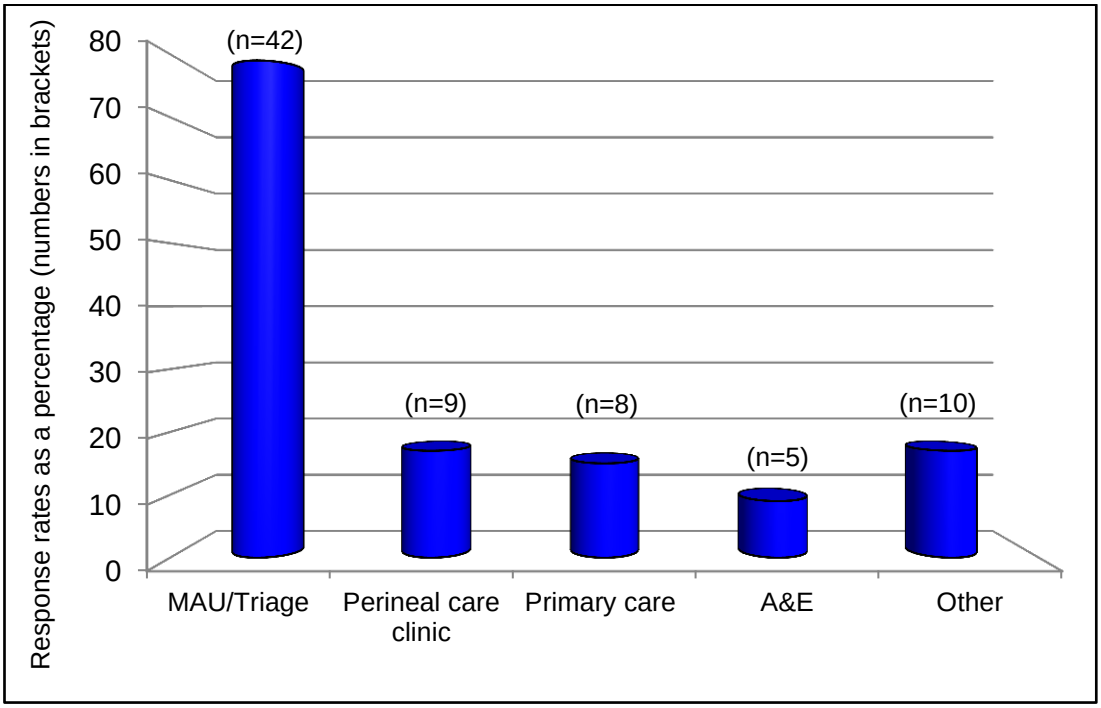
developed primarily to follow-up women who have sustained 3rd and 4th degree tears, commonly referred to as obstetric anal sphincter injuries (OASIS).

4.2.4.9 Question 9: Where are women referred to with perineal wound dehiscence?

Participants were asked to tick all applicable pre-specified responses. A free text option was also provided to allow for additional comments to other. All participants completed this question. The majority of women with dehisced perineal wounds were referred to a maternity assessment unit/maternity triage n = 42 (79.2%); additional referral sites were: perineal care clinics n =9 (17%), primary care n =8 (15.1%) and accident and emergency units n =5 (9.4%) respectively (figure 15).

Alternative referral sites revealed in the free text responses to other n = 10 (18.9%) included: gynaecology clinics n = 3, gynaecology emergency assessment unit n = 1, antenatal clinic n =1, private clinics n = 3, consultant clinic with urogynaecology interest n = 1, and 'we manage the referral process ourselves' n = 1.

Figure 15: Where are women referred to with perineal wound dehiscence? (Respondents n=53 were asked to tick all that applied)



4.2.4.10 Question 10: Is there any further information you would like to share with us relating to the management of dehisced perineal wounds?

The final question in the survey was designed to allow all participants to add additional information relating to the management of dehisced perineal wounds. Free text comments included:

"How to prevent its occurrence."

"In Africa HIV Aids causes a serious delay in the healing process and makes absorbable material less desirable."

"Do the primary repair carefully and this problem is rare."

4.2.5 Discussion

Whilst the number of those participating in the survey was somewhat disappointing, the actual response rate of 24.5% is slightly higher than the average response rate of 20% for RCOG facilitated surveys (Israfil-Bayli *et al*, 2014).

The results of the survey demonstrate the diversity of opinions for the management of dehisced perineal wounds. The findings also support the theory that women are managed in a variety of care settings throughout primary and secondary care (Thakar and Sultan, 2009) and whilst the referral process causes a dilemma for both clinicians and women alike, it also makes the collection of true epidemiological data equally inconsistent and unreliable. Adding to the dilemma is the apparent lack of clinical practice guidelines to support the collaborative decision-making between the woman and clinician on the best way to manage dehisced perineal wounds. This is largely due to the fact that there has been no vigorous randomised controlled trial comparing re-suturing versus healing by secondary intention. A recent Cochrane review (Dudley *et al*, 2013a) (chapter 3) concluded that there is currently insufficient evidence to assess the benefits and risks of secondary suturing for broken down

perineal wounds compared with non-suturing. The authors stressed that there is an urgent need for a robust randomised trial to fully evaluate the comparative effects of both treatment options. Retrospective studies have however, suggested that early secondary repair even in the presence of an infection is a safe, alternative option (American College of Obstetricians and Gynecologists, 2006; Arona *et al*, 1995; Hankins *et al*, 1990; Ramin *et al*, 1992; Uygur *et al*, 2004).

The results of this survey also demonstrate that when dehisced perineal wounds are re-sutured the choice of methods and materials are variable. In the absence of evidence to inform practice, it is likely that techniques and suture materials used are very much influenced by tacit knowledge based upon years of experience. Standard polyglycolic acid (for example Vicryl®) and rapidly absorbable polyglycolic acid (for example Vicryl Rapide®) were materials of choice detailed by the participants in this survey. The latter is currently the recommended suture material for the primary repair of second degree tears and episiotomies (Kettle *et al*, 2010; National Collaborating Centre for Women's and Children's Health, 2007). Rapidly absorbable polyglycolic acid has the same chemical composition of standard Vicryl but is absorbed in less time due to changes in the sterilisation process using gamma radiation (Kettle *et al*, 2010). A rational for using standard Vicryl® for the repair of dehisced perineal wounds would be that it has a longer absorption time. However, a Cochrane systematic review adds further caveats to consider; the authors reported that more women in the standard synthetic suture group required suture removal compared with those in the rapidly absorbed group (RR 0.24, 95% CI 0.15 to 0.36) (Kettle *et al*, 2010). An additional study by McElhinney *et al* (2000) included in the Cochrane review (Kettle *et al*, 2010) also reported that 30% of women sutured with standard Vicryl® n = 78 experienced wound problems such as wound dehiscence as compared to 1.7% in the group sutured with Vicryl Rapide® n = 75.

Sutures that remain in the tissues for prolonged periods act as a foreign body and may excite a significant inflammatory response that consequently lower the body's defence mechanism against infection. This increases the potential for impaired wound healing and dehiscence, (Greenberg and Clark, 2009) ultimately leading to inferior wound strength due to excessive scar tissue formation. Further studies are therefore needed to establish the efficacy of suture materials and methods used for the secondary repair of dehisced perineal wounds.

The majority of respondents in this survey indicated that the secondary repair is conducted in an operating theatre (obstetric or gynaecology theatre), by either a consultant obstetrician; staff grade/Trust doctor or a specialist trainee. This practice is recommended for the repair of complex trauma such as OASIS in the Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guideline, 'The Management of Third and Fourth Degree Perineal Tears' (Royal College of Obstetricians and Gynaecologists, 2007) and should be included in any future guideline for the management of dehisced perineal wounds. An operating theatre environment facilitates aseptic conditions, provides adequate lighting and the availability of appropriate instruments to conduct the repair. In addition, it also enables the woman to receive an appropriate method of anaesthesia, commonly a spinal or general anaesthetic prior to the secondary repair being performed. Ensuring the comfort of the woman throughout is paramount as some wounds will require debridement of infected, necrotic tissue and removal of suture from the primary repair that may impeded the healing process (Arona *et al*, 1995; Ramin and Gilstrap, 1994; Ramin *et al*, 1992; Uygur *et al*, 2004).

Whilst there appears to be some consistency in the location for the secondary repair of dehisced perineal wounds, this survey has confirmed the on-going diversity of opinions regarding the use of antibiotics. Undoubtedly, a positive bacteriology result

would lead to the administration of the appropriate antibiotics. Data from participants in this survey however, indicated that just over half would prescribe antibiotics in the absence of microbiology results. The discourse surrounding the administration of antibiotics similarly continues in the type of antibiotics used prior to sensitivity reports. Although Co-amoxiclav or Cephalexin with Metronidazole were the common antibiotics of choice with respondents in this survey; Amoxicillin and Erythromycin were also prescribed. It likely that standardising the type of antibiotic use would prove difficult as the incidence of resistant organisms varies throughout the UK. Indeed, Cefuroxime is no longer part of many hospital formularies because of the association with Clostridium difficile. Microbiology policy guidance should therefore be followed and therapy narrowed once the causative organism(s) has been identified (Royal College of Obstetricians and Gynaecologists, 2012a). Evidence from this survey supports the local audit findings discussed earlier in this chapter (section 4.1.9.3) that further studies are required to establish the efficacy of the administration of antibiotics in the management of perineal wound dehiscence and particularly towards preventing perineal wound infection in the first instance.

Participants in this survey were asked to provide information on where women with dehisced perineal wounds are referred to. Responses indicated that maternity triage at the local hospital was the most common referral pathway and supports national recommendations that signs and symptoms of infection, inadequate repair, wound dehiscence or non-healing should be evaluated and acted upon as a matter of urgency (National Institute for Health and Care Excellence, 2006). Avoiding delays in the provision of immediate care for these women is crucial and referral to maternity triage systems in many units is available twenty four hours a day, seven days a week. However following this initial referral, subsequent care tends to be fragmented, with limited availability of well-developed perineal care clinics. Less than half of the participants in the survey reported the provision of designated

perineal care clinics within their organisation. Furthermore, when perineal care clinics are developed, their purpose has usually facilitated the follow-up of women who have sustained more complex trauma such as OASIS and held either once or twice each month. It is evident from the data in the local case note audit presented in chapter four, (tables 8 and 9) that dehisced perineal wounds managed by secondary intention (expectancy) can take up to 17 weeks to heal. Perineal care clinics are therefore considered a valuable resource to provide the optimum environment for the continued provision of evidence-based quality care by experienced healthcare professionals (Thakar and Sultan, 2009). An example of a well-developed perineal care clinic is a model provided by the University Hospital of North Staffordshire which has been in operation for over a decade now. The clinic provides standardised continuity of care adopting a multi-disciplinary team approach which is crucial for optimal postnatal recovery and guiding decision making for subsequent deliveries. This particular model is attended by the specialist midwife, with direct access to a consultant obstetrician and gynaecologist obstetrician, a colorectal surgeon, a senior physiotherapist, a senior manometry technician and a urogynaecology specialist nurse. This multi-disciplinary approach is particularly valuable in the management of dehisced perineal wounds towards improving both short and long term outcomes for women.

Without doubt, the availability of multi-disciplinary perineal care clinics can benefit both women and clinicians alike. There are however various systems of care throughout the UK and their implementation in the current climate are largely dependent upon resources and the availability of specialist interest clinicians.

4.2.6 Limitations of this survey

The survey was completed by a small number of Obstetricians and Gynaecologists and the respondents may have been an elite group that had prior experience of managing dehisced perineal wounds. In comparison, non-responders may have had limited knowledge of the subject, therefore the cohort may not have been a totally representative sample. However, despite a degree of response bias, the information gained from conducting this survey has provided a knowledgeable insight into how dehisced wounds are currently managed.

4.2.7 Conclusion

The purpose of carrying out this survey was to explore the current management of dehisced perineal wounds with a representative cohort of clinicians and establish if practice was underpinned by evidence based guidelines. The results confirmed that there appears to be wide variation and lack of consistency relating to the current management of dehisced perineal wounds including whether to re-suture or not, the choice of suture methods and materials and the administration of antibiotics. Clinical practice is largely based on expert opinion with little robust evidence to inform clinical practice guidelines, creating inconsistent management and lack of standardised care. The apparent lack of designated perineal care clinics, accompanied with various referral pathways for women with dehisced perineal wounds also has the potential to contribute towards the fragmented care and information provided for these women.

4.2.8 Implications for practice and future research

It is vital that now gaps in evidence to inform the management of dehisced perineal wounds have been identified, that every attempt is made at both local and national levels to address those key areas that have previously been neglected. Full collaboration with all stakeholders including service users and the public will be fundamental towards the successful development and implementation of future clinical practice guidelines and the provision of designated perineal care clinics.

The findings of this survey can play a crucial part in the design of experimental research studies such as phase four (part one) of PREVIEW, the pilot and feasibility RCT presented in this thesis and also the planning of the subsequent definitive study.

The quantitative and qualitative research methods of phase four of PREVIEW will now be presented in chapter five.

CHAPTER FIVE:
RESEARCH METHODS
FOR PHASE FOUR OF THE PREVIEW STUDY

Mixed methods research: an interaction between the descriptive richness of the qualitative study and the experimental precision of the RCT that conveys accounts of social phenomena to progressively greater depths of clarity (Cupchik, 2001)

5.1 Introduction

Phase four of PREVIEW was conducted in two parts with the sequential use of both quantitative and qualitative research commonly referred to as a mixed methods design. The study design and research questions were largely influenced by the paucity of literature surrounding the management of dehisced perineal wounds and women's individual experiences of this complication of childbirth. Part one was a multi-centre pilot and feasibility randomised controlled trial (RCT) whilst part two involved semi-structured interviews using a phenomenological approach.

This current chapter will begin with stating the research questions and hypothesis for phase four of PREVIEW and provide a clear rationale for each paradigm and the use of a mixed methods research design. The methodology for quantitative and qualitative approaches will then be described in detail. This chapter also addresses how the study was planned, organised and implemented.

Consideration will be given to the theoretical framework and the differences in epistemological and ontological thoughts that illuminate the two distinct approaches as this can have a profound influence towards how research evidence is collected, analysed, interpreted and used (Alderson, 1998; Bowling, 2009; Craig *et al*, 2008).

Epistemology, a branch of philosophy that deals with knowledge underpins the whole of PREVIEW study and this chapter clearly demonstrates that the research process for PREVIEW encompassed the four different sources of knowledge commonly recognised by epistemologists: intuitive, authoritative, logical and empirical (Henrichsen *et al*, 1997).

5.2 Research question and the null hypothesis

The original inspiration for the study which led to the development of the research questions, study design and methodological approaches arose from intuitive reasoning, from the author of this thesis and several key members of the research team. Following an extensive search of the literature, the completion of a Cochrane systematic review and a survey of the management of perineal wound dehiscence presented in chapters two, three and four respectively, it was evident that there was a paucity of both authoritative and empirical knowledge surrounding the phenomena. Clinical and personal experiences involving family, friends and colleagues evoked a process of critical thinking and reflection with a desire to challenge the management of dehisced perineal wounds, which was historically based upon 'custom and tradition'.

5.2.1 Research questions

The main research questions addressed by phase four of PREVIEW are:

- What is the feasibility of conducting a definitive RCT comparing the effectiveness of re-suturing dehisced perineal wounds versus expectant management?
- What are women's experiences of a dehisced perineal wound?
- What are women's experiences of participating in the RCT?
- Will the treatment options be acceptable to women?

5.2.2 Null hypothesis

The pilot RCT has been designed to test the feasibility of examining the null hypothesis (H_0) that re-suturing of a dehisced perineal wound makes no difference in the time taken to heal, in comparison to allowing the wound to heal by secondary intention (expectancy). For statistical reasons this is the preferred hypothesis for experimental research which can then be rejected or accepted (Field, 2013).

5.2.3 Alternative hypothesis

The alternative hypothesis (H_1) would be that re-suturing of a dehisced perineal wound does make a difference to healing times in comparison to allowing the wound to heal by secondary intention.

The study will aim to investigate if there is a difference between the two groups. Data obtained will be used to conduct non-directional (two tailed) tests to establish if they are statistically significant. A 5% significance level or *P* value < 0.05 will be used to justify rejecting the null hypothesis.

5.3 Rationale for the chosen methods

5.3.1 Rationale for part one: a multi-centre pilot and feasibility RCT

Part one of PREVIEW consisted of a multi-centre pilot and feasibility RCT; women who presented with a dehisced perineal wound were randomised into either re-suturing or expectant management.

The research team proposed that empirical knowledge gained by using an experimental scientific approach for this phase of PREVIEW would provide preliminary evidence of the effectiveness of re-suturing compared to expectancy for the management of dehisced perineal wounds. The collective findings from the RCT

would then inform the design and feasibility of a larger definitive trial. This experimental scientific approach is considered appropriate for research such as the RCT which aims to test cause and effect relationships between independent and dependent variables and requires the three elements of a true experiment: randomisation, control and manipulation (Bowling, 2009; Parahoo, 2006; Polit and Beck, 2010). Achieving these key features will help to ensure that as far as possible the findings obtained by the researchers are achieved as a direct result of the effects of the intervention (Parahoo, 2006).

Positivism is the dominant philosophy underlying the quantitative scientific methods of the RCT presented in this thesis, viewed by some as being appropriate for deductive explanatory analysis (Cluett and Bluff, 2006; Bowling, 2009). This is categorised by the testing of an hypothesis developed from existing theory (hence deductive or theory testing) through measurement of observable social realities (Flowers, 2009) such as the primary and secondary outcome measures of the PREVIEW RCT.

The ontological position of the quantitative paradigm is that there is only one truth, an objective reality that exists independent of human perception (Sale *et al*, 2002). This is clearly illustrated in the following statement:

"The truth is out there somewhere the facts are objective and can be identified and measured" (Cluett and Bluff, 2006, p. 21).

Epistemologically, the research team and the participant are therefore capable of studying a phenomena without either actually influencing it or being influenced by it (Sale *et al*, 2002). The aim being to measure and analyse casual relationships between variables within a value-free framework (Denzin and Lincoln, 1994).

A degree of confidence in this approach can also be gained from the National Institute for Health and Care Excellence (NICE) who have persistently viewed randomised controlled trials (RCTs), as the gold standard of research evidence upon which to guide clinical practice. RCTs which are highly privileged in the so-called 'evidence hierarchy' table (Marks, 2002) are widely accepted as the most reliable method of determining effectiveness (Campbell *et al*, 2007; Prescott *et al*, 1999). Its major strength being that it minimises bias (the risk of being misled by systematic errors) and misleading results (Prescott *et al*, 1999).

It is important to acknowledge at this point that PREVIEW was not the first RCT to compare the management of dehisced perineal wounds. However, the two similar RCTs included in the Cochrane systematic review, (Christensen *et al*, 1994; Monberg and Hammen, 1987) chapter three, both revealed methodological weaknesses and only one study (Christensen *et al*, 1994) referred to wound healing as an outcome measure.

The literature also suggests that surgical intervention studies have historically reported difficulties with recruitment into RCTs particularly when two interventions are distinctly different such as those compared in the PREVIEW RCT (Jackson *et al*, 2010; Kaur *et al*, 2013; McCulloch *et al*, 2002; Paramasivan *et al*, 2011). Therefore, it was particularly important to evaluate the proposed trial design, and implementation of the study prior to proceeding with any future definitive clinical trial. The quantitative design of phase four of PREVIEW was consequently conducted as a pilot and feasibility RCT. The rationale for this phase of the study is described in detail below.

Definition of pilot study and feasibility studies

Pilot and feasibility studies such as PREVIEW are defined as a version of the main study that is run in miniature to test whether the components of the main study can all work together (Arain *et al*, 2010). Ultimately, as Davies (2009) suggests the primary aim of conducting a pilot study is to strengthen the design of the full scale trial. Easterbrook and Matthews (1992) argue that to ensure the overall success of a RCT it is crucial to explore both the pragmatic as well as the scientific aspects of the study, as many of the problems cannot be anticipated and may only present themselves during the course of the study. Whilst others maintain that pilot and feasibility studies are an essential step in the development and testing of an intervention (re-suturing versus expectancy for dehisced perineal wounds), prior to a large-scale evaluation (Craig *et al*, 2008).

Reflecting upon the National Institute for Health Research (NIHR) (2009) features for pilot studies (Davies, 2009) and guidance from the Medical Research Council (Craig *et al*, 2008), conducting phase four of PREVIEW as a pilot RCT would allow the researchers to:

- Assess the feasibility of the protocol that was designed for a full scale trial
- Gauge the acceptability of the research plan to the participants, clinicians, researchers, the clinical environment and the organisation
- Refine the research questions and hypotheses
- Refine the sample size if appropriate (a power calculation for the RCT presented in section 5.5.2 of this chapter was based upon data from women at the UHNS)
- Test the recruitment and randomisation process, estimate the likely attrition rates and data collection and analysis techniques

- Determine whether we can ensure that the intervention of re-suturing is consistently delivered in a standardised fashion by all clinicians across the research sites assessing the feasibility of a multi-centre RCT
- Establish staff training needs to provide the intervention of re-suturing
- Facilitate the determination of effect sizes for use in sample-size calculations for any future definitive study
- Provide a realistic estimate of the organisational cost implications for delivering the proposed intervention of re-suturing
- Further determine what outcomes are important for women
- Assure a future funding body of the soundness of the research design and the competence of the research team (Craig *et al*, 2008; Davies, 2009).

Phase four of PREVIEW also carefully incorporated the following key features of a feasibility study, (Arain *et al*, 2010; Thabane *et al*, 2010) which will be used to estimate important parameters considered pre-requisite towards designing the main study:

- Willingness of participants to be randomised
- Willingness of clinicians to recruit participants
- The number of participants who actually fulfil the eligibility criteria
- Clinical follow-up rates for assessments of perineal healing; response rates to questionnaires and compliance rates with completion
- Organisational, researcher and participant barriers towards recruitment.

The key parameters detailed above were assessed throughout PREVIEW using recruitment and document tracking logs and at collaborators and trial steering committee meetings; the results are presented in the following chapter.

5.3.2 Rationale for part two: a qualitative study

Part two of this phase of PREVIEW was a qualitative study following a phenomenological approach which is inductive, with no proposed theory (Murphy *et al*, 1998). Although qualitative research can take on various forms, descriptive phenomenology was the methodology of choice for this phase of the study. This is an essential approach towards exploring new topics and obtaining insightful and rich data on complex issues thus allowing the researcher to explore and describe the 'lived' experience of an individual (Bowling, 2009).

Interviews are commonly associated with phenomenology and have been recognised as the ultimate approach towards exploring the lived experience of the women who have a knowledge and understanding of the impact of perineal wound dehiscence; thereby enabling them to narrate that experience (Nunkoosing, 2005). Semi-structured interviews with participants from the RCT were therefore, considered the most appropriate choice to answer the research questions for this part of the PREVIEW study.

The main aims for conducting the interviews supported the philosophy of phenomenology and were developed to capture information relating to women's unique and personal physical and psychosocial experiences following perineal wound dehiscence at 6 months following childbirth. They also allowed the researcher to explore their experiences of participating in PRVIEW and receiving either the intervention of re-suturing or the usual standard care of expectancy. Reflecting upon the words of Nunkoosing (2005, p. 699) interviews were chosen as the author of this thesis was "interested in the woman's cognition, emotion and behaviour as unifying the whole rather than as independent parts to be researched separately."

Unlike the positivist tradition of knowledge gained from the methodology of the RCT, this part of the study was not about providing data for the prediction of illness or treatment strategies, which does little to focus upon the women as a human being (Cluett and Bluff, 2006; Moore and Cowman, 2009). This phase was about providing a more holistic picture of differing aspects of the study and revealing a more meaningful picture of women's personal experiences (Mapp, 2008; Parahoo, 2006). Moreover, this phase was fundamentally crucial to the study as it provided a window of opportunity to research women's unique experiences of an aspect of childbirth, which would otherwise not be known and can facilitate improvement in practice (Mapp, 2008).

Phenomenology is based within the humanistic research paradigm (Mapp, 2008), but was born out of philosophy as opposed to research methodology and therefore has a different epistemological foundation (Snow, 2009). It did, however, grow out of a need to understand how individuals gain knowledge and experience and what it actually means to them (Iaquinta and Larrabee, 2004). Ontologically, there are multiple realities or truths based on an individual's construction of reality which is constantly changing (Denzin and Lincoln, 2003; Sale *et al*, 2002). According to Smith (1983) epistemologically, there is no access to reality independent of our minds, no external referent by which to compare the claims of truth. The researcher (the author of this thesis) and the women being interviewed are interactively linked so that findings are mutually created within the context of the situation which shapes the enquiry (Denzin and Lincoln, 2003).

It is widely accepted that phenomenology has a great deal to offer midwifery as it provides the perspectives of those receiving the services (re-suturing or expectancy in PREVIEW) which might open up understandings that may not be available through other methods (Cluett and Bluff, 2006; Mapp, 2008; Rees, 2011; Snow,

2009). Advocates of this particular method stress that only those that have experienced phenomena can communicate them to the outside world (Todres and Holloway, 2004). There are however, two distinct frameworks towards phenomenology first used by philosophers in the mid-18th century and subsequently developed by the German Philosopher Edmund Husserl (1859-1938). Creating a dichotomy of choice for novice researchers, these are the descriptive approach, commonly referred to as Husserlian and the interpretive approach preferred by Martin Heidegger. Husserl felt driven to establish a rigorous science that found truth in their lived experience (LoBiondo-Wood and Haber, 2002). Bracketing (discussed further in section 5.6.8.2) which requires the suspension of personal views, experiences or preconceptions so that they do not influence either the collection of the information or the interpretation of the respondents experience, is a key principle of Husserlian phenomenology (Moustakas, 1994; Parahoo, 2006). In contrast Heidegger, mentored by Husserl had a different approach to Husserl in that researchers are actively encouraged to interpret the data collected in terms of their own experience and knowledge; commonly referred to as interpretive analysis (IPA) (Finlay, 2009).

Describing women's personal experiences underpinned this phase of the study and with neither a detailed professional knowledge of the most appropriate way to manage a dehisced perineal wound and no personal experience of childbirth, the author of this thesis concluded that the former descriptive approach of Husserl appeared the most appropriate to adopt. This method also seems to have fewer constraints and adopt a less prescriptive style than the interpretive approach favoured by Heidegger.

As Alderson (2001) suggests, women participating in phase four of PREVIEW were respectfully viewed as a reliable authority of knowledge and partners in the research process. Without doubt women who have experienced perineal wound dehiscence are an immense source of knowledge for both researchers and clinicians alike. The purposive population interviewed, reflected both the intervention (re-suturing) and the control (expectancy) arms of the study and demonstrates that efforts were made to obtain the best representation of both clinical and social reality. Knowledge is then derived from both the woman being interviewed and the researcher. There are suggestions that when the researcher and the participant are compared as authorities of knowledge, that the power of the interviewer, for instance the author of this thesis, rested with a degree of authority as a seeker of knowledge and methodological expertise and that of the woman, as a more or less privileged knower (Nunkoosing, 2005). Whilst others propose that by allowing women to give their detailed views, the researcher can treat them more fully as knowledgeable partners rather than relatively passive participants (Alderson, 2001).

Capturing qualitative data on women's views of the impact of perineal wound dehiscence on their own well-being will help to ensure that a future definitive trial captures outcome areas that are relevant to women themselves. Likewise, the knowledge gained from women participating in the RCT will facilitate the feasibility of the trial itself (O' Cathain *et al*, 2013) and enable the whole research team to understand any barriers to participation before embarking on a full scale evaluation.

This qualitative phase of PREVIEW will complement the data obtained from the RCT adding as Bowling (2009) quite rightly acknowledges, a degree of comprehensiveness and richness to the whole study, placing the quantitative data in meaningful social contexts.

A critical rationale for choosing the mixed methods design will now be discussed in more detail.

5.3.3 Rationale for the chosen mixed methods research design

Combining quantitative and qualitative methods in a single study is commonly referred to in the health service as mixed methods research, (Creswell *et al*, 2011; O' Cathain *et al*, 2007; Sale *et al*, 2002). The key principles of mixed methods research provided by Creswell *et al* (2011) underpinned the whole research design for PREVIEW.

PREVIEW focused upon a research question in response to a need for evidence in the management of dehisced perineal wounds and recognised that multi-level perspectives were needed to provide comprehensive answers. Rigorous quantitative and qualitative research was combined to intentionally draw on the strengths of each paradigm to answer the research questions. This particular approach is commonly referred to in the literature as complementary (Bowling, 2009; Carroll and Rothe, 2010; Migiro and Magangi, 2011; Sale *et al*, 2002).

Whilst the unique theoretical perspectives of each approach have been both considered and acknowledged in the previous sections, staunch advocates of qualitative research will argue prolifically the limitations of empirical observations in understanding human phenomena (Berkwits and Aronowitz, 1995; Grypdonck, 2006; Parahoo, 2006). Having previously been disregarded by medical practitioners, qualitative research is now being viewed as just as scientific, systematic and rigorous as its quantitative counterpart (Cluett and Bluff, 2006; Creswell *et al*, 2011; O' Cathain *et al*, 2007; Ziebland and McPherson, 2006).

The surge of international interest in combining quantitative and qualitative methods in a single study has the potential to satisfy both critics (O' Cathain *et al*, 2007). Without doubt, there is an increasing demand on healthcare providers to have conceptually sound, holistic knowledge to guide practice, policy and research (Carroll and Rothe, 2010). One could also argue as others have that more widespread use of mixed methods research in trials such as PREVIEW, which evaluate complex interventions, are likely to enhance the overall quality of the evidence base upon which to inform practice (Campbell *et al*, 2000; Craig *et al*, 2008; Moffatt *et al*, 2006; Protheroe *et al*, 2007).

Despite the fact that mixed methods research is not a new phenomenon and is more frequently being used in health service research one cannot fail to be apprehensive and somewhat confused by the on-going debate surrounding the paradigm (Morris and Burkett, 2011). Whilst some authors question the divide profoundly, there are also suggestions that avoiding these arguments in any discussions has been a response by others (Morris and Burkett, 2011). Attempting to rationalise the discourse, Bowling (2009) suggests that the debate should not focus upon quantitative versus qualitative, but proposes that researchers should be identifying more innovative strategies for combining the varied perspectives of both methods in a single study.

A review of the literature surrounding the on-going debate of mixed methods research often referred to as a 'paradigm of wars' clearly acknowledges that the theoretical framework underpinning the two methodological approaches are actually recognised as being diametrically opposed (Bowling, 2009; Cluett and Bluff, 2006; Mason, 2006; Morris and Burkett, 2011). This has created a widespread divide amongst advocates of each method. The author of this thesis has her own ontological and epistemological opinion which supports that of Clarke (2009), in

that reality (morbidity associated with dehisced wounds for instance) is something that can be both measured and generalised but also that phenomena is unique to each individual woman and her family.

Whilst quantitative studies are variable focused, measureable and objective, qualitative methods lend themselves towards a holistic and subjective phenomenon (Morris and Burkett, 2011). However, complex phenomena such as perineal wound dehiscence requires a more complete knowledge of both 'objective' observations and an understanding of the personal significance and the context within which the trauma occurs (Carroll and Rothe, 2010). Conversely, both methods are valid if applied to appropriate research questions; complementing and not opposing each other (Bowling, 2009).

The ultimate aim however of disciplined enquiry, regardless of the research paradigm is to gain an understanding about an aspect of the world in which we are interested in (Polit and Beck, 2006). Clinical studies such as PREVIEW are specifically designed to generate knowledge in health care to guide clinical practice (Polit and Beck, 2006). The mixed methods complementary design supports the concept that knowledge ranges from practical to theoretical (Carroll and Rothe, 2010). Each source of knowledge as Carroll and Rothe (2010) reveal will necessitate varying levels of reconstruction of individual experiences, the combination of which helps both researchers and participants to understand the complexity and context of that phenomenon.

Within the context of phase four of PREVIEW, the main aim for adopting a mixed methods complementary approach was that the information gained from exploring women's individual experiences would add overall richness to the whole study. However, an alternative rationale commonly provided for combining methods is to

achieve cross validation of data also referred to as triangulation (Bowling, 2009; Greene *et al*, 1989; Sim and Sharp, 1998) . This is often used in an attempt to minimise research bias and enhance the external validity of the results by exploring similarities in the data obtained by different methods (Greene *et al*, 1989). Critics though, argue that quantitative and qualitative methods cannot be combined for triangulation purposes because the two paradigms, as referred to earlier do not study the same phenomena (Brannen, 2005; Sale *et al*, 2002). The PREVIEW study semi-structured interview guide (referred to later in section 5.6.7) used for interviewing participants was informed by the RCT questionnaires and therefore there was the potential for cross validation of the data. However, the author of this thesis did not intend to use the interview findings to validate the RCT data. The overall aim of the mixed methods design was that both paradigms would complement each other in order to gain a greater depth of understanding of the phenomenon under investigation, 'the management of dehisced perineal wounds.'

Whilst we must acknowledge that not all phenomena in the complexities of current day midwifery practice lend themselves to mixed methods research, a powerful argument towards a rationale for this approach is argued below:

"Social experience and lived realities are multi-dimensional and that our understandings are impoverished and may be inadequate if we view these phenomena only along a single dimension" (Mason, 2006, p. 10).

Similarly, Mapp (2008) also believes that researching only one part for instance, a quantitative approach is inconsistent with midwifery practice. Midwifery is most certainly an eclectic discipline of both art and science grounded in a holistic approach which encompasses the mind, body and spirit and therefore benefits from

a varied mixed methods approach towards developing and testing theory (Bowling, 2009; Cluett and Bluff, 2006).

Logically, both the pilot and feasibility aspects of the study and the qualitative phase will enhance the overall scientific rigour and value of the full-scale study.

5.4 Research funding, ethics committee approval and research governance

5.4.1 Research funding

PREVIEW was funded by a research grant from the National Institute for Health Research, Research for Patient Benefit (RfPB) (PB-PG-090920079) from February 1st 2010 to June 30th 2014 and a Doctoral Nursing Studentship award from the Smith and Nephew Foundation in November 2008. The financial commitment was continued by Research into Ageing (RIA) Age Concern (June 2009-2011) following the end of the charitable sector of the Smith and Nephew Foundation.

The University Hospital of North Staffordshire acted as the sponsor organisation for the study.

5.4.2 Research ethics committee approval

At the heart of all NHS research is protecting the dignity, rights, safety and wellbeing of participants in any research study (Department of Health, 2005). The Department of Health requires that research involving service users, care professionals or volunteers, is reviewed independently to ensure it meets ethical standards (Department of Health, 2005).

The PREVIEW study was therefore reviewed by the North Wales Research Ethics Committee Central and East and received ethical approval prior to commencing the study, reference number 10/WNo03/16 (appendix 5). Ethical approval was also sought from local Research and Development (R&D) Departments at all recruiting sites.

The National Institute for Health Research (NIHR) adopted PREVIEW as an NIHR portfolio study, ID number 9098 and the study was also co-adopted by the Primary Care Research Network. In addition, as potential participants were mostly identified by community midwives, general practitioners or health visitors a participant identification centre (PIC) agreement was also required from all Primary Care Trusts, currently referred to as clinical commissioning groups (CCGs) for the recruiting organisations (appendix 6 provides correspondence from a PCT).

5.4.3 Research Governance

The whole research study has been conducted in accordance with all the applicable regulatory research governance requirements, including the:

- NHS Research Governance Frameworks for Health and Social Care (Department of Health, 2005)
- MRC Guidelines for Good Clinical Practice in Clinical Trials (Medical Research Council, 1998)
- Good Clinical Practice recommendations of the NIHR
- ICH Steering Committee (1996) ICH Harmonised Tripartite Guideline for Good Clinical Practice (International Conference on Harmonisation, 1996)

- Consolidated Standards of Reporting Trials (CONSORT[2] 2010 Statement: updated guidelines for reporting parallel-group randomised trials) (Schulz *et al*, 2010)
- Consolidated Criteria for Reporting Qualitative Research (COREQ[2]): A 32 Item Checklist for Interviews and Focus Groups (Tong *et al*, 2007)
- The research governance policy at all recruiting sites.

The PREVIEW study was registered on the electronic database: International Standard Research for Clinical Trials (ISRCTN05754020). Further sequential discussion of both the quantitative and qualitative methodology for PREVIEW will now follow.

5.5 The methodology for the quantitative phase of PREVIEW

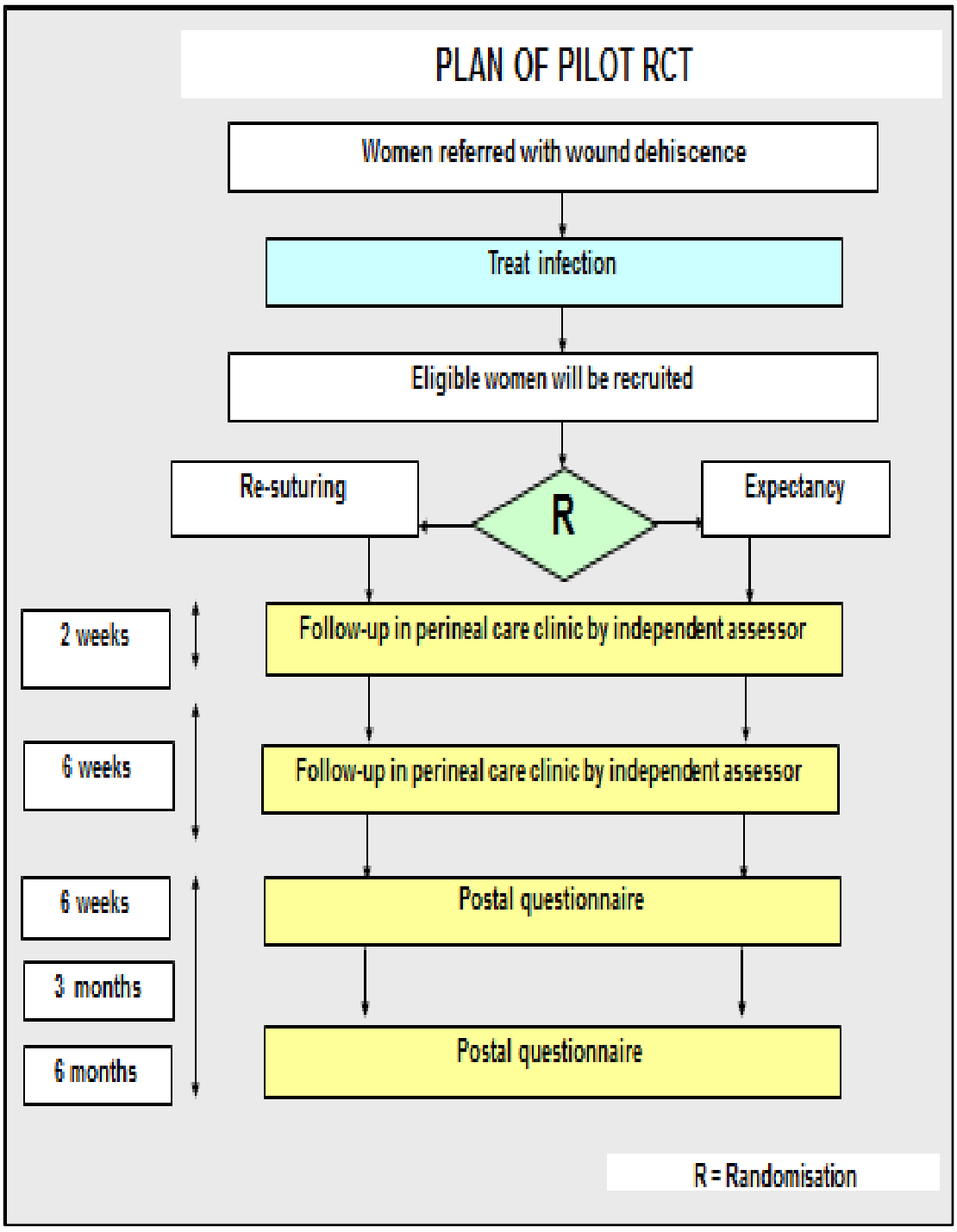
5.5.1 Study setting and population for the RCT

The University Hospital of North Staffordshire (UHNS) was the host organisation for the PREVIEW study. Ten NHS organisations in England were recruiting centres, whilst the Primary Care Trusts associated with each recruiting sites acted as participant identification centres.

The population being studied over a 2 year recruitment period, were post natal women who had experienced a vaginal delivery and sustained perineal trauma (a second degree tear or episiotomy) needing primary suturing which subsequently dehisced involving both the skin and muscle layers, within the first two weeks following delivery. Figure 16 provides a summary of the RCT plan.

[2] CONSORT and COREQ are endorsed by the 'EQUATOR' Network (Enhancing the QUAlity and Transparency Of health Research) which is an organisation directed by an international steering group that brings together leading experts in health research and methodology, statistics, reporting and editorial work with a mutual interest in improving the quality of research publication and of research itself.

Figure 16: A Plan of the multi-centre pilot RCT



5.5.2 Sample size for the RCT

The current literature did not support a formal sample size calculation for the primary outcome of interest. One of the purposes of this pilot study was to collect data to inform a sample size calculation for a full scale RCT. Three aspects of this are to estimate (a) the recruitment rate, (b) attrition rate and (c) the proportion of women whose wound had healed at 6-8 weeks. Hence, in estimating the sample size of this pilot study the research team attempted to ensure a sufficient degree of precision of these estimates (using the lower and upper limits of the 95% confidence interval).

Data collection at the UHNS, the host research site identified that there were 117 women referred to the perineal care clinic with a dehisced perineal wound during a 4 year period (30 women / year). The research team therefore estimated that there would be around 45 eligible women for recruitment in each of the 4 participating centres during the 18 months of the study period.

Previous experience with recruitment into RCTs at the UHNS consistently demonstrated an 80% take-up rate and a 20% attrition rate. The research team anticipated similar rates for PREVIEW. Hence with 45 women approached in each of the participating centres (180 in total) there was an expected recruitment figure of 144 women and 115 of these to complete the pilot study. This would allow for recruitment in each site to be estimated with precision of +/-12%, and overall recruitment rate to be estimated with precision +/- 6%. Loss to follow-up would be estimated with precision +/- 7%, and healing at 6-8 weeks (assumed to be around 50% from the collection of retrospective data referred to above) would be estimated to +/-13% in each trial arm.

Although the sample size was considered quite large for a pilot study the research team felt that this was necessary in order for recruitment to start 'bedding down' in each of multiple sites. Estimating effect size was not a specific aim of this pilot, however, with a sample size of 115 the effect size for the primary outcome would be estimated with a precision of +/-18%, and feed into deliberations regarding plausible effect sizes to be used for future sample size calculations.

5.5.3 Recruitment and eligibility criteria for the RCT

Women with dehisced perineal wounds were referred to the specialist perineal care clinics (or alternative clinic in the absence of a designated perineal care clinic), maternity triage areas or maternity assessment units at the recruiting sites with a dehisced perineal wound following primary suturing of a spontaneous 2nd degree tear or episiotomy within 2 weeks following childbirth.

Recruitment into the study was based on the 'uncertainty principle' advocated by Collins *et al* (1992) in that both the participants and the clinician needed to be substantially uncertain about the appropriateness of each of the interventions. Adopting this principle helps to ensure that the degree of informed consent should not differ widely from that which is applied outside the trial and is viewed as providing an approximate parallel between good science and good ethics (Collins *et al*, 1992).

All women who agreed to participate in PREVIEW, including those interviewed were able to withdraw at any time, without giving reason and without their clinical care being affected. Women were also asked to provide their written consent to notify their general practitioner should any health related problem be identified. Primary Care Trusts within the locality of the recruiting sites received information about the study and referral pathway.

As recruitment into the study was within the first two weeks of childbirth the research teams were not fully aware of women who would subsequently be diagnosed with postnatal depression. The current recommendations are that at 10-14 days after childbirth women should be asked about resolution of symptoms of baby blues (National Institute for Health and Care Excellence, 2006). If research teams were aware of any unresolved symptoms, close liaison with the woman's individual community midwife, health visitor and general practitioner was ensured. NICE guidance would have been followed where the woman would be assessed for postnatal depression and if symptoms persist, further management and referral as per local protocols would be followed (National Institute for Health and Care Excellence, 2006).

5.5.3.1 Exclusion criteria for the RCT

The following women were excluded from participating in the study:

- Women that had not given their written consent to participate in the study
- Women who had delivered a stillborn infant or suffered any form of pregnancy loss in the current pregnancy
- Women under the age of 16 years
- Women who sustained a third or fourth degree perineal tear
- Women who were considered by the anaesthetist and the obstetrician to have an unacceptable anaesthetic risk
- Women who could not speak English or could not read or write English.

Whilst studies have demonstrated that secondary repair following wound dehiscence of third or fourth degree perineal trauma is a feasible option when compared to expectancy, the complexity of the primary repair led to this group of

women being excluded from the study. However a record of these cases was retained in accordance with CONSORT guidance (Schulz *et al*, 2010).

Women from all ethnic backgrounds were eligible to participate but financial constraints in terms of translation services meant that in the pilot study we were not able to recruit women who could not speak English or could not read or write the English language. A record of the number of these potential participants and their first language was retained, again in accordance with CONSORT guidance (Schulz *et al*, 2010). The data from these cases would assist project planning and resource allocation for the definitive study.

Data from women excluded from the study who did not fulfil the eligibility criteria is also particularly relevant when planning for the definitive study. Recruitment logs were therefore also retained by each recruiting site. The CONSORT flow diagram presented in chapter six, figure 26 presents information relating to this group of women.

5.5.4 Consent for the RCT

Consent for the RCT adhered to national and international guidance for the consent of research participant's in clinical trials and was conducted in accordance with the declaration of Helsinki (World Medical Association, 2008), the International Conference on Harmonisation, (International Conference on Harmonisation, 1996) and recommendations from the National Patient Safety Agency (National Patient Safety Agency, 2007).

Women eligible for the study were provided with the study information leaflet (appendix 7) by their community midwife, hospital midwife or obstetrician. They were allowed time to ensure that they understood the information and clarify any

queries they had. Women who subsequently did not wish to participate in the study were managed in accordance with local hospital practice. Women were recruited into the study by either a midwife or doctor who was GCP trained and had received additional information relating to the trial protocol and consent process for PREVIEW. A valid written consent (appendix 8) was obtained from women wished to participate.

5.5.5 Randomisation to the RCT

A bespoke randomisation schedule was developed by the Bristol Clinical Trials Randomisation Services (BCTRS) in full collaboration with the trial study team. Paper copies for ease of reference were included in all participant packs (appendix 9).

Researchers were provided with a choice of either web or telephone based randomisation. The allocation ratio was 1:1 and randomisation was in blocks, stratified by study centre. The study participants were assigned to either re-suturing of the dehisced perineal wound; the procedure preferably being completed within 48 hours of randomisation or expectant management (allowing the wound to heal by secondary intention). The recruiting organisation and the woman's date of birth were the only details needed for the randomisation. A unique study identification number was provided for each woman randomised. With the participant's agreement, a letter was sent to individual general practitioner's confirming trial entry and follow-up appointments (appendix 10).

A successful randomisation process which was independently administered by BCTRS carefully avoided selection bias which is the systematic differences between the baseline characteristics of the women in the study (Higgins *et al*, 2011a). The process also ensured allocation concealment at the point of randomisation from the

participant, clinician and researcher. Although, allocation concealment irrespective of the method of randomisation can introduce a high element of bias if the clinician favours a treatment option for the woman. The clinician may then not choose (consciously or unconsciously) to randomise the woman into the study (Farrokhyar *et al*, 2010).

5.5.6 Clinical training for the RCT interventions

Two Standard Operating Procedures (SOPS) were developed specifically for the PREVIEW study: re-suturing dehisced perineal wounds and expectant management of dehisced perineal wounds. The SOPs were developed in collaboration with key stake holders, namely: obstetricians, midwives, theatre staff, professional head of midwifery and the directorate manager at the host organisation.

Careful consideration was given to avoid performance bias which refers to the systematic differences between the two groups in the care that is provided or in exposure to other variables in addition to the trial interventions (Higgins *et al*, 2011a). However, due to discourse surrounding the administration of antibiotics in the absence of confirmed microbiology and following consultation with recruiting organisations, the study team were not prescriptive regarding the administration or indeed the type of antibiotic used. At the discretion of the operating surgeon an additional dose of intravenous antibiotics was also administered if the participant was randomised to re-suturing of the dehisced perineal wound.

Information relating to the type, dose and route of administration of antibiotics was collected at randomisation for both groups and on the operative record for participants allocated to secondary repair.

To ensure the standardisation of secondary re-suturing, the research team provided recommendations for both the materials and methods to be used (table 11). These recommendations were based upon clinical expertise and knowledge and would have been reviewed in light of any new evidence that became available throughout the course of the study.

Table 11: Recommended suturing material and methods for the repair of dehisced perineal wounds

PREVIEW Study: Recommended suturing material & methods for the repair of dehisced perineal wounds	
Recommended suture material	To ensure standardisation of materials the PREVIEW study team recommend the use of standard synthetic polyglactin 910 (gauge 2/0).
Recommended suture methods	Standard surgical procedures for secondary suturing should be followed including wound debridement if needed.
Repair of the vaginal mucosa	Continuous suturing technique.
Repair of the perineal muscle	Interrupted sutures.
Repair of the skin	Depending on the length of the wound the skin could be sutured by interrupted or subcutaneous sutures or left un-sutured if the edges are approximated by suturing the underlying tissues.

5.5.7 Primary and secondary feasibility outcome measures for the RCT

5.5.7.1 Primary feasibility outcome measure for the RCT

The primary outcome measure for the RCT was the proportion of women with a healed wound at 6-8 weeks following trial entry (randomisation).

5.5.7.2 Secondary feasibility outcome measures for the RCT

The secondary outcome measures for the PREVIEW RCT were:

- Pain at 2 weeks, 6 weeks, 3 months and 6 months following trial entry (randomisation)
- Dyspareunia (painful sexual intercourse) at 6 weeks, 3 months and 6 months following trial entry
- Rates of breast feeding at 6 weeks, 3 and 6 months following trial entry
- Woman's satisfaction with the aesthetic results of the perineal wound at 6 weeks, 3 and 6 months following trial entry.

5.5.8 Data collection methods for the RCT

Standardised bespoke PREVIEW RCT questionnaires (seven in total) were based upon and adapted from those used and validated by members of the research team in other childbirth-related perineal trauma studies (Bick *et al*, 2010; Kettle *et al*, 2002). The series of questionnaires were designed to specifically measure the primary and secondary outcome variables of the PREVIEW RCT. Wound healing, the primary outcome, was reported by the clinician and the secondary outcome measures detailed above were self-reported by the women themselves.

Whilst adapting questionnaires necessitated revalidation, the time and resources needed to develop and validate a lengthy list of new ones can be vastly reduced (Boynton and Greenhalgh, 2004). The trial statistician recommended using a Market Research Group (MRG) at Bournemouth University to assist in the overall layout of the questionnaires, printing all the documents and scanning in completed responses.

Attention was given to the layout and general appearance of all the questionnaires considered a vital role in determining whether or not a potential respondent (participant or clinician) will complete the document in full (Boynton and Greenhalgh, 2004). All questionnaires completed by clinicians (midwives, nurses, doctors and researchers) were printed in a pastel green colour. All participant questionnaires were printed in a pastel yellow colour. According to Bowling (2009) coloured paper may enliven a questionnaire even potentially influencing the mood of the respondents. Market research companies on occasions consult psychologists for advice on their product designs and they use colour deliberately to package their products to imply a targeted image. Green for example is associated with 'healthy lifestyles' whilst yellow is associated with 'optimism' (Bowling, 2009). Interestingly the MRG at Bournemouth had a preference for white paper, the rationale being that scanned data, an increasingly common way of inputting data, is visually clearer.

Free text annotations were detailed in various sections of all the RCT questionnaires which had the potential to enrich the quantitative data (Boynton and Greenhalgh, 2004). Closed ended items are often a source of frustration with questionnaires, largely because researchers have not considered all potential responses (Houtkoop-Steenstra, 2000). The free text comments were therefore crucial to ensure that any future study will truly reflect outcomes that are significantly relevant to both women and clinicians alike. Extracts from the data could then be used to illustrate the quantitative findings of the RCT where appropriate.

Filter questions were used in all questionnaires to guide respondents around irrelevant questions but kept to a minimum to avoid confusion to the respondents (Jenn, 2006). Care was also taken to avoid overcrowding the sections which may have the potential to influence response rates (McColl *et al*, 2001).

All clinicians completing questionnaires attended a training session on the study protocol and the consent process and were identified on the delegation of duties log (a GCP requirement).

All clinician's questionnaires were photocopied; the originals were hand delivered to the Bournemouth market research group and copies were retained in the research site file and within the participant's hospital records. All research data was subsequently archived at the UHNS with the assistance of the research and development team.

5.5.8.1 Reliability and validity of the RCT questionnaires

Reliability

The same questionnaires in an identical format were used for all participants irrespective of treatment allocation (Boynton and Greenhalgh, 2004). This helped to increase reliability, (referred to as the homogeneity) of the questionnaire and the degree of which it is free from random error (Bowling, 2009).

Content validity

A team of experienced researchers including the trial statistician, all of whom have conducted studies in similar areas, obstetric consultants and registrars and the Bournemouth University marketing company had an input into the design and layout of all the questionnaires. Following numerous meetings with trial steering group members including input from two patient representatives with previous personal experience of perineal trauma, the numbers of questions asked were significantly reduced. The aim of this was to keep the length of the questionnaire as short as possible but also to ensure that the questions asked were relevant to the actual purpose of the questionnaire.

Ensuring a questionnaire logically examines and comprehensively includes the full scope of characteristics of what it is intended to measure is fundamental to achieving content validity (Bowling, 2009; Cluett and Bluff, 2006; Polit and Beck, 2010). In relation to the mother's questionnaires, questions asked also reflected outcomes that women themselves have previously considered important (Perkins *et al*, 2008).

Face validity

Face validity refers to whether experts of the phenomenon under investigation agree that the questions being asked will actually measure what they are supposed to measure (Bowling, 2009; McColl *et al*, 2001).

Face validity was achieved within the construct of the PREVIEW trial questionnaires by ensuring that they were evaluated not only within the research team but also with midwifery and obstetric colleagues, a small cross section of women in the ante natal and postnatal ward areas, and the two patient representatives. Agreement was reached when all trial questionnaires focused upon relevant, unambiguous questions that reflected the outcome measures for the study.

Each data collection questionnaire will now be discussed in more detail below.

5.5.8.2 RCT entry details questionnaire

All women randomised into the study had specific base line data collected in relation to the following ante-partum and intra-partum characteristics:

- Obstetric history, both past and present
- Delivery details for the current labour
- Medical and surgical history.

A full clinical examination of the wound was recorded, including measurement of the area of wound dehiscence; examples of wound measurements were provided (see figure 17). Clinicians and researchers were also asked to document if a wound swab had been taken or not including results when available and to record the type of antibiotics prescribed. The entire above source data was then recorded in the RCT 'entry details questionnaire' (appendix 11) by either the clinician obtaining consent or a member of the research team at the recruiting site.

5.5.8.3 RCT perineal assessment questionnaires

Data relating to the primary outcome measure of time taken to heal were recorded in perineal assessment questionnaires at 2 weeks and 6 weeks following randomisation.

Participants, clinicians and researchers involved in the RCT all had the potential to introduce bias into the study at these time points by virtue of having knowledge of the intervention received (Farrokhyar *et al*, 2010; Higgins *et al*, 2011a). Due to the nature of the interventions it was not possible to blind either outcome assessors, care providers or participants themselves. There could have been a possibility of blinding the assessors regarding wound healing and intervention, particularly at the 6 week perineal assessment of wound healing, as no reference towards group allocation was entered on the questionnaires. Although, it is highly likely that discussions between the woman and clinician would alert the assessor to group allocation.

The study team did however make concerted efforts to limit detection bias which refers to the systematic differences between the two groups in how the study outcomes are determined (Higgins *et al*, 2011a). For the primary outcome measure, assessment of perineal wounds at 2 weeks and 6-8 weeks following randomisation

was therefore conducted whenever practically possible, by independent clinicians who were not part of the research team. Women were asked to attend the perineal care clinic or alternative at the recruiting organisation for this assessment. A visual assessment of wound healing using the REEDA evaluation tool (explained in section 5.5.8.4 and illustrated in figures 18 and 19) was performed and the findings documented in the relevant 2 weeks or 6 weeks questionnaire. All perineal assessment questionnaires recorded the same information, the 6 weeks questionnaire is provided as an appendix to this thesis (appendix 12). Additional perineal assessment questionnaires were also included in participant research packs to allow the clinician a degree of flexibility with follow-up assessment visits.

5.5.8.4 Measurement of the primary outcome: wound healing

Wound healing as demonstrated in the literature review is a complex process affected by numerous intrinsic and extrinsic variables making a single definition almost as complex as the process itself. However in its broadest sense wound healing can be defined as the physiology by which the body replaces and restores function to damaged tissues (Tortora and Grabowski, 1996). Conversely this is not a totally functional definition for the purpose of a clinical trial; therefore wound healing for the purpose of the primary outcome measure measurements for the RCT was defined as ‘no evidence of wound dehiscence.’

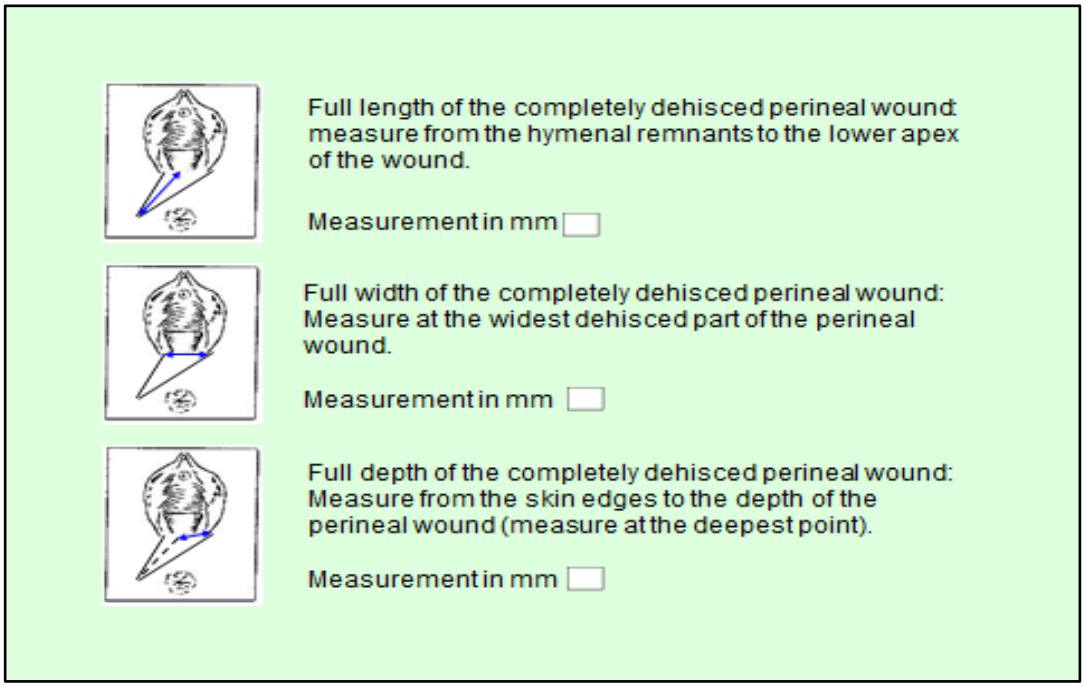
Wound measurement in general which can help to assess the effectiveness of management strategies has historically not been without its challenges, centred upon available resources, costs, ethics not to mention the complexities of the wound to be measured. It has been acknowledged that there is apparently no current method of wound measurement that is accurate, repeatable, inexpensive and practical for use in everyday clinical situations (Salcido, 2000).

The most widely used techniques for measuring wounds are revealed as: linear measurements of length, width and depth; wound tracing, photography and the more recent methods of computer-based or digital planimetry (Goldman and Salcido, 2002; Metcalfe *et al*, 2008; Oldfield, 2010). In the current economic climate, digital and computerised photogrammetry is an advanced and costly level of wound measurement. Neither of which may be considered an attractive financial alternative in the field of obstetrics, particularly as only relatively small numbers of women experience healing complications from either their perineal or caesarean section wound.

Historically, formal evaluation of wound assessment tools is continually recognised as an on-going neglected area of women's health care (Bick, 2009; Steen, 2010). Unfortunately this issue is not particularly confined to childbirth but appears to be an area of contention for other health care disciplines too (Goldman and Salcido, 2002; Metcalfe *et al*, 2008; Oldfield, 2010).

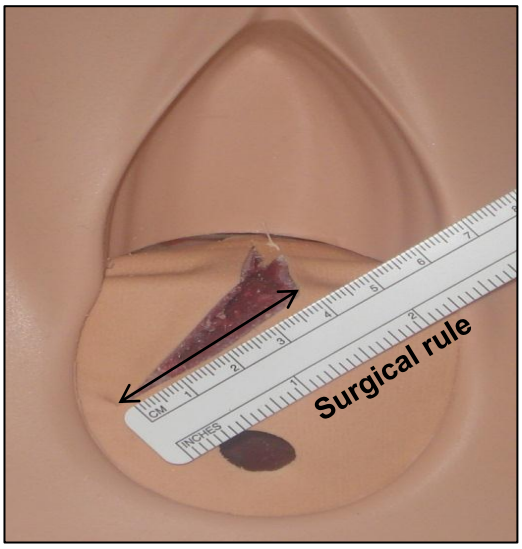
At trial entry into the RCT the area of wound dehiscence including the length, depth and width was recorded in millimetres (mm). This enabled the researchers to account for the extent of dehiscence and to provide a baseline upon which to assess wound healing as an outcome measure. Diagrams were included in the questionnaires to visually depict the areas for measurement (figure 17). It is unlikely however that a completely accurate measurement would be obtained 100% of the time largely due to any pain and discomfort the woman may have been experiencing and the presence of remaining suture materials.

Figure 17: Wound measurement: an extract from the perineal assessment questionnaire



Following consultation with obstetricians, researchers and midwifery colleagues, a decision was made to use the Peri-rule™ for the measurement of the dehisced perineal wound and subsequent evaluation of healing. However, four weeks prior to commencing active recruitment to the study it was apparent that the manufacturing license for the Peri-rule™ had expired and was not going to be renewed. The sterile services department at the host organisation were therefore not able to autoclave the stock of Peri-rules™ delivered to them. As a compromise a sterile surgical rule (photograph 1) was used as an alternative.

Photograph 1: Measuring perineal trauma using the surgical rule on suturing models



The surgical rule is a measurement tool that obstetric surgeons were familiar with, but was also readily available for a small cost. The Peri-rule™, the Clini-Rule, a recent licensed alternative device to the Peri-rule™ and the surgical rule are discussed further below.

Peri-rule™

The Peri-rule™ which was developed for the measurement of first and second degree tears is made from flexible medical grade plastic with moulded millimetre marks (Metcalfe *et al*, 2002). The tool was validated for inter-rater reliability reporting a string level of agreement within 5 mm for all assessments (P <0.05).

The Clini-Rule

The clini-rule, a flexible, medical grade plastic tool has also been demonstrated to be more pragmatic and economical to use, proving less time consuming for both patients and nurses when compared with wound tracings, (surface area of

dimensions measured using a digitising pad) (Metcalfe *et al*, 2008). The device can be used in the assessment of different types of wounds.

The surgical rule and level of agreement of measurement

Similar to the clini-rule, the 15 cm, vinyl plastic surgical rule used for perineal wound measurements in the PREVIEW study was both sterile and latex free. Due to time constraints and the requirement of additional ethical approval to conduct a full scale evaluation of its use for the measurement of dehisced perineal wounds, a decision was made to use suturing models (see photograph number 1) to assess the reliability of this tool with individual midwives.

Fifteen midwives each measured the length, width and depth in mm of a wound on two perineal repair suturing models (model 1 and model 2) reported in tables 12 and 13 respectively.

Table 12: Midwives measurements of a perineal repair suturing model 1

Model 1 Date 18/07/2013			
Midwife	Length	Width	Depth
1	50	23	21
2	50	26	25
3	50	27	21
4	50	25	25
5	48	16	24
Model 1 Date 25/07/2013			
6	46	26	16
7	50	25	25
8	50	25	20
9	45	26	37
10	47	27	20
11	45	24	20
12	48	28	25
Model 1 Date 06/08/2013			
13	40	17	15
14	48	25	20
15	42	20	17

Table 13: Midwives measurements of a perineal repair suturing model 2

Model 2 Date 18/07/2013			
Midwife	**Length**	**Width**	**Depth**
1	59	16	24
2	50	25	25
3	55	20	20
4	50	26	20
5	55.5	25	24
Model 2 Date 25/07/2013			
6	55	25	30
7	55	24	19
8	52	26	27
9	54	25	23
10	55	24	24
11	60	25	22
12	54	27	22
Model 2 Date 06/08/2013			
13	50	20	22
14	47	24	20
15	47	25	22

All results were then assessed for the level of agreement using SPSS. The mean and standard deviations (SD) for the length, width and depth measurements are presented in table 14.

Table 14: Midwives measurements of the perineal repair suturing model 1 and 2, the mean and SD

Mean (SD) in mm	**Model 1 Length**	**Model 2 Length**	**Model 1 Width**	**Model 2 Width**	**Model 1 Depth**	**Model 2 Depth**
Midwives n = 15	47.27 (3.15)	53.20 (3.84)	24.00 (3.59)	23.80 (2.91)	22.07 (5.30)	22.93 (2.92)

Measurement error, that is the extent to which the midwives' measurements are in agreement, is best estimated using Standard Error of Measurement (SEM) (de Vet *et al*, 2006). Reliability (e.g. intra-class correlation), the degree to which measurements can discriminate between women cannot be estimated with this design, because it does not involve measurement of women (de Vet *et al*, 2006).

The SEM for models 1 and 2 which are presented in table 15 are individually identical to the standard deviations (for the set of 15 midwives). The overall SEMs were calculated using Variance Components models in SPSS; as the measurements were made in mm the SEMs were also presented in mm. The SEM describes the variation between the measurements made by the 15 midwives. Ideally a SEM would have been 0 mm, indicating no variation in measurements with all midwives recording the same values.

Table 15: SEM agreement from 15 midwives

$SEM_{agreement}$ n = 15	Model 1	Model 2	Overall
$SEM_{agreement}$ for length	3.15 mm	3.84 mm	3.51 mm
$SEM_{agreement}$ for width	3.59 mm	2.91 mm	3.26 mm
$SEM_{agreement}$ for depth	5.30 mm	2.92 mm	4.64 mm

The results of the SEM presented in table 15 would suggest that the SEM is good for length, moderate for width and not that good for depth when the SEM is 6%, 12% and 18% of the mean respectively. In relation to PREVIEW, this means that length, with the least degree of variation was the most reliable measurement when compared to width and depth.

REEDA scoring of wound assessment

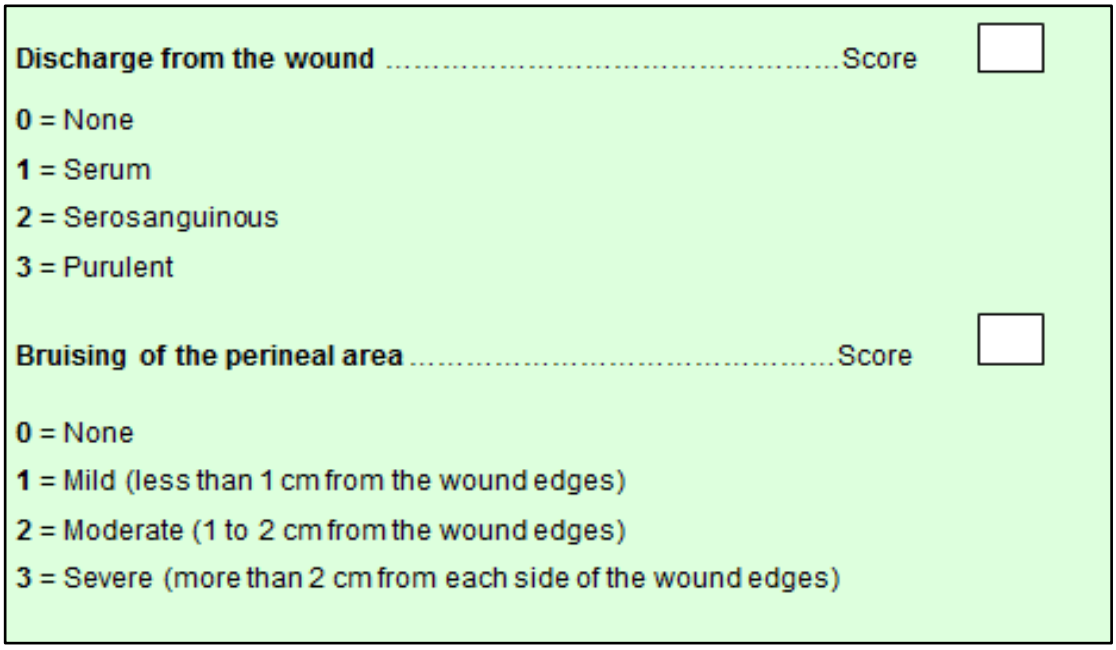
The REEDA scoring tool is a popular means of wound assessment in midwifery (Fleming *et al*, 2003; Kettle, 2002; Kindberg *et al*, 2008). A modified version used in a previous clinical trial investigating suturing methods and materials for perineal repair (Kettle *et al*, 2002) was adopted for use in the PREVIEW study (figures 18 and 19). Initially developed and evaluated some 40 years ago, the REEDA score comprises of 5 components, using a 0-3 point scale, tape measurement and observations (Davidson, 1974).

The REEDA tool assesses redness (R), oedema (E), ecchymosis (E) an alternative name for bruising, discharge (D) and approximation of the perineal wound edges (A). Its scientific merit relies upon precise measurement of the degree of trauma whilst providing descriptive data specifically relevant to the perineal trauma associated with each individual woman (Fleming *et al*, 2003).

Figure 18: A modified version of the REEDA score adopted for PREVIEW

Score	Redness	Edema	Ecchymosis	Discharge	Approximation
0	None	None	None	None	Closed
1	Mild Less than 0.5 cm from each side of the wound edges	Mild Less than 1 cm from each side of the wound edges	Mild Less than 1 cm from each side of the wound edges	Serum	Skin separation 3 mm or less
2	Moderate 0.5 cm to 1cm from each side of the wound edges	Moderate 1 to 2 cm from each side of the wound edges	Moderate 1 to 2 cm from each side of the wound edges	Serosanguinous	Skin and subcutaneous fat separation
3	Severe More than 1 cm from each side of the wound edges	Severe More than 2 cm from each side of the wound edges	Severe More than 2 cm from each side of the wound edges	Purulent	Skin and subcutaneous fat and fascial layer separation
Total					

Figure 19: The REEDA scoring tool: an extract from the RCT entry details questionnaire



5.5.8.5 Mothers RCT questionnaires

Mothers questionnaires were designed topically based to assess the secondary outcome measures of pain, dyspareunia, breast feeding rates and women's satisfaction with the aesthetic results of wound healing. Further discussion of how the outcomes were assessed is provided in the section below. Topic based questionnaires are thought to be more professional and less irritating for participants (Bowling, 2009).

All participating women in the RCT were asked to complete a pre-paid postal questionnaire at 6 weeks 3 months and 6 months following trial entry. The content of all the mothers questionnaires remained the same at each time point, the 6 month questionnaire is included as an appendix to this thesis (appendix 13).

Secondary outcome assessments were self-reported by the women themselves and therefore assessor bias was avoided. Re-call bias though, can be a potential issue when asking women to remember their experience to an outcome measure such as pain (Bick, 2005). Efforts were made to limit this as far as possible by asking them to recall exposure to the particular outcome either in the past 24 hours or the past week.

5.5.8.6 Measurement of the secondary outcomes

Pain measurement

In addition to the three specified time points, the secondary outcome measure of pain was also assessed at 2 weeks following trial entry. A section was included in the clinicians 2 weeks perineal assessment questionnaire for the mother to complete.

The literature review revealed that perineal wound pain irrespective of dehiscence is a common problem following childbirth. The experience of pain itself however is a multi-dimensional, highly subjective perception involving sensory, affective, behavioural and cognitive parameters (Melzack and Katz, 2013). The variants of these factors, unique to the individual do indeed make the measurement of pain somewhat challenging for both clinicians and researchers alike.

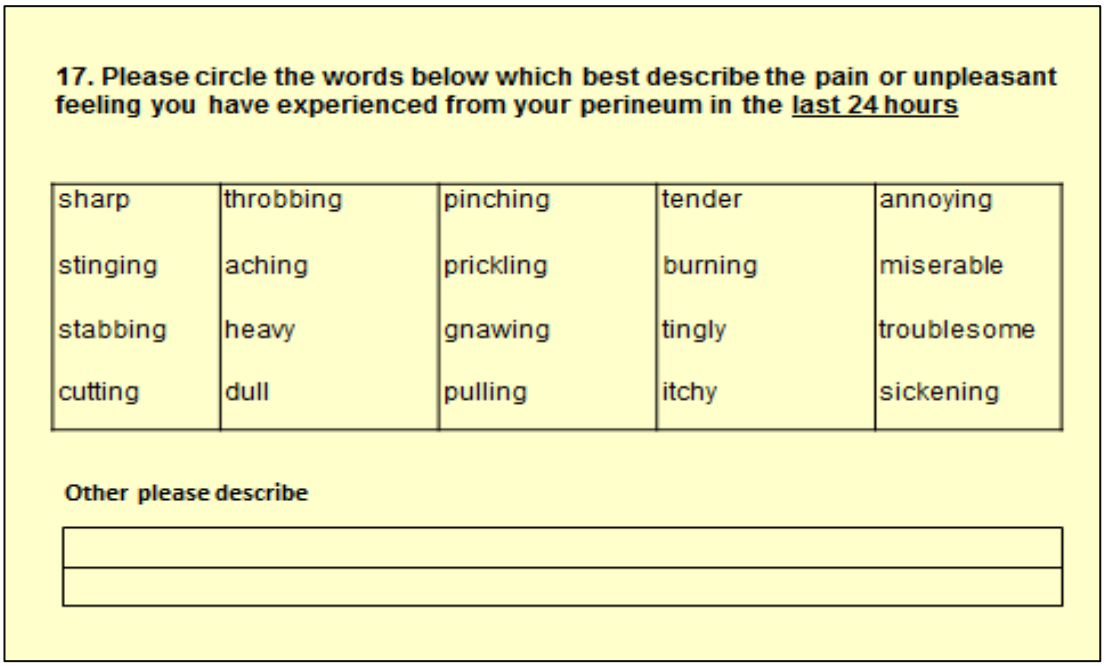
In attempts to assess pain in both clinical practice settings and in the research arena the use of pain scales to measure pain intensity have been suggested (World Union of Wound Healing Societies, 2004). Commonly referred to scales for adult use include the visual analogue scale (VAS), the Wong-Baker Faces scale, the numerical rating scale (NRS) and the verbal rating scale (VRS) (Vuolo, 2006; World Union of Wound Healing Societies, 2004). Whilst these scales are synonymous across a variety of clinical settings, issues such as the patient population as well as

specific needs, such as language differences or the visually impaired should be taken into account when selecting a suitable scale (Vuolo, 2006). Once chosen the same scale should be used to enable valid comparisons between assessments to be made (Vuolo, 2006).

Following a general consensus of opinion amongst several members of the trial study team a decision was made to use a four point categorical scale whereby the mother describes her level of pain in the explanatory words of none, mild, moderate and severe. This tool has good compliance rates, has been used successfully in similar perineal management studies (Kettle *et al*, 2002; Kindberg *et al*, 2009; McCandlish *et al*, 1998) and is considered less complicated to explain than other tools (World Union of Wound Healing Societies, 2004). However isolating pain merely in terms of its intensity does little to illuminate the true extent of its experience upon the individual. Indeed as Melzack and Wall (1988) state: “to describe pain solely in terms of its intensity is like specifying the visual world only in terms of light flux without due regard to pattern, colour, texture and the many other dimensions of the visual experience” (p. 37).

To enable the assessment of pain to be more meaningful, women were asked to circle a pre-specified table of words which best reflected the pain they were experiencing (figure 20). Free text was also provided to enable the woman to describe the pain using her own words.

Figure 20: Descriptive words used to describe perineal pain: an extract from the mothers questionnaires



17. Please circle the words below which best describe the pain or unpleasant feeling you have experienced from your perineum in the last 24 hours

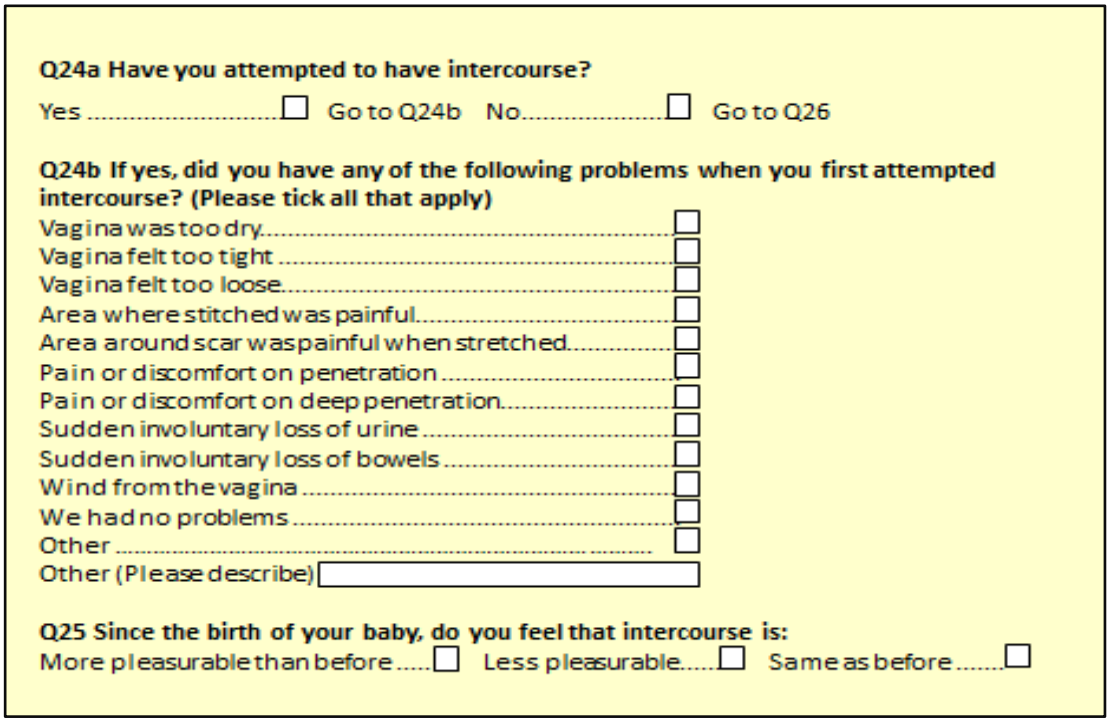
sharp	throbbing	pinching	tender	annoying
stinging	aching	prickling	burning	miserable
stabbing	heavy	gnawing	tingly	troublesome
cutting	dull	pulling	itchy	sickening

Other please describe

Dyspareunia

Rates of dyspareunia and areas of sexual morbidity were self-assessed at the three time intervals using the categorical variables illustrated in figure 21. Women who had not resumed intercourse were asked to provide additional information to determine whether or not this was associated with concerns relating to wound healing (figure 22). Additional responses to other variables added a degree of overall comprehensiveness to the data. The information obtained would then provide comparative data between the two groups.

Figure 21: Dyspareunia and Sexual morbidity: an extract from the mother's questionnaire



Q24a Have you attempted to have intercourse?

Yes ☐ Go to Q24b No ☐ Go to Q26

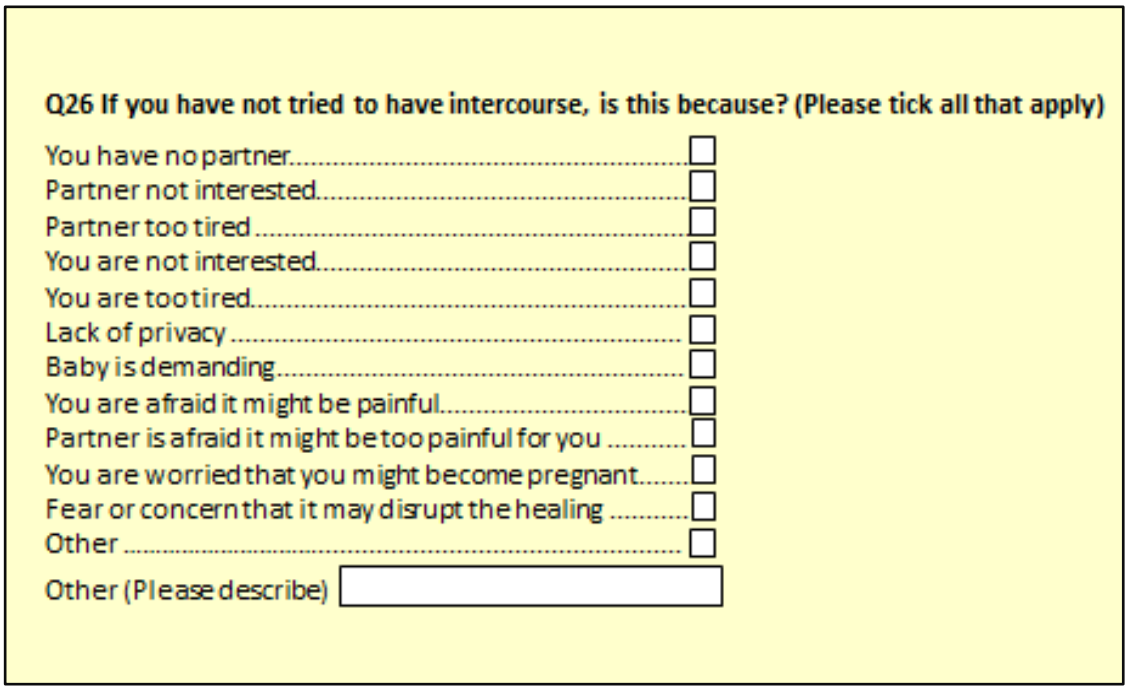
Q24b If yes, did you have any of the following problems when you first attempted intercourse? (Please tick all that apply)

Vagina was too dry ☐
Vagina felt too tight ☐
Vagina felt too loose ☐
Area where stitched was painful ☐
Area around scar was painful when stretched ☐
Pain or discomfort on penetration ☐
Pain or discomfort on deep penetration ☐
Sudden involuntary loss of urine ☐
Sudden involuntary loss of bowels ☐
Wind from the vagina ☐
We had no problems ☐
Other ☐
Other (Please describe) ☐

Q25 Since the birth of your baby, do you feel that intercourse is:

More pleasurable than before ☐ Less pleasurable ☐ Same as before ☐

Figure 22: Reasons for not attempting sexual intercourse: an extract from the mother's questionnaire



Q26 If you have not tried to have intercourse, is this because? (Please tick all that apply)

You have no partner ☐
Partner not interested ☐
Partner too tired ☐
You are not interested ☐
You are too tired ☐
Lack of privacy ☐
Baby is demanding ☐
You are afraid it might be painful ☐
Partner is afraid it might be too painful for you ☐
You are worried that you might become pregnant ☐
Fear or concern that it may disrupt the healing ☐
Other ☐
Other (Please describe) ☐

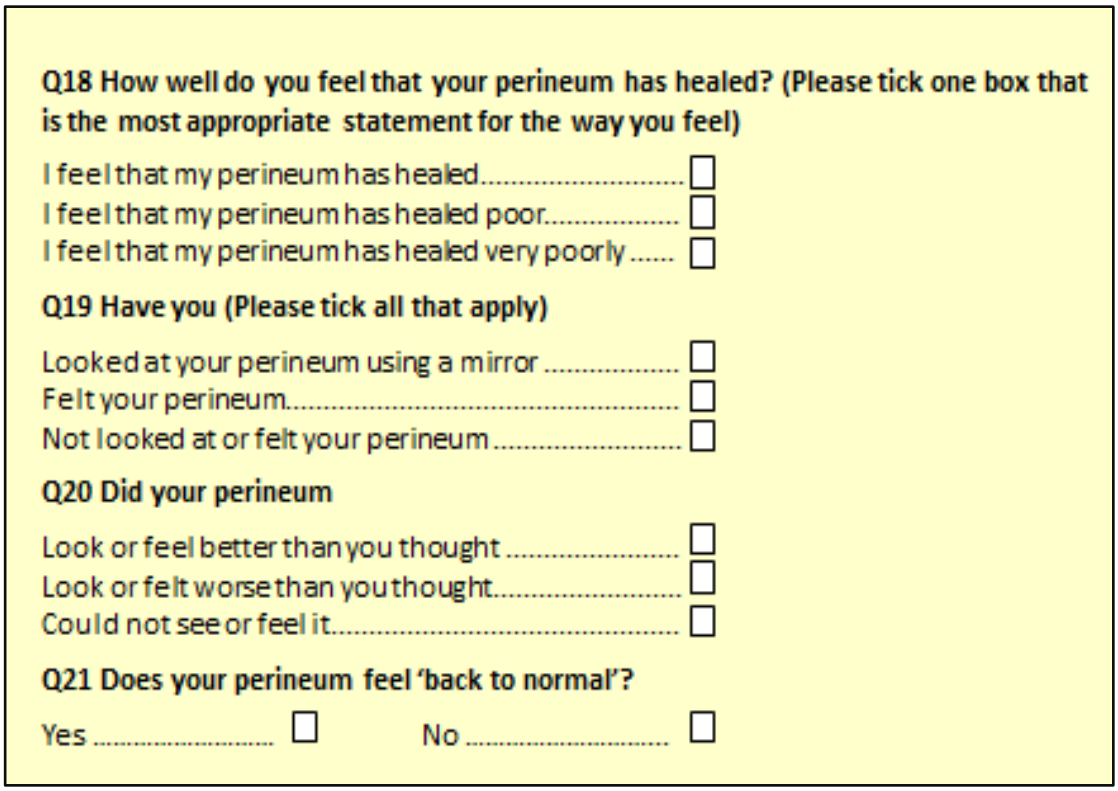
Breast feeding rates

Women were asked at the three time points if they had breast fed their babies since childbirth; if they responded yes, they were then asked if they were they still feeding at completion of the 6 week, three month and six month questionnaires. Additional questions were asked in relation to reasons for stopping breast feeding. Women who chose to formula feed their babies were also asked if their perineum was too uncomfortable or painful at any time to allow them to feed their baby. Comparative data for breast feeding rates between the two groups were then provided.

Aesthetic results of wound healing

Women's satisfaction with the aesthetic results of wound healing was self-reported by women at 6 weeks, three months and six months following randomisation in to the study (figure 23).

Figure 23: Women's satisfaction with wound healing: an extract from the mother's questionnaire



Q18 How well do you feel that your perineum has healed? (Please tick one box that is the most appropriate statement for the way you feel)

I feel that my perineum has healed ☐
I feel that my perineum has healed poor ☐
I feel that my perineum has healed very poorly ☐

Q19 Have you (Please tick all that apply)

Looked at your perineum using a mirror ☐
Felt your perineum ☐
Not looked at or felt your perineum ☐

Q20 Did your perineum

Look or feel better than you thought ☐
Look or felt worse than you thought ☐
Could not see or feel it ☐

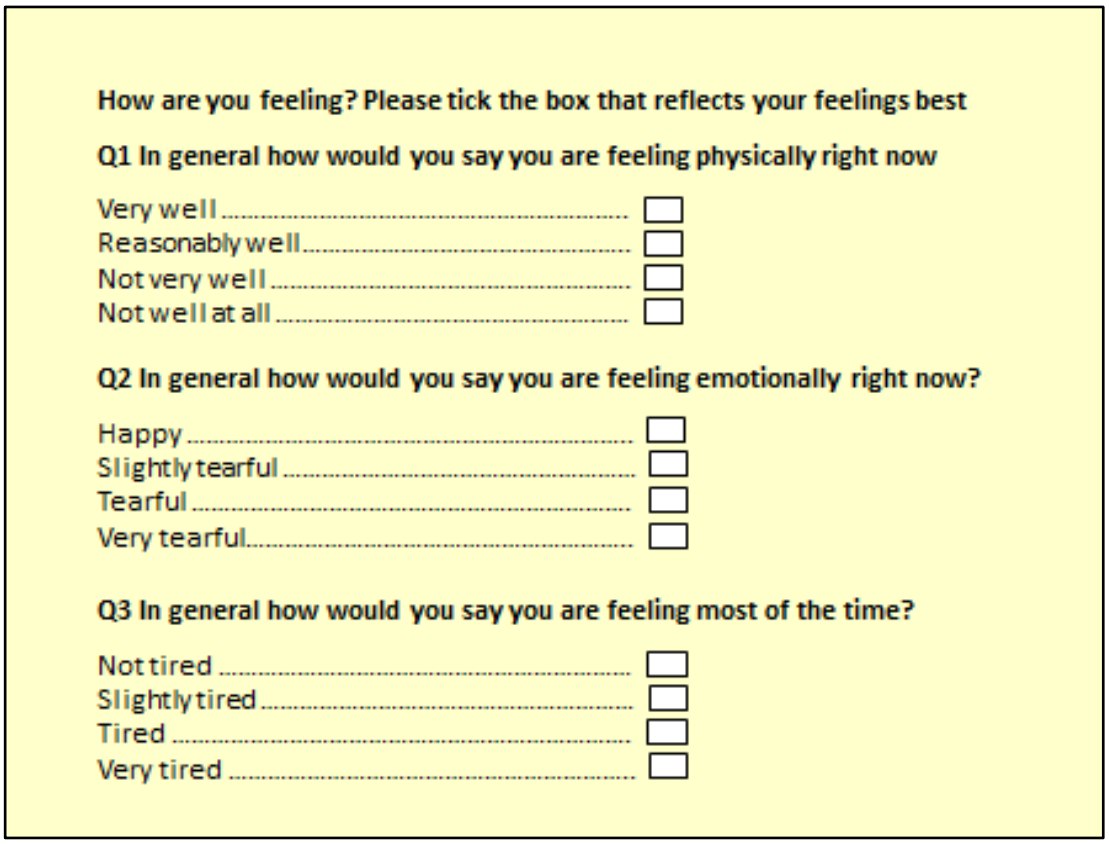
Q21 Does your perineum feel 'back to normal'?

Yes ☐ No ☐

Women's physical and emotional health

Although not a pre-specified outcome measure, women were also asked to comment on their physical and emotional health (figure 24). As there remains no gold standard questionnaire to assess women's physical and emotional health following childbirth the questions asked were adapted from the Short Form (36) Health Survey (Ware and Sherbourne, 1992). This is a patient-reported survey of their health status and has been used in previous obstetric studies investigating the management of perineal repair (Kettle *et al*, 2002).

Figure 24: Women's physical and emotional health: an extract from the mother's questionnaire



How are you feeling? Please tick the box that reflects your feelings best

Q1 In general how would you say you are feeling physically right now

Very well ☐
Reasonably well ☐
Not very well ☐
Not well at all ☐

Q2 In general how would you say you are feeling emotionally right now?

Happy ☐
Slightly tearful ☐
Tearful ☐
Very tearful ☐

Q3 In general how would you say you are feeling most of the time?

Not tired ☐
Slightly tired ☐
Tired ☐
Very tired ☐

5.5.8.7 Measuring compliance with the recommended methods and materials for the secondary perineal repair

An operative record sheet was developed in collaboration with a number of the recruiting sites for the purpose of the RCT and personalised with individual organisational logos (appendix 14). The operative sheet was printed on carbon copied paper; the top copy retained in the hospital records and the duplicate copy returned to the site file to facilitate monitoring and audit of protocol compliance in relation to the methods and material used.

The pilot RCT allowed for the project team to consider whether there was evidence of a learning curve effect in relation to secondary repair of the dehisced wound by allowing the research team to consider any evidence that suggested variations in the intervention between surgeons that may affect either delivery of the intervention and or outcomes. In a paper which focused upon problems and solutions when conducting RCTs in surgery, the learning curve effect was referred to as the variability in the intervention over time ('learning curve effects') or between surgeons, and the related problem of fidelity and quality control (McCulloch *et al*, 2002). Any evidence of a learning curve effect would demand careful consideration towards the level of education and training required for the full scale RCT (Craig *et al*, 2008).

An audit of compliance with the suturing methods and materials is presented in the following chapter, section 6.2.10.2 and table 39.

5.5.9 Data analysis for the RCT

Recruitment and attrition rates (overall and at each site) and the proportion of women with a healed wound at 6-8 weeks were calculated and precision of these estimates expressed using 95% confidence intervals. A series of sample size calculations for a definitive RCT will then be performed incorporating these interval estimates.

Completed data was scanned into a bespoke database by the Market Research Group at Bournemouth University and then imported into SPSS for statistical analysis. The scanning process was witnessed by both the trial co-ordinator and the trial statistician. Participant records were anonymised in the SPSS file which detailed only the randomisation number as a study code identifier for each participant. To ensure that analysis was blinded to treatment allocation the intervention was not added to the SPSS database. The completed database was then supplied to the research team for analysis, carried out under the supervision of the trial statistician.

Prior to statistical analysis all the data in the SPSS file was subject to an additional data quality check with hard copies of all completed questionnaires. Data checking and editing was also conducted looking at frequency distributions and inconsistency in data items to identify data points for further examination.

Primary analysis was conducted on an intention-to-treat basis (ITT). This method of analysis includes all participants randomised according to treatment allocation and disregards anything that happens after including non-compliance, protocol deviations and study withdrawal (Gupta, 2011; Newell, 1992). ITT analyses are generally preferred, as primarily they are the least biased approach and secondly

because they address a more pragmatic and clinically relevant question (Higgins *et al*, 2011b).

Data analysis was conducted by the author of this thesis. Professor Peter Thomas, Director (Methodology) Bournemouth University Clinical Research Unit and Consultant for the NIHR Research Design Service and Dr Zoe Shepphard, Research Fellow in Research Methods, Research Design Service Consultant, Bournemouth University Clinical Research Unit, supervised the data analysis.

Comparisons were made between the interventions (immediate secondary repair versus expectant management). Baseline characteristics of the comparative groups were summarised using standard descriptive statistics, namely the mean, standard deviations and percentages. Chi-squared significance tests were conducted on dichotomous data to assess if one intervention was more effective than another. For the analysis of non-dichotomous variables a range of appropriate statistical tests were applied. In the case of ordinal data, relating to pain for example (mild, moderate and severe pain), the Chi squared test for trend was used. Continuous data (length of second stage) were analysed using *t-t*ests (parametric) where the data was normally distributed or the Mann-Whitney U test the non-parametric equivalent of the independent *t*-test which does not assume normal distribution of the sample.

The primary outcome, 'the proportion of wounds healed at 6-8 weeks' was compared between the 2 groups. The intention was to use a logistic regression model that incorporated the study site as a variable (since randomisation was stratified by site). Precision of estimates of effect size were summarised using 95% confidence intervals.

Results from the analysis are presented in chapter six using tables, charts and forest plots and represent a format that will facilitate inclusion in future systematic reviews.

5.5.9.1 Measures to limit loss of follow-up

Strategies were developed to avoid attrition bias which refers to systematic differences between groups in withdrawals from a study (Higgins *et al*, 2011a) by ensuring that data relating to the primary outcome measure for both groups was as complete as possible at all-time points. Specific approaches included: reminder letters and telephone phone calls to offer alternative clinic dates, liaising with community midwives and offering home visits where appropriate. Similar strategies were developed to also ensure that data on secondary outcome measures assessed using postal questionnaires at six weeks, three months and six months were as complete as possible. This was a crucial consideration in the follow-up phase as non- response rates to postal questionnaires can reduce the effective sample size and introduce attrition bias (Edwards *et al*, 2002).

The first page of each participants questionnaire comprised of an introductory letter; essential for not only 'selling' the questionnaire but also for communicating the credibility of the RCT to the respondents (Douglas *et al*, 2005). Women were reminded that their personal responses were both confidential and important to the study and that by sharing their experiences with us will help to decide which method of care is best for future mothers. Pre-paid stamped white addressed envelopes were provided and the return address was also given at the end of the questionnaire, should the woman mislay the envelope attached. Two contact numbers were provided for respondents to call if they had any queries about the RCT, or completing the questionnaires. All participants were also provided with an additional 24 hour contact telephone number. Women who failed to return the initial

copy of the questionnaire were contacted by telephone to confirm their address and a further copy posted. Only one attempt was made to contact non-respondents for their six weeks, three and six month questionnaires out of respect for their privacy and in accordance with the ethics committee approval, but also to ensure as Nakash *et al* (2006) point out that the women and their families do not feel harassed by continued follow-up efforts.

5.6 The methodology for the qualitative phase of PREVIEW

5.6.1 Study setting and population for the interviews

All women invited for interview had previously been recruited into the RCT. In-depth, semi-structured interviews were conducted with consent (appendix 15). The interviewee chose the interview site which was either in the home environment or a designated area within the hospital setting. The use of the interviewer's workplace privileges the interviewer and his or her project whilst the choice of the interviewee's home conversely invites the interviewer into his or her private life, shifting the balance of power (Manderson *et al*, 2006).

5.6.1.1 Letters of access to conduct the interviews

Research governance procedures required letters of access to recruiting organisations if the interviews were conducted in the hospital setting and these were obtained where appropriate. However, all women chose to be interviewed in their home.

5.6.2 Sample Size for the interviews

A sample of women were invited for interview using a purposive sampling technique from women who had been recruited into the RCT. Purposive sampling was adopted by Williams *et al* (2005) in their qualitative study, referred to in the literature

review (chapter 2) and is used in phenomenological research because it selects individuals who will have knowledge of the phenomena concerned (Clifford, 1997). It is generally acknowledged that sample sizes in phenomenological research are small and that each personal experience is examined in some depth (Carpenter, 1999; Cluett and Bluff, 2006). The author of this thesis intended to interview 12 women; six women who were randomised to the re-suturing group and six women randomised to healing by expectancy. However the final number of participants was also linked to data saturation (further explained in section 5.6.7).The consent form developed for the purpose of the RCT had a question designated to asking women to initial the box if they would consider taking part in a recorded interview. Geographical convenience also influenced women approached for interview, with cost and time being the main reason women were interviewed at locations more locally to the interviewer.

5.6.3 Recruitment and eligibility criteria for the interviews

Women were eligible to participate in the interviews if they had taken part in the RCT and detailed their consent to be contacted by initialling the box on the consent form for the RCT.

5.6.4 Exclusion criteria for the interviews

Women were excluded from the interviews if they did not provide their written consent to participate.

5.6.5 Consent for interviews

Women who agreed to take part in the interview process were initially contacted by telephone to confirm their continued consent to participate. A detailed information booklet was then posted to their home address several days prior to the interview. Women were then asked to sign a consent form of which they received a copy; a

copy was also retained in the woman's hospital records and a further copy in the research site file (the interview consent form and the interview information leaflet are provided as appendices 15 and 16 respectively).

5.6.6 Training in qualitative methodologies

In addition to completing a postgraduate certificate in research methodologies, the author of this thesis attended a two day intensive in-depth interviewing workshop and a two day course relating to the analysis of qualitative interviews.

The in-depth interviewing workshop was crucial towards addressing interview techniques. The knowledge gained, 'addressing silences' for instance, a particular personal weakness, proved instrumental towards successful interviewing. Barbour (2008) recognises that dealing with silences can prove uncomfortable for novice researchers, but that these pauses give time for the interviewee to consider the question even though they may at times seem endless to the interviewer lacking in confidence. Adopting a pause and wait approach is suggested by Trochim (2006) who suggests that in this way you are more respectful of the interviewee as opposed to finishing their sentence, which implies that what they had to say is transparent or obvious, or that you don't want to give them the time to express themselves in their own language (Trochim, 2006). Reflective journal extracts (appendix 18) illustrate the author's ability to manage silences, but equally highlight the emotional risks of conducting interviews with participants when the interviewer has developed a relationship with the interviewee.

The use of a reflective journal created an audit trail of personal experiences, reasoning, judgement and reactions of the sometimes emotive accounts related by the women, thereby enhancing ethical and methodological rigour the study (Smith, 1999). The journal is further discussed in section 5.6.8.2 of this current chapter.

The author of this thesis was particularly conscious of her professional role as a midwife and her abilities to be able to retain the purpose of the interview, particularly if the woman began to reflect on her childbirth experiences as opposed to the phenomenon being explored. Similarly, the skills gained from the interactive group work at the in-depth interviewing course, clearly came to fruition. The journal extracts (appendix 18) demonstrate her personal abilities as a reflexive interviewer by quickly 'reflecting in action', to ensure that the purpose of the interviews were retained.

The qualitative phase of the study was supported throughout by researchers experienced in the field of qualitative methods.

5.6.7 Data collection for the interviews

A semi-structured interview guide (appendix 17) was used in the collection of data and facilitated the exploration of women's experience of both perineal wound breakdown and participating in the study. Content validity for the interview guide was gained by a review of the literature, clinical experience of both the research team and fellow midwifery and obstetric colleagues and two patient representatives. The interview guide was particularly helpful as a researcher new to the field of interviewing. As van der Putten (2008) found in her study on 'the lived experience of newly qualified midwives,' it ensured that all participants were asked the same questions, allowed for good use of limited interview time and made interviewing multiple participants more systematic and comprehensive, with the opportunity for both flexibility and probing. All interviews were conducted by the author of this thesis and digitally recorded with the participants consent. Each interview was commenced by engaging in social conversation (thanking them for their time and allowing the researcher into their home; enquiring about their baby) with the aim of creating a relaxed and trustworthy atmosphere (Moustakas, 1994).

Questions raised with each of the women reflected the secondary outcome measures of pain, dyspareunia, breast feeding rates and satisfaction with the aesthetic results of wound healing assessed in the trial questionnaires, in addition to exploring their experiences of participating in the RCT.

Interviews continued until data saturation was reached, confirmed by both the interviewer and a member of the qualitative research support team. Saturation being when no new information was being revealed (Morris and Burkett, 2011).

5.6.8 Qualitative data: transcription and analysis

5.6.8.1 Transcription

The services of a professional transcribing company were factored into the original grant application and were therefore utilised for each interview. Time was still needed to correct spellings and text possibly due to dialect and occasional background noise and to repeatedly listen to the audio recordings to ensure an accurate transcript of the interview. Repeated listening to the audio recordings and reading the transcripts allowed the author of this thesis to become familiar with the data. The transcript was also annotated in parts, highlighting laughter or expressions that were not detailed in the transcript that may affect the interpretation of the transcribed text (Ziebland and McPherson, 2006). On the advice of one of the research supervisor's each line was numbered to facilitate the process of coding and analysis.

All interview transcripts were analysed for experiences of taking part in the RCT and emerging themes by the author of this thesis. The findings were then discussed and agreed upon with a member of the research team providing qualitative research

support. Incorporating this level of objectivity increased the credibility to the analysis phase of this study

Characteristics of the participants including age, employment, ethnicity, number of vaginal deliveries, previous perineal trauma and wound dehiscence, method of delivery, randomisation allocation and the postnatal day of wound dehiscence were also recorded and are presented in the following chapter (table 40).

5.6.8.2 Qualitative data analysis using Giorgi's phenomenological method

Following a critical evaluation of the commonly referred to frameworks for the analysis of qualitative data using a Husserlian phenomenological approach (Colaizzi, 1978; Giorgi, 1985; Van Kaam, 1966) and after much deliberation, a decision was made to follow Giorgi's phenomenological method. Using an established framework to provide a degree of structure and guidance to aid analysis of the data proved invaluable, particularly as the author of this thesis was new to the field of qualitative research.

Personal reasons for choosing Giorgi's phenomenological method are similar to those of Whiting (2001) and are summarised below:

- Giorgi (1970) focuses on descriptions of experiences and follows the Husserl tradition; the qualitative phase of PREVIEW focused upon women's descriptive experiences of perineal wound dehiscence and taking part in the RCT
- Quality of data, as opposed to quantity of data is emphasised (Giorgi, 1970)
- The phenomenological method offered by Giorgi (1975) appeared understandable and applicable to this phase of PREVIEW. He suggests that consideration should be given to the same phenomena (dehisced perineal wounds) as it manifests itself to individuals (new mothers). The method does not require the adherence to certain fixed criteria, for example Van Kaam (1966)

who advocates that a large sample population is drawn on or Colaizzi (1978) who requires revalidation of the data with the participants

- Various studies obstetric and non-obstetric related appear to have used this approach with success (Ashworth and Hagan, 1993; Billhult *et al*, 2007; Enriquez *et al*, 2004; Ericksen and Henderson, 1992; Murtagh and Folan, 2014)
- Giorgi (1975) analysed and developed Husserl's phenomenological approach and his method included a data analysis process**.**

An outline of the four basic stages associated with Giorgi's methods of data analysis is provided by Polit and Beck (2008, p. 520) table 16.

Table 16: An outline of the four basic stages associated with Giorgi's method of data analysis

An outline of the four basic stages associated with Giorgi's method of data analysis (Polit and Beck, 2008, p. 520)	
1	Reading all of the interview material to obtain a 'sense of the whole'
2	Identify the 'meaning units' or commonalities, within the descriptive data
3	Determining and describing the relevance of each of these meaning units
4	Bringing together the experiences of the participants in a statement that is consistent with the interview material

Applying Giorgi's Phenomenological method

An important concept of the initial data analysis is phenomenological reduction (or bracketing) referred to previously in section 5.3.2 of this current his chapter. Husserl referred to the word 'epoché' to describe phenomenological reduction, with the aim being the suspension of belief in the 'outer world' which prevents the researcher from making any judgements or having any pre-conceived ideas (Husserl, 1960). The researcher sets aside prejudgements and opens the interview with an unbiased, receptive presence (Moustakas, 1994).

Whilst accepting some of the discourse that surrounds the practicalities of this concept (Hamill and Sinclair, 2010; Snow, 2009; Somers-Smith, 2001) the author of this thesis chose to consciously explore her personal attitudes and beliefs towards the management of perineal wound dehiscence by the use of a reflective journal (appendix 18). This reflexivity as acknowledged by others then facilitated the evaluation of oneself, including how this may have influenced question phrasing, data collection and analysis, whilst also providing a verifiable audit trail of the research process (Chan *et al*, 2013; Hamill and Sinclair, 2010; Jasper, 2005; Snow, 2009; Wall *et al*, 2004). It is argued that reflective writing is so central to the methodological processes within research studies that it should be recognised as an essential part of their methodology (Jasper, 2005). The accounts within the reflective journal should then build up a relationship between the writer and the reader (Ghaye, 2007) demonstrated in this thesis with personal extracts from the journal entries made by the author (appendix 18).

Using the one sheet of paper approach

To facilitate the analysis of data the researcher adopted the 'one sheet of paper approach' (OSOP) described by Ziebland and McPherson (2006) and used by social scientist researchers at the DIPEx (Database of Individual Personal Experiences of health and illness) research group, University of Oxford, UK. Following stage one of Giorgi's method of data analysis outlined in table 16, this necessitated the use of a large single sheet of paper (A3 size) to extract all the various issues raised by the women interviewed. Each extract was then represented by the woman's identification code 1-6, the sequence order of the interviews (Appendix number 18 presents an A4 size replica of the OSOP used for the analysis). The process was continued until all issues were noted on the paper. Commonalities appearing in the data, stage 2 of Giorgi's analysis, were then grouped into broader themes and where necessary sub-themes. The author of this thesis then described the relevance of each of these themes in relation to the phenomenon being investigated (dehisced perineal wounds). The main themes and sub-themes revealed from the analysis, which underpin women's experience of living with a dehisced perineal wound and taking part in the RCT will then be presented in chapter six. Individual extracts from the interview transcripts are used to validate the research findings. Chapter seven discusses the findings of the qualitative study in light of the relevant literature.

5.6.9 Rigour of the qualitative phase of PREVIEW

Qualitative rigour must be visibly and systematically considered from the outset of the study (Cluett and Bluff, 2006). Credibility, transferability, dependability and confirmability, are four quality measures suggested by Lincoln and Guba (1985) and are reflected throughout the reporting guidance for qualitative research in COREQ guidance (Tong *et al*, 2007). They are commonly referred to by researchers in attempts to establish trustworthiness of their qualitative findings. The author of this

thesis adopted both the well-structured framework of Lincoln and Guba (1985) and the COREQ guidance (Tong *et al*, 2007) to demonstrate the quality and rigour of this phase of PREVIEW discussed in more detail in the next section.

Credibility

Faithful, honest descriptions of women's experiences are presented in the following chapter and references to the interviewer's own experiences in relation to that of women will be made. Adhering to a process that creates honesty and transparency is crucial towards ensuring credibility in the research findings (Hamill and Sinclair, 2010) presented in chapter six and discussed further in chapter seven. Acknowledgements are also provided that avoiding complete personal opinions at all times was not achievable by the author of this thesis (the interviewer) due to her close engagement with the whole research process and the participants. This fact is recognised by Tong *et al* (2007) in COREQ, domain one of three: the research team and reflexivity. However, extracts from a reflective journal and bracketing, referred to above demonstrate that to the best of her knowledge the author of this thesis has not influenced either the collection or analysis of the data.

Applicability/transferability

A study is considered applicable when the findings can be applied to other settings that are of a similar context outside the study situation, allowing comparisons to be made (Gethin and Clune-Mulvaney, 2009; Ryan-Nicholls and Will, 2009; Shenton, 2004). Readers are then able to view the findings as meaningful in terms of their own experience (Gethin and Clune-Mulvaney, 2009; Ryan-Nicholls and Will, 2009).

Auditability/dependability

Similar to the RCT the author of this thesis has endeavoured to ensure that each step of the study process for the qualitative phase of PREVIEW is openly explicit to enable the future replication of the study by other researchers. This is an important consideration to ensure that auditability in qualitative studies can be achieved (Ryan-Nicholls and Will, 2009; Shenton, 2004).

Confirmability

It is apparent from the literature that in order to achieve confirmability, then credibility, applicability and auditability must be accomplished (Gethin and Clune-Mulvaney, 2009). Researchers must take steps to demonstrate that findings emerge from the data are not prejudiced by their own biases (Shenton, 2004). The key findings presented in chapter six from exploring women's experience of perineal wound dehiscence are purely from the descriptive accounts of the women themselves. Open and honest personal opinions when recognised were both acknowledged and set aside. These can be demonstrated in journal extracts and have not influenced the analysis of the transcripts or the presentation of the results.

5.7 The study protocol

The research protocol was developed in collaboration with specialists in the field of perineal care including: obstetricians, midwives, statisticians, a qualitative research fellow, anaesthetists, service users, the West Midlands Research Design Service team and the research committee at Staffordshire University. The PREVIEW protocol was published on line in British Medical Journal Open (Dudley *et al*, 2012).

Electronic and paper copies of the protocol were available in all recruiting units in all relevant clinical areas and departments. The protocol became a frequent reference source for clinicians and researchers alike and contained the following information: the study background, the rationale for the design and methodology, the research question, aims and null hypothesis, inclusion and exclusion criteria, consent and randomisation details; the implementation, data collection and analysis strategies and the plans for publication and dissemination. Standard operating procedures for the trial interventions and all trial questionnaires were included as appendices to the protocol. All trial documents were version managed; any amendments were subject to research ethics committee and local research and development approval.

5.8 Consumer participation: Consultation and collaboration

A review by Staley (2009) found that public involvement was reported to be of particular value in clinical trials where it helped to improve trial design and ensured the use of relevant outcome measures. Members of the PREVIEW team worked closely with a group of consumers both in the UK and Brazil, who have been crucial in determining outcomes considered to be important for women's health research using a multiple iteration Delphi methodology (Perkins *et al*, 2008). Several of these outcomes were used in determining the primary and secondary outcome measures for the RCT.

As PREVIEW was a pilot and feasibility study, it was particularly important that service users were actively involved in the design and the management of this study. Two women with previous experience of perineal wound dehiscence were invited to sit on the Trial Steering Committee during the project lifetime and work in collaboration with research team from reviewing protocol documents to dissemination of the results. Service users collaborated in checking information prepared for the study participants to ensure lay understanding. A member of the

project team with expertise in patient and public involvement in research provided support and mentorship to the lay members of the project team.

Through personal clinical contact, a small cross section of women prior to and following childbirth were approached to comment upon the information leaflet designed for the RCT. Guidelines on best practice for patient and public involvement in research were followed (Involve, 2009).

Local press and radio raised an awareness of the study when both funding awards were received.

5.9 Data protection

All personal and identifiable data collected for both phases of this study were kept strictly confidential. All research data and information retained was kept in locked cupboards only accessed by members of the research team.

Any identifiable data was kept to a minimum and records when used were anonymised where possible. All electronic personal data was stored securely on an encrypted computer and encrypted safe stick where password access is required. The data that could potentially identify the study participants was protected at all times. No individual names or details that would specifically identify individuals were included in any publications or conference presentations both throughout the course of the study or following. All reports both published and unpublished disguised the identity of specific individuals.

Primary research data, questionnaires, audio recordings were archived in their original form at the UHNS in accordance with the Medical Research Council's (MRC) Personal Information in Medical Research (Medical Research Council,

2000); the MRC Good Research Practice (Medical Research Council, 2005) and the relevant ethics committees. The MRC recommend that research records relating to clinical studies should be retained for 20 years to provide scope for longer follow-up if necessary (Medical Research Council, 2000; Medical Research Council, 2005).

5.10 Trial set up and monitoring

5.10.1 Trial set up and site file management

A research site file was provided for each recruiting unit by the lead research midwife for the study at the site initiation visit. The contents of the site file followed the National Institute for Health Research guidance template for site file management (National Institute for Health Research, 2011). Each recruiting unit was responsible for maintaining their own site file.

5.10.2 Trial monitoring

5.10.2.1 Trial Steering Committee (TSC)

A TSC was convened by the lead midwife to provide overall supervision of PREVIEW and adhered to the Medical Research Council Guidelines for Good Clinical Practice (Medical Research Council, 1998). The TSC provided advice through its independent chairman to the Chief Investigator, the Principle Investigators at the research sites and the sponsor. Involvement of independent members who were not directly involved in other aspects of the study provided protection for both the trial participants and the Chief Investigator.

A TSC Charter was developed by the lead midwife in collaboration with the research team for the purpose of PREVIEW and reflected guidelines for Good Clinical Practice (Medical Research Council, 1998).

5.10.2.2 Data Monitoring Committee (DMC)

An independent data monitoring committee (DMC) was convened for PREVIEW by the sponsor organisation.

The DMC were an advisory committee to the TSC and were the only body involved in the study that had access to the comparative data. The DMC consisted of following three members:

- Mr Christopher Foy, Research Design Service, South West Gloucester Office, Gloucestershire Royal Hospital. Mr Foy is a statistician and acted as chair of the DMC. Mr Foy had previous experience of DMC membership and chairing DMC meetings
- Professor Debra Bick, Professor of Evidence Based Medicine, Kings College, London. Professor Bick also has clinical expertise in the field of perineal care
- Professor Mike Wee, Senior Consultant Anaesthetist, Poole Hospital, NHS Foundation Trust, Poole, Dorset.

The role of the DMC was to monitor trial data and make recommendations to the TSC on whether there are any safety reasons why the trial should not continue, including monitoring evidence for treatment harm e.g. serious adverse events.

The safety, rights and wellbeing of the trial participants was paramount throughout the study. The DMC met 14 months into trial recruitment and did not consider that an interim analysis of data was necessary.

A Standard Operating Procedure (SOP) for the DMEC was developed specifically for phase four of PREVIEW. The SOP followed both the Medical Research Council guidelines for the DMC (Medical Research Council, 1998) and the template produced by the Data Monitoring Committees: Lessons, Ethics, Statistics (DAMOCLES) Study Group (Data Monitoring Committees Lessons Ethics Statistics Study Group, 2005). Recommendations from the ICH Harmonised Tripartite Guideline, for Good Clinical Practice were also referred to in the SOP (International Conference on Harmonisation, 1996). The lead midwife for PREVIEW had delegated responsibility from the Chief Investigator for calling and organising the DMC meetings in collaboration with the Chair of the DMC.

5.11 Health economic evaluation

The research team acknowledged that the effectiveness in terms of resources, costs and benefits to both the NHS and women themselves of any new interventions or treatments are an essential component of any research study. However, due to the financial resources and timelines for PREVIEW, a full health economic evaluation was outside remit for the study. There is the potential though for data on health resource use to be collected at a later date including re-admissions for corrective surgery and referrals for complications associated with either re-suturing or expectancy.

5.12 Conclusion of chapter five

This current chapter has presented a clear rationale for the mixed methods design and a detailed, explicit and critical analysis of the methodological approaches used for each paradigm.

The following chapter will now present the findings from both the quantitative and qualitative studies conducted as phase four of PREVIEW. The CONSORT guidance for the reporting of clinical trials and the COREQ guidance for the reporting of qualitative research will be used to ensure a transparent and systematic approach towards reporting of the results for each phase of the study.

CHAPTER SIX:
RESULTS FOR PHASE FOUR OF THE PREVIEW STUDY

6.1 Introduction

Chapter six will present and describe the results of both the quantitative and qualitative paradigms in a systematic and detailed way. As the mixed methods were conducted sequentially, the results will also be organised consecutively. The results of the pilot and feasibility RCT will be presented in the first part of this chapter followed by the interview findings conducted as part of the qualitative study.

The aim of the pilot and feasibility RCT was to assess the feasibility of conducting a definitive RCT comparing the effectiveness of re-suturing dehisced perineal wounds versus expectant management.

To determine whether a full scale study can be conducted it was essential that a comprehensive assessment of key parameters was completed. Data relating to trial recruitment experiences, numbers of women who fulfilled eligibility criteria, adherence to methods and materials for re-suturing, clinical follow-up rates for the assessment of wound healing and both response rates and completion of questionnaires are therefore presented in this chapter.

A power calculation was conducted for the pilot RCT and statistical analysis techniques of the data, described in chapter five of this thesis have been tested as part of the pilot and feasibility design of the study. Preliminary evidence of the effectiveness of treatment options is provided in this chapter. Analysis of the data was conducted on an intention to treat (ITT) basis and the results are presented

around the feasibility outcome measures for the study. Frequency tables, bar charts and forest plots are used to illustrate the data throughout this chapter. Effect sizes for the feasibility outcomes are presented as 95% confidence intervals. Discussion relating to the inclusion of outcome measures and the use of descriptive and inferential statistics for the pilot and feasibility study is provided in section 7.2 of the following chapter.

The aim of the qualitative phase was to explore women's personal experiences of perineal wound dehiscence and taking part in the RCT, to ensure that specific outcomes, important to women are addressed in future research. Key themes that have emerged from the analysis of the interview transcripts will be revealed and illustrated by using quotations from the women themselves.

This chapter will conclude with an overall summary of the main study findings. Further discussion of the results from both research paradigms will then be provided in chapter seven.

6.2 Quantitative results of the pilot and feasibility RCT

6.2.1 Recruitment

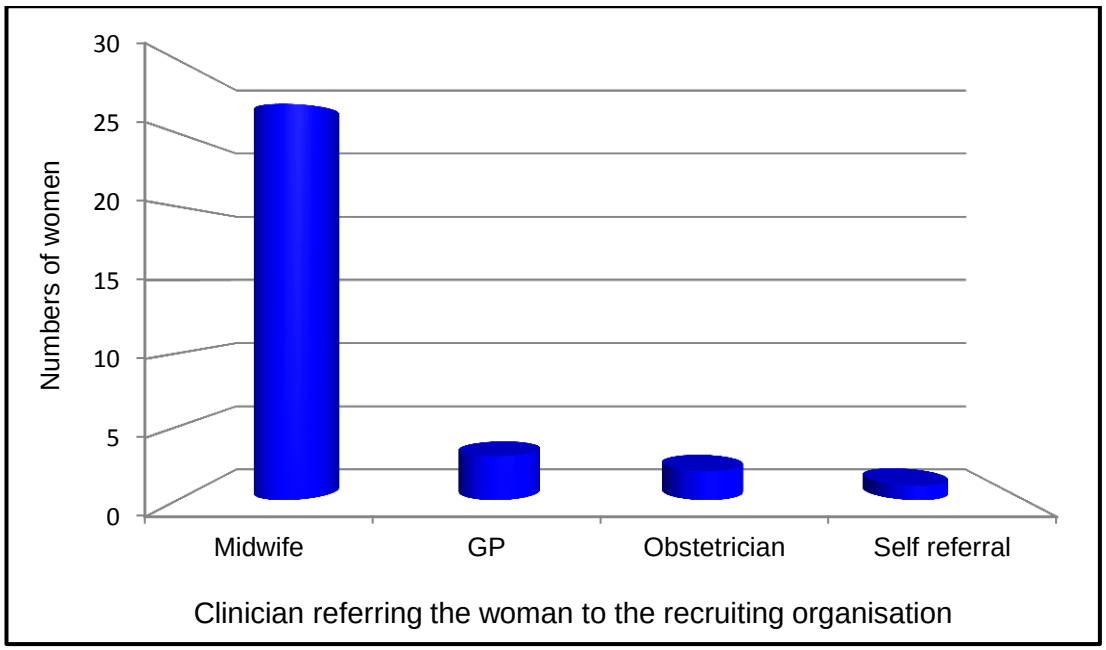
Recruitment for PREVIEW commenced on the 25th July 2011; the initial recruitment period was for 18 months. Target recruitment was less than expected after 7 months of recruitment and the Trial Steering Committee (TSC) provided the Data Monitoring Committee (DMC) with a progress report at this time point and again prior to a formal meeting with the DMC on the 28th September 2012. The DMC were provided with a presentation by trial co-ordinator (the author of this thesis) relating to recruitment figures, recruitment strategies and reasons for non-randomisation of eligible women into the study. Following the meeting and in recognition of the

concerted efforts to improve recruitment figures, the DMC supported the TSC to request a formal study extension of 12 months to the National Institute for Health Research, Research for Patient Benefit Programme. The DMC also supported the TSC decision to reduce the target recruitment figure to forty. The formal extension request which allowed for an additional 6 months of recruitment and an additional 6 months follow-up was subsequently approved. The Research Ethics Committee were informed of both the study extension period and the reduction in target recruitment, both were formally processed as minor amendments to the study. The UK Clinical Research Network portfolio study database was amended accordingly. Barriers towards recruitment, strategies implemented to achieve targets and the final recruitment figures are discussed in chapter seven. Recruitment ended on the 25th July 2013 and the last participant 6 month questionnaire was returned at the end of January 2014.

Four sites commenced recruitment on the 25th July 2011 with the remaining six sites becoming active at various time points. One site withdrew from the study in February 2013 due to a lack of a full research team to deliver the study.

In the two year recruitment period 321 women were referred to the recruiting sites by various clinicians and were assessed for eligibility as detailed in chapter five. As part of the trial entry documentation, data was collected on the profession of the clinician who referred the woman to the recruiting organisation and is presented in figure 25.

Figure 25: Professional status of the clinician's referring women, with dehisced perineal wounds to the recruiting organisations who were subsequently randomised (2011-2013)

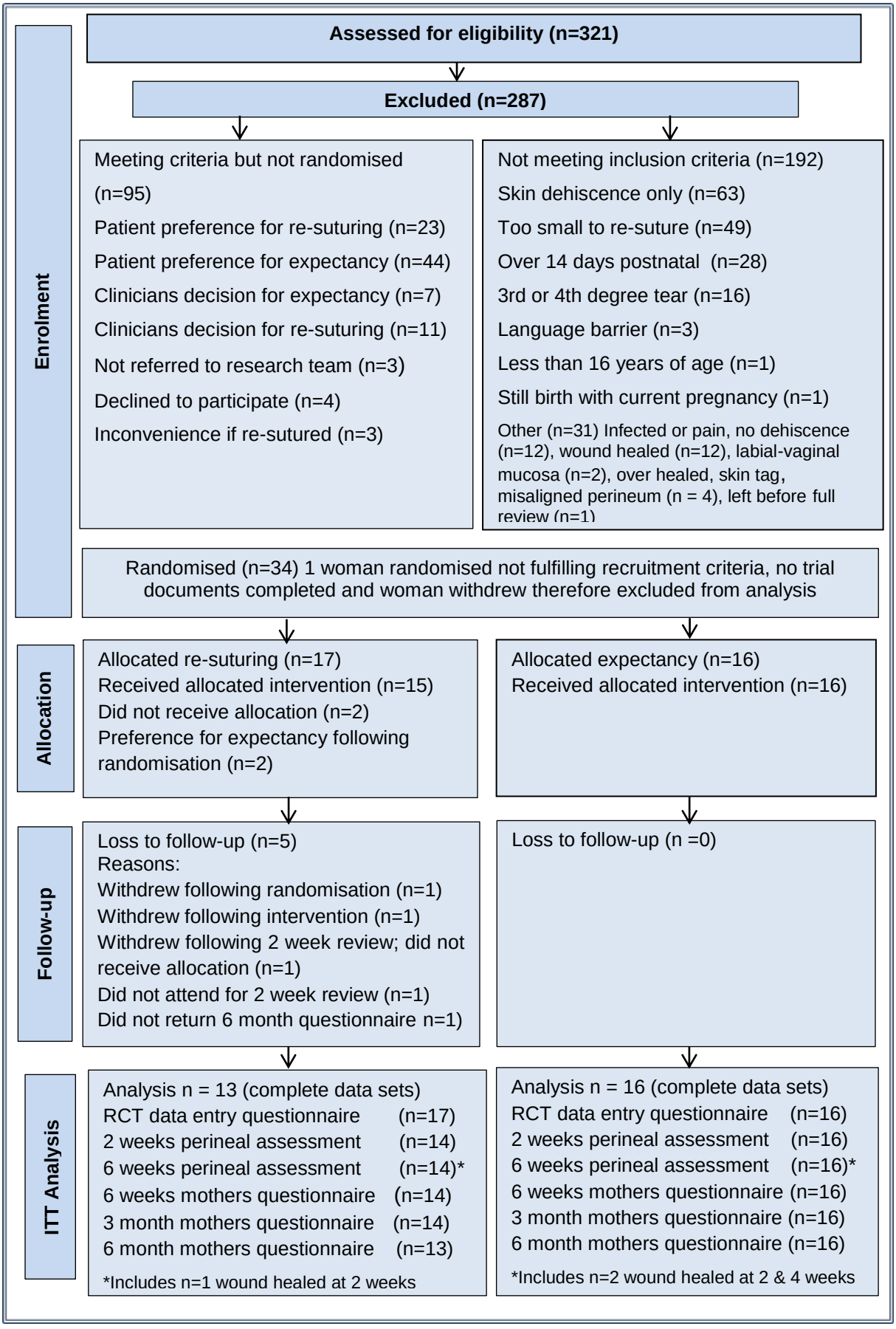


Women meeting the eligibility criteria but not randomised n=95 and women who did not fulfil the eligibility n=192.

Thirty three participants were correctly randomised to the RCT with 17 participants allocated the intervention of re-suturing and 16 participants allocated to expectancy. Therefore out of all participants who were eligible n=128 only 26% were randomised. One additional participant was randomised to expectant management with a skin dehiscence only, which was against protocol guidance. No baseline data and no trial questionnaires were completed by either the clinician or the participant who subsequently withdrew following randomisation. A decision was made in collaboration with the trial statistician to exclude this participant from the analysis.

The CONSORT flow diagram figure 26 outlines the progress through the RCT and includes: enrolment, treatment allocation, follow-up and analysis.

Figure 26: CONSORT flow diagram for the RCT 2011-2014



Research teams at each site were asked to retain comprehensive recruitment logs, table 17 therefore provides data of women recruited, women who fulfilled eligibility criteria but were not randomised and women who did not fulfil the eligibility criteria.

Table 17: Total numbers of women reviewed for eligibility criteria by clinicians at recruiting sites including: women randomised; women eligible but not randomised and women not eligible for randomisation (2011-2013)

Recruiting Site	Women reviewed (n)	Women randomised (n)	Women suitable but not randomised (n)	Women not suitable (n)
1	103	14	17	72
2	1	0	1	0
3	20	2	18	0
4	54	1	24	29
5	Included in randomisation schedule: site subsequently declined to take part			
6	62	4	15	43
7	5	1	4	0
8	15	5	7	3
9	2	1[†]	1	0
10	10	3	3	4
11	49	3	5	41

Site 5: Declined to take part due to lack of full research team
Site 9: Centre withdrew Feb 2013
[†]Randomised against protocol guidance

The main reason for non-randomisation of eligible participants in 74% of the cases (n=70) was patient preference for a treatment option. Almost a quarter of all women 24% (n=23) had a preference for re-suturing, whilst 50% (n=47) had a preference for expectancy. Similarly, clinicians were not always in equipoise with 12% (n=11) revealing a preference for re-suturing and 7% (n=7) for expectancy.

Whilst the main reasons for women not fulfilling eligibility criteria were: the dehisced area only involved the skin and not the muscle layer 33% (n=63) and that the dehiscence was too small to re-suture 25% (n=49).

6.2.2 Follow-up and analysis

All participants recruited into the RCT were included in the statistical data analysis unless they were lost to follow-up (n=5).

Out of the 17 participants in the re-suturing group, one withdrew following randomisation of the treatment allocation of re-suturing (allocation not received) and did not attend for either of her 2 or 6 week appointments to assess perineal healing or complete any of the mother's questionnaires at any time point. A further participant withdrew following the intervention of re-suturing and again did not attend for either of her 2 or 6 week appointments to assess perineal healing or complete any of the mother's questionnaires at any time point. Another participant withdrew following her 2 week review to assess perineal healing and did not complete any of the mother's questionnaires at any time point (allocation not received). One participant did not attend for her 2 week appointment, but the 6 week perineal assessment of wound healing was completed and all mother's questionnaires were duly returned. A fifth participant did not return her 6 month questionnaire.

One participant in the re-suturing group did not need to attend for a 6 week assessment of perineal healing. Similarly, two participants in the expectancy group did not need to attend for a 6 week assessment of perineal healing as their wounds had healed at two and four weeks respectively following randomisation

The primary outcome of time taken to heal was therefore assessed in 82% (n=14/17) of participants in the re-suturing group at 2 weeks and 6 weeks (the latter including the one wound healed at 2 weeks). In comparison in the group managed by expectancy this was 100% (n=16) at two weeks and 100% at 6 weeks (the latter including the two wounds healed at 2 and 4 weeks).

Secondary outcome measures (pain, dyspareunia, breast feeding, women's satisfaction of aesthetic results of healing) were assessed in 82% (n=14) of participants in the re-suturing group at 6 weeks and 3 months and 76% at 6 months. In comparison 100% (n=16) of women in the expectancy group returned their questionnaires at all pre-specified time points.

Complete data analysis at each pre-specified time points was available in 88% of all participants: 13 participants in the re-suturing group and 16 in the expectancy group.

Comparisons between the interventions (immediate secondary repair versus expectant management) are now presented in sections 6.2.3 to 6.2.9.

6.2.3 Baseline characteristics for both treatment groups

6.2.3.1 Baseline ante-partum and intra-partum clinical characteristics

A table demonstrating baseline ante-partum and intra-partum clinical characteristics for each group is provided in tables 18 and 19 respectively.

Table 18: Descriptive statistics to demonstrate baseline ante-partum characteristics at trial entry, of RCT participants as recorded by clinicians in recruiting site: Comparative data between both treatment groups (2011-2013)

Baseline antepartum characteristics	Re-sutured (n=17) n (%)	Expectancy (n=16) n (%)	*P*-value[†]
Age (years)			0.460[L]
20-24	7 (41.2%)	3 (18.8%)	
25-29	3 (17.6%)	5 (31.3%)	
30-34	5 (29.4%)	7 (43.8%)	
35 and over	2 (11.8%)	1 (6.3%)	
Ethnicity[#]			0.007[F]
White	17 (100%)	10 (62.5%)	
Non- white	0 (0.0%)	6 (37.5%)	
BMI (NICE reference range, kg/m^2)[‡]			0.065[L]
Underweight: <18.5	0 (0.0%)	1 (6.3%)	
Healthy: 18.5-24.9	5 (29.4%)	10 (62.5%)	
Overweight: 25-29.9	7 (41.2%)	2 (12.5%)	
Obese: ≥ 30	5 (29.4%)	3 (18.8%)	
Pre-delivery medical conditions[§]			0.895[C]
Yes	6 (35.5%)	6 (37.5%)	
No	11 (64.7%)	10 (62.5%)	
Smoking (woman's self-reported status)			0.601[F]
Yes	3 (17.6%)	1 (6.3%)	
No	14 (82.4%)	15 (93.8%)	
First vaginal delivery			1.000[F]
Yes	14 (82.4%)	13 (81.3%)	0.642[F]
No	3 (17.6%)	3 (18.8%)	
Previous perineal trauma			1.000[F]
Yes	3 (17.6%)	3 (18.8%)	0.642[F]
No	14 (82.4%)	13 (81.3%)	
Previous perineal wound dehiscence (in women with previous perineal trauma)			0.400[F]
Yes	2 (66.7%)	0 (0.0%)	
No	1 (33.3%)	3 (100%)	

[#]**Ethnicity:** Variation due to some recruiting units being in a high prevalence area
[‡]**BMI =** Body Mass Index **and NICE =** National Institute for Health and Clinical Excellence
[§]**Pre-delivery medical conditions:** Re-suturing = Scoliosis; raised blood pressure; antibiotics for pyelonephritis 1 week prior to birth; bicuspid aortic valve and supra ventricular tachycardia; mild thoracolumbar scoliosis - reported back pain during pregnancy. Expectancy = Factor 5 Leiden; possible obstetric cholestasis; mild thrombocytopenia in pregnancy; gestational hypertension on labetalol; hypothyroidism.
[†]**P values: C =** Pearson Chi-square **F =** Fisher's Exact **L = Liner-by-Linear**

It is apparent that the baseline ante-partum characteristics for both groups are comparable with the exception of ethnicity. Although numbers in both groups were small, ethnicity revealed a significant difference. In the re-suturing group 17/17 (100%) were white ethnicity compared to 10/16 (62.5%) in the expectancy group which was resulted in *P*= 0.007).

Table 19: Descriptive statistics to demonstrate baseline intra-partum characteristics at trial entry, of RCT participants as recorded by clinicians in recruiting sites: comparative data between both treatment groups (2011-2013)

Baseline intra-partum characteristics	Re-sutured (n=17) n (%)	Expectancy (n = 16) n (%)	*P*-value[†]
Analgesia used in labour			1.000[F]
Entonox			0.642[F]
Yes	14 (82.4%)	13 (81.3%)	
No	3 (17.6%)	3 (18.8%)	0.118
Epidural			
Yes	11 (64.7%)	6 (37.5%)	
No	6 (35.3%)	10 (62.5%)	
Duration of 2nd stage of labour (minutes) Mean (standard deviation)	80.4 (63.9)	92.9 (66.3)	0.584[T]
Mode of vaginal delivery			0.387[C]
Spontaneous	7 (41.2%)	9 (56.3%)	
Operative	10 (58.8%)	7 (43.8%)	
Birth weight ≥ 4Kg			1.000[F]
Yes	3 (17.6%)	2 (12.5%)	0.530[F]
No	14 (82.4%)	14 (87.5%)	
Meconium liquor present			0.965[L]
Yes	4 (23.5%)	2 (12.5%)	
No	11 (64.7%)	14 (87.5%)	
Information not available	2 (11.8%)	0 (0.0%)	
Type of perineal trauma			1.000[F]
Spontaneous (2nd degree)	5 (29.4%)	4 (25.0%)	0.543[F]
Episiotomy	12 (70.6%)	12 (75.0%)	
Clinician performing primary repair			0.611[C]
Midwife	7 (41.2%)	8 (50.0%)	
Doctor	10 (58.8%)	8 (50.0%)	
Vicryl Rapide® used for repair of 2nd degree tear or episiotomy			0.513[L]
Yes	15 (88.2%)	15 (93.8%)	
No	1 (5.9%)	1 (6.2%)	
Information not available	1 (5.9%)	0 (0.0%)	
Location of perineal repair			1.000[F]
Delivery room	14 (82.4%)	13 (81.2%)	0.642[F]
Theatre	3 (17.6%)	3 (18.8%)	
Estimated blood loss > 500mLs			0.667[L]
Yes	5 (29.4%)	4 (25.0%)	
No	12 (70.6%)	11 (68.8%)	
Information not available	0 (0.0%)	1 (6.2%)	
Most recent hemoglobin (Hb) <11.0 g/dL			0.791[L]
Yes	5 (29.4%)	4 (25.0%)	
No	10 (58.8%)	11 (68.7%)	
Information not available	2 (11.8%)	1 (6.3%)	
Antibiotics in labour			1.000[F]
Yes	2 (11.8%)	2 (12.5%)	0.676[F]
No	15 (88.2%)	14 (87.5%)	

[†]***P*-value C =** Pearson's chi-square test **F =** Fishers exact test **L =** Linear-by-Linear value using the chi-square test for trend **T** = Independent *t* –test (findings consistent with *t*-test and Mann-Whitney U test)

6.2.3.2 Baseline wound assessment

Baseline wound assessments were completed at randomisation for all women using the REEDA scoring tool as described in chapter five and illustrated in figures 18 and 19. The wound was also assessed for signs of infection and the size of the dehisced area was measured in millimetres (mm) for length, width and depth.

Signs of infection

Table 20 below reveals signs of infection reported by the clinicians at the initial wound assessment. If the wound appeared infected clinicians were then asked to answer a list of indicators associated with wound infection. There were no clinical or statistically significant differences between the two groups.

Table 20: Baseline wound assessment for signs of infection at randomisation reported by clinicians at recruiting sites: comparative data between the two treatment groups (2011-2013)

Wound assessment for signs of infection at randomisation	Re-sutured n=17 n (%)	Expectancy n=16 n (%)	*P*-value[†]
Any signs of infection			0.619[C]
Yes	11 (64.7%)	9 (56.2%)	
No	6 (35.3%)	7 (43.8%)	
Wound painful when touched[‡]			1.000[F]
Yes	8 (72.7%)	7 (77.8%)	
No	3 (27.3%)	2 (22.2%)	
Localised swelling[‡]			0.642[F]
Yes	3 (27.3%)	4 (44.4%)	
No	8 (72.7%)	5 (55.6%)	
Redness[‡]			0.285[F]
Yes	10 (90.9%)	6 (66.7%)	
No	1 (9.1%)	3 (33.3%)	
Wound heat[‡]			0.479[F]
Yes	2 (18.2%)	0 (0.0%)	
No	9 (81.8%)	9 (100%)	
Purulent discharge[‡]			0.670[F]
Yes	5 (45.5%)	3 (33.3%)	
No	6 (55.5%)	6 (66.7%)	

[‡]Assessment of wound for: pain, swelling, redness, heat, purulent discharge completed by clinician in re-suturing group n=11/17 (11 women had signs of infection) and expectancy group n=9/16 (9 women had signs of infection).
[†]***P*-value C =** Pearson's chi-square test **F =** Fishers exact test

Wound appearance using the REEDA scoring tool

Total comparative REEDA scores, mean and standard deviation (SD) out of a total maximum REEDA score of 15 between the groups were: re-suturing 5.8 (1.9) and expectancy 4.8 (1.6) *P* = 0.133 analysed using the independent *t* test.

Table 21 below represents the comparative results of the wound assessment at randomisation by clinicians between the two groups relating to the extent of redness, oedema (edema), ecchymosis (bruising), discharge from the wound and approximation of the skin edges (REEDA)**.** Results are presented as frequencies and percentages.

Table 21: Descriptive data to demonstrate baseline wound assessment by clinicians at randomisation using the REEDA scale. Comparative data between the two treatment groups (2011-2013)

REEDA: wound assessment at randomisation	Re-sutured (n=17) n (%)	Expectancy (n=16) n (%)	*P*-value[†]
Redness			0.037[L]
None	2 (11.8%)	4 (25.0%)	
Mild (<0.5cm)	10 (58.8%)	12 (75.0%)	
Moderate (0.5-1cm)	5 (29.4%)	0 (0.0%)	
Severe (>1cm)	0 (0.0%)	0 (0.0%)	
Oedema			0.704[L]
None	10 (58.8%)	8 (50.0%)	
Mild (1cm)	4 (23.5%)	8 (50.0%)	
Moderate (1-2cm)	3 (17.6%)	0 (0.0%)	
Severe (>2cm)	0 (0.0%)	0 (0.0%)	
Ecchymosis			0.656[F]
None	13 (76.5%)	14 (87.5%)	
Mild (<1cm)	4 (23.5%)	2 (12.5%)	
Moderate (1-2cm)	0 (0.0%)	0 (0.0%)	
Severe (>2cm)	0 (0.0%)	0 (0.0%)	
Discharge			0.315[L]
None	4 (23.5%)	9 (56.3%)	
Serum	6 (35.3%)	2 (12.5%)	
Serosanguinous	6 (35.3%)	3 (18.7%)	
Purulent	1 (5.9%)	2 (12.5%)	
Approximation of skin			0.849[C]
Closed	0 (0.0%)	0 (0.0%)	
Skin separation	0 (0.0%)	0 (0.0%)	
Skin and subcutaneous fat	8 (47.1%)	7 (43.8%)	
Skin, subcutaneous fat and fascial layer	9 (52.9%)	9 (56.3%)	

REEDA has total maximum score value of 15 (maximum score of 3 for each of the 5 parameters assessed)

[†]***P*-value C =** Pearson's Chi-square test **F =** Fishers exact test **L =** Linear-by-Linear value using the chi-square test for trend

Dehisced wound measurements at randomisation

Table 22 presents the dehisced wound measurements mean score and standard deviation (SD) in all participants. Table 23 presents a comparison of the wound measurements between the two groups.

Table 22: Dehisced wound measurements recorded by clinicians at recruiting sites prior to randomisation, presented as the mean and standard deviation (SD): Combined totals for both treatment groups (2011-2013)

Dehisced wound measurements in mm at randomisation	Mean (SD)
Length	33.2 (11.7)
Width	20.8 (7.9)
Depth	15.0 (7.5)

Table 23: Dehisced wound measurements recorded by clinicians at recruiting sites prior to randomisation, presented as the mean and standard deviation (SD). Comparative data between the two treatment groups (2011-2013)

Dehisced wound measurements in mm at randomisation	Re-sutured n=17 Mean (SD)	Expectancy n=16 Mean (SD)	*P*-value
Length	34.6 (14.5)	31.6 (7.8)	0.475
Width	18.9 (7.6)	22.8 (8.1)	0.166
Depth	13.8 (8.0)	16.3 (7.0)	0.373
***P*- value =** Independent t-test			

6.2.4 The primary outcome measure of wound healing: a comparison of the results between the two treatment groups

Wound healing was assessed in both groups at 2 weeks and 6 weeks following randomisation and the results are presented in table 24. For the purpose of the RCT, wound healing was defined as ‘no areas of wound dehiscence’.

Table 24: A comparison of wound healing between the two treatment groups based on an intention to treat analysis: assessed by clinicians at recruiting sites, 2 weeks and 6 weeks following randomisation (2011-2013). Wound healing was defined as no areas of dehiscence

Wound healing	Re-sutured n=17 n (%)	Expectancy n=16 n (%)	Odds ratio (95% CI)	*P*-value[†]
2 weeks: post randomisation			20.00 (2.04,196.37)	0.004
Yes	8 (57.1%)	1 (6.3%)		
No	6 (42.9%)	15 (93.8%)		
6 weeks: post randomisation			0.27 (0.01, 7.25)	0.467
Yes	13 (92.9%)	16 (100%)		
No	1 (7.1%)	0 (0.0%)		

2 weeks Re-suturing: 3 women not included in analysis as 1 woman did not attend for review and 2 women had withdrawn. **6 weeks Re-suturing:** Includes 1 woman whose wound had healed at 2 weeks, no appointment needed at 6 weeks; 3 women withdrew and not included in analysis **6 weeks expectancy:** Includes 1 woman whose wound had healed at 2 weeks and 1 woman whose wound had healed at 4 weeks.
[†]***P*-value =** Fishers exact test

At the two week time point data in relation to wound healing was available in 14/17 (82%) of women in the re-suturing group and 16/16 (100%) of women in the expectancy group. At 6 weeks data was available in 14/17 (82%) women in the re-suturing group (3/17 women withdrew at an earlier time point and includes one woman whose wound had healed at 2 weeks) and 16/16 (100%) women in the expectancy group (includes one woman whose wound had healed at 2 weeks and one woman whose wound had healed at just over 4 weeks post randomisation).

As previously referred to, the numbers in both groups are small, therefore any results need to be interpreted with caution, however the findings presented in table 24 suggest an increase in the number of wounds healed at 2 weeks in the re-suturing group 8/14 (57.1%) compared to 1/16 (6.3%) in the expectancy group (odds ratio (OR) 20.00, 95% confidence interval (CI) 2.04, 196.37) $P = 0.004$. The total sample size and the expected values were small, therefore the Fisher exact value was reported as opposed to the Pearson Chi-square value. The Fisher exact test performed on the data was significant at the 0.001- 0.05 level (2-tailed $P =$

0.004) of significance. There was no difference in wound healing at 6 weeks apart from the wound in one of the women in the re-suturing group had two superficial areas of skin dehiscence.

If the perineal wound had healed an assessment of the appearance of the scar was made by the clinician. At 6 weeks the results revealed a trend towards moderate scar tissue of less than 0.5cm thickness but greater than a pencil line in the expectancy group 5/12 (41.7%) compared to 2/12 (16.7%) in women who were re-sutured (table 25).

Table 25: Perineal wound scar assessed by clinicians at recruiting sites: comparative data between the two treatment groups at 2 and 6 weeks following randomisation if the wound had healed (2011-2013)

Perineal wound scar if healed	Re-sutured n=17 n (%)	Expectancy n= 16 n (%)	*P*-value[†]
2 weeks: post randomisation			0.480
Minimal (scar tissue no thicker than pencil line)	5 (62.5%)	1 (100%)	
Moderate (scar tissue < 0.5cm thick)	3 (37.5%)	0 (0.0%)	
Severe (scar tissue > 0.5cm thick)	0 (0.0%)	0 (0.0%)	
6 weeks: post randomisation			0.187
Minimal (scar tissue no thicker than pencil line)	10 (83.3%)	7 (58.3%)	
Moderate (scar tissue < 0.5cm thick)	2 (16.7%)	5 (41.7%)	
Severe (scar tissue > 0.5cm thick)	0 (0.0%)	0 (0.0%)	

2 weeks re-suturing: 9 women not included in analysis as 1 woman did not attend for review and 2 women had withdrawn and 6 wounds not healed. **2 weeks expectancy:** 15 women not included in analysis as wounds not healed. **6 weeks re-suturing:** 5 women not included in analysis as 3 women had withdrawn, 1 woman's wound healed at 2 weeks and 1 woman needed additional appointments as not fully healed. **6 weeks expectancy:** 3 women not included in analysis as needed additional appointments due to excessive granulation and 1 woman's wound had healed at 2 weeks. Results also include 1 woman whose wound healed at 4 weeks post randomisation.
[†]***P*-value**: liner-by-liner value presented using the chi-square test for trend

At the 6 week time point the scar was not assessed in three women in the expectancy group due to excessive granulation tissue. One of these women was subsequently discharged at 14 weeks following randomisation with moderate scar tissue and the second woman's perineal wound healed with minimal scarring. The information was not recorded for the third woman who was discharged from the perineal care clinic at 26 weeks following randomisation, electronic records revealed considerably less granulation tissue. One woman's wound from the re-suturing group had not fully healed at 6 weeks and therefore no assessment of scar tissue was made. The woman was subsequently discharged at 13 weeks following randomisation; electronic records revealed that two small areas of dehiscence following secondary suturing had healed.

Wound healing was also assessed using the REEDA scale, table 26 represents the comparative results of wound healing between the two groups at 2 weeks. As previous, data is presented in both frequency and percentages.

Table 26: Wound healing assessed by clinicians at recruiting sites, 2 weeks following randomisation using the REEDA scale. Comparative data between the two treatment groups (2011-2013)

REEDA wound healing assessment at 2 weeks post randomisation	Re-sutured (n=17) n (%)	Expectancy (n=16) n (%)	*P*-value[†]
Redness			0.393
None	8 (57.1%)	8 (50.0%)	
Mild (<0.5cm)	6 (42.9%)	6 (37.5%)	
Moderate (0.5-1cm)	0 (0.0%)	2 (12.5%)	
Severe (>1cm)	0 (0.0%)	0 (0.0%)	
Oedema			0.024
None	14 (100%)	11 (68.8%)	
Mild (<1cm)	0 (0.0%)	5 (31.2%)	
Moderate (1-2cm)	0 (0.0%)	0 (0.0%)	
Severe (>2cm)	0 (0.0%)	0 (0.0%)	
Ecchymosis (bruising)			
None	0 (0.0%)	0 (0.0%)	
Mild (<1cm)	0 (0.0%)	0 (0.0%)	
Moderate (1-2cm)	0 (0.0%)	0 (0.0%)	
Severe (>2cm)	0 (0.0%)	0 (0.0%)	
Discharge			0.690
None	12 (85.7%)	9 (56.2%)	
Serum	2 (14.3%)	5 (31.3%)	
Serosanguinous	0 (0.0%)	0 (0.0%)	
Purulent	0 (0.0%)	2 (12.5%)	
Approximation of skin			0.003
Closed	7 (50.0%)	1 (6.3%)	
Skin separation	5 (37.5%)	5 (31.3%)	
Skin and subcutaneous fat	1 (7.1%)	4 (25.0%)	
Skin, subcutaneous fat and fascial layer	1 (7.1%)	6 (37.5%)	

Re-suturing group: 3 women not included in analysis as 1 woman did not attend for her 2 week assessment and 2 women had withdrawn
[†]***P*-value =** Linear-by-Linear value using the chi-square test for trend

At 2 weeks following randomisation visible sutures were present in 8/14 women in the re-suturing group, and 2/8 women had sutures removed. In comparison visible sutures were present in 3/16 women in the expectancy group and one woman need sutures removing.

At 6 weeks following randomisation the REEDA assessment of wound healing was comparable between the two groups. None of the wounds demonstrated any level of oedema or ecchymosis and there was only a minor difference reported in the redness of the wound. Mild redness was present in n = 3 (23.1%) of the wounds in

the re-suturing group and none in the expectancy group *P* = 0.071. In the re-suturing group n = 12 (92.3%) of the wounds had healed and n = 1 (7.7%) wound had minor skin separation, all wounds in the expectancy group had healed 16 (100%) *P* = 0.299.

At 6 weeks following randomisation visible sutures were present in 2/13 women in the re-suturing group and one woman need sutures removing. No visible sutures were present in the expectancy group.

Five women in the RCT needed additional appointments to evaluate wound healing after the 6-8 weeks assessment. Out of the group managed by expectancy after the 6-8 weeks wound assessment visit, 2/16 (12.5%) needed one further additional appointment and were discharged at 12 weeks following randomisation and 2/16 (12.5%) needed two additional appointments and were both discharged at 14 weeks following randomisation. The main reasons for additional appointments were over granulation tissue. Out of the group who were re-sutured one woman needed two additional appointments after the 6-8 weeks assessment due to small superficial areas of skin separation along the wound edges and was finally discharged at 13 weeks following randomisation.

6.2.5 Perineal pain: a secondary outcome measure.

6.2.5.1 Rates of perineal pain

Women were asked to report (yes or no) if they were experiencing any perineal pain or discomfort at 2 weeks, 6 weeks, 3 months and 6 months following randomisation. To increase the validity of recall, at 2 weeks women were asked if they had any perineal pain or discomfort in the previous 24 hours, whilst at the other time points women were asked to report pain or discomfort in the previous week. The comparative results are presented in table 27.

Table 27: Women's self-reported assessment of perineal pain following randomisation, recorded in their questionnaires at 2 week, 6 week, 3 month and 6 month time points. Comparative data between the two treatment groups (2011-2013)

Self-reported perineal pain: post randomisation	Re-sutured n=17 n (%)	Expectancy n=16 n (%)	Odds ratio (95% CI)	*P*-value[†]
2 weeks			0.56 (0.13,2.41)	0.431[C]
Yes	5 (35.7%)	8 (50.0%)		
No	9 (64.3%)	8 (50.0%)		
6 weeks			1.33 (0.32,5.64)	0.696[C]
Yes	8 (57.1%)	8 (50.0%)		
No	6 (42.9%)	8 (50.0%)		
3 months			0.40 (0.09,1.83)	0.232[C]
Yes	4 (28.6%)	8 (50.0%)		
No	10 (71.4%)	8 (50.0%)		
6 months			1.25 (0.07,22.13)	1.000[F]
Yes	1 (7.7%)	1 (6.2%)		
No	12 (92.3%)	15 (93.8%)		

Re-suturing: The question was completed by 14/17 women at 6 weeks and 3 months (3/17 women had withdrawn at these time points and 13/17 women at 6 months (1 additional woman did not return her 6 month questionnaire

[†]**P-value C =** Pearson's Chi-square test **F =** Fishers exact test

Women that reported being in pain were asked to assess their level of pain as mild, moderate or severe. Table 28 demonstrates that there were no statistical differences at any time point. Likewise, although there were small differences in the frequency of pain women were experiencing this was not statistical significant, with most women at all-time points reporting their pain as being present some of the time. Only one woman in the re-suturing group at 2 weeks reported pain most of the time. In the expectancy group at 2 weeks, two women reported being in pain most

of the time; at 6 weeks, one woman reported being in pain most of the time and one all of the time and at 3 months one woman revealed that she was still experiencing pain most of the time.

Table 28: Women's self-reported assessment of the level of their perineal pain following randomisation, recorded in their questionnaires at 2 week, 6 week, 3 month and 6 month time points. Comparative data between the two treatment groups (2011-2013)

Self-reported level of perineal pain: post randomisation	Re-sutured n=17 n (%)	Expectancy n=16 n (%)	*P*-value[†]
2 weeks			1.000[F]
Mild	3 (60.0%)	5 (62.5%)	
Moderate	2 (40.0%)	3 (37.5%)	
6 weeks			0.696[L]
Mild	7 (57.1%)	6 (75.0%)	
Moderate	1 (42.9%)	1 (12.5%)	
Severe	0 (0.0%)	1 (12.5%)	
3 months			1.000[F]
Mild	4 (100%)	7 (87.5%)	
Moderate	0 (0.0%)	1 (12.5%)	
6 months			
Mild	1 (100%)	1 (100%)	

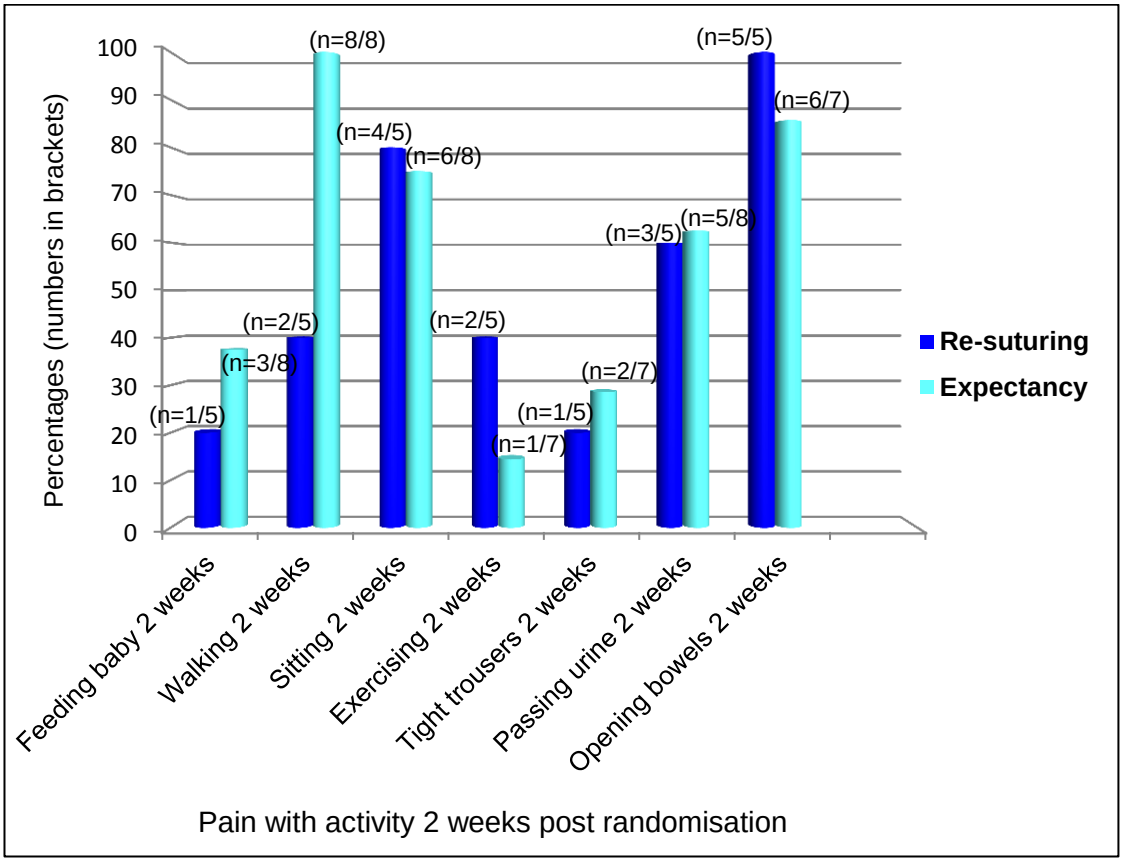
[†]**P-value F =** Fishers exact test **L =** Linear-by-Linear value using the chi-square test for trend

6.2.5.2 Women's self-reported measures of perineal pain with activities of daily living

If women reported experiencing pain they were then asked to assess the pain felt in relationship to completing activities associated with daily living. These included: feeding their baby (breast or formula), walking about, sitting down, exercising, wearing tight trousers passing urine and opening their bowels. The results at 2 weeks, 6 weeks and 3 months are presented in percentages in figures 27, 28 and 29 respectively. At 6 months perineal pain was only reported by one woman from each group and the results are therefore not included in the table. In the re-suturing group at 6 months one woman still had perineal pain during exercise and when wearing tight trousers. In the expectancy group at 6 months one woman remained in pain on defecation. Results for pain on activity were similar at most other time points. The main difference was apparent at 2 weeks in that all women in the

expectancy group who had reported pain, n=8/8 (100%) experienced pain on walking, compared to n=2/5 (40%) in the re-suturing group.

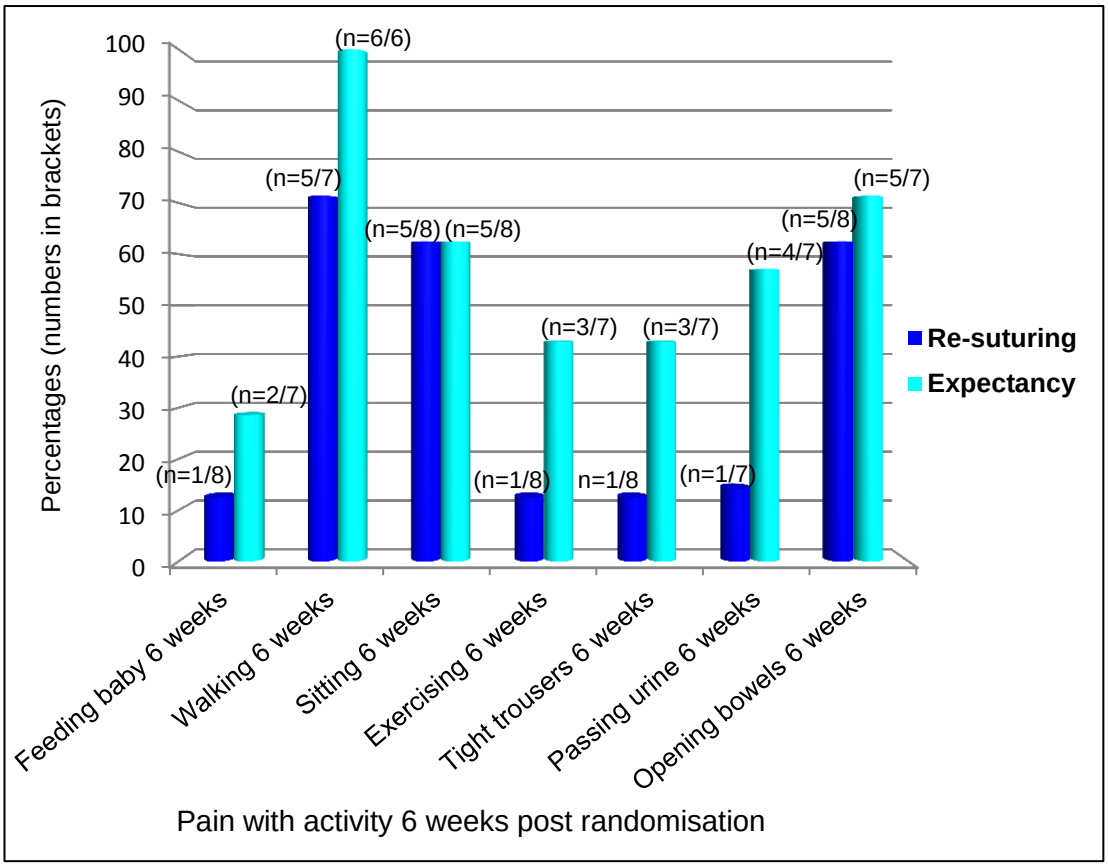
Figure 27: Women's self-assessment of perineal pain on activity following randomisation, recorded in their 2 week questionnaires. Comparative data expressed in percentages and numbers between the two treatment groups (2011-2013)



Re-sutured: At 2 weeks 5/14 women who completed the questionnaire reported pain.

Expectancy: At 2 weeks 8/16 women who completed the questionnaire reported pain (where number does not = 8 value not answered).

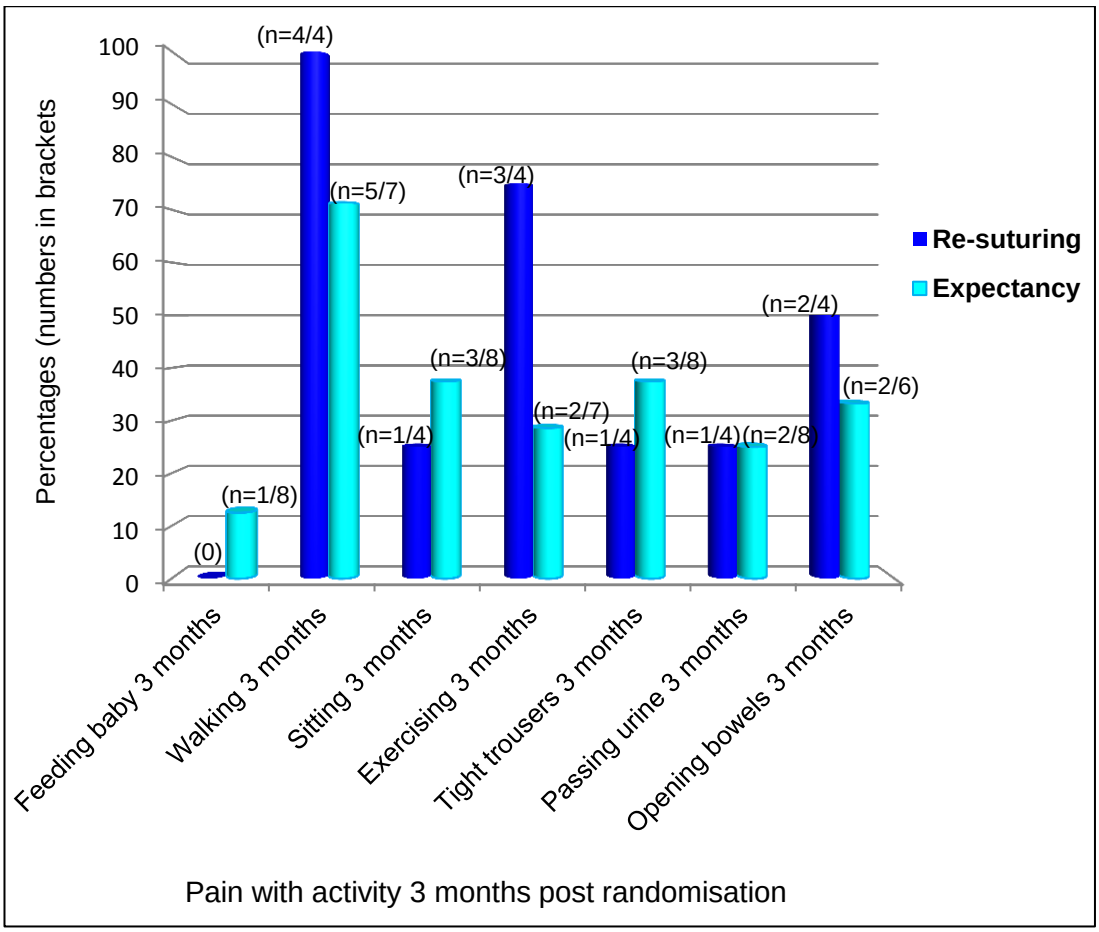
Figure 28: Women's self-assessment of perineal pain on activity following randomisation, recorded in their 6 week questionnaires. Comparative data expressed in percentages and numbers between the two treatment groups (2011-2013)



Re-sutured: At 6 weeks 8/14 women who completed the questionnaire reported pain (where number does not = 8 value not answered).

Expectancy: At 6 weeks 8/16 women who completed the questionnaire reported pain (where number does not = 8 value not answered).

Figure 29: Women's self-assessment of perineal pain on activity following randomisation, recorded in their 3 month questionnaire. Comparative data between the two treatment groups (2011-2013)



Re-sutured: At 3 months 4/14 women who completed the questionnaire reported pain

Expectancy: At 3 months 8/16 women who completed the questionnaire reported pain (where number does not = 8 value not answered.

Free text comments from women relating to the experience of pain recorded in their questionnaires illustrate the extent of this pain on their relationship with their newborn baby.

"After having been re-sutured again, this time has been less painful than the original stitches. I can now bath my baby and get down on the floor to play with him and to change him." (6 weeks: participant number 1010 re-suturing)

"The pain has made it difficult to enjoy the first six weeks with my baby." (6 weeks: participant number 1092 expectancy)

These feelings continued for this woman who in her 6 month wrote:

"I would say that the whole process has put me off having another baby. I would only consider it if I could have a C-section. I feel it ruined the first 4 months that I spent with my son." (6 months: participant number 1092 expectancy)

6.2.5.3 Women's self-reported perineal pain descriptors

To add more meaning to the nature of perineal pain women experienced, those women who reported yes were also asked to circle the following words that they would use to describe their pain: sharp, stinging, stabbing, cutting, throbbing, aching, heavy, dull, pinching , prickling, gnawing, pulling, tender, burning, tingly, itchy, annoying, miserable, troublesome, sickening, other. Free text annotation boxes to other were provided. The results in frequencies and percentages at 2 weeks, 6 weeks are presented in table 29 and at 3 months table 30. One woman in the expectancy group who reported experiencing pain at 3 months did not complete the section describing her perineal pain.

Table 29: Women's self-reported description of perineal pain: comparative data between the two treatment groups, recorded in their questionnaires at 2 and 6 weeks following randomisation (2011-2013)

Perineal pain description	Re-sutured n (%)	Expectancy n (%)	Re-sutured n (%)	Expectancy n (%)
	2 weeks post randomisation		6 weeks post randomisation	
Sharp	1 (20.0%)	3 (37.5%)	0 (0.0%)	1 (12.5%)
Stinging	1 (20.0%)	5 (62.5%)	2 (25.0%)	3 (37.5%)
Stabbing	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)
Cutting	1 (20.0%)	1 (12.5%)	1 (12.5%)	0 (0.0%)
Throbbing	1 (20.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)
Aching	2 (40.0%)	5 (62.5%)	4 (50.0%)	3 (37.5%)
Heavy	0 (0.0%)	2 (25.0%)	1 (12.5%)	2 (25.0%)
Dull	1 (20.0%)	2 (25.0%)	4 (50.0%)	1 (12.5%)
Pinching	1 (20.0%)	3 (37.5%)	0 (0.0%)	2 (25.0%)
Prickling	1 (20.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)
Gnawing	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pulling	1 (20.0%)	4 (50.0%)	2 (25.0%)	3 (37.5%)
Tender	2 (40.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)
Burning	1 (20.0%)	1 (12.5%)	0 (0.0%)	1 (12.5%)
Tingly	2 (40.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)
Itchy	1 (20.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)
Annoying	1 (20.0%)	4 (50.0%)	2 (25.0%)	3 (37.5%)
Miserable	0 (0.0%)	0 (0.0%)	1 (12.5%)	2 (25.0%)
Troublesome	0 (0.0%)	1 (12.5%)	2 (25.0%)	0 (0.0%)
Sickening	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)

n = the number of women who described the pain according to the variable out of the number of women who actually reported pain at the pre-specified time point.
2 weeks re-sutured: 5/14 women who completed the questionnaire reported pain
2 weeks expectancy: 8/16 women who completed the questionnaire reported pain
6 weeks re-sutured: 8/14 women who completed the questionnaire reported pain
6 weeks expectancy: 8/16 women who completed the questionnaire reported pain

There were three free text responses to 'other' pain descriptor. At 2 weeks one woman in the re-suturing group described the pain as "mainly at night time" and at 6 weeks two women in the expectancy group described the pain as sore, with one adding "sometimes so sore, it makes me feel sick."

At two weeks, women in the expectancy group were more likely to describe their pain as stinging n=5/8 (62.5%), aching 5/8 (62.5%) and annoying 4/8 (50%) compared to the re-suturing group, stinging 1/5 (20%), aching 2/5 (40%) annoying 1/5 (20%). At 6 weeks and 3 months pain descriptors were comparable.

The main difference at 3 months was that 5/7 (71.4%) women in the expectancy group described their pain as stinging compared to 1/4 (25%) in the re-suturing group.

Table 30: Women's self-reported description of perineal pain: comparative data between the two treatment groups recorded in their questionnaires at 3 months following randomisation (2011-2013)

Perineal pain description	Re-sutured n (%)	Expectancy (n (%)
	3 months post randomisation	
Sharp	0 (0.0%)	1 (14.3%)
Stinging	1 (25.0%)	5 (71.4%)
Stabbing	0 (0.0%)	1 (14.3%)
Cutting	1 (25.0%)	0 (0.0%)
Throbbing	1 (25.0%)	0 (0.0%)
Aching	2 (50.0%)	1 (14.3%)
Heavy	1 (25.0%)	0 (0.0%)
Dull	1 (25.0%)	1 (14.3%)
Pinching	0 (0.0%)	1 (14.3%)
Prickling	1 (25.0%)	1 (14.3%)
Gnawing	0 (0.0%)	0 (0.0%)
Pulling	2 (50.0%)	2 (28.6%)
Tender	1 (25.0%)	2 (28.6%)
Burning	0 (0.0%)	0 (0.0%)
Tingly	0 (0.0%)	0 (0.0%)
Itchy	0 (0.0%)	2 (28.6%)
Annoying	1 (25.0%)	1 (14.3%)
Miserable	0 (0.0%)	0 (0.0%)
Troublesome	1 (25.0%)	0 (0.0%)
Sickening	0 (0.0%)	0 (0.0%)

Re-suturing: At 3 months pain was reported by 4/14 women
Expectancy: At 3 months pain was reported by 8/16 women, the section describing perineal pain was completed by 7/16 women

6.2.6 Dyspareunia: a secondary outcome measure

The 6 weeks, 3 months and 6 months mother's questionnaires asked each woman to report if they had resumed sexual intercourse or not. Women who had resumed sexual intercourse were then asked to report if they had any dyspareunia (painful sexual intercourse) either on penetration, deep penetration or around the perineal scar. The comparative rates of resuming sexual intercourse and dyspareunia are presented in tables 31 and 32 respectively.

Table 31: Resuming sexual intercourse and rates of dyspareunia following randomisation, self-reported by women in their 6 week, 3 month and 6 month questionnaires. Comparative data between the two treatment groups who completed the question (2011-2013)

Resuming sexual intercourse (SI) and dyspareunia post randomisation	Re-sutured n=17 n (%)	Expectancy n=16 n (%)	Odds ratio (95% CI)	*P*- value[†]
Resumed SI 6 weeks			1.73 (0.31,9.57)	0.675[F]
Yes	4 (28.6%)	3 (18.8%)		
No	10 (71.4%)	13 (81.3%)		
Dyspareunia 6 weeks			1.50(0.06,40.63)	1.000[F]
Yes	3 (75.0%)	2 (66.7%)		
No	1 (25.0%)	1 (33.3%)		
Resumed SI 3 months			1.67 (0.32,8.74)	0.689[F]
Yes	11 (78.6%)	11 (68.8%)		
No	3 (21.4%)	5 (31.3%)		
Dyspareunia 3 months			2.10 (0.38,11.59)	0.392[C]
Yes	6 (54.5%)	4 (36.4%)		
No	5 (45.5%)	7 (63.6%)		
Resumed SI 6 months			Not estimable	
Yes	13 (100%)	16 (100%)		
Dyspareunia 6 months			3.30 (0.54,20.27)	0.238[F]
Yes	11 (84.6%)	10 (62.5%)		
No	2 (15.4%)	6 (37.5%)		

Re-suturing: The question was completed by 14/17 women at 6 weeks and 3 months (3/17 women had withdrawn at these time points and 13/17 women at 6 months (1 additional woman did not return her 6 month questionnaire. [†]***P*-value** F = Fishers exact test **C =** Chi-square test

Table 32: Women's self-reported experience of dyspareunia if sexual intercourse resumed, recorded in their 6 week, 3 month and 6 month questionnaires. Comparative data between the two treatment groups (2011-2013)

Dyspareunia: post randomisation	Re-sutured n=17 n (%)	Expectancy n=16 n (%)	*P*- value†
Dyspareunia at 6 weeks			
Pain on penetration			0.143[F]
Yes	3 (75.0%)	0 (0.0%)	
No	1 (25.0%)	3 (100%)	
Pain on deep penetration			1.000[F]
Yes	1 (25.0%)	1 (33.3%)	
No	3 (75.0%)	2 (66.7%)	
Pain around scar site			1.000[F]
Yes	2 (50.0%)	2 (66.7%)	
No	2 (50.0%)	1 (33.3%)	
Dyspareunia at 3 months			
Pain on penetration			1.000[F]
Yes	3 (27.3%)	4 (36.4%)	
No	8 (72.7%)	7 (63.6%)	
Pain on deep penetration			1.000[F]
Yes	3 (27.3%)	2 (18.2%)	
No	8 (72.7%)	9 (81.8%)	
Pain around scar site			1.000[F]
Yes	3 (27.3%)	3 (27.3%)	
No	8 (72.7%)	8 (72.7%)	
Dyspareunia at 6 months			
Pain on penetration			1.000[F]
Yes	5 (38.5%)	6 (37.5%)	
No	8 (61.5%)	10 (62.5%)	
Pain on deep penetration			0.192[F]
Yes	5 (38.5%)	2 (12.5%)	
No	8 (61.5%)	14 (87.5%)	
Pain around scar site			0.897[C]
Yes	6 (46.2%)	7 (43.8%)	
No	7 (53.8%)	9 (56.2%)	

Re-sutured: At 6 weeks 4/14 who completed the question had resumed sexual intercourse; at 3 months 11/14 and 6 months 13/13 (3 women had withdrawn by 6 weeks and 1 woman did not return her 6 month questionnaire)
Expectancy: At 6 weeks 3/16 who completed the question had resumed sexual intercourse; at 3 months 11/13 and 6 months 13/13
†P- value C = **Pearson chi-squared test** F = **Fishers exact test**

6.2.7 The aesthetic results of wound healing: a secondary outcome measure

Women were asked at the pre-specified time points to comment on how they felt about the healing of their perineal wound. The results are presented in tables 33-35 respectively.

Table 33: Women's self-reported assessment of their satisfaction with the aesthetic results of wound healing, (healed or healed poorly) recorded in their 6 week, 3 month and 6 month questionnaires. Comparative data between the two treatment groups (2011-2013)

Satisfaction with the results of wound healing post randomisation: healed or healed poorly	Re-sutured n = 17 n (%)	Expectancy n = 16 n (%)	Odds ratio (95% CI)	*P*-value[†]
Perineal healing 6 weeks			0.10 (0.00,1.96)	0.103[F]
Felt that perineum had healed	14 (100%)	12 (75.0%)		
Felt that perineum healed poorly	0 (0.0%)	4 (25.0%)		
Perineal healing 3 months			0.07 (0.00, 1.44)	0.045[F]
Felt that perineum had healed	14 (100%)	11 (68.8%)		
Felt that perineum healed poorly	0 (0.0%)	5 (31.2%)		
Perineal healing 6 months			0.11 (0.01, 1.44)	0.232[F]
Felt that perineum had healed	13 (100%)	13 (81.3%)		
Felt that perineum healed poorly	0 (0.0%)	3 (18.7%)		

Re-suturing: self-assessment of perineal healing was completed by 14/17 women at 6 weeks and 3 months (3 women had previously withdrawn) and 13/17 women at 6 months (1 woman did not return her 6 month questionnaire)
[†]***P*-value F =** Fishers exact test

Table 34: Women's self-assessment of their satisfaction with how the wound looked or felt, recorded in their 6 week, 3 month and 6 month questionnaires. Comparative data between the two treatment groups (2011-2013)

Satisfaction with how the wound looked or felt, post randomisation: better or worse	Re-sutured n = 17 n (%)	Expectancy n = 16 n (%)	Odds ratio (95% CI)	*P*-value[†]
6 weeks			0.20 (0.02, 2.17)	0.322[F]
Looked or felt better	11 (91.7%)	9 (69.2%)		
Looked or felt worse	1 (8.3%)	4 (30.8%		
3 months			0.07 (0.00, 1.39)	0.041[F]
Looked or felt better	11 (100%)	8 (61.5%)		
Looked or felt worse	0 (0.0%)	5 (38.5%)		
6 months			0.16 (0.02, 1.66)	0.166[F]
Looked or felt better	10 (90.9%)	8 (61.5%)		
Looked or felt worse	1 (9.1%)	5 (38.5%)		

At 6 weeks: not being able to see or feel their perineum was reported by re-suturing n=2 (3 women had also previously withdrawn) and expectancy n=3**. At 3 months:** not being able to see or feel their perineum was reported by re-suturing n=3 (3 women had previously withdrawn) and expectancy n=2 (variable not completed by n=1 from expectancy). **At 6 months:** not being able to see or feel their perineum was reported by re-suturing n=2 (3 women had also previously withdrawn and 1 woman did not return her 6 month questionnaire) and expectancy n=2 (variable not completed by n=1 from expectancy).

[†]***P*-value F =** Fishers exact test

Table 35: Women's self-assessment of whether their perineum felt back to normal or not, recorded in their 6 week, 3 month and 6 month questionnaires. Comparative data between the two treatment groups (2011-2013)

Did the woman's perineum feel back to normal, post randomisation	Re-sutured n = 17 n (%)	Expectancy n = 16 n (%)	Odds ratio (95% CI)	*P*-value[†]
6 weeks			0.40 (0.09, 1.83)	0.232[C]
Yes	10 (71.4%)	8 (50.0%)		
No	4 (28.6%)	8 (50.0%)		
3 months			0.46 (0.10, 2.13)	0.245[F]
Yes	11 (78.6%)	8 (53.3%)		
No	3 (21.4%)	7 (46.7%)		
6 months			0.18 (0.03, 1.10)	0.114[F]
Yes	11 (84.6%)	8 (50.0%)		
No	2 (15.4%)	8 (50.0%)		

Re-suturing: At 6 weeks and 3 months 3 women had previously withdrawn and 1 woman did not return her 6 month questionnaire

[†]***P*-value C=** Chi-square test **F =** Fishers exact test

Women in the re-suturing group persistently reported that they felt that their wound had healed at 6 weeks, 3 months and 6 months. In comparison, more women in the expectancy group felt that their wound had healed poorly at the same respective time points. At 3 months the Fisher exact test demonstrated statistical significance with 5/16 women (31.2%) reporting that their perineum had healed poorly in the expectancy group, compared to none in the re-suturing group $P = 0.045$. Although by 6 months this was not significant 3/16 (18.7%) women in the expectancy group continued to feel that their perineum had healed poorly. Similar responses were revealed when women were asked how their perineum looked or felt. More women in the re-suturing group reported that their perineum looked or felt better than they thought it would, at 6 weeks, 3 months and 6 months. Again the Fisher exact test revealed statistical significance at the 3 month time point with 5/13 (38.5%) women in the expectancy group reporting that their perineum felt or looked worse than they thought it would, compared to 11/11 (100%) of women in the re-suturing group reporting that they thought their perineum felt or looked better $P = 0.041$.

Some women did acknowledge however that they had neither looked at nor felt their perineum.

Numerous free text comments were entered by women in relation to wound healing. Several extracts are provided below to illuminate the statistical data.

"I felt quite frustrated about it healing slowly." (6 weeks: participant 4029 expectancy)

"Extremely pleased with the results and the treatment I have received, the scar is not noticeable, thank you." (6 weeks: participant 1024 re-suturing)

"I am glad I had the operation to repair the perineum, as I do feel it has healed a lot quicker. I was in a lot of discomfort before it was carried out. Overall I am very pleased." (6 weeks: participant 8021 re-suturing)

"I think there is small swelling still. I went to doctors for a check-up, they said it is fine, but to remove it requires minor surgery. It just feels like a thick bulk of dead skin or something." (3 months: participant 10027 expectancy)

"Feels back to normal, glad I let it heal naturally now." (3 months: participant 4029 expectancy)

"I think now it would have been better if I had been re-stitched. The wound itself healed weeks ago but I still have granular tissue which has been treated three times which is painful and I wonder if I will ever feel back to normal with no pain." (3 months: participant 1092 expectancy)

"Visited GP she said you can't even tell I had an episiotomy so this makes me confident the re-suture was the best option for me." (6 months: participant 8013 re-suturing)

"It has healed well but you can see a dip where the tear was and it feels a lot thinner skinned. I think if I was it have another child it would be by caesarean section as I would be very concerned about having to go through this process again." (6 months: number 11016 re-suturing)

"Perineum feels good but looks slightly different. Overall I'm very happy with now it has healed." (6 months: participant 6026 expectancy)

6.2.8 Breast feeding rates: a secondary outcome measure

The results in table 36 reveal rates of women who reported breast feeding their baby following delivery and those who were still breast feeding up to 6 months postpartum.

Table 36: Women's self-reported rates of breast feeding recorded in postal questionnaires at 6 weeks, 3 months and 6 months following randomisation. Comparative data between the two treatment groups (2011-2013)

Breast feeding: post randomisation	Re-sutured n = 17 (n %)	Expectancy n = 16 (n %)	Odds ratio (95% CI)	*P*-value[†]
Breast fed since delivery			7.00 (1.14, 42.97)	0.046
Yes	7 (50.0%)	14 (87.5%)		
No	7 (50.0%)	2 (12.5%)		
Breast feeding at 6 weeks			1.39 (0.19, 9.97)	1.000
Yes	5 (71.4%)	9 (64.3%)		
No	2 (28.6%)	5 (35.7%)		
Breast feeding at 3 months			1.00 (0.16, 6.25)	1.000
Yes	4 (57.1%)	8 (57.1%)		
No	3 (42.9%)	6 (42.9%)		
Breast feeding at 6 months			1.33 (0.21, 8.29)	1.000
Yes	4 (57.1%)	7 (50.0%)		
No	3 (42.9%)	7 (50.0%)		

Re-suturing: The question was completed by 14/17 women at 6 weeks and 3 months (3/17 women had withdrawn at these time points and 13/17 women at 6 months (1 additional woman did not return her 6 month questionnaire.
***P*-value F =** Fishers exact test

More women in the expectancy group reported breast feeding their baby following delivery 14/16 (87.5%) compared to 7/14 (50%) in the re-suturing group which was statistically significant *P* = 0.046. However at 6 months the results were comparable with just over 50% of women in both groups still breast feeding their babies (4/7 (57.1%) in the re-suturing group and 7/14 (53.8%) in the expectancy group.

6.2.8.1 Reasons provided for the cessation of breast feeding

At the 6 week mothers questionnaire two women (one from each group) cited a painful perineum as the reason for stopping breast feeding. Both woman ceased breast feeding within the first week following childbirth. Painful nipples n=2 (expectancy) and insufficient milk supply n= 2 (expectancy) and n=1 (re-suturing) were other reasons women provided for the cessation of breast feeding within the first month following childbirth. None of the women at any time point, reported that their perineum was too painful to formula feed their babies.

6.2.9 Physical and emotional health

Although not a primary or secondary outcome measure, all women were asked to provide an overall assessment of their physical and emotional health in the 6 weeks, 3 month and 6 month questionnaires. Table 37 reveals the comparative results of both groups presented as total numbers and percentages.

Table 37: Women's self-reported assessment of their physical and emotional health, recorded in their questionnaires at 6 weeks, 3 months and 6 months following randomisation. Comparative data between the two treatment groups (2011-2013)

Physical & emotional health: 6 weeks, 3 months & 6 months post randomisation	Re-sutured n=17 n (%)	Expectancy n=16 n (%)
Physical health at 6 weeks		
Very well	8 (57.1%)	7 (46.7%)
Reasonable well	6 (42.9%)	8 (53.3%)
Not very well	0 (0.0%)	0 (0.0%)
Not very well at all	0 (0.0%)	0 (0.0%)
Emotional health at 6 weeks		
Happy	10 (71.4%)	12 (80.0%)
Slightly tearful	4 (28.6%)	3 (20.0%)
Tearful	0 (0.0%)	0 (0.0%)
Very tearful	0 (0.0%)	0 0.0%)
Physical health at 3 months		
Very well	10 (71.4%)	6 (37.5%)
Reasonable well	4 (28.6%)	10 (62.5%)
Not very well	0 (0.0%)	0 (0.0%)
Not very well at all	0 (0.0%)	0 (0.0%)
Emotional health at 3 months		
Happy	12 (85.7%)	11 (68.8%)
Slightly tearful	2 (14.3%)	3 (18.7%)
Tearful	0 (0.0%)	2 (12.5%)
Very tearful	0 (0.0%)	0 (0.0%)
Physical health at 6 months		
Very well	9 (69.2%)	11 (68.8%)
Reasonable well	3 (23.1%)	5 (31.2%)
Not very well	1 (7.7%)	0 (0.0%)
Not very well at all	0 (0.0%)	0 (0.0%)
Emotional health at 6 months		
Happy	12 (92.3%)	12 (75.0%)
Slightly tearful	1 (7.7%)	3 (18.8%)
Tearful	0 (0.0%)	1 (6.2%)
Very tearful	0 (0.0%)	0 (0.0%)

Re-suturing: The question was completed by 14/17 women at 6 weeks and 3 months (3/17 women had withdrawn at these time points and 13/17 women at 6 months (1 additional woman did not return her 6 month questionnaire.

6.2.10 Protocol adherence

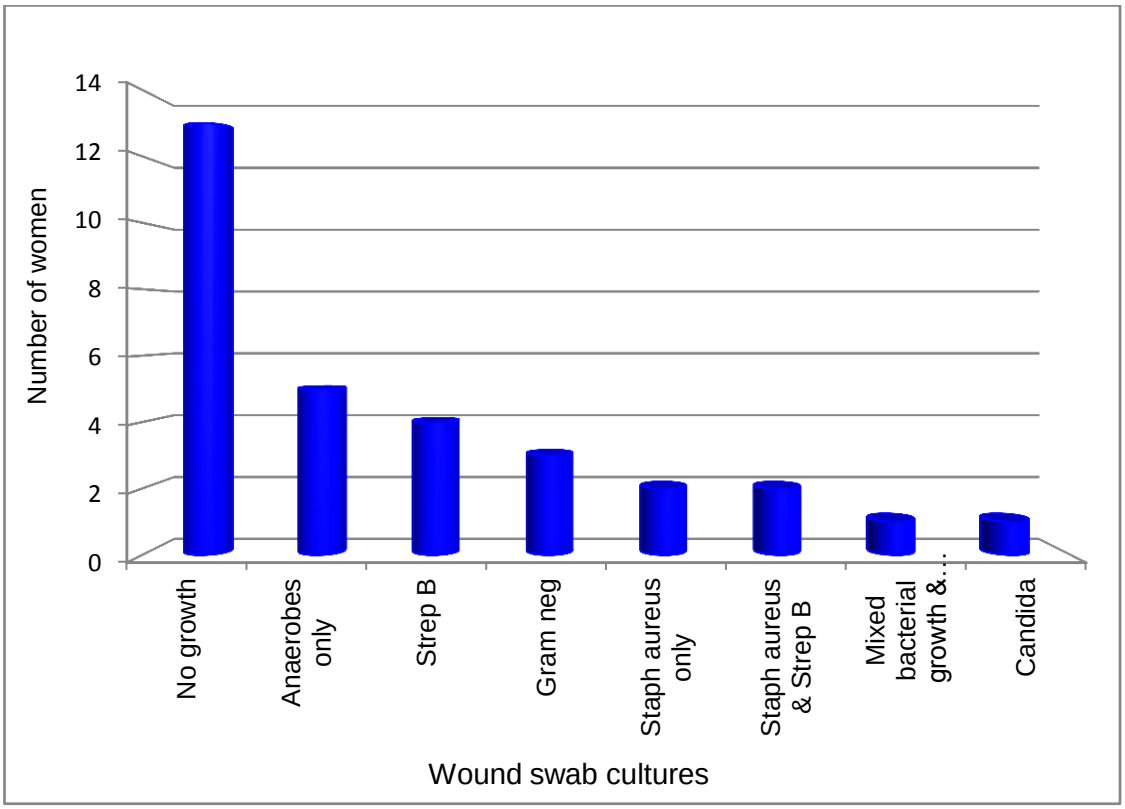
Protocol adherence was good in many aspects and only one woman as referred to previously was randomised against trial guidance. Important considerations for the definitive study are that procedures are standardised as much as possible to reduce bias in the treatment groups. The following sections therefore provide data which highlight some of the areas that need full collaboration with all future stakeholders who will be involved in the design of the full scale study.

6.2.10.1 Perineal wound swabs and the administration of antibiotics

Perineal wound swabs

Wound swabs were requested at randomisation if one had not already been taken prior to referral at the recruiting site. Perineal wound swabs were obtained from 32/33 (97%) of women who participated in the study. Wound swab cultures presented in figure 30 were available for 31/32 (96.9%) women who had a wound swab obtained. The results for one woman could not be located.

Figure 30: Microbiology cultures taken by clinicians at recruiting sites from women with dehisced perineal wounds, prior to randomisation (2011-2013)



Administration of antibiotics

For the pilot and feasibility RCT antibiotic administration including the type prescribed was as the discretion of the clinician at the individual recruiting sites. Out of 33 RCT data entry questionnaires, (appendix 11) 79% (n=26) of women had been prescribed antibiotics either prior to or at the point of randomisation in the absence of positive microbiology. Whilst 21% (n=7) of women were not prescribed antibiotics either prior to or at the point of randomisation.

Antibiotics received in re-sutured group (n=17)

For those women who were randomised to re-suturing oral antibiotics were prescribed in 71% (n=12) of women at or before randomisation.

Intravenous antibiotics were received by 65% (n=11) at the operative procedure, whilst both oral and intravenous antibiotics (at the operative procedure) were received by 53% (n= 9) of women. Information regarding the administration of intravenous antibiotics at operative procedure was not available for one of the women.

Intravenous antibiotics only were received by 12% (n=2) at the operative procedure.

Two women did not receive the allocated intervention of re-suturing.

Antibiotics received in expectancy group (n=16)

Oral antibiotics were prescribed in 88% (n=14) of women at or before randomisation; intravenous antibiotics (one dose) and oral antibiotics were prescribed in 6% (n=1).

Choice of antibiotic treatment at randomisation

Twenty-six women out of the 33 who participated in the study were prescribed five different types of antibiotics either prior to or at randomisation including Cephalexin, Co-amoxiclav, Metronidazole, Flucloxacillin and Erythromycin (table 38).

Table 38: Type of antibiotics prescribed by clinicians at recruiting sites for women with dehisced perineal wounds at or prior to randomisation (2011-2013)

Type of antibiotic prescribed	Number of women prescribed antibiotic
Co-amoxiclav	11
Flucloxacillin	3
Cephalexin and metronidazole	2
Cephalexin	2
Erythromycin	2
Metronidazole	1
Metronidazole and Co-amoxiclav	1
Metronidazole and Erythromycin	1
Information not available	3

Out of the women 79% (n=26) of women who were prescribed antibiotics subsequent microbiology revealed normal skin flora or no growth in 27% (n=7) of women.

Out of the 21% (n=7) who were not prescribed antibiotics a positive microbiology result (heavy growth of anaerobic organisms) was isolated in only one woman.

6.2.10.2 Protocol adherence for secondary re-suturing

Table 39 reveals the operating obstetricians adherence with the recommended suturing materials and techniques for secondary re-suturing. The recommendations presented in chapter five and table 11 are summarised below for ease of reference.

A standard synthetic polyglactin suture was the recommended suture material and the recommended techniques were detailed as: continuous technique for the vaginal mucosa, interrupted to the muscle layer and clinicians discretion with the

skin, using either the continuous or interrupted technique, or not sutured if skin edges well opposed.

Table 39: Obstetrician's adherence with the recommended suturing technique and materials for the secondary repair of perineal wound dehiscence (2011-2013)

Secondary repair of dehisced perineal wound (n=15)[†]	n (%)
Re-sutured using recommended materials all layers	
Yes	9 (60.0%)
No	5 (33.3%)
Not recorded	1 (6.7%)
Vaginal mucosa (8 mucosa intact) re-sutured using the recommended technique	
Yes	5 (71.4%)
No	1 (14.3%)
Not recorded	1 (14.3%)
Perineal muscle re-sutured using the recommended technique	
Yes	13 (86.6%)
No	1 (6.7%)
Not recorded	1 (6.7%)
Perineal skin re-sutured using the recommended technique	
Yes	13 (86.7%)
Not recorded	2 (13.3%)
Re-sutured using continuous technique	7 (54.0%)
Re-sutured using interrupted technique	6 (46.0%)

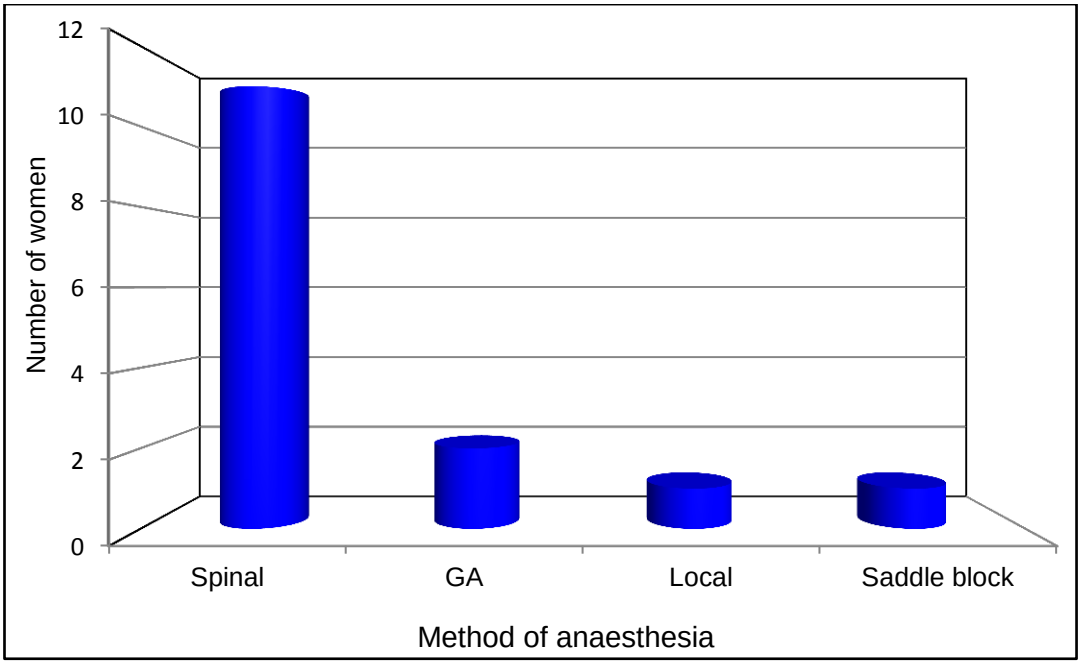
[†] **2/17** women randomised to re-suturing did not receive the allocation and were managed expectantly.

The protocol recommended that re-suturing of the dehisced wound was conducted as close to randomisation as organisationally possible, preferably within 48 hours. No instances of women who were re-sutured outside this time period were reported to the trial co-ordinator. In addition despite some organisational barriers regarding location of the perineal re-suturing, all procedures were conducted in maternity theatres by a senior obstetric registrar or Consultant.

6.2.10.3 Protocol adherence for the method of anaesthesia for secondary re-suturing

Guidance relating to the mode of anaesthesia was at the discretion of the operating surgeon and the anaesthetist following a full discussion with the woman prior to the procedure. The methods of chosen anaesthesia presented in figure 31 reveal that spinal anaesthesia was the most common form of anaesthesia provided.

Figure 31: Methods of anaesthesia received by women in the operating theatre prior to the secondary repair of their dehisced perineal wound (2011-2013)



6.2.10.4 Protocol adherence for the assessment of wound healing

The protocol for the RCT recommended that perineal assessments were conducted by a clinician independent from the research study to limit the potential for the introduction of bias. At 2 weeks out of the 30 women whose wound was assessed this was achieved 43% (n=13/30) of the time. At 6 weeks independent assessment was achieved 44% n=12/27 of the time.

6.2.11 Adverse incidents

There were no adverse incidents reported in either group at any of the recruiting sites.

6.3 Qualitative results

This section will now present the results of the qualitative paradigm of PREVIEW, the purpose of which was to explore women's personal experiences of living with a dehisced perineal wound and taking part in the RCT. Giorgi's methodological approach described in chapter five, guided the analysis of the transcripts.

The interviews continued until data saturation was achieved (n = 6 interviews). Characteristics of the interview participants are outlined in table 40. Pseudonym names of the participants and their partners are used throughout to protect identities for future publication. All women interviewed apart from one, delivered their babies at the host organisation the UHNS. Geographical location of five out of the ten recruiting organisations was the reason that most interviews were carried out locally to the researcher. Three women randomised to re-suturing and three randomised to expectancy were interviewed in their own home and the women were between 6 and 9 months postnatal. All women had their babies present which limited the interview length as they were either awake or became disturbed during the course of the interview. Out of the six women interviewed the researcher had met one of the women previously, prior to the allocation of the intervention.

Table 40: Characteristics of the six women interviewed at home by the author of this thesis. All women had taken part in the RCT (2011-2013)

Characteristics of women interviewed Participant names changed						
Characteristics	**Sue 1**	**Nicola 2**	**Diane 3**	**Fiona 4**	**Jenny 5**	**Cathy 6**
Age	38	23	20	29	27	28
Ethnicity	White	White	White	White	White	White
Relationship status	Married	Co-habiting	Co-habiting	Married	Co-habiting	Co-habiting
Employment	Yes	Yes	No	Yes	Yes	Yes
1st vaginal delivery	No	Yes	Yes	No	Yes	Yes
Previous perineal trauma	Yes	N/A	N/A	Yes	N/A	N/A
Previous dehisced perineal wound	Yes	N/A	N/A	No	N/A	N/A
Mode of delivery	Normal	Normal	Forceps†	Normal	Forceps†	Ventouse†
RCT allocation R= re-sutured E= expectancy	R	E	R	E	R	E
Months postnatal	8	7	6	7	9	8
Length of interview (Minutes)	29	18	23	18	26	40

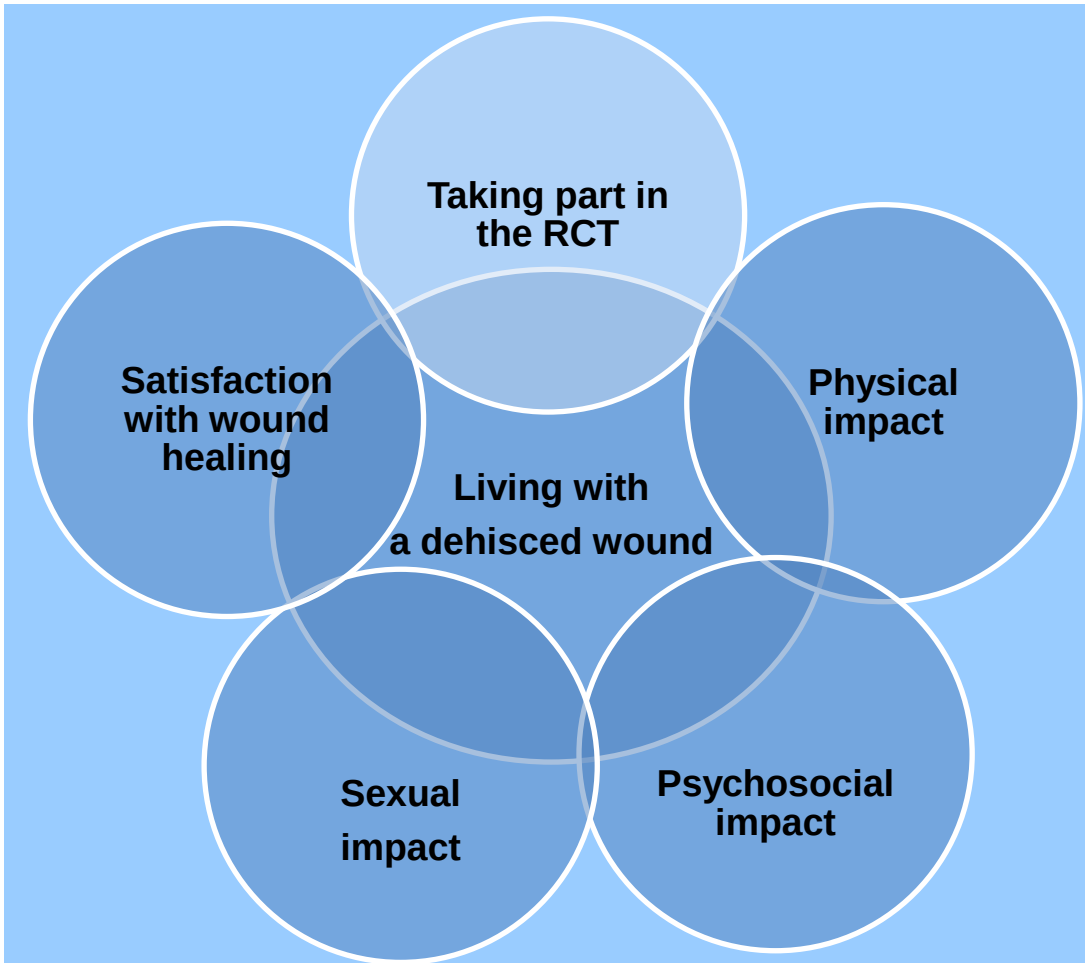
†Forceps and Ventouse delivery are classified as operative vaginal deliveries
All wounds dehisced within the first postnatal week

6.3.1 Identified themes

The 'one sheet of paper' approach (appendix 19) described in the previous chapter was used to assist the identification of commonalities amongst the narratives and followed Giorgi's analytical framework. Five main themes (figure 32) were identified from the data analysis in relation to women's experiences of wound dehiscence. Four of the emergent themes which represented commonalities with all six women interviewed were: 'physical impact', 'psychosocial impact', 'sexual impact', and 'satisfaction with healing.' A fifth theme 'participating in the RCT' was 'a priori' a

term which Moher *et al* (2009) acknowledge as being derived from the characteristics of the phenomenon (dehisced perineal wounds) being studied. This 'a priori' theme was particularly relevant towards planning for the definitive study and establishing if the intervention was acceptable to the women.

Figure 32: The five main themes obtained from six interviews with women who participated in the RCT (2011-2013)



Several of the main themes were supported by one or more sub-themes all of which are detailed below with extracts from the interview transcripts.

The symbols in table 41 were used in the interview transcripts to represent either a pause in the interview, non-verbal communication, laughter, or the interviewer's clarification of the narrative for the reader.

Table 41: Transcription symbols

Symbol	Representation in quotation
…	A brief pause Hesitation The woman is thinking about her response
{ }	Laughter from participant
[ ]	Non-verbal communication
( )	Interviewer's clarification of narrative for the reader for example Tim (husband), she (perineal care midwife)

All themes and sub-themes were identified primarily by the author of this thesis and subsequently discussed and agreed upon by the researcher providing qualitative support and guidance.

6.3.2 Theme 1: Physical impact of perineal wound dehiscence

This theme describes the physical impact of the dehisced perineal wound and reflects upon the descriptive words women used to express the type of pain they were experiencing and how this affected their activities of daily living. This theme also captures the concerns women have relating to infection and wound healing.

6.3.2.1 Sub-theme: Perineal pain

Perineal pain associated with their dehisced wound was one of the first areas raised by all six women interviewed when they were asked to remember how they felt when their wound broke down. The women used various terms to describe the intensity and depth of their pain for instance:

> *"I thought I was dying {laughter}, it really hurt that much." (Nicola, line 55)*
>
> *"The pain, it was really bad." (Diane, line 140)*
>
> *"I was really sore … raw, it was very, very painful." (Fiona, lines 66 and 68)*
>
> *"I was very sore. It was terrible to be honest." (Jenny, lines 31 and 37)*
>
> *"It was petrifying." (Cathy, line156)*
>
> *"When you are examined in the hospital and you took out the stitch … that was horrific." (Sue, line 260)*

Whilst Sue, described the suture removal process as horrific she also spoke about the brief respite from pain she felt, which consequently led her to question if she actually needed to have the wound re-sutured.

> *"After you took the stitches out in the afternoon, I came home and did the load of ironing, I said to Tim (husband), look at me, I am better. You know, I don't need to have anymore, (referring to re-suturing) and Tim was like, you are not better, and then like later I was like actually no, it does still really hurt so yes, I did know deep down it was the right decision really and definitely has been so yes." (Sue, line 277)*

6.3.2.2 Sub-theme: The impact of the wound dehiscence upon daily activities

Whilst the descriptors of pain were emotive, the impact of this pain upon the women themselves and their families became clearly evident when they started to talk about how the pain affected their daily living activities. Difficulties such as walking, sitting, shopping, housework, and getting in and out of a car were mentioned by all women. Whilst for some of the women, the perineal pain also impacted upon their ability to feed their baby either breast or formula. Extracts from the interviews provided below illustrate the extent of how perineal wound dehiscence impacted upon those initial precious weeks following childbirth.

Pain with walking and sitting

> "*Not good because when my stitches popped open they were really sore, I couldn't even hardly walk. I was in a bit of a mess really to be honest … but it was, a lot of it was worry as well because of like, you know, it's not nice to have an open wound down there … my knickers sort of kept rubbing on it and it was just like every time I walked, I could hardly walk." (Jenny, lines 28 and 205-206)*

The following account of pain by Nicola suggests that focusing on something other than the pain allowed her to carry on with some of her normal daily activities.

> *"After a while, it stopped like hurting when I was walking because I was thinking about other things {laughter} and it just, I think when I thought about it, it hurt more." (Nicola, line 383-384)*

Some women acknowledged that the pain relief they had been prescribed was not that effective at relieving their pain.

> *"The pain, it was really bad, I was struggling to go to sleep, they gave me some paracetamols but they just weren't working. Walking and sitting down was hard and going to the toilet." (Diane, lines 147, 214, 217)*

Fiona was prescribed stronger analgesia (co-codamol) but as the following extract suggests, even this did not appear to relieve the pain enough for her to continue with normal daily activities.

> *"It was still very, very painful, too painful to take Lewis (other child) to nursery school because I couldn't drive for a bit, it was too … too painful to sit down in the car, very painful. I just couldn't walk very much, really because it was very, very swollen. I'd say because my mum had a week off and Steve (husband) had two, I was probably back driving about after three weeks, I'd say." (Fiona, lines 197-198 and 221-222)*

Jenny's account of pain reflected upon what she was not able to do following her wound dehiscence and the difference following the secondary repair.

> *"Before I had it done, I could hardly walk so, I didn't even venture out to the shops or anything. The shopping yeah, my partner had to do it all, I had to give him a list and he had to go and get it, which is why I say I was lucky that he had the time off that he did, because otherwise, I don't know what I would have done because my mum works full-time. I've got sisters but they've got little kids themselves…I just feel like a bit of a pain asking people all the time*

even though they probably don't mind, I like to just get all my things myself, I'm that type of person, so, yeah …'I could do like a bit of hoovering and things like that and just, do you know what I mean, just help out a bit more than it was before I had it done, because I couldn't do anything." (Jenny, lines 219-221 and 246-247)

Whereas Cathy who was allocated to expectancy clearly demonstrated how difficult it was for her to simply sit down and how she had to position herself to facilitate this. Cathy also expressed the length of time she experienced discomfort in her wound and how this affected the clothes that she wore.

"I couldn't sit down and I couldn't sit on a hoop or anything so I had to sit on my feet because I just literally couldn't sit down anywhere [demonstrates sitting with one leg tucked under bottom] … if I sit down and 'I'd be in pain it was more of a case of I'm going to sit down and that was going to take me about 5 minutes to sit down cause I'd have to lower myself down really carefully. I think I literally lived in my joggers four … four months … my tracksuit … um because it felt comfy and it wasn't tight on." (Cathy, lines 80-81, 170 and 365)

Pain with passing urine

Several of the women interviewed reflected upon the pain and difficulties they encountered whilst passing urine.

"It stung, (frightened to pass urine) mum told me the longer you keep it in, it will hurt even more." (Nicola, line 628 and 635)

"Having a wee… it was horrible it's was on the side so I'd, lean over." (Cathy, line 140)

"It was a bit strange at first because sometimes, I had to run because I felt like it was coming quite quickly and spurting everywhere." (Fiona, line 238 and 242)

Pain with feeding baby

Naturally women want to feel comfortable when feeding their baby's, however the extracts below reveal that most of the women interviewed expressed some degree of difficulty with this.

"I contemplated putting him on the bottle, just because I'd had enough really and I wanted one of the pains to go away." (Sue, line 150)

"I couldn't feed him on a night …. I was lucky that my partner had 20-odd days off to help me because I was struggling to do just simple things, like change his nappy and things like that." (Jenny, lines 28-29)

"I was quite surprised how much it did affect me to be honest because I thought, oh it will be alright, it will heal….but no, I was very sore…. so I really struggled once it happened. It was stopping me from doing simple things … I mean, even in the night I couldn't get up with him, do you know what I mean? And it's like I couldn't sit on the bed to feed him. I could hardly sit down. It was terrible, to be honest. When I was sitting downstairs, I was fine because I have the arm of the chair to lean on because I could only sit one-sided, but at night, when I have to sit on the end of the bed, I couldn't… I couldn't sit on the end of the bed. So, yeah, my partner had to do all the night feeding, but I felt a bit bad sometimes because I knew he was really tired, because he was

doing a lot around the house because I couldn't do housework or anything like that, he needed his sleep you know, he just couldn't have it … but we managed." (Jenny, lines 175-177 and 183-185)

6.3.2.3 Sub-theme: Avoiding infection

Most of the women interviewed expressed concerns about infection and measures they took in attempts to avoiding infection, particularly Jenny and Diane as the following extracts clearly illustrate.

"I was worried about infection because of where it is and it was quite deep the wound ... yeah, it was like so many centimetres, [demonstrates the depth with hands] … so yeah, I spent the night ... hours in the shower … I was in the shower all the time, I just like wanted to make sure I didn't get any infection or anything … I tried to keep it clean. I was in the shower like, loads of times a day." (Jenny 114-115 and 161)

When asked why she was so worried about infection Jenny replied:

"I don't know… because of where it is and it was … it was pretty deep. I would've worried a lot, I think and when you've got a newborn to look after, it's ... it was so difficult. Because it was that sore, I thought I had an infection." (Jenny, line 115)

Diane, whose wound had completely dehisced, paused several times as she struggled with her emotions.

> *"I think it was due to infection that it broke down so much. I was looking at them every day, to clean it. I could tell then and I got my mum to look at them as well. Because it didn't feel like it was, it was healing, and because I was so stressed and I didn't really want to go to the doctors anymore, I don't know. I was just ... because I was feeling them as well just to see like how deep it was and I don't know … I don't know … it was really ... rather I don't really know." (Diane, lines 131-134)*

Although Sue's account suggests that she was somewhat in denial about her dehisced perineal wound, Sue herself was not particularly concerned about infection but felt that her husband and the midwife were.

> *"I wasn't worried about infection, not really no ... I mean I think Tim was because Ruth (midwife) showed Tim the wound. So Ruth and Tim were but I think I just wanted it to go away, not want to think about it and just pretend it was not happening, nothing really in some ways." (Sue, line 82-83)*

6.3.3 Theme 2: Psychosocial impact of perineal wound dehiscence

This theme describes how some women did not really want to acknowledge the dehiscence and felt that by ignoring the wound it would still be alright or even better that it would actually go away. The sense of failure for not conforming to what women perceive as normality in day-to-day activities and socialisation including their feelings of 'self-blame' that they are in this situation are also described in this theme. Similarly, women also revealed the extent of their fears about the

consequences of their wound dehiscence, their altered body image, and the impact for future childbirth.

6.3.3.1 Sub-theme: Denial

A number of women spoke about their attempts to ignore the problem of wound dehiscence hoping that it would simply just go away. This is reflected in both Sue's and Jenny's accounts below and Nicolas account previously referred to in the section above relating to pain when walking.

> *"If you leave me alone, don't poke…it will go away type of thing…would have buried my head in the sand a bit really and left it." (Sue, lines 261-262)*

> *"I thought, oh it will be alright, it will heal." (Jenny, lines 30-31)*

6.3.3.2 Sub-theme: Sense of failure or self-blame

A sense of failure or an apparent sense of self-blame was expressed by several of the women interviewed particularly Diane as the following extract reveals.

> *"Really thought bad about myself, my stitches coming undone made me feel really bad about myself … honestly it was … I really thought that bad of myself." (Diane, lines 11 and 40)*

6.3.3.3 Sub-theme: Fear

A sense of fear was expressed by nearly all women interviewed either related to their current experience or for future childbirth. Women spoke about being scared of having stitches again, petrified of giving birth next time and that the whole process was too much to go through again.

Whilst fear was a common thought for most of the women it was particularly relevant for Jenny, who was currently pregnant for the second time. Sadly, despite talking to her midwife about it, the extract below illustrates that Jenny remained fearful of childbirth.

"I'm petrified, I'm petrified, I must admit ... I'm just worried because this scar being still sore and it's still quite new, I'm worried about it popping open or making it difficult while I'm in labour, don't know … I don't know. I just keep going over these things, going around my head thinking I'm not going to be able to do it. Maybe I'm being stupid. I would have liked the opportunity to discuss delivery this time. I told my midwife what had happened, but she didn't say anything so I thought it'd be alright, but it's still a concern of mine. It's sort of like I'm petrified." (Jenny, lines 520-523 and 562-564)

6.3.3.4 Sub-theme: Altered body image

Altered body images, with thoughts of being deformed were re-lived by several of the women.

"My stitches (breaking down) that was the worst thing, because it's your body isn't it ….my heart dropped, I thought I was going to be deformed. I don't think they should just leave a massive hole down there to heal back by itself, because it's just devastating. There's a lump where the scar tissue is, but not many people going to look there and it doesn't really bother me to be honest." (Diane, lines 25-27)

"It was a lot of worry…it's not nice to have an open wound down there… When I first had it I thought oh god, I was going to be deformed." (Jenny, lines 207 and 497-498)

"There was this piece of tissue hanging and it was raw for about 3 months, it wasn't right." (Fiona, lines 259 and 276)

6.3.3.5 Sub-theme: Isolation

Five out of the 6 women spoke about the feeling of isolation and not being able to leave the house as soon as they had expected either as a result of the pain or feelings of anxiety and lacking in confidence.

"I think he was about three weeks old before I even took him outside." (Jenny, line 222)

Whilst for Cathy after having several 'panicky' episodes with hospital visits it was almost 6 months before she felt confident to take her baby out on her own.

"Now, like I say now, I'll go to clinic and I do. It's not like… it's the best place to go. It's a bit… everyone's sitting up looking at me and stuff, but I'm loads better now so I'll go and I'll take her (referring to baby) places." (Cathy, line 248)

6.3.4 Theme 3: Sexual impact of perineal wound dehiscence

This theme describes the impact of both resuming sexual intercourse following their perineal wound dehiscence and the long term sexual morbidity that some women were still experiencing up to 9 months following childbirth.

Women in both treatment groups reported issues related to sexual morbidity as the following brief extracts reveal.

Re-sutured group:

"Very painful, (responded immediately) worse following this baby." (Sue, line 214)

"It was quite, it was very tight and sore when ... but, I think it was just because I was so tense, do you know? Like I was scared about it … I was so tense at first, really scared about it." (Diane, lines 360-261)

"Wasn't good at first … I must admit, it was quite painful, even now the scar tissue is quite sore sometimes when I wipe myself, when I go to the toilet." (Jenny, lines 297-298)

Expectancy group:

"I think it's like oh … it's different now, it's had a baby through it." (Nicola, line 600)

"At first it felt different because of the piece of tissue that was swollen." (Fiona, lines 304 and 308)

"First time was really scary, frightened about it just ripping apart and the pain. I was petrified and it did hurt, felt like bruising….asked him (referring to partner) to have a look, he was good like that, then I asked him how it felt … he'd wind me up for a bit, then he was like no it feels normal." (Cathy, lines 206, 589 and 592)

6.3.5 Theme 4: Satisfaction with healing

Theme 4 provides evidence from all of the women interviewed relating to their experiences of wound healing.

Re-sutured group:

"She (perineal care midwife) removed some stitches (Sue, line 414)

"They had to pull a stitch out." (Diane, line 178)

"Healed really well, after one or two had opened again…think I had gristle or something," (referring to over granulation tissue). (Diane, lines 71-72)

"It's still quite raised, so you can feel it. It's healed a lot better than I thought to be honest." (Jenny, line 497)

Expectancy group:

"Looked in the mirror, looks weird…it's just like you can see where it was stitched and come unstitched." (Nicola, lines 535, 543, 559)

"Felt like my right hand side looked lower than my left …. I was fretting that, that it all dropped if you get me. I asked him (partner) can you just please look….he said it looks fine." (Cathy, lines 632 and 641-642)

"She (perineal care midwife) said there was a little bit at the bottom that was taking longer to heal" (referring to over granulation tissue) and I said will I have to have them re-done? She (perineal care midwife) said no, no, no and then I was ok." (Cathy, lines 312-113)

"Looking back, would have been better to have it re-stitched straight away, it's taken a long time to heal and I thought at 7 months I'd have to go back to the beginning and have it re-stitched." (Fiona, lines 344-347 and 354)

6.3.6 Theme 5: Participating in the RCT ('A priori')

Theme 5 describes women's experiences of taking part in the RCT and encompasses their understanding of the randomisation process and how they felt about completing the trial questionnaires. Women's views of both of these aspects are fundamental to the design and conduct of a full scale study and crucial towards ensuring that the research team have truly captured outcomes that are significant to women.

6.3.6.1 Sub-theme: Understanding the randomisation process

Understanding the implications of the randomisation process is paramount towards successful recruitment and retention in RCTs. Despite the strong preference for treatment options apparent in the following interview extracts, women did appear to understand the concept of randomisation.

Diane was allocated to re-suturing:

> *"I was praying that I could be…they'd come back, that they'd stitch me. I was well happy when told I was going to be re-stitched and since I had it done, then that made a whole lot of difference. I did put it in the thing (referring to the questionnaire) that if I didn't have it done it would have made… played a big ….massive ….I don't know…I think I would have been really unhappy." (Diane, lines 13-14 and 25-28)*

Diane did indeed make a comment on her 3 month questionnaire:

> *"I am very happy with the perineum, I feel that is has healed well. I feel that if I didn't have the stitches re-done I would have had many problems physical and emotional."* She followed it with a smiley face, ☺ illustrating her contentment for being re-sutured.

Jenny was equally as delighted when she was informed of her treatment allocation*:*

> *"Well happy when told I was going to be re-stitched, I thought at least the pain is over now. If I was told I was going to be left, I'd be like 'oh' because I was so worried about infection." (Jenny, lines 56 and 108-109)*

Cathy, who revealed that she was extremely emotional when she attended the recruiting site for review of her dehisced perineal wound, also had a strong preference for a treatment option, only this time it was for expectancy:

> *"When the midwife asked me about putting the numbers in and picking which one you do, I was like please, please, please, please come back with tablets because I can't … I don't want an epidural anyway. She then (referring to the midwife researcher), she was like, you might have to have this … I said, no, no, no, no… {laughs} then she come back in and I was like 'I love you' {laughs} when I was told I was in that group" (referring to expectancy). (Cathy, lines 87-88 and 91-92)*

Apprehensions relating to being re-admitted to hospital, with concerns for childcare and the likelihood of requiring regional anaesthesia for the re-suturing were voiced by women who had a preference for expectancy:

> *"I preferred not to have it done (re-suturing) because of leaving her (referring to the baby), the spinal block, staying for six hours and then you've got the added issues if it doesn't work again and then that was … that scared me." (Cathy, lines 346-348)*

Fiona who was allocated to expectancy explained:

> *"It would have been okay to be re-stitched but I would have been concerned about going back in and getting a general anaesthetic." (Fiona, line 369)*

Similarly Nicola also tried to rationalise with the treatment options:

> *"I would have been gutted if I needed stitches again, but I would have done it … didn't know whether I'd have to stay in overnight and leave her." (Nicola, line 505)*

Given that Nicola also said:

> *"You know I'd even give birth to thousands of babies, but I could not have stitches again, that's the only thing that hurt me the most…I was scared." (Nicola, lines 149-150)*

It would have been reasonable to assume that in reality, she may not have consented to being re-sutured.

6.3.6.2 Sub-theme: Completing the trial questionnaires

All women interviewed were asked how they felt about completing the trial questionnaires. All six women felt that the questionnaires were straightforward easy to complete and that they were not too long.

Women were also asked if they felt there was anything else that should be added to the questionnaires for a future study. All women were reminded about the outcome measures assessed in the RCT. None of the women felt that there were any additional questions to ask and that the study had addressed outcomes that were important to them. The free text annotated sections were acknowledged as an area which allowed for any additional information that the women wished to include.

6.3.6.3 Sub-theme: Attending for hospital appointments

How women felt about attending for hospital appointments to assess wound healing is crucial for the planning of the definitive study to optimise follow-up rates. However, women's experiences can also demonstrate to commissioners the value of perineal care clinics in areas where these are not already established. The accounts below demonstrate that women felt reassured with the advice they were given, that continuity and familiarity of being seen by the same clinician was important to them and that the care they received was both sensitive and responsive to their individual needs.

Jenny's hospital appointments:

"It wasn't just all about the stitches if you know what I mean ….they (the midwife researchers) were going through things … asking me how I was in general. I felt comfortable around them … so because I mean, sometimes you think … I've got to take my knickers off again with someone else." (Jenny, lines 446-450)

Cathy's hospital appointments:

"The midwife, she was brilliant, she come and got me first" (waiting to be seen for trial eligibility). (Cathy, line 37)

At a subsequent follow-up appointment to assess healing Cathy also said:

"She was an angel, (referring to the perineal care midwife) when I come to the hospital one day and just burst into tears, I sat there and cried because I was terrified." (Cathy, line 296)

Diane's hospital appointment:

"On my last appointment the midwife said I had a bit of skin at the bottom of the vagina that made it a bit tighter … she said I could get it removed but said to massage and stretch it … it doesn't bother me anymore." (Diane, lines 368-369 and 375-376)

6.3.6.4 Sub-theme: Positive and negative experiences of the RCT

Women's positive experiences were primarily focused upon the fact that the study was taking place and receiving the preferred treatment allocation as the following extracts reveal:

> *"I was so grateful I was picked, it was all excellent…honestly." (Diane, line 597, re-sutured)*

> *"Definitely the right decision." (Sue, line 264, re-sutured)*

> *"I was pleased for you to come back in and said I was allocated into that group." (Nicola, line 497, expectancy)*

> *"Any questions I had were answered." (Jenny, line 450, re-sutured)*

Only one of the women interviewed had a negative experience associated with the trial procedure of re-suturing and this focused upon delays waiting to be transferred to theatre. This situation occurred due to emergency procedures taking priority. Sue expressed her discontentment:

> *"I felt neglected and ignored, just sat there (waiting to be transferred to theatre) without anyone coming near and giving us any information. Just something, it was like being in prison and this little eight by eight cell, stuck there all day with no daytime telly with a new born baby. And not even two chairs, there was only one chair. So that was, I thought that whole process perhaps could have been dealt with a bit better really." (Sue, line 287-290)*

Interestingly Sue was also able to turn a negative experience in to a more positive one, she explained that:

> *"It felt like more messing about, but I knew it was the right thing to do." (Sue, lines 414-415)*

6.3.6.5 Sub-theme: Women's acceptability of the treatment options

Listening to 6 women's accounts of their treatment allocation and the positivity that encapsulates their experiences, the majority of them were happy with the treatment they received. Only one woman (Fiona) referred to previously in this chapter (section 6.3.5) felt that perhaps re-suturing may have been a better option for her from the outset as she had a particularly protracted period of healing.

6.4 Conclusion

This chapter has presented the preliminary results of the primary and secondary outcomes for the pilot and feasibility RCT. The numbers in both groups are too small to demonstrate any statistically significance. However, the results do suggest a trend in favour of re-suturing for wound healing at 2 weeks following randomisation; pain at 2 weeks and 3 months and women's satisfaction of the aesthetic results of wound healing at 6 months. Rates of dyspareunia were comparable in each group.

The main themes and sub-themes revealed from the interview data analysis have been presented which illustrate women's individual experiences of dehisced perineal wounds and taking part in the RCT.

Data has also been provided from both methodological approaches to establish how feasible it would be to proceed to a full scale multi-centre study.

Further discussion of both the quantitative and the qualitative findings will now be provided in relation to the relevant literature, theory and practice in chapter seven.

CHAPTER SEVEN:
DISCUSSION OF PHASE FOUR OF THE PREVIEW STUDY

7.1 Introduction

It is clear from the previous chapters that infected and dehisced perineal wounds are significant causes of maternal morbidity worldwide. However, this poorly researched area of childbirth, has led to a distinct lack of robust evidence to inform clinical practice throughout the UK and the rest of the world. It has already been acknowledged in seminal research that retrospective studies conducted between 1990 and 2004 (chapter two) and the two small RCTs included in the Cochrane systematic review, (chapter three) have concluded that re-suturing of dehisced perineal wounds is a safe and feasible alternative to the protracted period of healing and morbidity associated with expectancy. However, the inherent bias of retrospective studies and the methodological weakness of the two RCTs currently demand a more comprehensive research strategy to establish the clinical effectiveness of the management options that are available to women. Furthermore there have been no UK based research studies that have explored the management of perineal wound dehiscence.

As no robust RCT had previously been conducted to establish the effectiveness of re-suturing dehisced perineal wounds, with the primary outcome of healing, the RCT of phase four of PREVIEW which formed the basis of this thesis was therefore designed as a pilot and feasibility study. The collective findings from this preparatory work including a comprehensive assessment of the pilot and feasibility aspects of the RCT will now inform the design of a larger definitive trial.

Phase four of PREVIEW also had a qualitative component incorporated into the mixed methods trial design and followed a descriptive phenomenological approach based on the work of Husserl (1960) using semi-structured interviews to answer the research questions. Six women who participated in the RCT were interviewed by the author of this thesis on a one to one basis. The analysis of the transcripts was guided by Giorgi's analytical framework (Giorgi, 1975).

For ease of reference the research questions that guided the qualitative methodology are outlined below:

- What are women's experiences of a dehisced perineal wound during the early postnatal period?
- What are women's experiences of participating in the RCT?
- Will the treatment options be acceptable to women?

The primary aim of this chapter is to provide an integrated discussion of the quantitative results of the RCT as a pilot and feasibility RCT and the qualitative findings from conducting the six interviews. The results of both studies will be discussed within the perspective of existing knowledge, theories and practice, some of which are referred to in previous chapters (chapters two, three and four). As previously acknowledged there have been no primary qualitative studies that have explored women's experiences of dehisced perineal wounds. The main themes of the qualitative paradigm will therefore be discussed with reference where appropriate, to the available literature which has investigated the phenomenon of perineal trauma from a woman's perspective.

The pilot and feasibility aspects of the RCT will be discussed in full. The use of a mixed methods design for phase four of PREVIEW will be evaluated including the strengths and limitations of both research paradigms. The chapter will conclude with the implications for future research and clinical practice.

7.2 A discussion of the findings from the pilot and feasibility RCT and the qualitative study

The pilot RCT was designed to test the feasibility of conducting a full scale definitive study that would either reject or accept the null the hypothesis that re-suturing of a dehisced perineal wound makes no difference in the time taken to heal, in comparison to allowing the wound to heal by secondary intention. Hypothesis testing does require a powered sample size calculation, a feature not usually available for pilot and feasibility studies (Arain *et al*, 2010; Leon *et al*, 2011; Tickle-Degnen, 2013). Uncharacteristically, the RCT was able to state a hypothesis as a powered sample size was conducted using electronic data of women attending a local perineal care clinic that was available to the author of this thesis. The RCT also consisted of other features including primary and secondary outcome variables and a control group, which again are argued as not always a requirement of pilot studies (Arain *et al*, 2010).

The RCT included an assessment of the primary feasibility outcome variable: the proportion of women with a healed wound at 6-8 weeks following randomisation and secondary feasibility outcomes: pain, dyspareunia, women's satisfaction with the aesthetic results of wound healing and breast feeding.

Despite the debate surrounding hypothesis testing, and pre-specified outcome variables for pilot and feasibility research, the methods used to conduct the RCT do appear to support those used in similar studies. Interestingly most of the research

included in a review of pilot and feasibility studies by Arain *et al* (2010) contained a control group 18/26 (69%) and had both conducted and reported hypothesis testing for one or more of the outcome variables in 21/26 (81%). Some authors tested the effectiveness of an intervention whilst others performed statistical testing to determine any relevant associations between the study variables (Arain *et al*, 2010). Acknowledging the discourse surrounding pilot and feasibility studies, specific CONSORT guidance for reporting is currently being prepared (Eldridge *et al*, 2013) to address clarity of definitions and publication bias.

Whilst the results of the preliminary findings have been presented with a significance level of $P = <0.05$, the focus as has been about evaluating the feasibility of the processes of the RCT that are crucial to inform a successful full scale study. The author of this thesis also acknowledges the cautionary advice for researchers of pilot studies in that any effect size estimate derived from this study may not represent the true effect size, mostly as a result of the smaller sample size and need to be reported cautiously (Arain *et al*, 2010; Kraemer *et al*, 2006; Thabane *et al*, 2010). This became particularly pertinent to the PREVIEW study which despite being appropriately powered to detect statistical significance, was not able to report upon efficacy of the interventions as recruitment fell considerably below projected figures. It is the intention that the preliminary results will however feed into deliberations regarding plausible effect sizes to be used to inform future sample size calculations.

The following sections will now discuss the preliminary results of the RCT, integrating the main themes and sub-themes from the qualitative study where appropriate.

7.2.1 Wound healing

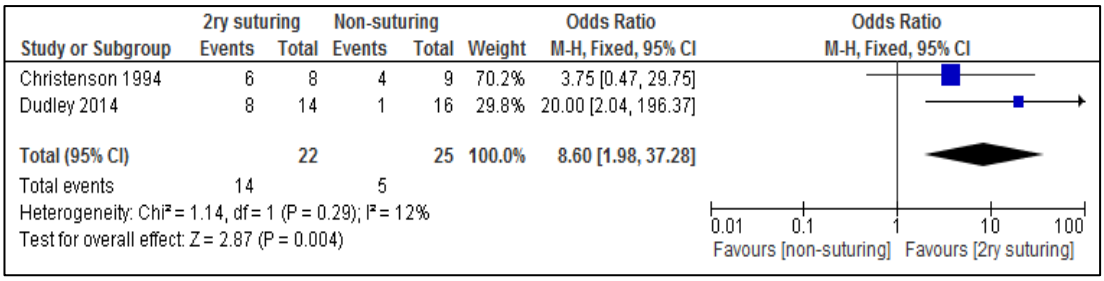
Clinicians assessing wound healing were asked has the wound healed ‘yes’ or ‘no’. The literature review relating to the pathophysiology of wound healing (chapter two) demonstrates that complete wound healing can take up to 12 months or more. However, wound healing for the purpose of the primary outcome measure was defined as ‘no evidence of wound dehiscence’.

Despite the fact that demonstrating statistical significance was not a specific aim for the pilot and feasibility RCT, the results relating to wound healing did reveal a trend towards favouring re-suturing at 2 weeks following randomisation $P = 0.004$. The results at 2 weeks were not surprising given that healing by secondary intention can take considerably longer. The numbers of women with healed wounds at 6 weeks was comparable in both groups and although one woman in the re-suturing group had superficial skin dehiscence this went on to complete wound healing by 13 weeks following randomisation.

Other studies that have referred to wound healing following secondary re-suturing have evaluated this outcome at 2-3 weeks (Ramin *et al*, 1992; Uygur *et al*, 2004). Complete wound healing at 2 weeks was reported by Uygur and colleagues in 18/25 (72%) women who underwent early secondary re-suturing, 3/25 (12%) had superficial separation of the skin edges and 4/25 (16%) women were lost to follow-up (Uygur *et al*, 2004). They did not report wound healing times for the 12 women who received expectant management. Similarly, although no precise figures were provided, Ramin *et al* (1992) revealed that most wounds 29/34 (85%) had completely healed by 2-3 weeks. The small study by Christensen *et al* (1994) evaluated wound healing at less than 4 weeks and found that women who were not re-sutured experienced longer healing times (greater than 4 weeks) n = 4/9 (44%) than women who were re-sutured 2/8 (25%).

Figure 33 compares the findings of the RCT conducted as phase four of PREVIEW with those of Christensen *et al* (1994) described in chapter three for wound healing.

Figure 33: Meta-analysis of two studies for wound healing by 2 weeks following the intervention of either re-suturing or expectancy.



REEDA scores and the assessment of wound healing

The REEDA tool was used to assess the wound at randomisation and at the 2 and 6 week time intervals. Clinician's compliance with completing the REEDA assessment was excellent at all-time points. The results demonstrated no significant statistical differences between the two groups at randomisation apart from an incidental finding that revealed a higher percentage of wounds in women who proceeded to re-suturing with mild to moderate redness *P* = 0.037 than those who proceeded to expectancy. At two weeks more wounds in women managed by expectancy group demonstrated oedema *P* = 0.024 and as expected only one woman in this group had skin closure *P* = 0.003. There were no statistical differences between the groups at 6 weeks in the REEDA score.

None of the studies that have investigated wound dehiscence have either referred to this method of assessment in their research or actually defined wound healing for the purpose of their study. This is despite the fact that the REEDA tool is one of the most common methods of assessing wounds and wound healing and is frequently reported in obstetric studies world-wide relating to perineal trauma (Fleming *et al*, 2003; Kettle *et al*, 2002; Kindberg *et al*, 2008; Mahishale *et al*, 2013; Mohamed and

El-Nagger, 2012). However, reducing in-patient and out-patient episodes appeared to a focus of some of the earlier studies (Monberg and Hammen, 1987; Ramin *et al*, 1992) as opposed to directly measuring wound healing.

Wound measurements

The literature referred to in chapter five (section 5.5.8.4) acknowledges that objective measurement of wound healing across various disciplines is very challenging. In obstetrics, there is some evidence to suggest reliability of the Peri-Rule and the Clini-Rule and the small study conducted for PREVIEW using the surgical rule demonstrated a degree of reliability for length but not so precise for width and depth. Several principle investigators for the RCT conducted as phase four of PREVIEW questioned the purpose of retaining the measured assessments in women whose wound had been well approximated with re-suturing. The rationale for this was to enable areas of dehiscence to be measured should the wound break down for a second time.

On reflection, what may have been beneficial would have been the wound measurements of all women who were not recruited to the study if the clinician assessed the area of dehiscence as being too small to re-suture. Recruitment logs revealed that out of the 192 women who did not fulfil the eligibility criteria just over 25% (n=49) women were not randomised for this reason. Potentially if pre-specified measurements of dehiscence were agreed upon by two clinicians then one may postulate that recruitment in this area may increase for the definitive study.

It is often assumed that a major cause of any wound dehiscence is infection. Clinicians in the RCT (phase four of PREVIEW) were asked to identify indicators of infection from a pre-specified list including: pain, swelling, redness, wound heat and purulent discharge. The most commonly reported indicators were pain, which was

present in 15/33 (45.5%) cases and redness present in 16/33 (48.5%) cases. Purulent discharge often considered a key indicator of infection (Horan *et al*, 2008; Thakar and Sultan, 2009) was present in 8/33 (24.2%) of women randomised into the PREVIEW RCT.

Perineal wound swabs were obtained at or prior to randomisation from 32/33 (97%) of women in the PREVIEW RCT and the results were available for 31/32 (96.9%) women, the results for one woman could not be located. A positive bacteriology report was reported in just over half of women with a dehisced perineal wound 18/31 (58%). This demonstrates that clinical assessment of the wound was almost on a parallel with microbiology investigation. Ramin *et al* (1992) did report clinical signs of infection in 27/34 (79%) women, but no bacteriology results were provided by the authors. In comparison the audit by Ajibade *et al* (2013) acknowledged common bacteriology findings but did not reveal the incidence of infection in the 19 women with perineal wound dehiscence. Higher rates of perineal wound infection were reported in the PREVIEW RCT in contrast to Hankins *et al* (1990) 12/31 (39%) but were lower than that those revealed in other studies 27/34 (79%) (Ramin *et al*, 1992), 12/17 (70%) and 25/37 (68%) (Uygur *et al*, 2004).

Oral antibiotics were prescribed in 26/33 (79%) women in the PREVIEW RCT even in the absence of positive microbiology, with various types of antibiotics being administered (demonstrated in chapter five, table 38). Individual antimicrobial policies are the most likely reason for the variation in antibiotics. Standardising the type of antibiotic administered would therefore prove challenging for the definitive study. Traditionally, antibiotics are used during expectant management, however if oral antibiotics are not administered to all women this co-intervention could also be considered a source for bias. Moreover, the concomitant use of a single dose of intravenous antibiotic administration in addition to oral antibiotics with the re-

suturing group not controlled for in the PREVIEW pilot RCT may also be viewed as introducing an element of bias, a factor which needs to be considered when interpreting the results. There is however, much discourse surrounding the administration of antibiotics particularly in the absence of positive microbiology. The results of RCT conducted as part of PREVIEW and the findings of the national survey (chapter four, figure 13) suggest that it is currently common practice and although no one would argue the urgency of antibiotic administration for the management of suspected sepsis, the eighth triennial maternal mortality report (2006-2008) (Centre for Maternal and Child Enquiries, 2011) only serves to add to the debate.

Irrespective of the trend in favour of re-suturing for wound healing times at 2 weeks, any results must also be interpreted in combination with women's experiences of the interventions received and the extent of their morbidity. To disregard women's views and experiences when developing evidence based clinical guidelines is regarded as "not only an injustice to women, but an indictment of the professional care ethic" (Walsh, 2000, p. 735).

The physical impact of the dehisced wound was a recurrent theme from the PREVIEW qualitative study and encompassed infection as a sub-theme. When women were asked what their main concern was when their wound broke down, all expressed anxieties about avoiding infection. Not surprising given that a recent study suggested that one in ten women will sustain a wound infection following primary repair of perineal trauma (Johnson *et al*, 2012). Women's narratives in the PREVIEW qualitative study are consistent with other studies referred to in the literature review (Li *et al*, 2014; Perkins *et al*, 2008) and Walsh (2000) that healing of perineal trauma wounds particularly avoiding infection and dehiscence is paramount to many women and their partners following childbirth. One woman

interviewed in the PREVIEW study acknowledged that she herself was not too concerned about infection, but that her husband and the midwife were, although she was also in denial of the dehiscence somewhat, wanting to ignore it in the hope that it would just go away. Several women interviewed, recalled the lengths they went to with constant showering to either prevent infection or stop it from becoming worse.

In contrast despite the increased risk of infection and dehiscence with OASIS (Royal College of Obstetricians and Gynaecologists, 2007) the two qualitative studies focusing upon severe perineal trauma revealed that women's physical concerns were primarily focused upon faecal and urinary continence issues with little reference to infection (Priddis *et al*, 2014; Williams *et al*, 2005). This may be attributed to the fact that women are prescribed prophylactic antibiotics following OASIS to reduce the potential for infection and dehiscence (Royal College of Obstetricians and Gynaecologists, 2007) and that issues particularly of faecal incontinence are primarily associated with OASIS.

7.2.2 Women's satisfaction with the aesthetic results of wound healing

There currently remains a paucity of both quantitative and qualitative evidence relating to women's satisfaction with the aesthetic results of perineal wound healing. Women in the PREVIEW RCT were asked how well their perineum had healed and despite the small numbers, there was a trend at all-time points that favoured the intervention of re-suturing for women's satisfaction with wound healing. Statistically, this was more significant at 3 months when all women who completed the question reported that their wound looked or felt better $P = 0.045$. At 6 months, although not statistically significant all women in the re-suturing group who completed the question relating to wound healing felt that their wound had healed compared to 3/16 (18.7%) women in the expectancy group who still reported that they felt that their wound had not healed $P = 0.232$. Similarly at the same time point out of all the

women who had either looked at or felt their perineum, 1/11 (9.1%) in the re-suturing reported that their wound looked or felt worse, compared to 5/13 (38.5%) in the expectancy group *P* = 0.166. Likewise more women who were re-sutured felt that their perineum was back to normal 11/13 (84.6%) compared to only half of the women managed by expectancy 8/16 (50%) *P* = 0.114.

Free text responses in the RCT questionnaires also revealed a tendency to favour re-suturing, with several reports of women being satisfied with wound healing compared to women managed by expectancy who expressed a retrospective preference for re-suturing. Prolonged healing, not feeling back to normal, altered body image and over granulation tissue being reasons cited for being dissatisfied. Several randomised and prospective studies that have evaluated the effectiveness of primary (not secondary) suturing of spontaneous trauma (first and second degree) compared to not suturing the trauma, have also revealed results comparable to the PREVIEW RCT (Langley *et al*, 2006; Metcalfe *et al*, 2006).

The PREVIEW RCT was not able to demonstrate any statistical significance relating to scar tissue between the two treatment groups. Although, it can be argued that even if the results were highly significant there are suggestions that the size of the scar may in fact be disproportionate to the impact it has on a woman's body image (Way, 1996). Two women in the expectancy group did not have the perineal scar assessed at this point due to over granulation tissue needing further treatment with silver nitrate. As referred to in the literature review, short term use of silver nitrate sticks are commonly used in obstetrics to cauterise in the area of over granulation tissue but can also cause the mother considerable pain (Borkowski, 2005).

Satisfaction with wound healing was a recurrent theme from the qualitative study conducted with women who participated in the PREVIEW RCT. All 6 women

interviewed reflected upon their experiences perineal wound healing. Women recalled having perineal sutures removed from the group who were re-sutured, already referred to as a procedure that can be distressing for some women. Qualitative findings for suture removal support the quantitative results and have implications for the future definitive study and further research, particularly as the recommended suture material for the PREVIEW RCT was a standard synthetic polyglactin suture. This was chosen due to longer absorption times (56-70 days) when compared to a more a rapidly absorbing suture such as Vicryl Rapide® (42days).

Most of the women interviewed were between 7 to 9 months following childbirth and their experiences suggest that the aesthetic results of wound healing extend beyond that of the 6 months outcome measure commonly associated with quantitative research investigating perineal trauma. In addition, women from both groups revealed accounts of being treated for over granulation tissue. One woman in the expectancy group also referred to a discussion between herself and a perineal care specialist midwife regarding the possible need for further surgery at a follow-up appointment some 7 months following childbirth. To her relief this was subsequently not required. The outcome was not quite the same for a woman in the study by Salmon (1999) who after 18 months of desperation with perineal morbidity was finally referred back to the hospital for perineal re-fashioning.

Altered body images (a sub-theme of the psychosocial impact of the wound dehiscence), with thoughts of being deformed and in some circumstances accepting that the perineal area 'looks different' were re-lived by several women interviewed in the PREVIEW qualitative study and support the findings of other published qualitative research (Salmon, 1999; Williams *et al*, 2005). Whilst there were some who felt and looked at their perineum's even asking their partners to look for

reassurance of normality, other studies have reported that women couldn't bear to look at it or touch the area (Williams *et al*, 2005). This may have been the reason that several women who completed the RCT questionnaires in PREVIEW acknowledged that they had not seen or felt their perineum.

Unfortunately for some women who experience a perineal wound infection and or dehiscence particularly those that have been managed by expectancy, there is also the potential for further corrective surgery, perineal refashioning, and excision of excessive scar tissue or other procedures associated with treating perineal dysfunction and altered body image (Ganapathy *et al*, 2008). As referred to previously, 50% of the women who were managed by expectancy felt that their perineum was not back to normal, one may therefore postulate that the potential for further intervention is not an unrealistic assumption.

7.2.3 Perineal pain

Perineal pain following randomisation was a self-reported secondary outcome measure (yes or no) at 2 and 6 weeks and again at 3 and 6 months. Women were also asked to rate the level of their pain using a 3 point ordinal scale of mild, moderate or severe and the frequency of their pain again using a 3 point ordinal scale. Although there were no statistical differences at any time point, there was a marginal trend towards favouring re-suturing. The main difference was at the three month time point where more women in the expectancy group reported pain or discomfort in their perineum 8/16 (50.0%) in comparison to those managed by re-suturing 4/14 (29%) $P = 0.232$. There was only one report of being in severe pain most of the time and this was experienced by a woman in the expectancy group at 6 weeks.

Women who reported pain at the pre-specified time points in the PREVIEW RCT were also asked to comment on their pain in relationship to activities of daily living. These included: feeding their baby, walking, sitting, exercising, wearing tight trousers, passing urine and opening their bowels. The numbers were actually too small to establish any statistical significance and the results were essentially similar in both groups. The main difference being at 2 weeks when 8/8 (100%) women who reported pain in the expectancy group revealed that they experienced pain on walking, compared to 2/5 (40%) women in the re-suturing group. The most likely explanation for this is the friction from underwear or sanitary protection on unhealed, exposed perineal tissues.

Women's descriptions of their pain taken from a modified McGill questionnaire were also similar, again the main noticeable difference being at 2 weeks and 3 months. More women in the expectancy group 5/8 (62.5%) described their pain at 2 weeks as stinging, (a sensory descriptor) compared to 1/5 (20%) in the re-suturing group, possibly due to urine coming in to contact with exposed perineal tissues as 5/8 (62.5%) also reported pain with passing urine. The trend continued at 3 months with 5/7 (71.4%) in the expectancy group describing their pain as stinging compared to 1/4 (25%) in the re-sutured group. Urinary pH which can range from 4.5 to 8 (seven being the neutral point) is usually slightly acidic at 5.5 to 6.5 largely due to metabolic activity (Simerville *et al*, 2005). Passing urine whilst there are still areas of dehiscence can therefore be a potentially painful process for some women.

No RCT or retrospective study referred to in this thesis investigating secondary re-suturing has revealed rates of self-reported perineal pain. Only the retrospective study by Ramin *et al* (1992) that examined case notes of women at 1 and 2 weeks post-secondary repair (no comparative group) revealed that none of the women complained of perineal pain.

Several randomised and prospective studies some of which have previously been referred to that have evaluated the effectiveness of primary (not secondary) suturing of spontaneous trauma (first and second degree) compared to not suturing the trauma, have also concluded that there were no significant differences between pain at several pre-specified time points (Fleming *et al*, 2003; Langley *et al*, 2006; Lundquist *et al*, 2000; Metcalfe *et al*, 2006).

Measuring pain can be an extremely complex and challenging process by the very nature of its subjectivity (Steen, 2008). The reliability of the McGill pain assessment tool and its sensitivity in assessing the complexity of pain experience (Steen, 2008) have led to its widespread use in numerous obstetric studies. However, allowing women to describe their own personal experiences of pain, an approach used by Steen and Marchant (2007) may also provide potentially more meaningful data, rather than simply allowing women to make choices from a pre-specified list of adjectives.

Perineal pain a sub-theme of the physical impact of perineal wound dehiscence was one of the first areas raised by all six women interviewed when they were asked to remember how they felt when their wound broke down. In some respects this was anticipated as perineal pain of varying intensity is experienced by the majority of women following vaginal delivery (Albers *et al*, 1999; Macarthur and Macarthur, 2004; Thakar and Sultan, 2009). What the author of this thesis was not quite prepared for, demonstrated by journal extracts (appendix 18) was the emotive and powerful responses such as “horrific” and “petrifying” used by women to describe the intensity of their pain detailed in the previous chapter (chapter six, section 6.3.2.1). Even the most complex of quantitative measures of pain could not emulate the poignancy expressed in the narratives of women’s experiences of pain.

Women's descriptions of perineal pain became particularly meaningful when placed in the context of activities of daily living. New mothers interviewed in the PREVIEW study frequently reflected upon how this affected their ability to feed (breast or formula), care for and enjoy their newborn baby, all at a time that unfortunately can never be replaced. For some women this can result in a process of grieving that can take many years to come to terms with. Salmon (1999) also revealed reports of women feeling a sense of loss as they too came to terms with their perineal trauma. One woman in particular felt that she would never have back what she believed to be those first precious few months with her son. Several women who responded to the free text sections of the RCT questionnaires in PREVIEW also referred to this sense of loss at various time points and how this spoiled their enjoyment with their baby. For many there was this reliance upon others to fulfil this 'normal' mothering role, yet others just wanted to get on with it and cope by themselves.

Supporting the findings of Priddis *et al* (2014) and Way (2006), most of the women interviewed also recalled difficulties they experienced with sitting, not being able to walk far and driving, all of which resulted in a lesser or greater extent of social isolation. Listening to the women's accounts of pain there was an apparent lack of effective pain management not that dissimilar to the women in other studies (Salmon, 1999; Way, 2012). Although even when women were taking stronger prescribed analgesia, at times the nature and intensity of the pain still prevented them from continuing with some normal daily activities. Several women interviewed in the PREVIEW study appeared to be accepting of the pain whilst others tried to focus on other things like Nicola (chapter 6, section 6.3.2.2). Distraction theories described by Nicola and positive thoughts are believed to have a beneficial effect upon relieving pain, as they close the gate control consequently altering the perception of pain (Middleton, 2004).

As women relived their experiences of perineal wound dehiscence in the PREVIEW study interviews, the psychosocial impact of the wound dehiscence upon women was clearly evident and resulted in a common theme for the qualitative study.

Women interviewed in previous qualitative studies have been extremely emotional as they re-lived their experiences of perineal trauma, some even several years following childbirth (Salmon, 1999; Williams *et al*, 2005). Whilst none of the women were visibly upset during the PREVIEW study interviews there were numerous pauses (illustrated by the use of … in the interview extracts) in some of the recordings as women appeared to struggle with their emotions as they reflected upon their experiences.

When talking about personal and sensitive issue there is always the potential for emotions to take over as Williams *et al* (2005) found during their focus group interviews. Women became visibly upset during their sessions as they recalled 'feeling really bad' about what had happened to them, even blaming themselves for their injury (Williams *et al*, 2005). Similarly women in the study by Priddis *et al* (2014) thought that their OASIS was as a result of something physically wrong with them, using the words *"I'm not stretchy"* or *"I could have done more"* (p. 7). Whilst women in the PREVIEW qualitative study had not sustained an OASIS these sentiments of self-blame and a sense of failure, a sub-theme of the psychosocial impact of the wound dehiscence are echoed by the women interviewed following their wound dehiscence. Women can experience a protracted period of morbidity following wound dehiscence and can often feel quite negative about their health and blame themselves for their condition as Herron-Marx *et al* (2007) discovered in their study of women's experience of enduring postnatal perineal morbidity.

Women expect to return to normality almost immediately following childbirth (Priddis *et al*, 2014; Way, 2012) a fact intensified by the persistent glamorous media portrayal of high profile celebrities following childbirth. A woman's account of her experience following an OASIS in the Australian study (Priddis *et al*, 2014) probably reflects many women's thoughts when she said that …"*birth isn't this pretty picture. It isn't the 'Home and Away' birth of three pushes and you're out and you're up and you're glamorous the next five seconds"* (Priddis *et al*, 2014, p. 5). When reality does not quite meet with these expectations particularly with an unexpected morbidity such as a wound dehiscence there can be an incredible loss of self-esteem and sense of failure (Mercer, 2004). Qualitative researchers have referred to this reality, as *'the fractured fairy tale'* (Priddis *et al*, 2014) *'experiencing the unexpected'* (Way, 2012) and the *'unpredictable perineum'* (Priddis *et al*, 2012).

Several women in the PREVIEW qualitative study were so fearful (a sub-theme of the psychosocial impact of the wound dehiscence) about future childbirth and the potential of experiencing the whole process again, that they either expressed a wish for a caesarean section or did not wish to contemplate another pregnancy. Salmon (1999) also revealed accounts of women who were frightened by the prospect of repeating childbirth and their experiences of lengthy healing processes. Whilst Williams *et al* (2005) reported women who were fearful of a subsequent OASIS. For one woman interviewed as part of the PREVIEW study the timing could not have been more pertinent, currently 26 weeks pregnant again and *'petrified'* to use her words of pending childbirth.

On occasions, some women are so traumatised by their experience of poor perineal management that they will request subsequent deliveries by caesarean section. Furthermore, it is concerning that women who are pregnant for the first time are becoming increasingly worried about the consequences of perineal injury following

childbirth and the associated morbidity (Premkumar, 2005). This too may be a contributing factor to the increasing interest in elective caesarean section as a more 'attractive' alternative mode of delivery (Wagner, 2000).

7.2.4 Dyspareunia

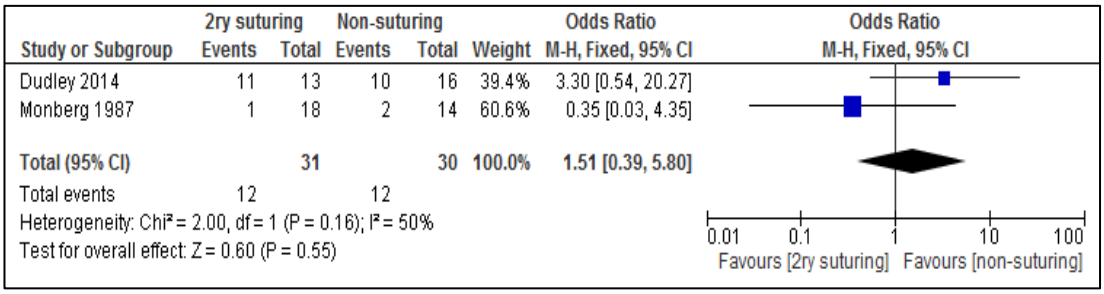
Rates of dyspareunia are persistently reported as an outcome measure for studies relating to perineal trauma due to the rates of on-going sexual morbidity women experience following childbirth. In the RCT for PREVIEW there were no significant differences between the groups relating to the resumption of intercourse and all women who completed the six month questionnaire n = 29 (100%) had resumed intercourse at 6 months. Similar results at 6 months were reported in the RCT by Monberg and Hammen (1987) and by Hankins *et al* (1990) in their the retrospective study of early repair of episiotomy dehiscence although the latter had no control group for comparative data.

Of the women who had resumed intercourse in the RCT for PREVIEW, there were no significant differences in self-reported dyspareunia either on penetration, or deep penetration or around the perineal scar site. However, 21/29 (72%) of all women reported dyspareunia at 6 months. Just under half of all women 13/29 (44.8%) reported pain around the scar site; re-suturing 6/13 (46.2%) and expectancy 7/16 (43.8%). Rates of dyspareunia at 6 months were higher than the 31%-42% reported in other studies (Barrett *et al*, 2000; Solana-Arellano *et al*, 2008) and considerably more than the 9.4% (3/32) reported by Monberg and Hammen (1987) included in the Cochrane review, chapter three of this thesis (figure 7) and figure 34 in this current chapter. A possible explanation for this is that women were specifically asked if they had experienced any pain around the perineal scar area during intercourse. When simply asked the question relating to pain on penetration 11/29 (37.9%) of women responded 'yes', this time supporting the findings of Solana-

Arellano *et al* (2008) referred to in the literature review (chapter two of this thesis) who reported rates of dyspareunia near to 42% at 2 to 7 months following childbirth. Dyspareunia in their study was particularly associated with infection, dehiscence and a constricted introitus (Solana-Arellano *et al*, 2008). Thin bands of scar tissue at the introitus are a common cause of superficial dyspareunia, which may need dividing surgically if symptoms do not respond to perineal massage with vitamin E or sweet almond oils (Kettle *et al*, 2005).

Figure 34 presents the findings of the RCT conducted for PREVIEW with that of Monberg and Hammen (1987) for dyspareunia at 6 months following randomisation.

Figure 34: Meta-analysis of two studies for dyspareunia at 6 months following the intervention of either re-suturing or expectancy.



The psychosexual morbidity associated with poor healing and altered body image must not be underestimated**,** the sexual impact of the wound dehiscence was a main theme from the PREVIEW qualitative study. Women interviewed from both treatment groups reported issues relating to sexual morbidity some 6 to 9 months after childbirth. They feared the unknown as intercourse was resumed, with an almost acceptance that it was going to feel different, having experienced childbirth, emulating the findings of other qualitative studies (Priddis *et al*, 2014). For several women there was no association with previous sexual morbidity but for others there was, particularly for one women who was still breast feeding, and whose other children were both under five years old. The cross sectional study by Barrett *et al*

(2000) of 796 first time mothers suggested that at 6 months postnatal, previous dyspareunia and breast feeding were risk factors for subsequent dyspareunia. The response rate however was 61% suggesting that the prevalence of sexual health problems as frequently acknowledged is very much under-reported. In addition only 15% of women reported that they had spoken to any healthcare professional about sexual morbidity. One can therefore assume that there are a considerable amount of women with unmet sexual health needs (Barrett *et al*, 2000).

Discussing issues around sexual health and sexual morbidity can be uncomfortable, even somewhat embarrassing and the silence comes not only from new mothers but also from some health care professionals too (Barrett *et al*, 2000; Glazener, 2005; Wray, 2009). The small qualitative study conducted for PREVIEW revealed that when asked, all women were in fact willing to share their experiences of varying degrees of sexual morbidity following childbirth. A caveat to note when interpreting findings from studies investigating sexual morbidity even those from the PREVIEW RCT is that numerous obstetric and clinical variables can affect prevalence and therefore results must be interpreted with caution.

7.2.5 Breast feeding

Apart from an incidental finding between the two groups in numbers of women who commenced breast feeding 7/14 (50%) in the re-suturing group and 14/16 (87.5%) in the expectancy group the persistent *P*-value of 1.000 (Fishers exact test) revealed that there were no significant differences at any time point in breast feeding cessation.

World Health Organization and United Nations Childrens Fund (2003) recommendations are that babies should be exclusively breastfed for the first six month. Although breast feeding initiation rates in the UK have considerably

improved over the years to 81% in 2010, only just over a third of these mothers (34%) were still breast feeding at 6 months (Health and Social Care Information Centre, 2012b). Similar results were found in the RCT for PREVIEW with 21/30 (70%) who completed their 6 week questionnaires reported having breast fed their babies since birth and only 11/29 (38%) were still breast feeding at 6 months.

Apart from Monberg and Hammen (1987) who simply acknowledged that lactation was continued no previous research investigating the management of dehisced perineal wounds has presented data on the continuation of breast feeding. Although studies relating to primary perineal repair (non-suturing versus suturing) have reported that women in a non-sutured group have a higher breast feeding initiation rates (Metcalfe *et al*, 2006) and a great satisfaction with breast feeding (Lundquist *et al*, 2000) all women in the RCT for PREVIEW had received primary perineal repair at the time of commencing breast feeding.

A priority for most women, particularly in those first few tentative weeks following delivery is that they are comfortable when feeding their newborn (Chou *et al*, 2013; Perkins *et al*, 2008). This is particularly crucial towards successful breast feeding and helping to achieve global targets for exclusive breast feeding (World Health Organization and United Nations Childrens Fund, 2003). Perineal pain was reported when breast feeding at several time points in the RCT for PREVIEW and although numbers were small this was cited as a reason by just under 10% (2/21 one from each group) of women for not breast feeding at six months. Larger numbers in both groups would be needed to determine actual treatment effect sizes upon breast feeding continuation rates.

7.3 The feasibility of the PREVIEW RCT

Assessing important parameters of the PREVIEW pilot and feasibility RCT were crucial to answering the question 'can this study be done'? Using the recognised features of both pilot and feasibility studies (Arain *et al*, 2010; Craig *et al*, 2008; Davies, 2010; Thabane *et al*, 2010) referred to in chapter five, the following sections provide a systematic and detailed evaluation of the PREVIEW RCT.

7.3.1 How feasible was the PREVIEW protocol for a definitive RCT

The trial team gained valuable experience of delivering numerous components of the protocol. Research findings including both the significant and the non-significant differences between study groups, attrition rates and reasons for not completing treatment have been reported in full and are crucial for not only the assessment of internal validity and interpretation of results (Higgins *et al*, 2011a; Moher *et al*, 2010) but also for the planning of the definitive RCT.

Considering the complexity of the interventions it was apparent that throughout the course of the RCT that most of the components of the protocol worked well together. Features of the protocol that worked particularly well were the randomisation process, the delivery of the interventions in a timely sequence and clinician's and researchers compliance with completion of trial questionnaires.

However data recorded in other aspects of the pilot study revealed a number of feasibility issues some more significant than others that would need to be addressed prior to proceeding with a definitive study. Each of these parameters will now be discussed in more detail.

7.3.2 How feasible was the sample size?

One of the purposes of this pilot study was to collect data to inform a future sample size calculation for the full scale RCT (chapter five, section 5.5.2). To facilitate this recruitment rates, attrition rates and the proportion of women with a healed wound at 6-8 weeks (the primary outcome) were all assessed and reported in chapter six of this thesis.

Although the initial sample size (n = 180 with attrition n=144) which was calculated on retrospective data from the host organisation, was considered quite large for the pilot study, the research team felt that this was necessary in order for recruitment to start 'bedding down' in each of multiple sites.

As with many surgical intervention studies across various clinical disciplines, recruitment into the RCT fell below that of projected figures.

Following 14 months of recruitment the RCT was well below target. Out of 50 eligible women only 10 had been recruited, a further 50 women did not fulfil eligibility criteria. In view of poor recruitment and following full discussions with the trial steering committee and the data monitoring committee for PREVIEW a collaborative decision was made to reduce the target recruitment figure to n=40. In addition a formal request to extend the recruitment period by 6 months was approved by the NIHR, RfPB programme. The study extension which allowed for 6 months additional recruitment and 6 months follow-up was submitted and approved as a minor amendment to the REC and all recruiting R&D departments.

A clear knowledge gap in relation to effective recruitment strategies has recently been acknowledged in a Cochrane systematic review and meta-analysis (Treweek *et al*, 2013). However, numerous strategies some more effective than others, have

been suggested to enhance recruitment into research studies (Campbell *et al*, 2007; Fletcher *et al*, 2012; McCulloch *et al*, 2002; Treweek *et al*, 2010). Many of these multi-faceted interventions were employed by the TSC for PREVIEW, led by the author of this thesis in a concerted attempt to enhance recruitment. Strategies included the following: providing pocket size recruitment cards, posters, additional site visits, newsletters, small financial rewards for recruiting organisations, liaising with Primary Care Trusts via GP connect newsletters and more frequent telephone conferences and attendance at community midwifery team meetings.

Despite the extension and repeated efforts to increase recruitment final recruitment figures remained both disappointing and disheartening. A recruitment rate of 33 out of the original sample size of 180 provides overwhelming evidence that the sample size and or the design of the study need careful discussion prior to proceeding with a definitive trial.

On a positive note, in addition to the 33 women correctly randomised an additional 95 women fulfilled pre-specified eligibility criteria providing evidence that there is the potential for larger numbers to be recruited in a full-scale study.

The literature in general terms suggests that recruiting to target persistently remains a major problem in RCTs (Campbell *et al*, 2007; Easterbrook and Matthews, 1992; McCulloch *et al*, 2002; Paramasivan *et al*, 2011; Prescott *et al*, 1999; Spaar *et al*, 2009; Tooher *et al*, 2008; Treweek *et al*, 2010). A cohort of trials n=122, funded by either the Medical Research Council or the Health Technology Assessment programme were reviewed by Campbell *et al* (2007) to establish factors that were associated with both good and poor recruitment. Cancer trials formed a significant proportion of the papers reviewed n= 25 (20.5%) followed by mental health and a combination of orthopaedic and rheumatology each with n =21 (17.2%) papers,

whilst obstetrics and gynaecology studies were not insignificant either at n=9 (7.4%) in comparison to the leading clinical areas. Only 38/122 (31%) of all trials achieved their original target recruitment and despite 42 trials (34.4%) trials revising their recruitment targets 8 (19.1%) were still unable to achieve 80% of their revised figures (Campbell *et al*, 2007). The PREVIEW pilot and feasibility RCT, even despite considerable recruitment efforts were only a fraction above 80%, recruiting 33 out of a revised recruitment target of 40 (82.5%). Campbell *et al* (2007) also reported that recruitment in 11/122 trials (11%) was stopped, due to the consequences of poor recruitment.

Studies such as PREVIEW with quite distinct treatment options whereby some women are offered re-suturing and others not, also often face additional challenges with recruitment (Cook, 2009; Jackson *et al*, 2010; Kaur *et al*, 2013; McCulloch *et al*, 2002; Paramasivan *et al*, 2011).

Lack of clinical equipoise and patient equipoise are continually cited in the literature as being the two main barriers towards achieving recruitment targets in RCTs and in relation to PREVIEW are discussed in the following sections. From personal experience, organisational constraints and lengthy research governance procedures can also potentially have a detrimental effect towards achieving recruitment trajectories on time.

7.3.3 How willing were participants to be randomised?

Despite the fact that 128 women over two years of recruitment fulfilled the eligibility criteria for trial entry, only 33/128 (26%) were successfully randomised. Irrespective of the small numbers, women were randomised from various ethnicities as the table of ante-partum characteristics demonstrates (chapter six, table 18) potentially increasing the generalisability of the results.

The most significant reasons for not being willing to participate were a strong preference for either re-suturing n= 23 or expectancy n=43. Interestingly, this was also evident in maternity units who do not offer re-suturing of dehisced perineal wounds. Fortunately, the RCT for PREVIEW continued with recruitment whereas others have been less fortunate. In a randomised trial investigating the management of menorrhagia (heavy periods), Rogerson *et al* (2000) expressed their utter disappointment with the early cessation of their study due to poor recruitment as result of a widespread refusal to accept the Mirena coil. This was in spite of a well-received multi-centre trial, with motivated, proactive clinicians. One clinician had assessed 30 women as being suitable for the study but only one woman agreed to be randomised. PREVIEW had similar experiences: site 3 assessed 20 women as suitable and recruited 2 and site 4 assessed 25 women as suitable and recruited one.

Concern for additional procedures (re-suturing of the wound) which may cause discomfort, inconvenience or additional expense; lack of available time to take part and an aversion towards treatment choice by random allocation have all been cited as reasons provided by participants, including those in the RCT conducted for PREVIEW who have declined participation in research (Campbell *et al*, 2007; Cook, 2009; Jackson *et al*, 2010; Kaur *et al*, 2013; Prescott *et al*, 1999).

Recruitment experiences for the PREVIEW also support data offered by Association of Medical Research Charities and National Institue for Health Research Medicines for Children Research Network (2011) who suggest that lower recruitment figures can be expected once the condition (perineal wound dehiscence) is diagnosed. During the development of the RCT information booklets, ten women (ante-natal and post-natal) were invited to comment on the content and design of the booklets. Remarkably, all women expressed a strong preference for re-suturing. However,

when personally faced with a dehisced wound in the first two weeks following childbirth from which they are trying to recover, whilst caring for their newborn and often other family members, their responses were not quite the same. The potential for an additional admission to hospital, an operative procedure and spinal anaesthesia were often too much for some to consider. Whilst other women with a strong preference for re-suturing, even considered seeking a private opinion outside their local NHS hospital if they were not offered re-suturing.

On reflection qualitative approaches to explore women's reasons for non-participation would have been useful towards planning for the definitive RCT. In addition, collecting data on treatment preference prior to randomisation would have been beneficial in the analysis plan (Thomas et al 2004). A modification to the definitive RCT such as this may be a significant prognostic variable and increase its rigour and external validity (Torgerson *et al*, 1996) and is certainly worthy of further consideration for a full-scale study.

7.3.4 How willing were clinicians to recruit participants?

Historically, the uncertainty of treatment options has resulted in the management of dehisced perineal wounds being very much based on custom and tradition. There is however an assumption that tradition and previous experience may result in a lack of clinical equipoise with the management of dehisced perineal wounds, resulting in a potential barrier towards recruitment into the RCT. Pragmatic RCTs such as PREVIEW are generally more acceptable to clinicians, allowing more clinical freedom (Ross *et al*, 1999). However the consequences of this from experience with PREVIEW is that personal preference for one treatment option leads to lack of equipoise and subsequent failure to recruit eligible women.

This has also been acknowledge in a recent protocol for a Cochrane systematic review by Preston *et al* (2012) who suggest that healthcare professionals can intentionally or unintentionally act as 'gatekeepers', the consequences of which may potentially introduce bias to patient selection, or affect the rate of patient identification and therefore recruitment. Loss of clinical autonomy, including loss of decision making power and independence, being accountable to a third party and restriction of the ability to individualise care were also revealed by Prescott *et al* (1999) as reasons provided by clinicians for not recruiting all participants to the respective research studies.

In the RCT conducted for PREVIEW, even in recruiting units with no policy or clinical guidance to re-suture, almost 20% (18/95) of eligible women were not randomised as the clinician had a preference for treatment. In addition, 26% (49/192) of women were classified as not meeting entry criteria as they had assessed the wound as too small to re-suture. Measurements (length, depth and width) of dehisced wounds classified as too small to re-suture, even if they involved the skin and muscle layer, were not recorded. The author of this thesis therefore cannot report with any degree of accuracy whether some of these women would in fact have been eligible to participate, thereby further increasing the potential generalisability of the results.

On reflection, as with non-participation of eligible women, interviewing clinicians and researchers either individually or by using a focus group approach, would have the potential to explore in more depth, reasons for non-randomisation of this particular group of women.

7.3.5 Can the intervention be delivered in standardised way across multi-centre sites?

The protocol provided a recommended method and material to be used for the intervention of re-suturing to establish if the procedure could be delivered in a standardised approach across multi-centre research sites. This was particularly important to the RCT given the evidence surrounding methods and materials in relation to wound healing, pain and dyspareunia. Data from an audit (chapter six, table 39) revealed several small areas of weaknesses with the procedural aspects of re-suturing, particularly materials used and in reality in pragmatic research were expected. However, additional time devoted to education and training would increase the generalisability of the results in a multi-centre study.

Not all women in the RCT received antibiotics and over half of the women who were allocated re-suturing also received an additional stat dose of intravenous antibiotics. This co-intervention could also been viewed as an additional source of performance bias and collaborative discussions with obstetricians, microbiologists and tissue viability teams need to consider how to avoid or limit this threat to internal validity for the definitive study.

7.3.6 How feasible were the primary and secondary outcome measures?

Overall, the mixed methods study has revealed that the pre-specified primary and secondary outcomes measured were feasible, and all would be repeated in the definitive study. All outcomes were generalisable across the sample population and the childbearing population as they were already determined from areas that were of prime concern to women (Perkins *et al*, 2008).

The clinical outcome measures were then evaluated to determine the feasibility of data collection techniques and the statistical analysis strategy which would subsequently provide conclusive evidence of the effectiveness of the interventions in the definitive study.

Personal experiences of conducting the trial have established the need for further consideration relating to how some of the outcomes, revealed in sections 7.3.6.1 - 7.3.6.2 below would be measured in the definitive study.

7.3.6.1 Refining the primary outcome measure of wound healing

The results of the PREVIEW pilot RCT suggest that prior to the full scale study there needs to be careful consideration towards refining the primary outcome measure of time taken to heal from the pre-specified time point of 6-8 weeks to 2 weeks. The definitive RCT also needs to consider weekly visits to a perineal care clinic or an alternative clinic to enable a more accurate assessment of the time the wound takes to heal. However a reason provided by one woman for non-attendance at her 2 week appointment was lack of transport and availability of childcare. Indeed using public transport would have necessitated several bus changes. Although this was an isolated occasion, one may postulate that these were possible reasons that three women withdrew at the point of randomisation or following the intervention.

Potentially, there could be some benefit towards using more sophisticated methods of measuring wound healing for the definitive study. However, obtaining additional funding to support the evaluation of wound healing tools in the current financial climate may prove difficult. Considering the simplicity of REEDA and the precise measurements and descriptive accounts embedded within the tool (Fleming *et al*, 2003) it would seem plausible to continue with this method of data collection for the definitive study.

7.3.6.2 Refining the secondary outcome measure of pain

Perineal pain can dominate the experience of early mother hood (Walker, 1990) and this was clearly demonstrated in both the quantitative and qualitative results of the studies conducted as part of this thesis. It is one of the most frequently reported primary or secondary clinical outcome measures in studies investigating perineal trauma. Pain would therefore continue to be evaluated as a secondary outcome measure in the future definitive study, although there would be some value in exploring alternative ways to capture meaningful data exploring women's experience of pain. This may include the use of a numerical pain rating score and allowing women to describe their pain as opposed to using the McGill Pain assessment tool.

7.3.7 How feasible was the statistical analysis plan?

The outline of the statistical analysis plan in the protocol included adjusting for study site using a regression analysis model. This was also based on the assumption that the sample size was going to be reasonably large and the number of sites would be four with suitable numbers of women recruited at each site. However the final sample size was not sufficiently large enough despite the additional recruiting sites to support regression analysis. However, as demonstrated in the previous chapter, the revised analysis plan continued with both descriptive and inferential statistics.

Primary analysis of the trial data was conducted on an intention-to-treat basis. Secondary analysis by treatment administered similarly referred to as 'per protocol analysis' was also considered as several participants chose not to receive their allocated treatment. Unfortunately there was insufficient data to conduct the analysis. Although critics of 'per protocol' analysis suggest that the benefits of the robust randomisation schedule would have been lost and there would have been a

risk of introducing a degree of prognostic differences between the two groups if this method of analysis had of been conducted (Farrokhyar *et al*, 2010).

Although women were allocated a unique identification code to ensure that no personal identifying information was entered into SPSS, analysis of the data was not totally blinded. A question in the 6 month questionnaire asked the woman if she was allocated to re-suturing or not. In addition, the author of this thesis was also the trial co-ordinator and therefore received notification regarding treatment allocations from the randomisation centre. As the woman's identification code commenced with a numerical site code, for example, UHNS = 1 and due to the small numbers recruited, the trial co-ordinator was therefore aware of randomisation allocations at recruiting sites. For instance, the three women recruited from unit 10 were allocated expectancy, the two women from unit 3 re-suturing and the one woman from unit 4 expectancy. Data analysis for the definitive study though would be conducted blinded.

7.3.8 Can compliance with clinic follow-ups and trial questionnaires be achieved?

The protocol recommended that perineal wound assessments at all-time points were conducted by a clinician independent from the study with the intention to limit the introduction of detection bias. In reality this was achieved in less than half of all assessments (44%) conducted at the pre-specified time points suggesting that further consideration needs to be given towards achieving independent assessments when planning for the definitive study. Organisational constraints with increased periods of clinical activity in addition to an education and training issue were the main reasons for not achieving higher compliance rates.

Farrokhyar *et al* (2010) do suggest that where independent assessment is not achievable then two or more individuals assess the outcomes and resolve any disagreements until consensus is reached. Whilst the author of this thesis is in agreement with this and actually adopted this approach locally, again in reality, this would need concerted efforts by committed recruiting sites to achieve in practice.

Secondary outcome measures for the RCT were self-reported by women completing the trial questionnaires at pre-specified intervals, thereby avoiding assessor bias. There is some suggestion though that their particular preferences for a treatment option, despite agreeing to be randomised may have the potential to reduce the validity and generalisability of the trial (Brewin and Bradley, 1989; King *et al*, 2005; Torgerson and Sibbald, 1998). Evidence from a meta-analysis (Preference Collaborative Review Group, 2008) and observational cohort studies (Thomas *et al*, 2004) do propose that there is the potential for clinical outcomes to be affected by whether a participant is allocated to their preferred treatment or not. However they both demonstrated considerable homogeneity in that they were related to treatment preferences for patients with musculoskeletal conditions and therefore cannot be generalised across various health care settings.

All women randomised into the RCT were accounted for to avoid any major threat to the internal validity of the study (Farrokhyar *et al*, 2010; Higgins *et al*, 2011a). Attrition bias was evident however: in the re-suturing group there were 14/17 (82.4%) data sets for the primary outcome measure and 13/17 (76.5%) complete data sets for the secondary outcome measures. In comparison there were 16/16 (100%) complete data sets in the expectancy group for all outcome measures. Overall complete follow-up rates of 29/33 women 88% (91% up to 3 months) were lower than those reported by Christensen *et al* (1994) (94%) and Monberg and Hammen (1987) (100%) investigating secondary perineal repair, but similar or

higher to that of other obstetric studies which have compared suturing or no suturing for primary perineal repair (Fleming *et al*, 2003; Metcalfe *et al*, 2006). A plausible explanation for these attrition differences in the RCT may be due to the fact that women in the re-suturing group did not receive their preferred treatment allocation.

It has been suggested that attrition of 5% or less is unlikely to introduce bias, and conversely, attrition of 20% and more would raise questions about the validity of the study (Sackett *et al*, 2000; Schulz and Grimes, 2002). However in terms of comparing treatment effects it is the attrition difference between the two groups that is of relevance (Schulz and Grimes, 2002). Whilst it is unrealistic that the definitive PREVIEW study would totally eliminate attrition bias, the trial team must consider all opportunities to reduce the level of bias to ≤ 5%.

Incentive strategies (monetary or gift vouchers, car parking refunds) to increase retention may be worthy of further consideration. In addition there may be some value in exploring the potential to follow-up women at their primary care centre to assess wound healing.

7.3.9 How acceptable was the research plan within the recruiting organisations?

As previously acknowledged re-suturing dehisced wounds is not common practice so study set up within the recruiting organisations was not without its challenges even with enthusiastic and motivated principle investigators all of whom were consultants in either obstetrics, gynaecology, or urogynaecology. Particular challenges during study set up focused upon the following key areas:

- Ensuring that there was a seamless referral and review process
- Agreeing upon the location for the secondary perineal repair to be completed Some organisations if a secondary perineal repair was conducted would be performed in the obstetric theatres whilst some would admit the woman onto a gynaecology ward and perform the secondary repair in gynaecology theatres
- Location for post-operative recovery following discharge from theatre recovery area
- Identifying a designated clinic in the absence of a perineal care clinic where women could be followed up to assess wound healing
- Obtaining consent to participate from GCP trained clinicians
- Change of policy in a unit that re-sutured dehisced perineal wounds.

Specific areas which impeded recruitment opportunities following study set up included the following:

- Lack of availability of a full research team to recruit participants
- Unclear referral pathways despite this being formalised at site initiation visits
- NHS organisations experiencing a management of change
- Lengthy research governance procedures.

Despite recent attempts to streamline the administrative aspect of research governance procedures, personal experiences with organisational research governance support those identified by experienced trial teams (Gates *et al*, 2004). Lengthy research governance procedures can often lead to delays in recruiting sites commencing active recruitment; particularly frustrating when funding is only awarded for a specified time period. All recruiting sites for the RCT needed Participant Identification Centre agreements from all individual Primary Care Trusts

(PCTS) associated with the NHS organisation; one recruiting unit for instance had three PCTS, whilst another had four.

The length of formal approval time for trial amendments to enhance recruitment to research studies are also a frustration for researchers when the 'clock is ticking'. Whilst the relevant REC for PREVIEW processed amendments efficiently, approved documents then needed to be validated by Clinical Research Network managers, uploaded onto the electronic Coordinated System for gaining NHS Permission (CSP), approved by local research and development departments and then approved by the relevant obstetric divisions at recruiting sites. Although these research governance procedures aim to ensure the safety of participants, clinicians and recruiting organisations, work needs to be focused upon improving overall efficiency of the approval systems.

Many NHS organisations have been undergoing a management of change over recent years and clinicians and researchers in post during study set up and site initiation visits in some sites were moved areas or left to take up alternative positions. In addition, as women may present for review in the evenings and at weekends there was a potential for missed recruitment opportunities if there was not a researcher or clinician who was GCP trained available to consent the woman. This is a particular issue in obstetrics and acute care environments such as accident and emergency and has recently been the focus of a paper by Kenyon *et al* (2013) leading to the development of a standardised tool kit for training clinic staff in GCP activities. In relation to the PREVIEW study RCT women were unlikely to return for the purpose of recruitment once they have a newborn baby to attend to.

From personal experience, once the organisation has in full collaboration with all stakeholders agreed to act as a recruiting centre for a clinical trial, the on-going active participation of clinicians (principle investigators, obstetricians, researchers, and midwives) is crucial towards successful completion of the study. Clinicians need to participate when invited, recruit eligible participants and comply with both trial protocols and standard operating procedures (Prescott *et al*, 1999). The research questions addressed by RCTs should themselves be of significant importance to clinicians for them to engage and achieve compliance (Prescott *et al*, 1999). So enthused by PREVIEW one recruiting site actually agreed with organisational consent to withhold their current policy of re-suturing dehisced perineal wounds to enable them to take part in the study. Moreover several recruiting sites have also introduced perineal care clinics within their organisation as a consequence of PREVIEW, a huge benefit to women who have complications associated with perineal trauma such as infection and or dehiscence or who have sustained an OASIS.

Whilst considerable efforts from the trial team resolved some of the organisational challenges, the following key areas need careful consideration with all stakeholders including lay representation prior to a definitive study being conducted:

- Collaboration with sites who have demonstrable recruitment figures and have a full time equivalent research midwife in post and a perineal care clinic
- Increasing the visibility of the trial co-ordinator across recruiting sites
- Qualitative study using focus groups or one-to-one interviews with researchers and clinicians to explore their perceptions surrounding poor recruitment
- Trial incentives such as education and training updates surrounding the pathophysiology of wound healing, in addition to small financial rewards for both the women and the research teams.

7.3.10 How acceptable was the research plan and the interventions to women?

To ensure that the definitive study is as robust as possible it was crucial that women's experience of participating in the RCT was explored to establish how acceptable the research plan was to them. This resulted in the 'a priori theme of 'participating in the RCT.'

Failing to achieve recruitment targets led to further probing of women's experience towards participating in the RCT, particularly towards the randomisation process. The actual interview schedule was not altered; however the questioning approach after the first two interviews was more in-depth than earlier interviews. Supplementary questions and prompts can appear shocking to clinicians from quantitative backgrounds (Ziebland and McPherson, 2006) and on reflection created some degree of uncertainty for the interviewer personally. Moreover, when appropriate, it is actually considered good practice to revise the interview schedule during data collection (Ziebland and McPherson, 2006). Interviews create a forum to explore varied perspectives and understandings of the phenomena in question and topics that are not specifically asked about may be raised directly or indirectly by the respondents (Ziebland and McPherson, 2006).

Women interviewed were asked about their understanding of the randomisation process (a sub-theme of participating in the RCT) and the findings suggest that they were all aware that they would be allocated either re-suturing or expectant management. However nearly all of the women in the study had a strong preference for a treatment option and yet still consented to take part in the study. Sharing their incredibly emotive experiences as they waited in suspense of the randomisation allocation would lead the author of this thesis to postulate that compliance may have been a potential issue if, by chance, they were not allocated their treatment

preference. Two of the women who were actually randomised to re-suturing in the RCT did not receive the intervention. Although this was attributed to anxiety surrounding the procedure in one case, it is possible that both women would have preferred expectancy.

For some women interviewed, their experience of childbirth and the vulnerability of that early postnatal period clearly demonstrates some of the reasons why recruitment into research studies at a particularly vulnerable time can prove challenging. Diane clearly recalled that she had a preference for re-suturing (chapter six: 6.3.6.1). What was humbling in this case was that Diane was a young 20 year old new mother, who had experienced a difficult vaginal delivery, requiring the use of double application instruments and an episiotomy to facilitate a vaginal delivery. Her baby daughter was then subsequently transferred to the neonatal intensive care unit for several days. Diane's perineal wound then dehisced leaving a *"massive hole"* to use her own words and yet here she was, desperate to take part in the study so she had a chance of being re-sutured. An intervention that she clearly believed should be offered as a treatment option for women *"so glad I was picked, it (re-suturing) should be offered to most women."*

Diane's motivation to take part in the study was driven by the possibility of receiving an intervention that she actually wanted, but one that was currently only offered as part of a clinical trial. She also had a genuine desire to help other women by participating in the research. In fact, a degree of altruism was evident in all women in this qualitative study and supports similar motivational theories revealed in other studies (Dixon-Woods and Tarrant, 2009; Jackson *et al*, 2010; Townsend and Cox, 2013).

The qualitative phase of this study made additional attempts to establish if the intervention of re-suturing is an acceptable treatment option for the women (a sub-theme of participating in the RCT). Women's experience of receiving the intervention of re-suturing was extremely positive in the three women interviewed. Their accounts were supported by the free text comments in the RCT questionnaires. The only negativity associated with the secondary re-suturing is referred to below (section 7.3.10.3) and was associated with the theatre delays and waiting to be transferred for the procedure. In contrast, retrospectively, more women who had received expectant management felt that they would have preferred to have been re-sutured. Although there were also reports from women who felt that expectancy had been the right approach for them.

7.3.10.1 How satisfied were women attending for their trial appointments?

Women's satisfaction with attending for trial appointments was a sub-theme of participating in the RCT. Women were extremely satisfied with their clinical appointments to follow-up wound healing with most women appreciative of the additional information and support they received. All women interviewed were from organisations where access to a perineal care clinic was available. However women in some of the other recruiting organisations would not have received the level of follow-up unless they were in the PREVIEW study and several comments in the free text sections of the RCT questionnaires reflected this.

There have been repeated recommendations that have stressed the need for perineal care clinics (Herron-Marx *et al*, 2007; Priddis *et al*, 2014; Thakar and Sultan, 2009; Williams *et al*, 2005). The value of dedicated multi-disciplinary perineal care clinics are without doubt, unquestionable (Thakar and Sultan, 2009). Nationally, the PREVIEW study has been catalyst for change in a number of units that have submitted successful business cases for the introduction of perineal care

clinic. Providing much needed information, support and reassurance is an area that women have persistently expressed as lacking (Priddis *et al*, 2014; Way, 2012; Williams *et al*, 2005). Perineal care clinics can enable the provision of timely evidence based, woman centred care, which is sensitive and responsive to the needs of individual women at a time when they need it the most.

7.3.10.2 How satisfied were women completing their trial questionnaires?

Women's experience of completing the trial questionnaires (a sub-theme of participating in the RCT) was good and there were no further suggestions for additional outcomes for the definitive study, confirming that the study had reflected areas that women felt important to them. Free text annotations proved valuable to both the women and the research team.

7.3.10.3 What were women's positive and negative experiences with participating in the RCT?

Women's positive and negative experiences were sub-themes of participating in the RCT. Women's positive experiences were primarily focused upon the fact that the study was taking place and receiving their preferred treatment allocation. Whilst negative experiences were associated with the length of time waiting to be transferred to theatre for re-suturing and the apparent lack of communication between the ward and theatre staff. Interviewing a wider cross-section of women from the recruiting sites would have enabled the author of this thesis to establish if theatre delays were a commonality in all units. More recently the introduction of elective obstetric surgical lists are growing in popularity and at the host organisation, there has been an agreement that if a decision has been made to re-suture a dehisced perineal wound then this may be conducted at the end of the elective list.

7.3.11 Can the PREVIEW pilot and feasibility RCT proceed to a definitive study?

The wealth of evidence gained from conducting the RCT suggests that a full scale RCT is feasible but that adaptation to the research design and methodology need careful consideration in collaboration with all stakeholders if a future definitive study is to be successful.

There is no doubt that the traditional well-designed RCT will provide the most scientific reliable evidence for treatment efficacy. What researchers cannot afford to ignore, however, is the persistent evidence acknowledging that the RCT design can be extremely challenging in terms of recruitment. The consequences of this can prove a threat to the overall validity of the trial (Preference Collaborative Review Group, 2008), limiting the generalisability of the findings to the wider clinical population (King *et al*, 2005). Whilst the RCT will remain the gold standard for assessing the efficacy of healthcare interventions, including surgery (Tincello *et al*, 2009), there will always be a number for questions that simply cannot be answered using this approach.

Women and clinicians in the RCT expressed strong preferences for either re-suturing or expectancy of the dehisced perineal wound. Even in women who were randomised, the qualitative findings of phase four of PREVIEW clearly demonstrate the depth of emotion felt and expressed by women when they receive their preferred allocation.

One solution towards addressing women's preferences proposed by the author of this thesis would be to include a patient preference arm alongside the traditional RCT, conducted when women are in equipoise, thus resulting in a 'four armed' trial (Brewin and Bradley, 1989). Critics of this approach have argued though that

comparing non-randomised groups is unreliable particularly if confounding variables are not controlled for and that preferences may change during the trial period (Farrokhyar *et al*, 2010; Harvey *et al*, 1989; Howard and Thornicroft, 2006). There is also the potential for unbalanced arms of the trial as Tincello *et al* (2009) experienced and this would need to be factored into any discussions and sample size calculations. Crowther *et al* (2012) recently published the findings of their prospective cohort study consisting of a patient preference study, and a small nested randomised trial to compare benefits and risks of a planned elective repeat caesarean (ERC) with planned vaginal birth (VBAC). The authors concluded that in women with one prior caesarean, planned ERC compared with planned VBAC was associated with a lower risk of fetal and infant death or serious infant outcome. Interestingly their findings were based primarily upon the women assigned by preferred method of delivery n = 2,323 compared with randomisation n = 22 (planned VBAC n= 1,225 patient preference, 12 randomised; planned ERC n = 1,098 patient preference, ten randomised) (Crowther *et al*, 2012). Whilst there will no doubt be critics of their findings, the study clearly reveals the value of considering this design as an option for the definitive RCT.

7.4 Strengths and limitations of phase four of the PREVIEW study

7.4.1 Strengths

The author of this thesis has demonstrated that by conducting the PREVIEW pilot and feasibility RCT and exploring women's lived experiences of dehisced perineal wounds, the mixed methods approach has added both richness and precision to the overall findings. The interaction between the descriptive richness of the qualitative study and the experimental precision of the RCT has investigated the management of dehisced perineal wounds to greater depths of clarity as Cupchik (2001) suggested than previously attempted by seminal research in this area.

Each research paradigm has duly complemented each other (Cupchik, 2001) resulting in a more holistic understanding of the management of perineal wound dehiscence following childbirth and women's experience of participating in the RCT. Conducting phase four of PREVIEW as a mixed methods study has allowed the author of this thesis to explore women's experiences and opinions of receiving an intervention (re-suturing) within the RCT compared to usual standard expectancy practice. They have been given a voice in the assessment of the interventions, which future women will receive, and this can only serve but to enhance future practice and research (Gethin and Clune-Mulvaney, 2009). Moreover it has added true meaning towards the ethos of evidence-based medicine, the integration of best research evidence with clinical expertise and patient values (Sackett et al, 2000).

This mixed methods study has addressed an area of maternal morbidity that has previously been neglected by clinicians and researchers alike. Researchers are often criticised for measuring outcomes that they believe are important, however following a review of the literature and personal clinical experiences of the research team, both research paradigms have focused upon outcomes that are of prime concern to women throughout the UK and the rest of the world.

The pilot and feasibility RCT has allowed vital preparatory work to be conducted across multiple research sites, the findings of which are crucial towards the future planning of a robust and successful definitive study. Whilst the numbers recruited were much smaller than expected the overall findings suggest that a definitive study is feasible if certain features are addressed. Consequently this will enhance both the internal and external validity of the results and provide women and clinicians alike with robust evidence to guide decision making for the management of this distressing complication of childbirth.

The PREVIEW qualitative study is to the best of the author's knowledge the only research that has explored women's experiences of perineal wound dehiscence. Women have finally been given an opportunity to share with health care professionals and ultimately each other, their previously 'unheard' experiences of this unfortunate complication of childbirth. The author of this thesis has particularly focused on descriptive phenomenology staying close to women's experiences, to ensure that their open and honest accounts were equally respected and authentically presented. There is the potential for researchers and clinicians to argue that the findings of this study are unique to the six women interviewed relating to a specific phenomenon and population and therefore it would be impossible to demonstrate that the findings are applicable to other situations (Shenton, 2004). The author of this thesis however supports the view of Ryan-Nicholls and Will (2009) that the women interviewed are representative of the morbidity experienced by women world-wide and that findings therefore could be applied to the audiences personal experiences.

The study has raised awareness of the prevalence and disparity in management options for dehisced perineal wounds amongst clinicians and women. In some organisations the research has been a catalyst for the introduction of multi-disciplinary perineal care clinics. The continuity of care from specialised clinicians will benefit of all women who sustain complex perineal trauma or complications associated with perineal repair following childbirth.

In addition the mixed methods design has also contributed to the paucity of literature surrounding women's experiences of participating in surgical intervention trials with particular relevance to women following childbirth. This will be a much welcomed resource, given that researchers are continually presented with recruitment difficulties resulting in underpowered studies and the inability to

demonstrate efficacy of interventions or treatments. This is particularly relevant to studies as previously highlighted where trial interventions are quite dissimilar to each other.

7.4.2 Limitations

Conducting phase four of PREVIEW highlighted several limitations for the reader to consider.

In the qualitative study only women who participated in the RCT were interviewed. Interviewing non-randomised women who fulfilled eligibility criteria would potentially have proved beneficial to the planning of the definitive study, however this would have required the submission of an additional REC application and incur additional time and finances that were not factored into the original research proposal or funding application.

In addition, due to geographical locations of the recruiting sites, five out of the 6 women interviewed were recruited at the host organisation and therefore do not truly reflect women's experiences of participating in research in other recruiting organisations. The free text annotations in the RCT questionnaires do however suggested that women's experiences of taking part in the RCT were very positive, demonstrating the benefits of the mixed methodological approach.

A further limitation is that the small numbers of women recruited into the RCT, inherent in pilot and feasibility studies, restrict the overall generalisability of the findings and therefore any results presented must be interpreted with caution.

7.5 Implications for clinical practice

Supporting the findings of earlier studies the pilot and feasibility RCT has suggested that re-suturing of dehisced perineal wounds is a feasible alternative treatment option in comparison to healing by expectancy. Whilst the results suggest a trend in favour of re-suturing towards the primary outcome measure of healing, due to the design of the study and the small numbers recruited, no reliable estimates of effectiveness can be provided. Until the definitive study is conducted management should continue to be based in accordance with local hospital guidelines. In the absence of robust evidence based guidance management will continue to be based on opinion and experience of the individual clinicians.

The qualitative findings have described the experiences of women with perineal wound dehiscence and have confirmed that the interventions were acceptable to them. Organisational issues to avoid excessive theatre delays should be addressed where appropriate. Whilst all women are appreciative of the unpredictability of theatre activity, improved and timely communication between obstetric theatres and ward areas would help to allay anxieties women experience waiting to be transferred to theatre.

The need for the widespread introduction of multi-disciplinary perineal care clinics was identified in both the qualitative study and within the free text annotations of the RCT questionnaires completed by the participants. Whilst various models of care are gradually increasing, the findings from the whole of the PREVIEW study, including the national survey (chapter four) have demonstrated that these specialised clinics are clearly not available to all women.

7.6 Dissemination of the research findings

Papers are currently being prepared for publication in peer reviewed professional journals to present the findings of the mixed methods study. The findings will be presented in accordance with both CONSORT (Moher *et al*, 2010) and COREQ guidance (Tong *et al*, 2007). The two PREVIEW study patient representatives will be invited to be part of this process and acknowledged in any publications.

Copies of the report will be available to all recruiting sites and to the women who have participated in the study where this has been requested. The results will also be presented at relevant conferences and seminars, both locally, nationally and internationally and through personal networking.

The author is also aiming to publish a paper to share her experiences of the barriers experienced when recruiting women into a surgical intervention study whilst reflecting upon some of the strategies that have had a positive effect upon recruitment. Papers relating to the case note audit and national survey are also being prepared.

7.7 Implications for future research

The design of the RCT presented in this thesis has clearly demonstrated how crucial preliminary work is towards establishing whether a definitive study can actually be conducted or not. The findings of PREVIEW pilot and feasibility RCT do suggest that that a definitive study is possible. However in order to provide conclusive evidence of the effectiveness of re-suturing compared to expectant management for dehisced perineal wounds the research team now need to carefully consider the most appropriate research design to proceed with, taking into consideration the strong preferences of both women and clinician's. There now

remains an urgent need to provide NHS commissioners, obstetricians and women themselves with the most robust level of scientific evidence possible relating to the effectiveness of re-suturing versus expectancy for the management of dehisced perineal wounds.

The small qualitative study conducted for PREVIEW was the first time women with dehisced perineal wounds have had an opportunity to voice their personal experiences of this distressing complication of childbirth and their opinions of the treatment options.

Further qualitative research is now needed to explore women's preferences for treatment options and their willingness to take part in a clinical trial. Similarly, further research needs to explore clinician's preferences for treatment options, their willingness to recruit women into a future study and their thoughts on alternative research designs.

Chapter eight will now provide a summary of the overall conclusions from each phase of PREVIEW study.

CHAPTER EIGHT: OVERALL CONCLUSIONS

8.1 Innovations of the preview study

The whole of this thesis is both timely and significant to women, clinicians and commissioners of health care. Timely, because infection, a common cause of wound dehiscence is a leading cause of maternal mortality in a developed country. Significant, because to date there is no robust evidence to determine the efficacy of re-suturing dehisced perineal wounds compared to expectant management the current standard practice in most NHS organisations.

To the best of the author's knowledge this is the first mixed methods study to investigate the effectiveness of perineal re-suturing versus the standard management of expectancy for dehisced wounds, with the primary outcome measure of wound healing. Numbers recruited were lower than expected and therefore the study was underpowered to provide any reliable data to demonstrate efficacy of the interventions. However, the overall aim of conducting the RCT as a pilot and feasibility study was to establish if a definitive study could be conducted. This crucial preparatory work has been absolutely essential towards progressing to a future definitive study.

The author of this thesis has adopted an open and honest approach towards the presentation of the results from both research paradigms, creating transparency and credibility for the PREVIEW study. Addressing lessons learned and knowledge gained is now pivotal for securing future funding for the definitive study and towards providing much needed answers towards the efficacy of the interventions. The preliminary findings of the pilot and feasibility RCT and the qualitative phase of the

research which is the first study to provide an insight into women's experiences of perineal wound dehiscence and taking part in a RCT will now inform the design of the future definitive study.

The whole of the thesis has contributed to the paucity of literature surrounding perineal wound dehiscence including the first and newly published Cochrane review (chapter three). In the absence of the definitive study the findings from the pilot and feasibility RCT will contribute to future updates of the Cochrane review.

The case note audit (chapter four) is the largest comparative retrospective study and the first to be conducted in the UK which has identified episiotomy as the leading risk factor for perineal wound dehiscence. The audit has collected baseline data to inform the development of standards both locally and nationally against which future care is provided and measured.

Similar to the other phases of PREVIEW, the National Survey (chapter four) is the first study conducted to explore current management of dehisced perineal wounds, confirming the distinct lack of evidence based guidance to support clinical practice.

The entire thesis addresses an area of clinical research that has been extremely neglected and has the potential of making a significant impact on the future of women's health and well-being throughout world.

Three papers have been published to date, as a direct consequence of the PREVIEW study: 'The PREVIEW protocol' (Dudley *et al*, 2012), 'The Cochrane Systematic review' (Dudley *et al*, 2013a) and 'The prevalence, pathophysiology and current management of dehisced perineal wounds following childbirth' (Dudley *et al*, 2013b) appendices 20-22 respectively.

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PREVIEW STUDY APPENDICES

Appendix 1: PREVIEW study timeline January 2009 – November 2014

<table>
<tr><th></th><th>JAN</th><th>FEB</th><th>MARCH</th><th>APRIL</th><th>MAY</th><th>JUNE</th><th>JULY</th><th>AUG</th><th>SEPT</th><th>OCT</th><th>NOV</th><th>DEC</th></tr>
<tr><td>2009</td><td colspan="12">RECEIVED DOCTORAL NURSING STUDENTSHIP AWARD OCT 2008 - PREPARATORY WORK FOR THE RCT: PROTOCOL - TRIAL DOCUMENTS – ETHICAL APPROVAL - R&D APPROVAL IN RECRUITING SITES – ESTABLISH TRIAL STEERING COMMITTEE & DATA MONITORING COMMITTEE</td></tr>
<tr><td></td><td colspan="3">COCHRANE REVIEW REGISTERED</td><td colspan="9">REVIEWING LITERATURE FOR COCHRANE REVIEW</td></tr>
<tr><td>2010</td><td colspan="12">REGISTERED AUDIT WITH DIRECTORATE AUDIT DEPARTMENT & DEVELOPED CASE NOTE AUDIT TOOL & PROTOCOL FOR AUDIT</td></tr>
<tr><td></td><td colspan="12">PREPARATORY WORK FOR THE RCT & QUALITATIVE STUDY & PREPARATION & SUBMISSION OF SUCCESSFUL NIHR RfPB APPLICATION</td></tr>
<tr><td></td><td colspan="12">DEVELOPED COCHRANE REVIEW PROTOCOL</td></tr>
<tr><td>2011</td><td colspan="6" rowspan="3">RCT SET UP IN RECRUITING SITES</td><td colspan="6">RCT RECRUITING FROM 25.07.11</td></tr>
<tr><td colspan="6">COCHRANEREVIEW PROTCOL PUBLISHED</td></tr>
<tr><td colspan="6">COMMENCE DATA COLLECTION FOR AUDIT N = 200 CASENOTES</td></tr>
<tr><td>2012</td><td colspan="12">RCT RECRUITING & FIRST OF 6 INTERVIEWS CONDUCTED (06.07.12)</td></tr>
<tr><td></td><td colspan="12">CONTINUE DATA COLLECTION FOR AUDIT N = 200 CASENOTES</td></tr>
<tr><td></td><td colspan="9">ON-LINE QUESTIONNAIRE DEVLEOPED FOR SURVEY MONKEY</td><td colspan="3">SURVEY CONDUCTED 10.10.12 - 10.12.12</td></tr>
<tr><td>2013</td><td colspan="12">RCT RECRUITING (CLOSED 25.07.13) FINAL INTERVIEW CONDUCTED 09.08.13</td></tr>
<tr><td></td><td colspan="10">PREPARATION OF COCHRANE REVIEW, SUBMISSION & PUBLICATION (PUBLISHED OCT 2013)</td><td colspan="2">AUDIT DATA ANALYSIS</td></tr>
<tr><td></td><td colspan="12">ANALYSIS OF SURVEY MONKEY DATA</td></tr>
<tr><td>2014</td><td colspan="2">AUDIT ANALYSIS</td><td colspan="9">RCT DATA ANALYSIS & THESIS WRITE UP (THESIS SUBMITTED 07.11.14)</td><td></td></tr>
</table>

Appendix 2: Cochrane Review

Characteristics of Included and Excluded Studies

Included studies: Christensen 1994

Methods	Participants were allocated into 2 treatment groups. No methods of randomisation were provided. No details were provided regarding how the randomisation sequence was generated Outcome assessment - no details provided. 20women following vaginal delivery with an episiotomy wound were asked to participate and 17 women were randomised
Participants	17 women were included in the study - no inclusion criteria specified 11 women had wound infection and wound breakdown. 6 women had a wound infection but no wound breakdown. Exclusion criteria - Chron's disease, ulcerative colitis, immunosuppressive treatment
Interventions	Intervention group (n = 8) Incision, drainage, curettage and suture under antibiotic cover. No specific suture technique or material used detailed (referred to as 'primary suture') 7 of the 11 women with wound infection and wound breakdown were allocated the intervention group 1 of the 6 women with wound infection but no wound breakdown was allocated the intervention group Control group (n = 9) Incision and drainage (conventional treatment, also described as 'open healing') compared with intervention 4 of the 11 women with wound infection and wound breakdown were allocated the control group 5 of the 6 women with wound infection but no wound breakdown were allocated the control group
Outcomes	Included in the analysis: Healing time. Time spent in hospital (inpatient). Recidivism (relapse/reoccurrence) of abscess. Vaginal reconstructive surgery
Notes	Setting - Odense University Hospital. 3 women who were approached for inclusion did not want to participate 1 woman in the control group could not be contacted for assessment of wound healing Tables provided indicate an intention-to-treat analysis although not revealed in the paper There was no recidivism of abscess

Risk of bias: Christensen 1994 continued		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No details provided
Allocation concealment (selection bias)	Unclear risk	No details provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 women were asked to participate in the study; 17 women were randomised, 3 withdrew before being allocated to a treatment group 1 woman from the incision and drainage group was unable to attend the 4 week follow-up assessment
Selective reporting (reporting bias)	Unclear risk	We were not clear whether all pre-specified outcomes were reported in the published papers
Other bias	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participant: no details provided. Clinician: no details provided.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Due to the obvious differences in treatments, the women and outcome assessors could not be blinded to the allocated intervention

Included studies: Monberg 1987

Methods	Participants were randomised into 2 groups. No methods of randomisation were provided. No details regarding how the randomisation sequence was generated were provided. 35 participants with an infected and/or ruptured episiotomy were included.
Participants	35 participants (33 primipara) were randomised into 2 groups No exclusion criteria were provided.
Interventions	Intervention group A (n = 20) women had their episiotomy repaired (referred to as 'primary re-suturing') and received Clindamycin 600 mg 2 hours prior to suturing and continuously for 5 days (300 mg 3 times a day) Group B (n = 15) women were treated in accordance with the routine management of the department: cleaning the wound with chloramine and saline, resulting in spontaneous healing.
Outcomes	Included in the analysis: Healing time. Time spent in hospital (inpatient). Recidivism (relapse/reoccurrence) of abscess. Vaginal reconstructive surgery
Notes	Setting - Hvidovre Hospital, Copenhagen, Denmark. Tables indicate intention-to-treat analysis although not stated in the paper All episiotomies examined for bacteria, unfortunately the authors reported that the results had been lost Method of repair described. Lactation continued in both groups but length of times not provided. No losses to follow-up reported.

Risk of bias: Monberg 1987 continued		
Bias	**Authors judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No details provided
Allocation concealment (selection bias)	Unclear risk	No details provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Details unclear in paper
Selective reporting (reporting bias)	Unclear risk	We were not clear whether all pre-specified outcomes were reported in the published papers
Other bias	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participant: no details provided. Personnel: no details provided
Blinding of outcome assessment (detection bias) All outcomes	High risk	Due to the obvious differences in treatments, the women and outcome assessors could not be blinded to the allocated intervention

Excluded studies

Study	Reason for exclusion
Arona 1995	Not a randomised trial. Case note review of 23 women who underwent early secondary repair of third and fourth degree perineal tears. 21 women had wound dehiscence following primary repair of a fourth-degree tear and 2 had wound dehiscence following primary repair of a third-degree tear. All repairs were successful with no subsequent wound dehiscence occurring.
Hankins 1990	Not a randomised trial. Early repair of episiotomy dehiscence was performed in 22 women with a fourth degree tear and 4 with a third degree tear and 5 with a mediolateral episiotomy. Most of the women (n = 27) 1 year post-secondary repair demonstrated excellent anatomical results and the women reported complete continence and normal coital activity.
Ramin 1992	Not a randomised trial. Case note review of 34 women who underwent early repair of episiotomy dehiscence. Clinical follow-up was reported in 29 cases, 5 women were lost to follow-up. Most of wounds were healed completely in 2-3 weeks; 2 women had subsequent wound dehiscence.
Uygur 2004	Not a randomised trial. A retrospective case note review including 37 women with episiotomy dehiscence. 12 women with episiotomy dehiscence were allowed to heal by secondary intention and 25 women underwent early secondary repair. 3 women from the re-suturing group had superficial separation of the skin edges, whilst healing was complete in the remaining 22 women.

Appendix 3: Retrospective Case Note Audit Data Collection Form

Hospital Headed Paper

Perineal **Re-**suturing following **V**aginal Delivery Complicated by a Deh**i**sc**e**d **W**ound

(Version 1 June 1st 2010)

Case Note Audit Data Collection Sheet

Private and Confidential

Date of delivery dd / mm / yyyy ☐☐ / ☐☐ / ☐☐☐☐ **Patient Audit Code Number** ☐☐☐☐☐☐

1. Age … ☐☐

2. Parity Primip .. ☐ Gravida … ☐ Para …. ☐

3. Ethnic background (Please tick one box only)

White ☐ Black Caribbean ☐ Black African ☐ Black other ☐

Indian ☐ Pakistani ☐ Bangladeshi ☐ Chinese ☐

Other ethnic group ☐ Please describe ☐

4. BMI .. ☐

5. Does the woman smoke?

No ……. ☐

Yes (How many?) . ☐

Not documented … ☐

6. Does the woman have pre-existing diabetes mellitus?

Yes …. ☐

No …. ☐

7. Did the woman have gestational diabetes diet controlled?

Yes …… ☐

No …….. ☐

Not applicable .. ☐

8. Did the woman have gestational diabetes insulin controlled?

Yes…… ☐

No …… ☐

Not applicable … ☐

9. Were there any documented pre-existing medical conditions?

Yes ……. ☐

No …….. ☐

If yes, describe ☐

10. Did the woman have any previous perineal trauma? (tear or an episiotomy). (Please tick appropriate boxes)

Not applicable ……. ☐

No previous trauma ……. ☐

Previous trauma sutured ……. ☐

Previous trauma not sutured … ☐

11. Did the woman have a previous dehisced perineal wound?

Yes ☐ No ☐ Not documented ☐ Not applicable ☐

If yes was the dehisced perineal wound:

Left to heal by secondary intention .. ☐

Re sutured …… ☐

Not documented ……. ☐

12. What was the documented type of onset of labour?

Spontaneous ☐ Induced with prostaglandins ☐ Induced with ARM ☐

Induced with ARM and Syntocinon ☐ Induced with Syntocinon ☐

13. Type of analgesia in labour documented

No analgesia used ☐ Entonox ☐ Pethidine ☐ Epidural ☐

Remifentanyl infusion ☐ Use of analgesia not documented ☐

14. Were antibiotics administered in labour?

Yes … ☐ No … ☐

If yes what was the reason documented for the administration of antibiotics

☐

Reason not documented ☐

15. Type of delivery

Normal ☐ Kiwi ☐ Ventouse (metal cup) ☐ Forceps ☐

Type of forceps used ☐ Vaginal Breech ☐

16. Was meconium liquor present during labour?

Yes ….. ☐ No …. ☐

17. What was the duration of second stage of labour? (minutes) ☐

Duration of the second stage not documented ☐

18. What was the duration of ruptured membranes? (minutes) ….

Duration of ruptured membranes not documented ……..

19. What was the total duration of labour documented? (minutes)

Total duration of labour not documented ……..

20. What was the infant's birth weight? (e.g. 3500) ……

21. What was the degree of perineal trauma identified?

Episiotomy 2nd degree 3(a) 3(b) 3(c)

4th degree

Method and material of perineal repair documented

Method and material of perineal repair not documented

22. What was the grade of clinician performing the repair?

Midwife Obstetric Registrar Consultant SHO

Student Midwife under supervision

23. Where was the perineal repair carried out?

Delivery suite room … CMU/MBC .. Obstetric theatre …

24. Was there more than 30 minutes delay in commencing perineal repair?

Yes …. ☐ No …. ☐

25. What was the most recent documented haemoglobin? …… ☐

Most recent haemoglobin not documented …….. ☐

26. What was the estimated blood loss? ☐ Not documented ☐

27. Was a blood transfusion needed? Yes ….. ☐ No … ☐

28. How many days PN was the woman when the perineal wound dehisced? ☐

N/A ☐

29. Was a wound swab taken? Yes ☐ No ☐ N/A ☐

30. If a wound swab was sent, please document the result below (if unable to locate a result either electronically or in the notes, please document result not available /documented

☐

Audit sheet completed by: ☐

dd mm yyyy

Date of audit: ☐ / /

Appendix 4: Electronic Survey Data Collection Form

A survey on the management of perineal wound dehiscence following childbirth

1. Does your unit have an evidenced based clinical guideline for the management of a dehisced perineal wound?

- ○ Yes
- ◉ No
- ○ Don't know

2. What is your current management of a dehisced perineal wound, within two weeks from delivery, in your unit?

- ○ Left to heal by secondary intention (Please go to question 7)
- ○ Re-sutured
- ○ Don’t know
- ○ Other

Other (please specify, thank you)

3. If the dehisced perineal wound is re-sutured, who performs the secondary repair in your unit? Please mark all that apply

- ☐ Consultant Obstetrician
- ☐ Staff Grade/Trust Doctor
- ☐ Specialist trainee
- ☐ Don’t know
- ☐ Other

Other (please specify, thank you)

4. Where is the secondary repair performed in your unit? Please mark all that apply

- ☐ Obstetric theatre
- ☐ Gynaecology theatre
- ☐ Delivery room
- ☐ Don't know
- ☐ Other

Other (please specify, thank you)

5. What suture material is used for the secondary repair in your unit?

- ○ What suture material is used for the secondary repair in your unit? Standard Polyglycolic (like Vicryl®)
- ○ Rapidly absorbable Polyglycolic (Vicryl Rapide®)
- ○ Don't know
- ○ Other

Other (please specify, thank you)

6. What method do you use to repair the vaginal mucosa, the perineal muscle and the perineal skin? (Please add your response in the box below, thank you)

7. In your unit would you recommend commencing antibiotics for a suspected perineal wound infection without prior confirmation of infection from a wound swab?

- ○ Yes
- ○ No
- ○ Don't know

If you answered yes, please specify what antibiotic(s) you would prescribe; what dose and for how long, thank you

8. Does your unit have a designated perineal care clinic?

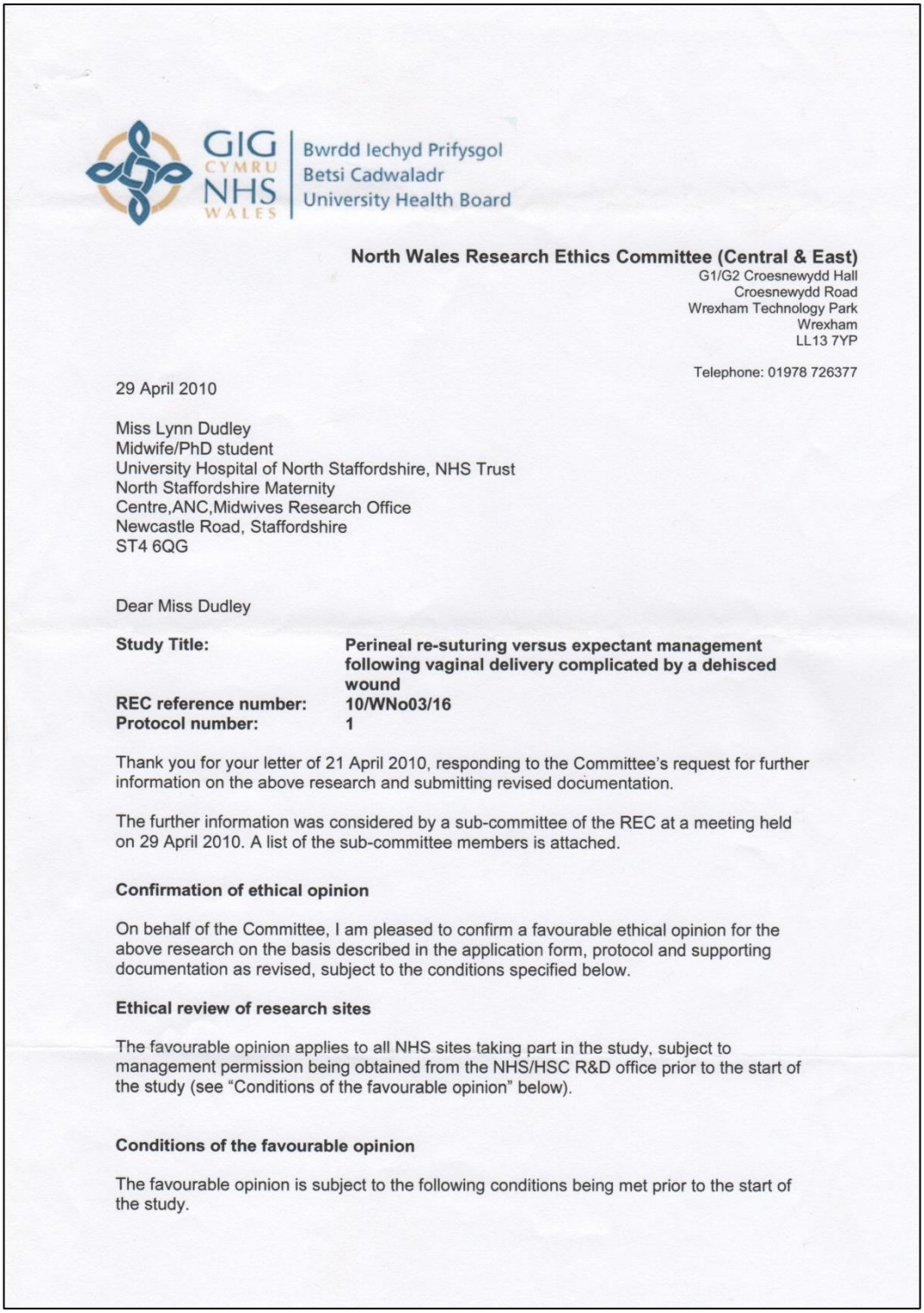
○ Does your unit have a designated perineal care clinic? Yes ○ No ○ Don't know
If you answered yes how often is the clinic held?

9. Where are women referred to with perineal wound breakdown? Please mark all that apply

☐ Perineal care clinic ☐ Primary care ☐ Maternity assessment unit/ maternity triage ☐ A & E ☐ Other
Other (please specify, thank you)

10. If you have any other information relating to the management of a dehisced perineal wound you would like to share with us please document below.

Appendix 5: Research Ethics Committee Approval for the PREVIEW Study



GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Betsi Cadwaladr
University Health Board

North Wales Research Ethics Committee (Central & East)
G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham
LL13 7YP

Telephone: 01978 726377

29 April 2010

Miss Lynn Dudley
Midwife/PhD student
University Hospital of North Staffordshire, NHS Trust
North Staffordshire Maternity
Centre,ANC,Midwives Research Office
Newcastle Road, Staffordshire
ST4 6QG

Dear Miss Dudley

Study Title: **Perineal re-suturing versus expectant management following vaginal delivery complicated by a dehisced wound**
REC reference number: **10/WNo03/16**
Protocol number: **1**

Thank you for your letter of 21 April 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered by a sub-committee of the REC at a meeting held on 29 April 2010. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Research Ethics Committee Approval for the PREVIEW Study 29th April 2010

Covering Letter		21 April 2010
Protocol	2	15 April 2010
Participant Information Sheet: PCT	2	15 April 2010
Participant Information Sheet: RCT	2	15 April 2010
SOP for the secondary repair of a Dehisced Perineal Wound	2	15 April 2010
Operation Sheet	1	15 April 2010
Response to Request for Further Information		21 April 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/WNo03/16	**Please quote this number on all correspondence**

Yours sincerely

T. A. Hume

pp

Professor Alex Carson
Chair

Email: Tracy.Hughes4@wales.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

Copy to: Dr Darren Clement Guy Hilton Research Centre UHNS Thornburrow Drive Newcastle Road, Newcastle Under Lyme ST 4 7QB

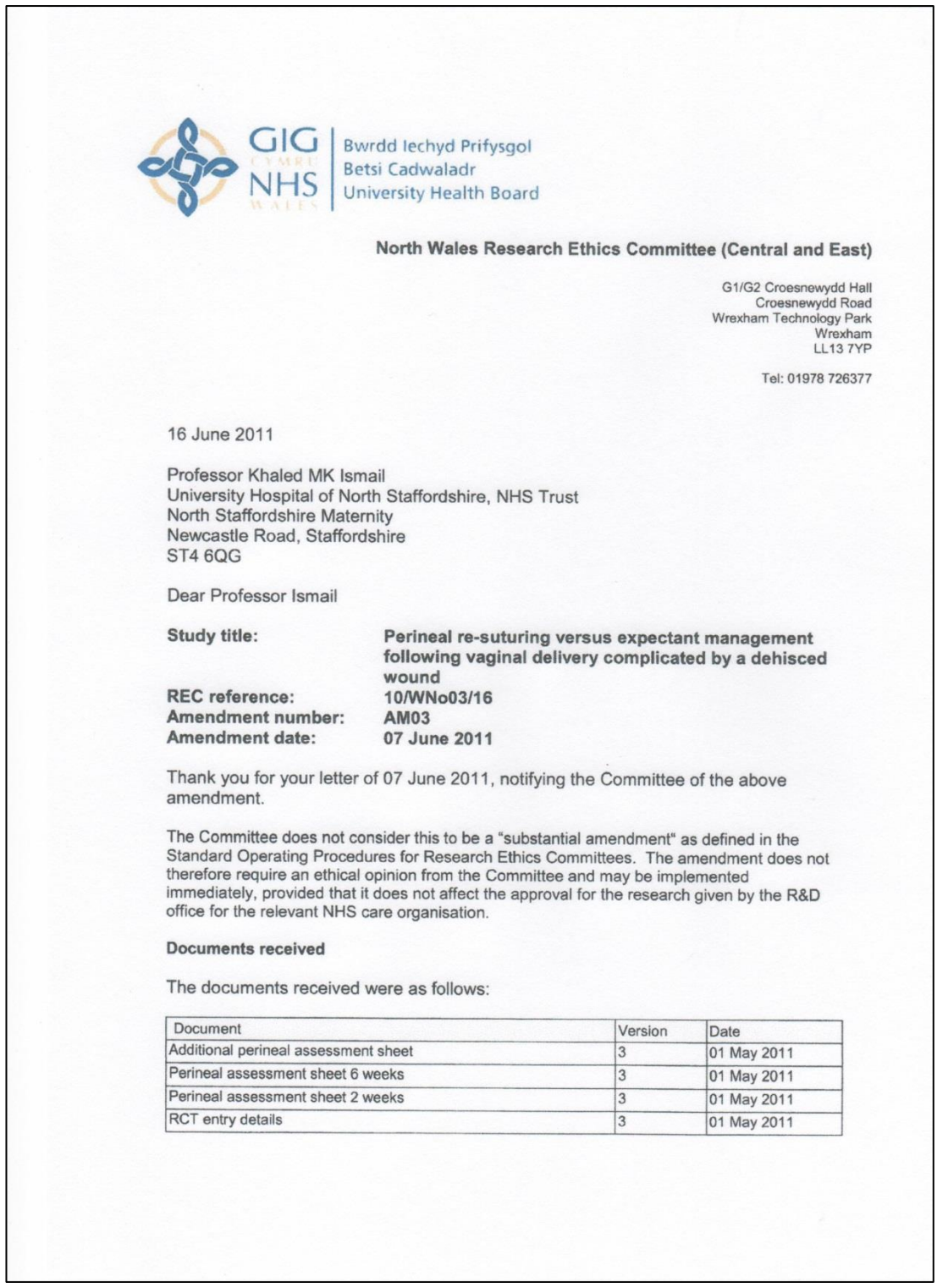
Professor Christine Kettle, University Hospital of North Staffordshire Maternity Centre, Newcastle Road Staffs ST4 6QG

North Wales Research Ethics Committee (Central & East)

Attendance at Sub-Committee of the REC meeting on 29 April 2010

Committee Members:

Name	*Profession*	*Present*	*Notes*
Professor Alex Carson	Associate Dean (Research)	Yes	
Mr Philip Richards	Associate Specialist - Surgery	Yes	
Dr David Southern	Consultant Anaesthetist	No	Yes



GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Betsi Cadwaladr
University Health Board

North Wales Research Ethics Committee (Central and East)

G1/G2 Croesnewydd Hall
Croesnewydd Road
Wrexham Technology Park
Wrexham
LL13 7YP

Tel: 01978 726377

16 June 2011

Professor Khaled MK Ismail
University Hospital of North Staffordshire, NHS Trust
North Staffordshire Maternity
Newcastle Road, Staffordshire
ST4 6QG

Dear Professor Ismail

Study title: **Perineal re-suturing versus expectant management following vaginal delivery complicated by a dehisced wound**
REC reference: **10/WNo03/16**
Amendment number: **AM03**
Amendment date: **07 June 2011**

Thank you for your letter of 07 June 2011, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
Additional perineal assessment sheet	3	01 May 2011
Perineal assessment sheet 6 weeks	3	01 May 2011
Perineal assessment sheet 2 weeks	3	01 May 2011
RCT entry details	3	01 May 2011

Research Ethics Committee Approval for the PREVIEW Study Version 3 Documents 16th June 2011

Operation Sheet	2	01 February 2011
Questionnaire: Mothers 6 months	3	01 May 2011
Questionnaire: Mothers 3 months	3	01 May 2011
Questionnaire: Mothers 6 week	3	01 May 2011
GP/Consultant Information Sheets	2	01 February 2011
Participant Consent Form	2	01 February 2011
Participant Information Sheet: Interviews	2	01 February 2011
Participant Information Sheet	3	01 February 2011
Protocol	3	01 February 2011
Notification of a Minor Amendment		07 June 2011
Covering Letter		07 June 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

10/WNo03/16:	Please quote this number on all correspondence

Yours sincerely

T. a Hughes

Ms Tracy Hughes
Committee Co-ordinator

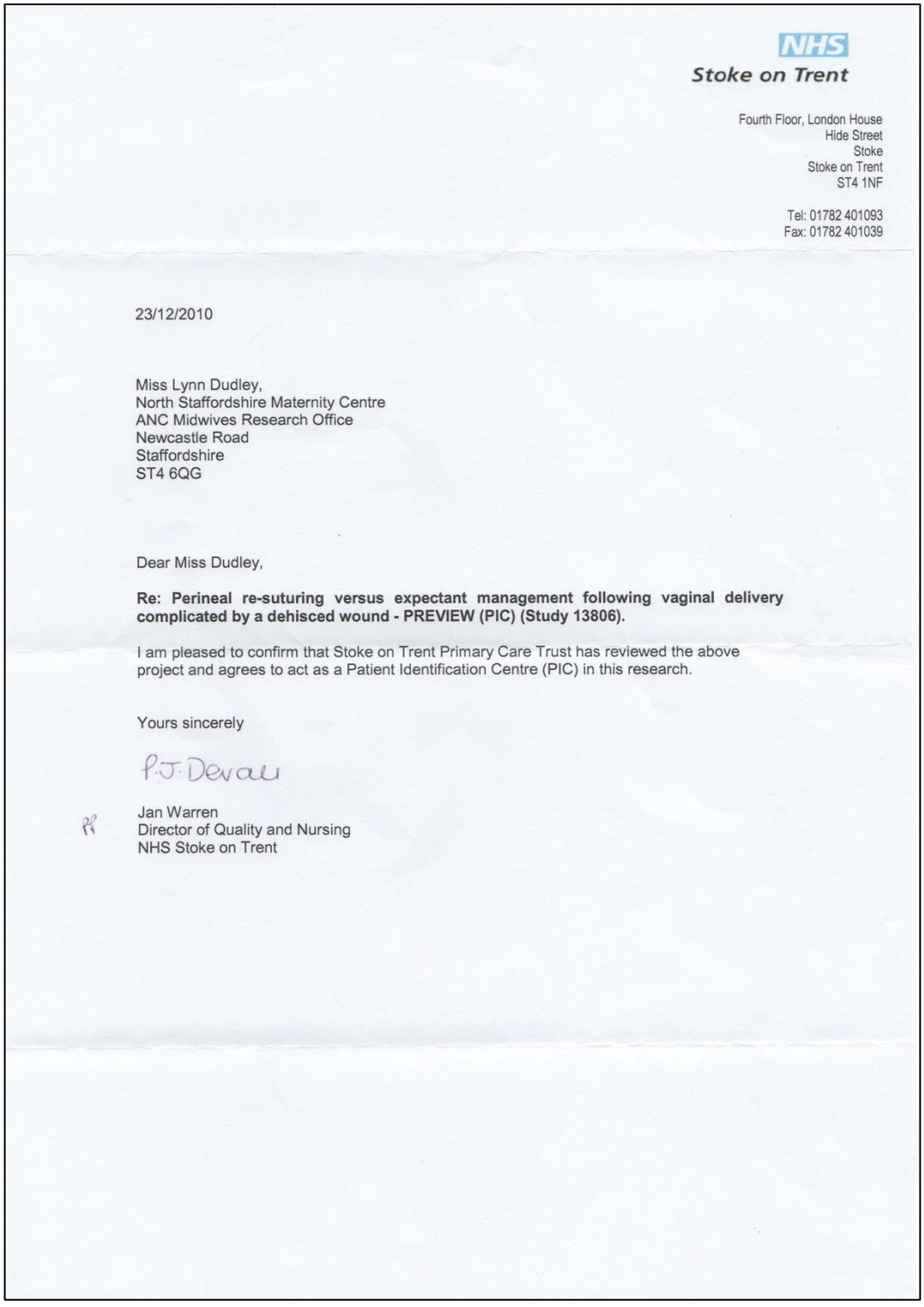
E-mail: Tracy.Hughes4@wales.nhs.uk

Copy to: Miss Lynn Dudley
Midwife/PhD student
University Hospital of North Staffordshire, NHS Trust
North Staffordshire Maternity
Centre,ANC,Midwives Research Office
Newcastle Road, Staffordshire
ST4 6QG

Dr Darren Clement Guy Hilton Research Centre UHNS Thornburrow Drive Newcastle Road, Newcastle Under Lyme ST 4 7QB

Research Ethics Committee Approval for the PREVIEW Study Version 3 Documents 16th June 2011

Appendix 6: Primary Care Trust, Participant Identification Centre Approvals for the PREVIEW Study



NHS
Stoke on Trent

Fourth Floor, London House
Hide Street
Stoke
Stoke on Trent
ST4 1NF

Tel: 01782 401093
Fax: 01782 401039

23/12/2010

Miss Lynn Dudley,
North Staffordshire Maternity Centre
ANC Midwives Research Office
Newcastle Road
Staffordshire
ST4 6QG

Dear Miss Dudley,

Re: Perineal re-suturing versus expectant management following vaginal delivery complicated by a dehisced wound - PREVIEW (PIC) (Study 13806).

I am pleased to confirm that Stoke on Trent Primary Care Trust has reviewed the above project and agrees to act as a Patient Identification Centre (PIC) in this research.

Yours sincerely

P.J. Devau

Jan Warren
Director of Quality and Nursing
NHS Stoke on Trent

Primary Care Trust, Participant Identification Centre Approval

Appendix 7: PREVIEW Study RCT Information Booklet

Hospital headed paper

PREVIEW STUDY

Perineal **r**e-suturing versus **e**xpectant management following **v**aginal delivery complicated by a dehi**s**c**e**d **w**ound
(Version 3 February 1st 2011)

Information leaflet for women

Invitation

You are being invited to consider taking part in a research study by the PREVIEW project team, which will look at the care women receive when they have had stitches after childbirth which have broken down.

Before you decide whether to take part it is important for you to understand why the study is being done and what it will involve. Please take the time to read the information provided in this leaflet carefully. You can ask us if there is anything that is unclear or if you would like any further information. Talk to others about the study if you wish.

Part 1 of this leaflet tells you the purpose of this study and what will happen to you if you take part.

Part 2 of this leaflet gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear.

Thank you for taking the time to read this information leaflet.

Part 1

What is the purpose of the study?

More than 350,000 women per year in the UK will need perineal (area between the vagina and back passage) stitches following their babies birth. Sometimes the wound where the stitches are breaks down, this is mostly from infection. If this happens it may lead to long term complications and the need for further surgery. For some women the broken down wound will be allowed to heal naturally, whilst others may be offered re-stitching. Currently we do not have any nationally agreed evidence to guide us on the best management of this complication.

There will be 2 parts to this study, one of the main parts will be a trial involving 180 women allocated into 2 groups to see if re-stitching compared to leaving the broken down wound to heal naturally, will improve healing times and reduce complications.

For the second part of the study we will be asking a small number of women from each group, if they would mind taking part in a short tape recorded interview. This will provide us with additional information about how your broken down wound has affected your well being and your ability to care for your new baby and your family and your experiences of taking part in the trial.

The whole of the study will be an educational project for the lead researcher.

Why have I been chosen?

We want to ensure that the way we treat perineal wound breakdown is based upon the best available evidence we have. You have been chosen because your midwife, general practitioner (GP), perineal care specialist or obstetrician has identified that your perineal wound has broken down.

Do I have to take part in the study?

Your consent to participate in this study is entirely voluntary; we will only be asking women to participate in this part of the study who have a broken down perineal wound. Once you have had time to read this information leaflet which we will give to you and ask any questions you may have, you will be invited to take part by the perineal care specialist, midwife or doctor attending to you in the perineal care clinic. You are free to withdraw from the study at any time, without giving a reason. The standard of care you receive will not be affected.

What will happen if I take part in the study and what will be expected of me?

If you agree to take part in the study and once you have signed your consent form, you will be computer allocated into either re-stitching of your broken down wound or leaving it to heal naturally. The results will then be compared to see if one is better. You will have a 50-50 chance of being allocated into either group. You will be given a copy of your consent form.

Whichever group you are allocated into, you will:

Be followed up in the perineal care clinic (or alternative clinic, dependent upon which hospital enters you into the study) at 2 weeks and 6 weeks after entering into the study. Additional appointments to assess how your wound is healing may also be necessary.

Be asked to complete a questionnaire at 6 weeks, 3 months and 6 months after entering the study. All questionnaires will take you approximately 20 minutes to complete. The 6 weeks questionnaire will be given to you at your clinic visit. The 3 and 6 months questionnaires will be posted to your home address. All questionnaires will be returned to the study team in pre-paid, addressed envelopes.

Be asked to complete all the questions as honestly and accurately as possible relating to your health and wellbeing including your experience of any pain or discomfort you have in relation to your perineum and how you feel it is healing.

What will happen if I am allocated into the re-stitching group?

If you are allocated into the re-stitching group you will be given a date and time when the wound will be re-stitched, this will usually be within 48 hours.

Your broken down wound will be re-stitched by an experienced doctor in the operating theatre at the hospital that enters you into the study.

You will be seen by an anaesthetist who will discuss the types of anaesthesia available (spinal, general or local) and also any benefits and risks associated with the procedure. If you require further information, this can be found on www.youranaesthetic.info or alternatively you could ask for a hard copy of this leaflet from the study team.

If you decide upon a spinal anaesthetic a urinary catheter will be inserted into your bladder once the spinal anaesthetic is effective, this will be removed after the procedure once you are mobile and you will need to pass urine prior to being discharged home.

After the procedure you will spend approximately 1 hour in the recovery area where the theatre is situated and will remain in hospital for approximately 6 hours before being discharged home. You will need someone to collect you from the hospital.

We will respect your wishes regarding your baby and he/she may accompany you into hospital. Your partner or family member will be asked to remain with your baby until you return to the ward area.

If your wound breaks down for a second time, it will not be re-stitched. You will remain in the study and you will be followed up in the perineal care clinic (or alternative clinic, dependent upon which hospital has entered you into the study).

What are the possible disadvantages to taking part?

The main disadvantage is the short hospital stay if you are allocated into the re-stitching group.

Both groups will be seen back at the perineal care clinic, (or alternative clinic) so you would need to make transport arrangements for this and pay the hospital car parking fees. However, even if you decide not to take part you will be seen again at various intervals in the perineal care clinic.

What are the possible benefits to taking part?

The information that you provide us with will enable us to decide upon the best management to treat perineal wound breakdown.

It will also help us to identify what types of information and support are most likely to benefit women's recovery.

What if something goes wrong?

We do not anticipate that you will come to any harm from taking part in this study. However, any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

If I agree to take part in the study, will it be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

What will happen if I decide not to take part in the PREVIEW study?

If you decide not to take part in the study, your broken down wound will be allowed to heal naturally. You will not be sent any questionnaires to complete. You will be seen in the perineal care clinic (or alternative clinic) at regular intervals.

This completes Part 1 of the information leaflet

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision

Part 2

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If the study needs to be stopped for any reason, we will tell you and arrange your continuing care.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without giving reason, but we will need to use the data collected up to your withdrawal. The standard of care you receive will not be affected and you will still be given appointments to be seen in the perineal care clinic.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers at your hospital who will do their best to answer your questions.

Alternatively, please contact Professor Khaled Ismail (Chief Investigator for the study) at the University Hospital of North Staffordshire on 01782 672377 or email khaled.ismail@uhns.nhs.uk

If you remain unhappy and wish to complain formally the contact information for the complaints procedure at your hospital will be made available to you.

We do not anticipate that you will come to any harm by taking part in this study, but in the event that something goes wrong and you are harmed during the research which is due to someone's negligence, then you may have grounds for legal action for compensation against the NHS hospital that has recruited you into the study. You may have to pay your legal costs. The normal National Health Service complaints mechanism will still be made available to you.

If I agree to take part in the study, will it be kept confidential?

The information collected for this study will be kept strictly confidential.

All information will be kept in locked cupboards and will only be accessed by members of the research team.

All electronic information will be stored on password secure computers and password secure memory sticks.

No individual names or details that would specifically identify individuals will be included in any publications or conference presentations.

Various quotations from questionnaire responses may be used in reports and conference presentations but these will not be traceable to any individual women. All reports both published and unpublished will disguise the identity of specific individuals.

Should you lose the ability to continue with your consent, data already collected with your consent will be retained and used in the study.

To provide scope for further long term follow-up, we may securely retain information we collect from you including your personal contact details for future research.

Informing your Family Doctor, General Practitioner (GP)

All health centres and GP practices have been informed of this study.

If you agree to take part we will ask for your consent to allow us to notify your GP that you are taking part in this study.

We will also ask your consent to allow us to contact your GP if we identify a health related problem that we feel your doctor should be aware of.

If you specifically do not wish to give us consent, then we will not inform your GP of your involvement in the study and we will not inform your GP if we identify a health related problem.

What will happen to the results of the PREVIEW research study?

The results of the study will be published in midwifery, nursing and medical journals and presented at local, national and international conferences.

If you would like a copy of the final report, journals articles or papers published as a result of this study, these will be sent to you.

The results of the PREVIEW study will influence the decision making for a much larger national and potentially international trial.

Following completion of the study, should the results of the study provide substantial evidence that re-stitching a broken down perineal wound causes less problems for women, then this will have the potential to change practice for the future.

Who is organising and funding the research?

The research has been funded by a National Institute for Health Research, Research for Patient Benefit Programme Award and by the Smith and Nephew Foundation.

The research is being conducted in 4 hospitals over 18 months and is being led by representatives from midwifery; Lynn Dudley (Research Midwife, University Hospital of North Staffordshire), Christine Kettle (Professor of Women's Health University Hospital of North Staffordshire) with clinical expertise in the field of perineal assessment and repair and Professor Khaled Ismail (Professor of Obstetrics and Gynaecology, University of Keele and University Hospital of North Staffordshire).

Members of the PREVIEW research team already have links through an on-going study in perineal assessment and repair with the Royal College of Midwives, The Royal College of Obstetricians and Gynaecologists and The National Childbirth Trust.

There is no organisational or individual payment made for participating in the study.

Who has reviewed the study?

The study has been reviewed by a panel of experts from the Smith and Nephew Foundation.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. The PREVIEW study has been given a favourable opinion by the North Wales Research Ethics Committee and your local research and development departments.

Contact for further information

If you require any further information about this study please contact Lynn Dudley (lead midwife for the study) on 01782 672123 or 07704242268 alternatively, email lynn.dudley@uhns.nhs.uk

Professor Khaled MK Ismail (Chief Investigator for this study) may also be contacted on 01782 672377 alternatively email Khaled.ismail@uhns.nhs.uk

Additionally INVOLVE is a national advisory group that has the main role of supporting and promoting active public involvement in NHS, public health and social care research. They have published a document entitled 'good practice in active public involvement in research' which you may wish to obtain at http://www.invo.org.uk/pdfs/GoodPracticeD3.pdf

This leaflet gives more information about medical research and looks at some questions you may want to ask.

A copy may be obtained from INVOLVE, Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD. Telephone 02380 651088 or Email admin@invo.org.uk

Please make use of this section to write down any questions you may need to ask us.

Appendix 8: PREVIEW Study RCT Consent

Hospital headed paper

PREVIEW

Perineal **r**e-suturing versus **e**xpectant management following **v**aginal delivery complicated by a dehi**sc**ed **w**ound

---

Site number ☐ **CONSENT FORM** **Study number** ☐

Name of researcher: Professor Khaled MK Ismail
University Hospital of North Staffordshire NHS Trust
Maternity Centre, Antenatal Clinic
Newcastle Road, Stoke-on-Trent, ST4 6QG

Please initial the box

1. I confirm that I have read and understood the information sheet for the above study. I have been given the opportunity to consider the information, to ask any questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I will be free to withdraw from the study at any time, without giving any reasons and without my medical care or legal rights being affected. ☐

3. I agree that my family doctor/General Practitioner (GP) can be informed about my consent to participate in this study. ☐

4. I agree that if any health problems are identified my family doctor/General Practitioner (GP) can be notified. ☐

5. I understand that relevant sections of my hospital medical records and data collected from the study, may be looked at by appropriate individuals from the PREVIEW study team. I give my permission for these individuals to have access to my medical records where it is relevant to my participation in this study. ☐

6. I agree to take part in the PREVIEW study ☐

7. I consent to being contacted to participate in a short interview ☐

8. I do not wish to participate in a short interview ☐

Name of Patient	**Date**	**Signature**

Hospital Unit number _____

Address _____

Name of Person taking consent (If not the researcher)	**Date**	**Signature**
Researcher	**Date**	**Signature**

Appendix 9: PREVIEW Study RCT Randomisation Schedule

PREVIEW Trial Randomisation Service

User Guide

Recruiting site number 11

The purpose of the PREVIEW Trial Randomisation Service is to allocate participants in the PREVIEW Trial to Re-suturing or Expectancy.

The Randomisation Service system is both telephone and web based. As you use the telephone system you will be required to respond to it by pressing numbers on your telephone keypad. This User Guide describes both interfaces.

Before you begin you should have the following information close at hand.

- Your site's 6-digit PIN 907061
- The mother's date of birth

TELEPHONE SYSTEM

Telephone Number is 0117 331 0163

You can abort the allocation of a patient at any time by ending the call

Part 1 – Introduction

Prompt	Your Response	
Welcome to the BRTC Randomisation System. Please enter your personal 6-digit PIN code. 907061		You should respond with the 6-digit PIN given to you by the PREVIEW trial co-ordinator.
		Example:- **123456**
You can abort the allocation of a patient at any time by hanging up the call.		
Prompt	**Your Response**	
Proceeding with trial PREVIEW. Press 1 to continue, 2 to finish.		You should respond by pressing 1 or 2
		Example:- **1**
You can abort the allocation of a patient at any time by hanging up the call.		

Part 2 – Site

Prompt	Your Response	
In which centre has this patient been recruited?		You should respond by pressing the appropriate site code (list below).
		Example:- **1**

Site codes:

1. Recruiting site 1
2. Recruiting site 2
3. Recruiting site 3
4. Recruiting site 4
5. Recruiting site 5
6. Recruiting site 6
7. Recruiting site 7
8. Recruiting site 8
9. Recruiting site 9
10. Recruiting site 10
11. Recruiting site 11

You can abort the allocation of a patient at any time by hanging up the call.

Prompt	Your Response	
You entered XXXX. Press 1 to confirm or 2 to try again.		You should respond by pressing either 1 or 2.
		Example:- **1**

You can abort the allocation of a patient at any time by hanging up the call.

Part 3 – Mother's date of birth

Prompt	**Your Response**	
Please enter the mother's date of birth.		You should respond by keying in the mother's date of birth.
		Example:- **25 12 2010**
You can abort the allocation of a patient at any time by hanging up the call.		
Prompt	**Your Response**	
You entered XX. Press 1 to confirm or 2 to try again.		You should respond by pressing either 1 or 2.
		Example:- **1**
You can abort the allocation of a patient at any time by hanging up the call.		

Part 4 – Allocation and confirmation

Prompt	**Your Response**	
You have entered all the required data and are now ready to randomise. Press 1 to recruit the patient, 2 to cancel.		You should respond by pressing either 1 or 2.
		Example:- **1**
At this point the randomisation is performed automatically by the system. There is no caller interaction.		
		Example:- **1**

This patient has been recruited successfully and has the ID number XXXX. This patient has been allocated to receive XXXX. Please confirm that you have understood the allocation by pressing 1 for Re-suturing or 2 for Expectancy. Press 1 to proceed or 2 to repeat the allocation information for this patient.		You should respond by pressing either 1 or 2. You should respond by pressing either 1 or 2.
		Example:- **2, 1**
Thank you. Press 1 to randomise another patient, press 2 to finish.		You should respond by dialling either 1 or 2.
		Example:- **2**

Email notification is automatically sent to PREVIEW trial manager

WEB SYSTEM

Web address is:

https://www.brtcrandomisation.bristol.ac.uk/cgi-bin/cgi?recruit

Login
Enter your 6 digit PIN 907061
Recruit a Participant
Choose trial from dropdown (only SSCM PREVIEW will be available unless you are working on more than 1 trial on the BRTC randomisation system) click 'Continue'
• Enter the recruiting site's code • Enter the mother's date of birth click 'Recruit'
You will then see a screen showing the data you have entered. click 'Recruit' – at this point the patient is allocated
You will then receive a message that patient has been successfully recruited, along with patient trial ID and allocation

Email notification is automatically sent to the PREVIEW trial manager

Appendix 10: PREVIEW Study RCT Letter to General Practitioner

Hospital headed paper

Date:

Dear Dr

Perineal **r**e-suturing versus **e**xpectant management following **v**aginal delivery complicated by a deh**i**sc**e**d **w**ound **(PREVIEW)**

PREVIEW is a pilot, feasibility randomised controlled trial, designed to provide preliminary evidence of the effectiveness of re-suturing of dehisced perineal wounds, versus healing by expectancy (secondary intention) and to feed into the design and feasibility of a larger definitive trial.

Your patient …… has been reviewed at …….. ……and has agreed to participate in the above study.

During childbirth she sustained perineal trauma requiring suturing which has subsequently dehisced.

……has been randomised into the trial and will be reviewed at …… in 2 weeks and 6 weeks respectively and subsequently will be asked to complete a questionnaire at 6 weeks, 3 months and 6 months.

The study has received ethical approval from the National Research Ethics Committee and local Research and Development Departments.

If you require any additional information relating to the study then please do not hesitate to contact me on the telephone number or e mail address provide below.

Yours sincerely

Professor Khaled M K Ismail MSc., MD, PhD, FRCOG,
Consultant Obstetrician & Gynaecologist
Birmingham Women's Foundation Trust,
Edgbaston, Birmingham, B15 2TG.
Email: k.ismail@bham.ac.uk Telephone: 0121-627-2775 Fax: 0121-623-6875

Appendix 11: PREVIEW Study RCT Data Entry Questionnaire

Hospital headed paper

PREVIEW STUDY

Perineal **r**e-suturing versus **e**xpectant management following **v**aginal delivery complicated by a deh**i**sc**e**d **w**ound
(Version 3 May 1st 2011)

Entry Details for Randomised Controlled Trial

This form should be completed in full by the person obtaining the mother's consent to take part in the study. When completed please return the form with the copy of the signed consent form in the envelope provided.

If you have any queries about the study, or this form, then please contact Lynn Dudley on either 01782 672123 or 07704 242268 or e mail lynn.dudley@uhns.nhs.uk

Study number ☐ **Site number** ☐

Mother's details

Name …… ☐

Address …… ☐

Postcode …….. ☐

Telephone number … (Including STD code) ☐

Mobile (optional) ……. ☐

Email (optional) ……... ☐

Hospital Unit Number ☐

Mothers Date of Birth **dd** ☐ **mm** ☐ **yyyy** ☐

Q1 Ethnic background (Please tick one box only)

White …… ☐
Mixed/multiple ethnic groups …… ☐
Asian/Asian British …… ☐
Black/African/Caribbean/Black British …… ☐
Other ethnic group …… ☐
Please describe ☐

Q2a BMI at booking ☐☐.☐

BMI not available ☐ Go to 2b

Q2b Please record height in cm ☐☐☐.☐

Q2c Weight in kg ☐☐.☐

Q3 Does the mother have diabetes mellitus?

Yes …… ☐
No …… ☐

Q4a Did the mother have gestational diabetes?

Yes …… ☐
No …… ☐

Q4b If yes was insulin required?

Yes …… ☐
No …… ☐

Q5 Were there any pre-delivery medical problems?

Yes …… ☐
No …… ☐
If yes, please specify ☐

Q6 Does the mother smoke?

Yes …… ☐
No …… ☐
If yes, how many cigarettes day? ☐

Q7 Number of previous vaginal deliveries over 24 weeks ……... ☐

Q8 Previous perineal trauma (tear or an episiotomy) please tick appropriate box

No previous trauma …….. ☐ Go to Q11
Previous trauma not sutured ……..... ☐ Go to Q9
Previous trauma sutured ……..... ☐ Go to Q9

Q9 Previous dehisced perineal wound: complete or partial separation of the perineal wound involving both the skin and muscle layers

Yes ……... ☐
No …… ☐

Q10 If yes was this left to heal by ….. (Please tick appropriate box

Secondary intention ……. ☐
Re-sutured…….. ☐

Q11 Birth details for this delivery (for twins please remember to complete 2nd baby)

1st Baby

Number of weeks gestation ☐☐

dd mm yyyy
Date of delivery ☐☐ ☐☐ ☐☐☐☐

Birth weight in grams ☐☐☐☐
Head circumference in cm ☐☐.☐

2nd Baby

Number of weeks gestation ☐☐

dd mm yyyy
Date of delivery ☐☐ ☐☐ ☐☐☐☐

Birth weight in grams ☐☐☐☐
Head circumference in cm ☐☐.☐

Q12 Type of delivery (1st baby for twins please remember to complete 2nd baby)

Spontaneous vaginal delivery …….. ☐

Forceps delivery …….. ☐

Ventouse…….. ☐

Breech……... ☐

Other please specify type of delivery ☐

Q12 Type of delivery (2nd baby)

Spontaneous vaginal delivery…… ☐

Forceps delivery …… ☐

Ventouse …… ☐

Breech ……... ☐

Other please specify type of delivery ☐

Q13 What type of analgesia was given to the mother during labour? (Please tick all that apply)

None …….. ☐

Entonox …… ☐

Pethidine…….. . ☐

Epidural …… ☐

Other please specify ☐

Q14 Was meconium liquor present during labour?

Yes …… ☐

No ……..... ☐

Information not available …… ☐

Q15 Were antibiotics administered in labour?

Yes …… ☐

No …… ☐

If yes please document name, route and indications for antibiotics

☐

Q16 What was the duration of the second stage of labour?

Hours ……. ☐ **Minutes**……. ☐

Q17a What degree of perineal trauma was documented at delivery? (Please tick 1 box only).

None …… ☐
First degree …….. ☐
Second degree …….. ☐
Episiotomy …… ☐
Extended episiotomy (not involving the anal sphincter) …… ☐

Q17b If the woman was given an episiotomy, what was the reason for this? (Please tick all that apply).

Maternal exhaustion …… ☐
Rigid perineum …… ☐
Fetal distress ……... ☐
Assisted delivery …… ☐
To prevent uncontrolled trauma …… ☐
Previous 3rd/4th degree tear …… ☐
Information not available …….. ☐
Other (please describe) ☐

Q18 Who performed the perineal repair?

Midwife …… ☐ Go to Midwife - Band
Student midwife ……... ☐ Go to Student midwife - Year
SHO …… ☐ Go to Q19
Registrar ……... ☐ Go to Q19
Senior Registrar …… ☐ Go to Q19
Consultant ……... ☐ Go to Q19
Other ……... ☐ Go to other
Perineal trauma not sutured at time of delivery … ☐
Midwife – Band ☐ Student midwife - Year ☐
Other ☐

Q19 Was the repair carried out under supervision?

Yes …… .. ☐
No …….. ☐
Information not available ……... ☐

Q20 Which suture material was used for the perineal repair?

Vicryl Rapide …… ☐
Vicryl …….. ☐
Dexon …….. ☐
Information not available……. ☐
Other (Please specify) …… ☐

Q21 Where was the perineal repair performed?

Delivery room ……... ☐
Maternity theatre …….. ☐

Q22 What was the total estimated blood loss recorded in mls following delivery? ☐

Q23 What is the most recent documented haemoglobin in g/dl? ……. ☐

Q24 Did the woman receive a blood transfusion?

Yes ……. ☐
No …… ☐

Q25 Which healthcare professionals did the mother consult regarding her perineum?
(Please tick all that apply?

GP …… ☐
Midwife …… ☐
Health visitor …… ☐
Obstetrician …… ☐
Physiotherapist …….. ☐

Q26 Which healthcare professional referred the mother to the perineal care clinic?

GP …… ☐
Midwife …… ☐
Health visitor …… ☐
Obstetrician …… ☐
Physiotherapist …….. ☐
Self referral …….. ☐

Wound assessment at trial entry

(Please obtain a wound swab if not already sent)

Q27a For a **complete perineal wound dehiscence** please record the measurements as demonstrated in figures 2 – 4 using a Peri-Rule or alternative

or

Q27b For a **partial perineal wound dehiscence** please record the measurements as demonstrated in figures 5 - 7 using a Peri-Rule or alternative

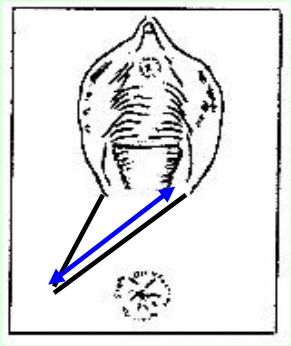
Figure 1

Please draw the dehisced perineal wound on the picture below

Q 27a For a <u>complete perineal wound dehiscence</u> please now record the measurements as demonstrated in figures 2 – 4

Full length of the completely dehisced perineal wound: measure from the hymenal remnants to the lower apex of the wound as shown in figure 2

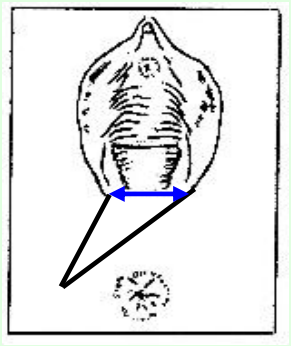
Figure 2



Length in mm ☐

Full width of completely dehisced perineal wound: Measure at the widest dehisced part of the perineal trauma as shown in figure 3

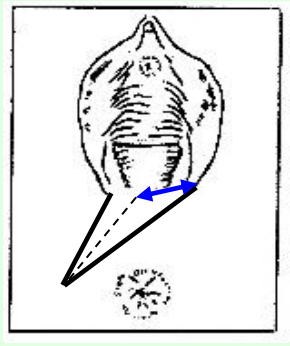
Figure 3



Width in mm ☐

Full depth of the completely dehisced perineal wound: Measure from the skin edges to the depth of the perineal wound (measure at the deepest point) as shown in figure 4

Figure 4



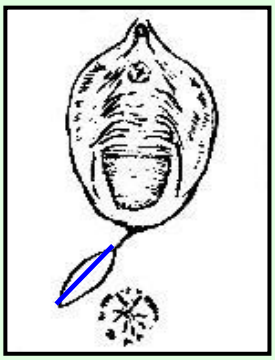
Depth in mm ☐

Please now complete the remaining questions 28-36

Q27b For a <u>partial perineal wound dehiscence</u> please now record the measurements as demonstrated in figures 5 - 7

Full length of the partially dehisced wound: If partial wound dehiscence please record the length of the breakdown as shown in figure 5

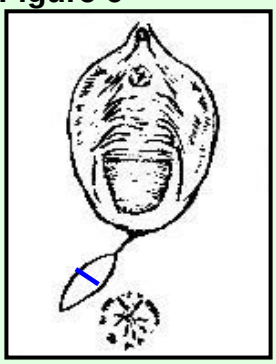
Figure 5



Length in mm ☐

Full width of the partially dehisced perineal wound: Please measure at the widest dehisced part of the perineal trauma as shown in figure 6

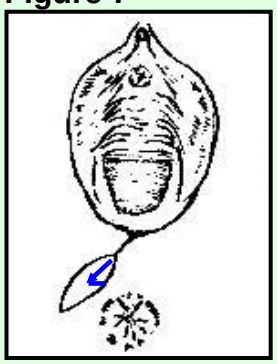
Figure 6



Width in mm ☐

Full depth of the partially dehisced perineal wound: Please measure from the skin edges to the depth of the perineal wound (measure at the deepest point) as shown in figure 7

Figure 7



Depth in mm ☐

Please now complete the remaining questions 28-36

Q28 Are there any signs of infection

Yes …….... ☐ Go to Q28b

No……... ☐ Go to Q29

Q28b If yes please tick all that apply

Perineal wound painful when touched …… ☐

Localised swelling …… ☐

Heat …… ☐

Purulent discharge from the wound …….. ☐

Redness …… ☐

Q29 Redness of the edges of the perineal wound **Score** …… ☐

0 = None …….. ☐

1 = Mild (less than 0.5cm of each side of the wound edges) …….. ☐

2 = Moderate (0.5cm to 1cm of each side of the wound edges) …….. ☐

3 = Severe (more than 1cm of each side of the wound edges) …….. ☐

Any other comments ☐

Q30 Oedema of the perineal area **Score** ……. ☐

0 = None …… ☐

1 = Mild (less than 1 cm from the wound edges) …… ☐

2 = Moderate (1 to 2 cm from the wound edges) …….. ☐

3 = Severe (more than 2 cm each side of the wound edges) …… ☐

Any other comments ☐

Q31 Bruising of the perineal area **Score** ……. ☐

0 = None …… ☐

1 = Mild (purple less than 1cm from each side of the wound edges) ……... ☐

2 = Moderate (purple 1 to 2cm each side of the wound edges) …… ☐

3 = Severe (purple more than 2 cm from each side of the wound edges) ……. . ☐

Any other comments ☐

Q32 Discharge from the wound **Score** …….. ☐

0 = None ……..... ☐

1 = Serum ……..... ☐

2 = Serosanguinous (consisting of blood and serum) ……..... ☐

3 = Purulent …… ☐

Any other comments ☐

Q33 Approximation of skin edges **Score** ..... ☐

0 = Closed ..... ☐

1 = Skin separation 3 mm or less ..... ☐

2 = Skin and subcutaneous fat separation ..... ☐

3 = Skin and subcutaneous fat and fascial layer separation ..... ☐

Any other comments ☐

Q34 Additional comments

☐

☐

Q35 Has a perineal wound swab sent?

Yes ..... ☐

No..... ☐

Date wound swab sent dd ☐☐ mm ☐☐ yyyy ☐☐☐☐

If you have ticked no and the wound appears infected, please obtain a wound swab and enter the date above

Wound swab results (if available)

☐

Q36 Has the mother received any antibiotic treatment associated with her perineal stitches prior to randomisation?

Yes ..... ☐

No..... ☐

If yes please specify the name of the antibiotic ☐

Please fill in the following

Signature of clinician completing the form

☐

Name of clinician completing form (please print)

☐

Date form completed ☐

Thank you on behalf of the PREVIEW study team for completing this form

Appendix 12: PREVIEW Study RCT 6 Week Perineal Assessment Questionnaire

Hospital headed paper

PREVIEW STUDY

Perineal Independent Assessment Sheet 6 weeks

Please complete this questionnaire in full with your assessment of the mother's perineum.

For perineal assessments carried out at the University Hospital of North Staffordshire, please place the completed perineal assessment sheets in the envelope provided and return to the PREVIEW study box located in the midwives research office ante-natal clinic.

For perineal assessments in other units, please return the completed perineal assessment sheets in the addressed envelopes provided.

If you have any queries about the study, or this form, then please contact: Lynn Dudley on either 01782 672123 or 672333.
Alternatively e mail **lynn.dudley@uhns.nhs.uk**

Study number | **Site number**

Mothers details:

Please attach address label

Please complete any missing information after checking details with the mother. Include: name, address, hospital unit number and date of birth

Section One

Wound healing for the purpose of this study will mean that there are no areas of wound dehiscence.

Q1a Has the wound healed?

Yes ……. ☐ Go to Q1b No …… ☐ Go to section 2

Q1b Would you assess the perineal wound scar tissue as:

Minimal (the scar tissue is no thicker than a pencil line)..…… ☐

Moderate (the scar tissue is less than 0.5cm thick) ……... ☐

Severe (the scar tissue is more than 0.5cm thick) ……..... ☐

Q1C Any other comments

Please now go to section three

Section Two

Measured Perineal Wound Assessment

Q2 If you ticked no, the wound has not healed then please complete the drawing in figure 1 <u>and</u> the following:

Q2a For a **<u>complete perineal wound dehiscence</u>** please record the measurements as demonstrated in figures 2 – 4 using a Peri-Rule or alternative

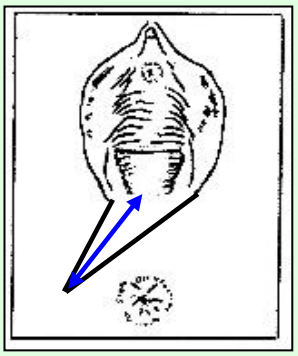
Q2b For a **<u>partial perineal wound dehiscence</u>** please record the measurements as demonstrated in figures 5 - 7 using a Peri-Rule or alternative

Figure 1 Please draw the dehisced perineal wound on the picture below

Q2a For a complete wound dehiscence please record the measurements as demonstrated in figures 2 - 4

Full length of the completely dehisced perineal wound: Measure from the hymenal remnants to the lower apex of the wound as shown in figure 2

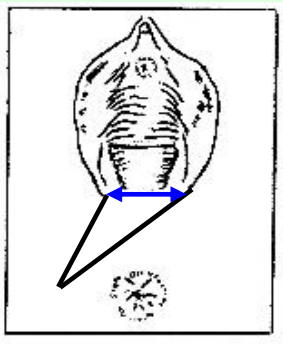
Figure 2



Length in mm ☐

Full width of the completely dehisced perineal wound: Measure at the widest dehisced part of the perineal trauma as shown in figure 3

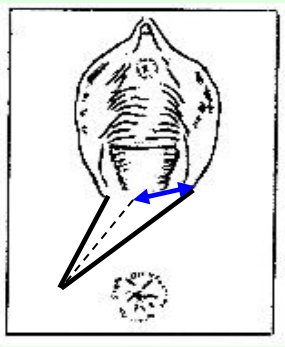
Figure 3



Width in mm ☐

Full depth of the completely dehisced perineal wound: Measure from the skin edges to the depth of the perineal wound (measure at the deepest point) as shown in figure 4

Figure 4



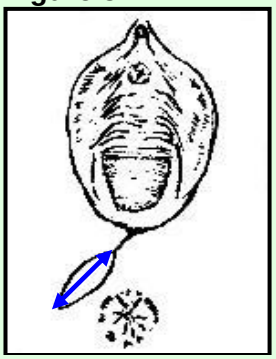
Depth in mm ☐

Please continue to Question 3

Q2a For a partial wound dehiscence please record the measurements as demonstrated in figures 5 - 7

Full length of the partially dehisced perineal wound: Please measure the length of the wound dehiscence as shown in figure 5

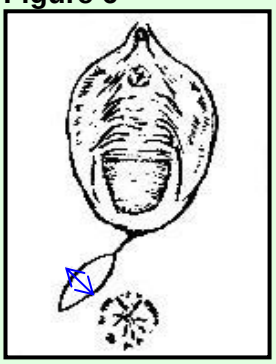
Figure 5



Length in mm

Full width of the partially dehisced perineal wound: Please measure at the widest dehisced part of the perineal trauma as shown in figure 6

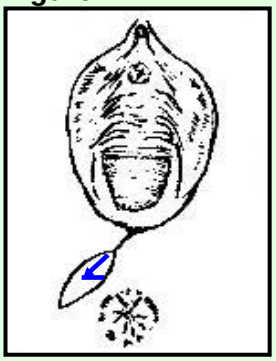
Figure 6



Width in mm

Full depth of the partially dehisced perineal wound: Please measure from the skin edges to the depth of the perineal wound (measure at the deepest point) as shown in figure 7

Figure 7



Depth in mm

Please continue to Question 3

Q3 Is the perineal wound painful when touched?

Yes …….. ☐ No…… ☐

Q4 Redness of the edges of the perineal wound **Score** ☐

0 = None …….. ☐
1 = Mild (less than 0.5cm of each side of the wound edges) …….. ☐
2 = Moderate (0.5cm to 1cm of each side of the wound edges) ……. ☐
3 = Severe (more than 1cm of each side of the wound edges) …….. ☐

Any other comments ☐

Q5 Oedema of the perineal area **Score** ☐

0 = None …… ☐
1 = Mild (less than 1 cm from the wound edges) …… ☐
2 = Moderate (1 to 2 cm from the wound edges) …… ☐
3 = Severe (more than 2 cm each side of the wound edges) …… ☐

Any other comments ☐

Q6 Bruising of the perineal area **Score** ☐

0 = None …….. ☐
1 = Mild (purple less than 1cm from each side of the wound edges) ……... ☐
2 = Moderate (purple 1 to 2cm each side of the wound edges) …… ☐
3 = Severe (purple more than 2 cm from each side of the wound edges) …… ☐

Any other comments ☐

Q7 Discharge from the wound **Score** ☐

0 = None …….. ☐
1 = Serum ……..... ☐
2 = Serosanguinous (consisting of blood and serum) ……..... ☐
3 = Purulent …… ☐

Any other comments ☐

Q8 Approximation of skin edges **Score** ☐

0 = Closed ……..... ☐
1 = Skin separation 3 mm or less …… ☐
2 = Skin and subcutaneous fat separation …… . ☐
3 = Skin and subcutaneous fat and fascial layer separation …… ☐

Any other comments ☐

Q9 Are the wound edges gaping more than 0.5cm? **Yes** ☐ **No** ☐

Q10 Are there any visible stitches in the perineal skin? **Yes** ☐ Go to Q11

No ☐ Go to Q12

Q11 If YES, are they cutting into the tissue? **Yes** ☐ **No** ☐

Q12 Have any sutures been removed? Yes ☐ Go to Q13 **No** ☐ Go to section 3

Q13 If YES, please state the reasons:

Section Three

Q14 Do you have any other comments you wish to add?

Please fill in the following: Signature of medical staff completing the form

Name: (block capitals please)

Date of completion:

Date and time of next appointment if necessary

Date **Time**

Please give the mother an appointment card and contact details if a further appointment is necessary.
Thank you for completing this form

Consider an additional appointment to assess wound healing if necessary.

Please remember to give the mother her 6 weeks questionnaire to complete.

The mother may complete this today before leaving or take it home with her to complete and return it in the pre-paid addressed envelope.

Please remind the mother that we will be sending her 2 further questionnaires to complete in approximately 6 weeks and 5 months time.

Appendix 13: PREVIEW RCT Mothers 6 Month Questionnaire

Hospital headed paper

PREVIEW STUDY

Perineal **r**e-suturing versus **e**xpectant management following **v**aginal delivery complicated by a deh**i**sc**e**d **w**ound
(Version 3 May 1st 2011)

Mother's questionnaire 6 months

Study Number ☐ **Site Number** ☐

It is now 6 weeks since you have kindly agreed to take part in the PREVIEW study and we are interested to find out how you are feeling.

We would be grateful if you would complete this questionnaire for us. When you have filled in your answers, please post the questionnaire back to us in the pre-paid addressed envelope provided.
The return address is also given at the end of the questionnaire.

All the information that you provide will be confidential and will help us to continually improve the care women receive after childbirth. Sharing with us your experiences will help us to decide which method of care is best for future mothers.

We still need your continuing help to complete this research study. We will send you another questionnaire in approximately 6 weeks and 5 months time. If you do change your address please let us know.

If you have any queries about the PREVIEW study or this form, please contact Lynn Dudley on 01782 672123 or 01782 672333

Thank you for your time and help.
Please check your details opposite and correct any information which may have changed.

Section 1

How are you feeling? Please tick the box that reflects your feelings best

Q1 In general how would you say you are feeling physically now?

Very well ☐
Reasonably well ☐
Not very well ☐
Not well at all ☐

Q2 In general how would you say you are feeling emotionally right now?

Happy ☐
Slightly tearful ☐
Tearful ☐
Very tearful ☐

Q3 In general how would you say you are feeling most of the time?

Not tired ☐
Slightly tired ☐
Tired ☐
Very tired ☐

Section 2

This section relates to pain or unpleasant feeling in your perineum – the part of your body between the opening of your vagina and your back passage

Q4 In the <u>past week</u> have you experienced any pain or unpleasant feeling in your perineum?

Yes ☐ Go to Q5
No ☐ Go to Q10

Q5 Would you describe the strength of the pain or unpleasant feeling as?

Mild ☐
Moderate ☐
Severe ☐

Q6 Is the pain or unpleasant feeling there?

Some of the time ☐
Most of the time ☐
All of the time ☐

Q7 In the <u>past week</u> how much pain or discomfort have you experienced from your perineum when doing the following activities (Please answer all the questions and tick one box for each activity)

	None	Mild	Moderate	Severe	Not tried
Feeding your baby (Breast or bottle)…..	☐	☐	☐	☐	
Walking about……	☐	☐	☐	☐	
Sitting down……	☐	☐	☐	☐	
Exercising ……	☐	☐	☐	☐	☐
Wearing tight trousers……	☐	☐	☐	☐	☐
Passing water……..	☐	☐	☐	☐	
Opening your bowels ……	☐	☐	☐	☐	

Other (please describe) ☐

Q8 Please circle the words below which best describe the pain or unpleasant feeling you have experienced from your perineum in the <u>past week</u>

sharp ….. ☐	aching …. ☐	Gnawing …. ☐	Itchy ……. ☐
stinging … ☐	heavy …. ☐	pulling …… ☐	annoying….. ☐
stabbing .. ☐	dull …… ☐	tender ……. ☐	Miserable … ☐
cutting …. ☐	pinching . ☐	burning ….. ☐	troublesome.. ☐
throbbing.. ☐	prickling.. ☐	tingly ……. ☐	Sickening … ☐

Other (please describe) ☐

Q9 In the <u>past week</u> have you needed any tablets to relieve the pain or discomfort in your perineum?

Yes …… ☐ No …… ☐

Q10 Have you needed to visit your GP (family doctor) since taking part in the study?

Yes …… ☐ Go to Q11 No …… ☐ Go to question 12

Q11 If yes, brief description of the reason

☐

Q12 Have an additional course of antibiotics been prescribed?

Yes …….. . ☐

No …… ☐

Section 3
This section relates to how you are feeding your baby

Q13 Have you breast fed your baby at any time since he/she was born?

Yes ……..... ☐ Go to Q14

No ……..... ☐ Go to Q17

Q14 If yes, are you still breast feeding your baby?

Yes …… ☐ Go to Q18

No …… ☐ Go to Q15

Q15 If no, how old was your baby when you stopped breast feeding?

Within the first 2 days after your baby's birth …….. ☐

Within the first week after your baby's birth…….. ☐

Within the first 2 weeks after your baby's birth…… ☐

Other …… ☐

Can't remember……..... ☐

Other please specify ☐

Q16 Why did you stop breast feeding? (Please tick all that apply)

Painful nipples ……..... ☐

Engorgement……..... ☐

Blocked milk duct……..... ☐

Thrush……..... ☐

Mastitis……..... ☐

Breast abscess……..... ☐

Not enough milk……..... ☐

Perineum was too uncomfortable or painful whilst feeding my baby …….. ☐

Other ……..... ☐

Other (Please describe) ☐

Q17 Bottle feeding - Has your perineum been too uncomfortable or painful for you to bottle feed your baby?

Yes ……..... ☐ Go to Q17a

No ……..... ☐ Go to Q18

Q17a If yes, please comment on how many times your perineum has been too uncomfortable or painful for you to bottle feed your baby

☐

Section 4
This section relates to how well you feel your perineum has healed

Q18 How well do you feel that your perineum has healed? (Please tick <u>one box</u> that is the most appropriate statement for the way you feel)

I feel that my perineum has healed …… ☐
I feel that my perineum has healed poorly …… ☐
I feel that my perineum has healed very poorly …….. ☐

Q19 Have you (Please tick all that apply)

Looked at your perineum using a mirror…… ☐
Felt your perineum…… ☐
Not looked at or felt your perineum …… ☐

Q20 Did your perineum

Look or feel better than you thought…….. ☐
Look or felt worse than you thought…… ☐
Could not see or feel it…….. ☐

Q21 Does your perineum feel 'back to normal'?

Yes…… ☐
No…… ☐

Q22 Have you been carrying out pelvic floor exercises during the last week?

Pelvic floor muscles are exercised by tightening the muscles around your anus and vagina (back and front passages) while lifting your pelvic floor)

Yes…… ☐
No…… ☐

Q23 If YES, how many times in the past 24 hours have you done pelvic floor exercises? (Please enter the number in the box)

Times per day…….. ☐
Squeezes and lifts each time…… ☐
Seconds you can hold each lift for…… ☐

Q24a Have you attempted to have intercourse?

Yes ……..... ☐ Go to Q24b

No …….. ☐ Go to Q26

Q24b If yes, did you have any of the following problems when you <u>first attempted</u> intercourse? (Please tick all that apply)

Vagina was too dry …….. ☐

Vagina felt too tight …….. ☐

Vagina felt too loose …….. ☐

Area where stitched was painful …….. ☐

Area around scar was painful when stretched …….. ☐

Pain or discomfort on penetration …….. ☐

Pain or discomfort on deep penetration …….. ☐

Sudden involuntary loss of urine …….. ☐

Sudden involuntary loss of bowels …….. ☐

Wind from the vagina …….. ☐

We had no problems …….. ☐

Other …….. ☐

Other (Please describe) ☐

Q25 Since the birth of your baby, do you feel that intercourse is:

More pleasurable than before …….. ☐

Less pleasurable …….. ☐

Same as before …….. ☐

Section 5

These questions relate to any other health problems you may have

Q26 If you have not tried to have intercourse, is this because? (Please tick all that apply)

You have no partner …… ☐

Partner not interested …….. ☐

Partner too tired …… ☐

You are not interested…….. ☐

You are too tired …… ☐

Lack of privacy……... ☐

Baby is demanding …….. ☐

You are afraid it might be painful …….. ☐

Partner is afraid it might be too painful for you …… ☐

You are worried that you might become pregnant …… ☐

Fear or concern that it may disrupt the healing …… ☐

Other …….. ☐

Other (Please describe) ☐

Q27 Is there anything else you would like to tell us about your perineum or how you are feeling now?

☐

☐

☐

☐

Date completed ….. ☐

Would you like to receive a copy of the results of this study?

Yes please …… ☐

No thank you …….. ☐

Would you like to receive an invite to an informal meeting to meet with other women who have taken part in this study and to discuss the results?

Yes please ……. ☐

No thank you …….. ☐

Thank you for completing this questionnaire

Without your help this study could not be undertaken

Should you mislay the pre-paid addressed envelope the PREVIEW study address is:

Lynn Dudley, PREVIEW Study, North Staffordshire Maternity Centre, Antenatal Clinic, Newcastle Road, Staffordshire, ST4 6QG

Appendix 14: Operative Record Sheet

PREVIEW study
Operation Sheet: Repair of a dehisced perineal wound

Name: **Address:**	**Study number**

Date: ……

Surgeon: …… **Grade: ……**

Anaesthetist: ……

Please will either the surgeon or the anaesthetist initial the box below to indicate that a discussion has taken place between the above surgeon and anaesthetist and that the anaesthetic risk has been deemed to be acceptable.

☐

Type of anaesthesia: Local ☐ Regional (Spinal) ☐ General ☐

Antibiotics administered: Yes ☐ No ☐

If yes, please document name of antibiotics administered ☐

Operative findings and procedure: Please document the suture technique and material used (type and gauge).

Post-operative instructions for the named nurse/midwife

Catheter: ……... Discharge: Medical ☐ Midwife ☐

Pack: ……

Suture removal: …… Perineal assessment appointment for 2 weeks ☐

TTOs: Please prescribe

Appendix 15: PREVIEW Study Interview Consent

PREVIEW STUDY

Perineal **r**e-suturing versus **e**xpectant management following **v**aginal delivery complicated by a dehi**sc**e**d** **w**ound

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RECORDED INTERVIEW CONSENT FORM

Name of researcher: Lynn Dudley **Study number**
University Hospital of North Staffordshire NHS Trust
Maternity Centre, Newcastle Road, Stoke-on-Trent**,** ST4 6QG

Please initial the box

1. I confirm that I have read and understood the information sheet for the recorded interviews. I have been given the opportunity to consider the information and to ask any questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I will be free to withdraw from the interview at any time, without giving any reasons and without my medical care or legal rights being affected. ☐

3. I agree that if any health problems are identified during the interview, my family doctor/ General Practitioner (GP) can be notified. ☐

4. I understand that I will be given the opportunity to review, edit or erase in my presence any tape recording to which I have contributed. ☐

5. I understand that various quotations and extracts from interview responses may be used in reports, and conference presentations, but these will not be traceable to any individual women. ☐

6. I agree to take part in the recorded interview for the PREVIEW study ☐

Name of Patient	**Date**	**Signature**

Hospital Unit number _____

Address _____

Name of Person taking consent **(If not the researcher)**	**Date**	**Signature**
Researcher	**Date**	**Signature**

For office use: Consent form: Interviews Version 1 January 1st 2010
When completed top copy to be retained in researcher site file, 1 copy for the medical notes, 1 copy for the patient.

Appendix 16 PREVIEW Study Interview Information Leaflet

PREVIEW STUDY

Perineal **r**e-suturing versus **e**xpectant management following **v**aginal delivery complicated by a deh**i**sc**e**d **w**ound

Information leaflet for women who are considering taking part in a tape recorded interview

Invitation

In addition to the study that you are already taking part in for the treatment of your broken down perineal (area between the vagina and back passage) wound, the PREVIEW project team are also inviting women to consider taking part in a tape recorded interview to improve our understanding of how it affected you and your family.

Before you decide whether to take part it is important for you to understand why the interview is being conducted and what it will involve. Please take the time to read the information provided in this leaflet. You can ask us if there is anything that is unclear or if you would like any further information.

Thank you for taking the time to read this information leaflet.

What is the purpose of the interviews?

We are aiming to conduct a small number of interviews to assess women's personal views relating to how perineal wound breakdown may affect their wellbeing and also explore areas that are important to women.

The interviews will also help us to determine women's acceptability of the study treatments and any other outcomes that we have not considered that women feel are important to include.

Why have I been chosen?

You have been chosen to take part in the interviews because your perineal wound had broken down and you either had this re-stitched or the wound was allowed to heal by itself.

Do I have to take part in the interview?

Your consent to participate in the interview is entirely voluntary. Once you have had time to read this information leaflet and ask any questions you may have, you will be invited to take part in the interview by Lynn Dudley (midwife and member of the PREVIEW study team).

You are free to withdraw from the interview at any time without giving a reason. The standard of care you receive will not be affected.

Should you wish to withdraw from the interview during the interview process, your rights will be respected and any recordings you have contributed to will be deleted in your presence.

What will happen if I take part in the interview and what will be expected of me?

If you agree to take part in the interview and once you have signed your consent form, you will be given a date and time convenient to yourself to attend for the interview.

The interview will be held at the University Hospital of North Staffordshire (UHNS) Maternity Hospital in a private room or in your own home and will take approximately 45 minutes.

You will be asked a series of questions to reflect upon your personal experiences of having a broken down perineal wound and participating in the PREVIEW study.

You will be given the opportunity to review, edit or erase any tape recording to which you have contributed.

The interviewer will be able to respond to any requests for advice and or information you may need in relation to your broken down wound either prior to or after completion of the recorded interview.

What are the possible benefits to taking part?

The information that you provide us with will help us to include important outcomes that are relevant to women relating to perineal wound breakdown.

It will also help us to identify what types of information and support are most likely to benefit women's recovery.

What are the possible disadvantages to taking part?

We are not expecting any disadvantages, however there will be expert advice and support available if required.

If I agree to take part in the study, will it be kept confidential?

The information collected for this study will be kept strictly confidential.

All information will be kept in locked cupboards at the UHNS and will only be accessed by members of the research team.

All tape recorded information will be stored safely at the UHNS

No individual names or details that would specifically identify individuals will be included in any publications or conference presentations. Participants will be given a unique reference code to allow the researcher to identify individual recordings.

Various quotations from interview responses may be used in reports, conference presentations and reports but these will not be traceable to any individual women. All reports both published and unpublished will disguise the identity of specific individuals.

To provide scope for further long term follow-up, we may securely retain information we collect from you at the UHNS including your personal contact details for future research.

Informing your Family Doctor, General Practitioner (GP)

All health centres and GP practices have been informed of the PREVIEW study.

If you agree to take part, we will also ask your consent to allow us to contact your GP if we identify a health related problem that we feel your doctor should be aware of.

If you specifically do not wish to give us consent, then we will not inform your GP if we identify a health related problem.

What will happen to the findings of the interviews?

The findings of the interviews will be published in midwifery, nursing and medical journals and at seminars and local, national and international conferences.

If you would like a copy of the final report, journals articles or papers published as a result of the interviews, these will be sent to you.

The results of the interviews may influence the decision making for a much larger national and potentially international trial.

Following completion of whole of the study, should the results of the PREVIEW study provide substantial evidence that re-stitching a broken down perineal wound causes less problems for women, then this will have the potential to change practice for the future.

Who is organising and funding the research?

The research has been funded by a National Institute for Health Research, Research for Patient Benefit Programme Award and by the Smith and Nephew Foundation.

The interviews are being conducted at the maternity hospital (UHNS) or in your own home by Lynn Dudley (research midwife, with 20 years experience in midwifery, at the UHNS). Lynn has received additional education and training to conduct the interviews.

Professor Christine Kettle (Professor of Women's Health UHNS) with clinical expertise in the field of perineal assessment and repair and Professor Khaled Ismail (Professor of Obstetrics and Gynaecology, Keele University and UHNS) are research supervisors for the whole of the study. A researcher who specialises in interpreting information obtained from interviews will also help us to examine the tape recordings.

There is no organisational or individual payment made for participating in the interviews.

Who has reviewed the interview phase of the PREVIEW study?

The whole study has been reviewed by a panel of experts from the Smith and Nephew Foundation.

PREVIEW has also received ethical approval from the NHS National Research Ethics Committee and local research and development departments.

What will happen if I decide not to take part in the interview phase of the PREVIEW study?

Your consent to participate in the interview is entirely voluntary, if you decide not to take part in the interviews, the PREVIEW study team appreciate the valuable contribution you have already made.

Contact for further information

If you require any further information about this aspect of the study please contact Lynn Dudley on 01782 672123 or 07704 242268 alternatively, email lynn.dudley@uhns.nhs.uk

Additionally INVOLVE is a national advisory group that has the main role of supporting and promoting active public involvement in NHS, public health and social care research. They have published a document entitled ‘good practice in active public involvement in research which you may wish to obtain at http://www.invo.org.uk/pdfs/GoodPracticeD3.pdf

This leaflet gives more information about medical research and looks at some questions you may want to ask.
A copy may be obtained from INVOLVE, Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD.
Telephone 02380 651088 or Email admin@invo.org.uk

Please make use of this section to write down any questions you may need to ask us.

Appendix 17: PREVIEW Study Interview Guide

Perineal **r**e-suturing versus **e**xpectant management following **v**aginal delivery complicated by a deh**i**sc**e**d **w**ound

Confidential Interview Guide

(Version 1 January 1st 2010)

Participant number ☐ Control ☐ Intervention ☐

Written consent obtained Yes ☐ No ☐

Date of interview ……

Name of interviewer ……..

Thank you for agreeing to take part in this interview which we will be recording and will take approximately 45 minutes.

- The interviews will help us to establish what women's real experiences of perineal wound breakdown are to help us to improve our practice
- The interviews will also help us to improve future research by understanding how women have felt taking part in the PREVIEW study.

1. How are you feeling in general?

2. How did you feel when your stitches had broken down?

3. Did you receive any advice relating to the care of your perineum at any time?

4. If yes can you remember what advice was given and by whom?

5. What were your main concerns when your wound broke down?

6. Do you feel anything could have been done differently?

7. Did your wound break down, stop you from doing any daily activities?

8. Did your wound break down affect you social activities in any way?

9. Was the relationship with your baby or your family affected?

10. Did you need extra help from family members and friends?

11. Was your return to work delayed because of your wound breakdown?

12. Are you considering having any more children in the future?

13. If yes, has your experience with your wound breaking down influenced how you would like to deliver next time?

14. Are you in any pain now in the area where you wound broke down?

15. Are you needing to take any pain killers now?

16. Do you feel that your wound has healed now?

17. Are you satisfied with the way your perineal area looks now?

18. Have you attempted sexual intercourse since the birth of your baby?

19. Have you experienced any problems with sexual in intercourse

20. Did you breastfeed your baby? (go to question 22 if no)

21. If yes, are you still breast feeding now?

22. If no, how old was your baby when you stopped breast feeding

23. What were the main reasons that you stopped?

24. Was your perineum ever too painful feed your baby? (breast or formula)

25. How did you feel when you were told how your broken down wound was going to be treated (re-sutured or expectant management)?

26. Did you have any problems completing the questionnaires we sent to you?

27. Is there anything that we could have done differently for you?

28. Do you think your experience will make you reconsider how you would like to deliver next time?

29. Do you have any additional comments you may wish to add?

Thank you very much for taking the time to attend today

Appendix 18: Extracts of Reflective Journal

	Interviews
Date	***Prior to the interviews***
May 2012	*Nervous moving out of my comfort zone of talking to new mothers in the postnatal period for the purposes of health promotion towards exploring in-depth their experiences of a complication of childbirth. Used to taking to women about sensitive issues so not embarrassed by questioning but I am aware that interviewing to explore experiences will be very different and crucial towards obtaining meaningful information from the respondents. Self-aware that I have no personal experience of childbirth or perineal suturing that may influence any questioning although I have gained an immense amount of knowledge and experience from literature searching and conducting the RCT so must try and not allow that to influence my questioning and responses and allow the women to express their own personal feelings and experiences.* *Slightly nervous about contacting women for interview; will they have time for me to talk to them; feel conscious they have new baby some may have even returned to work.* *Be flexible with times-evenings-weekends-hospital or home; ask if there is a family member or friend that could attend to the baby for the duration of the interview* *Equipment feeling confident with recording equipment, tips to avoid distortion. Trial run with equipment with friends, play back through computer* *Probing-will I be able to probe effectively particularly with yes/no answers to ensure I get the right information* *Silences-will I be comfortable with silences, will I let the woman speak or will I step in* *Will try and remember to avoid commenting on participant answers and putting forward my views* *Travel-will I find the location ok and in time; if in any doubts will do a trial run, not fair if I am late.* *I must listen to the vocabulary they will use and respond appropriately so they will understand my questioning* *Try and remember you are the researcher as opposed to being a clinician and address any clinical questioning off the record* *Feel happy that I have an interview guide so that I'll be prompted to ask the same questions to all women.* *Questions similar to those from the RCT such as pain, healing, feeding baby, dyspareunia; with the addition of their experiences of taking part in the RCT, but it will be interesting if the interviews reveal any additional outcomes that women have felt important that we have not considered.* *I'm hoping that the women have found the questionnaires easy to complete and were not too time consuming* *I am really interested to hear about women's experience of being re-admitted for re-suturing (time frames-communication-analgesia for the repair-how well their baby was accommodated)* *Each participant assigned an interview number e.g. 1,2,3 etc*
	Analysis
9th Feb 2013	*As a novice researcher I know that I will find it particularly helpful to follow a framework to provide me with some systematic guidance to conduct the analysis of the transcripts. However I was not surprised even though I was frustrated yet again, that there seemed to be various frameworks to guide the analysis……..more reading ……..more time……..more critical reflection of the*

10th February 2013	*approaches…….I guess this will enhance my skills in qualitative research but wished someone or one article would tell me… this is the way!! Then reality takes over and after much deliberation I choose the method which suits the purpose of the study to describe women's personal experiences of perineal wound dehiscence and settle on Giorgi. I hope my supervisors will agree. Hard managing data from interviews, data from RCT, being trial co-ordinator;* *Started to code the transcripts, going to use the 'one sheet of paper' techniques to see if that works for me. Reassured Jackie is going to code a transcript too hope we come up with similar themes but if we don't then at least we will have the opportunity to discuss them*
	Write up
	Have looked at how qualitative research is published and have had the opportunity to look at a couple of qualitative research PhD thesis. Checked out the COREQ guidance too. *Remember from the transfer interview the interviewers were keen that the mixed methods were not wrote up/published as two separate reports so I am keen to ensure that thesis reflects that's too*

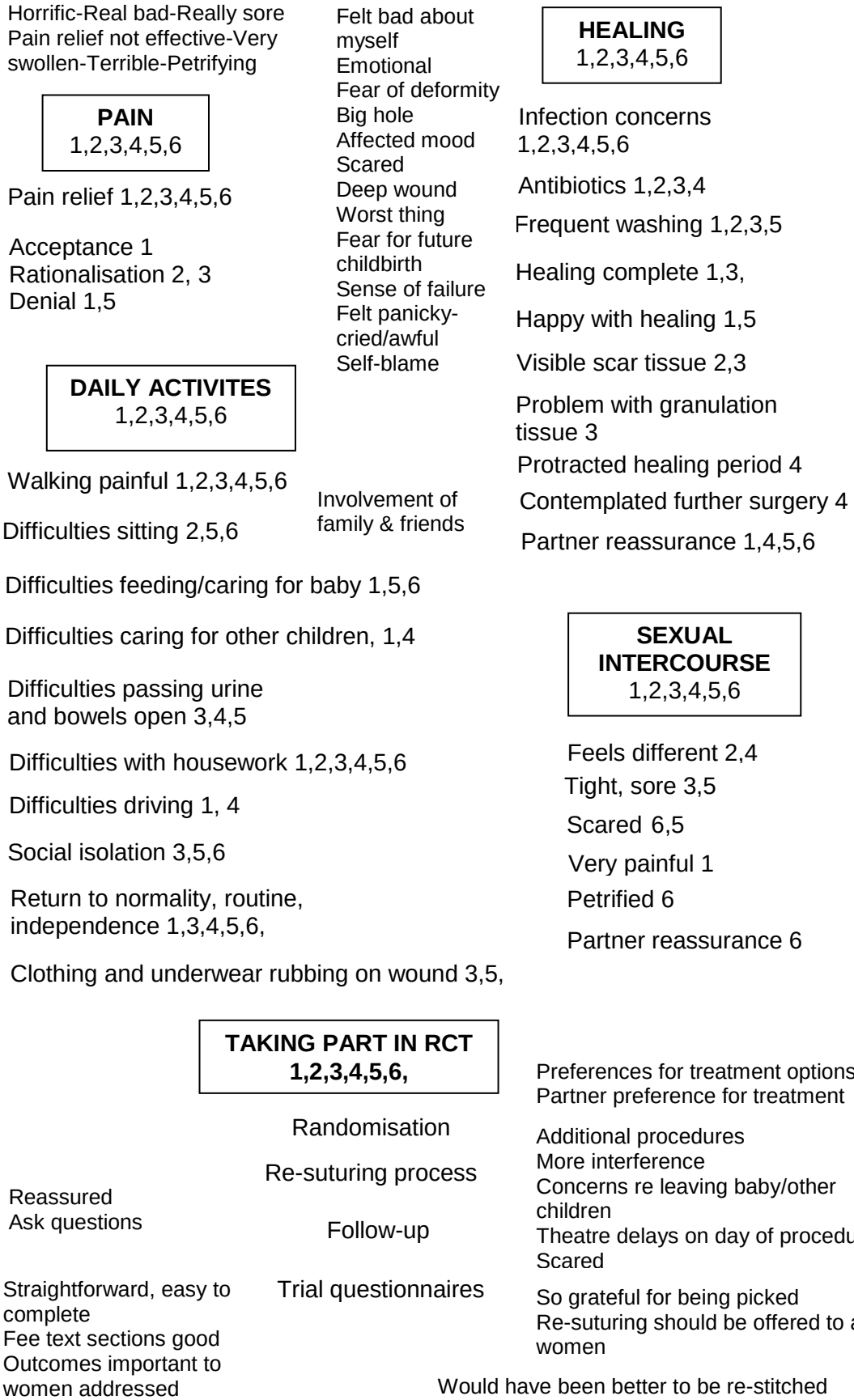
Interview number 1 (15th June 2012)
DOB: ***Parity:*** *Third baby* ***Mode of delivery:*** *Spontaneous vertex* ***Allocation:*** *Re-suturing (1003A)* ***Occupation:*** *Teacher* ***Accommodation:*** *Old rectory*
Prior to the interview
• *Telephoned to confirm happy to be interviewed* • *Posted out information booklet and letter of thanks* • *Nervous, how will it go?* • *Will I be able to ask the right questions, probe effectively?* • *How long will it take* • *Will the recording equipment work ok, will I be comfortable with silences, (will I speak up or allow time for the woman to speak up)* • *Met this lady and her husband several times previously; educated couple*
During
• *Felt comfortable in surroundings, made to feel very welcome and offered tea/coffee* • *Positioned recorder on several books (advice from Pam)* • *Baby woke during interview comforted by mother; kept the recorder going as didn't want to tempt fate (could have just pressed paused)* • *I wasn't prepared for woman's account of how painful she experienced the removal of some sutures which I had actually had removed, she described the removal as horrific although much more comfortable initially following removal of sutures that were too tight. As a midwife we are always taught that it is the women's perception of events that are paramount* • *Critical of the care she received whilst waiting to go to theatre; had to quickly think about how to respond to this. Thanked the woman for sharing her experience with me and being honest* • *Frequent eye contact made by us both; sat directly opposite each other*
Following

- *Relieved that first interview was over*
- *Felt guilty that she had described the removal of sutures that were too tight as horrific*
- *My response to the criticisms of care whilst waiting to go to theatre could have been done off the record once the interview was complete; tried to think that if I was not a clinician or had no knowledge of the processes when a patient goes to theatre all I would have been able to do was listen*
- *Found myself commenting on the occasional answer provided to a question, maybe that's a problem of me doing the interviews instead of someone who isn't a midwife or involved in the study.*
- *Immediately (in the car) had to make sure that the interview had actually recorded; again relieved that it had*
- *Keen to listen to the recording*

Interview number 3 (7th September 2012)
DOB: ***Parity:*** *First baby*   ***Mode of delivery:*** *Forceps delivery in theatre, failed kiwi (check this)*   ***Allocation:*** *Re-suturing (1005)*   ***Occupation:*** *Housewife and mum*   ***Accommodation:*** *Lives in rented accommodation with partner; downstairs accommodation of a terraced house*
Prior to the interview
• *Telephoned to confirm happy to be interviewed*   • *Posted out information booklet and letter of thanks*   • *Met this lady once previously*   • *Arrived at wrong house (mothers address where she had been staying, currently at partners house 9 miles away)*
During
• *Baby present (positioned in baby chair watching the TV and playing with toys)*   • *Asked if baby would be ok if we turned the noise off to the TV (agreed and caused no problems)*   • *Due to time delay for interview with additional travel, workman arrived to check boiler during interview causing slight distraction*   • *Had to try to keep to purpose of interview but my natural instinct was to want to listen to her birth experience with her*
Following
• *Found this interview particularly emotive; this was a young woman who had experienced a difficult birth (my perception too), her baby had sustained a fractured clavicle and had been admitted to the nnu; so not only had she been separated from her new born baby and had been unwell herself, her perineal wound had completely broken down. Despite all this she was very keen to take part in the study.*   • *I also felt a little overwhelmed at how important she felt this study had been to her own physical and psychological well being*   • *A learning curve from this interview was to double check the address where the participant was going to be for the interview. I went to her mother's address where she had been discharged to from the hospital but was actually at her partners address on the day of the interview.*

Interview number 5 (20th March 2013)
DOB: ***Parity: First baby*** ***Mode of delivery:*** *Forceps delivery* ***Allocation:*** *Re-suturing (….)* ***Occupation:*** *Housewife*
Prior to the interview
• *Telephoned to confirm happy to be interviewed* • *Not met this lady previously* • *Interested to hear her experience of taking part in the RCT in a different hospital to the previous women interviewed*
During
• *Felt comfortable in surroundings, very welcoming* • *Positioned recorder on several books (advice from Pam)* • *Baby present for interview; TV on and playing with toys; politely asked if we could turn the TV down* • *Woman revealed that she was pregnant again* • *I felt a little uncomfortable that the woman had been re-sutured under local anaesthesia but decided to question this a little further to establish if the anaesthesia was affective for the procedure*
Following
• *Found myself referring to the interview guide much less* • *Couple of pauses from the woman before answering that I felt comfortable with not interrupting* • *Questioning skills are improving* • *Recognised the need to continue an issue raised off the record (appointment back at the hospital to discuss plan of management for labour)* • *Still tending to use acknowledgments to answers like 'ok' and 'right' to indicate an interest almost in an attempt to please the woman maybe need to probe a little more* • *Did feel that I reflected back the occasional question as opposed to summarising it* • *Thought that at least one of the interviewees may have highlighted an outcome measure that we had not included but what was important to them*

Appendix 19: Interview analysis 'one sheet of paper technique'



Appendix 20: PREVIEW Protocol Published

Open Access Protocol

BMJ open accessible medical research

Perineal resuturing versus expectant management following vaginal delivery complicated by a dehisced wound (PREVIEW): protocol for a pilot and feasibility randomised controlled trial

Lynn Dudley,[1,2] Christine Kettle,[1,2] Pamela Carter,[3] Peter Thomas,[4] Khaled M Ismail[5]

To cite: Dudley L, Kettle C, Carter P, *et al*. Perineal resuturing versus expectant management following vaginal delivery complicated by a dehisced wound (PREVIEW): protocol for a pilot and feasibility randomised controlled trial. *BMJ Open* 2012;**2**:e001458. doi:10.1136/bmjopen-2012-001458

► Prepublication history for this paper is available online. To view this file please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2012-001458).

Received 9 May 2012
Accepted 22 June 2012

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For numbered affiliations see end of article.

Correspondence to
Professor Khaled M Ismail;
k.ismail@bham.ac.uk

ABSTRACT

Background: Each year, approximately 350 000 women in the UK experience perineal suturing following childbirth. For those women whose perineal wound dehisces, the management will vary according to individual practitioner's preferences. For most women, the wound will be managed expectantly (healing by secondary intention), whereas others may be offered resuturing. However, there is limited scientific evidence and no clear guidelines to inform best practice. PREVIEW is a two-part study aiming to identify the best management strategy for dehisced perineal wounds, in terms of clinical effectiveness and women's preferences.

Methods/design: The main part of this study is a pilot and feasibility randomised controlled trial designed to provide preliminary evidence of the effectiveness of resuturing versus expectant management for dehisced perineal wounds following childbirth and to feed into the design and feasibility of a larger definitive trial. 144 participants will be randomly allocated to either intervention. The primary outcome is the proportion of women with a healed perineal wound at 6–8 weeks from the trial entry. Secondary outcomes include perineal pain, breast feeding rates, dyspareunia and women's satisfaction with the aesthetic results of the wound healing at 6 weeks, 3 months and 6 months post randomisation. Information will be collected using validated questionnaires. The second part of this study will be to conduct semistructured interviews with 12 study participants, aiming to capture information relating to their physical and psychological experiences following perineal wound dehiscence, assess the acceptability of the research plan and ensure that all outcomes relevant to women are included in the definitive trial.

Dissemination: The results of this study will inform a definitive randomised controlled trial that will provide conclusive evidence of what is the best management of perineal wound dehiscence. This will potentially lead to significant improvements in perineal care and will help to reduce the short- and long-term morbidity experienced by women.

ARTICLE SUMMARY

Article focus

- This article provides the rationale and protocol for a pilot and feasibility randomised controlled trial, designed to provide preliminary evidence of the effectiveness of resuturing of dehisced perineal wounds, versus healing by expectancy (secondary intention) and to feed into the design and feasibility of a larger definitive trial.

Key messages

- This study addresses an area of clinical research that has been extremely neglected and has the potential of making a significant impact on women's health and well-being.

Strengths and limitations of this study

- As both a pilot randomised controlled trial and a feasibility study, this research will test out many of the procedures that will be used to inform the design of a definitive trial.
- As the definitive trial is likely to require many centres in order to meet sample size requirements, we may use this pilot to identify additional sites and also test out study procedures in those sites. Thus, the actual sample size might be larger than described here.

Clinical trials registration: PREVIEW is registered with the International Standard Research for Clinical Trials (no: ISRCTN05754020) and adopted as a National Institute for Health Research (NIHR) Reproductive Health and Childbirth specialty group portfolio study UKCRN ID 9098.

INTRODUCTION

Perineal trauma affects a vast amount of women both nationally and internationally with more than 350 000 women in the UK per

year needing stitches to facilitate healing of a spontaneous tear or episiotomy.[1] Given that the postpartum management of perineal trauma including the prevention of wound infection and assessing wound healing are core components of routine maternity care,[2 3] there is limited research evidence available on the management and consequences of wound dehiscence. Furthermore, the available evidence is based on retrospective audit or case reviews and tends to include small numbers of participants hence is subject to bias. Anecdotal evidence suggests that the number of women reporting perineal infections and dehiscence in the community is increasing; however, systems to track these complications following hospital discharge are lacking. It is vital that a true estimate of the problem is established using standardised definitions of wound infection and at the same time determine best practice when treating dehisced perineal wounds. It is apparent that perineal wound dehiscence both locally and worldwide has not been a high priority either in practice or in research, and therefore, management is not based on robust evidence. Due to the lack of evidence-based guidelines, clinical practice varies widely between individual practitioners and institutions.

Perineal wound dehiscence, which is commonly reported to be associated with infection,[4 5] may lead to major physical, psychological and social problems if left untreated. Although maternal mortality associated with perineal trauma is extremely rare in developed countries, an infected perineal wound is a potential route for systemic infection whereby sepsis and septic shock may ensue.[6] Indeed sepsis has for the first time been identified as the leading cause of maternal mortality in the UK. The Centre for Maternal and Child Enquiries recently published their eighth Report on Confidential Enquiries into Maternal Deaths.[7] The report revealed that during the 2006–2008 triennium, sepsis resulted in 26 direct maternal deaths with three further deaths classified as 'Late Direct Deaths' (occurring more than 6 weeks after delivery). Seven women died of sepsis following a vaginal delivery, including one woman with an infected perineum following a second-degree tear. The report clearly illustrates how healthy women with an uncomplicated pregnancy and delivery can become critically ill and die in a very short time.[7]

Moreover, morbidity associated with perineal wound dehiscence can and does pose a serious threat to the general well-being and quality of life of the new mother. Maternal morbidity centres around persistent pain and discomfort at the perineal wound site, urinary retention, defecation problems, dyspareunia and psychological and psychosexual issues from embarrassment and altered body image.[2 8] Furthermore, the relationship with her newborn baby may become affected, and she may find difficulty in breast feeding due to the distress caused by her perineal problems.[9]

Perineal wound infection and dehiscence is a burden on NHS resources, as quite often women who suffer this consequence of childbirth, have to undergo corrective surgery, perineal refashioning and excision of excessive scar tissue or other procedures associated with the management of perineal dysfunction.[10]

Members of our collaborative team conducted double iteration Delphi surveys in the UK and Brazil to identify childbirth-related perineal trauma outcomes deemed to be important by women.[11] These surveys consistently demonstrated that the highest ranked outcome was fear of perineal wound infection and delay in wound healing. Indeed, an outcome that appears to be prioritised by women across different backgrounds and cultures.

Rationale for PREVIEW

This study addresses an area of clinical research that has been extremely neglected and has the potential of making a significant impact on women's health and well-being. For those who suffer from dehisced perineal wounds, it can take up to 16 weeks to heal if treated expectantly and can leave the new mother feeling very traumatised. Some of these women may even request that the mode of delivery for subsequent pregnancies will be via caesarean section to avoid further perineal damage.

Currently, lack of established professionally agreed standards leave clinicians in equipoise as to what is the best management for dehisced perineal wounds following childbirth, hence supporting the need for a clinical trial to answer this question. As both a pilot randomised controlled trial (RCT) and a feasibility study, this research will test out many of the procedures that will be used to inform the design of a definitive trial. Although this is a pilot trial, the sample size is reasonably high (n=144), and in the absence of definitive trials, will contribute to the development of evidence-based best practice guidelines by policymakers, clinicians, patients and the public to develop, and to systematic reviews.

METHODS/DESIGN

Study design

PREVIEW is a pilot and feasibility RCT comparing resuturing versus expectant management for the treatment of dehisced perineal wounds following childbirth (figure 1).

The study will provide researchers with a unique opportunity to identify and prepare for the challenges and uncertainties of evaluating the clinical interventions within a larger RCT. Conducting this study will assess the acceptability of the study interventions to women, test the study protocol and facilitate a formal sample size calculation for the definitive study. Ultimately, it will enhance the scientific rigour and value of the full-scale study.

Setting

The pilot and feasibility RCT will be conducted in several maternity centres in the UK in order to assess likely recruitment rates and acceptability across different sites.

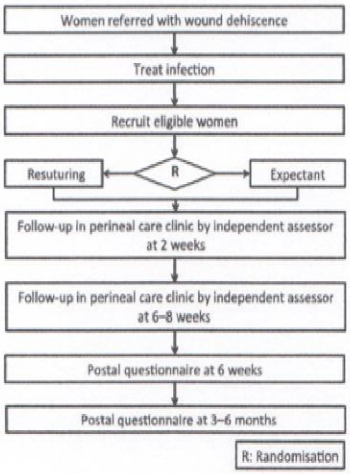

Figure 1 PREVIEW flowchart.

Study population, eligibility criteria

Women, who had a primary repair of a second-degree perineal tear or episiotomy, identified with a dehisced wound within 2 weeks following childbirth, in any of the recruiting sites.

For the purpose of the study, wound dehiscence is defined as separation of both the skin and muscle layers.

Exclusion criteria

- No valid written consent to participate in the study
- poor pregnancy outcome (women experiencing a pregnancy loss in current pregnancy)
- women younger than 16 years
- women who are considered by the anaesthetist to have an unacceptable anaesthetic, for example, complex cardiac anomalies
- due to financial constraints in relation to translation services, women who do not understand, read or write the English language will not be able to participate. However, a record of the number of these potential participants and their first language will be kept to help with project planning and resource allocation for the definitive study.

Consent and randomisation

Women eligible for the study will be provided with the study information leaflet, by their community midwife, hospital midwife or obstetrician and they will be allowed time to ensure that they understand the information and clarify any queries they have. Women who subsequently do not wish to participate in the PREVIEW study will be managed in accordance with local hospital guidelines. Women will be enrolled into the study by a midwife or doctor who is fully aware of Good Clinical Practice guidance. A valid written consent will be obtained from women who wish to participate. The PREVIEW Study integrated web- or telephone-based randomisation, and its treatment allocation service was developed by the Bristol Randomisation Trials Collaboration. The allocation ratio will be 1:1, and randomisation will be in blocks, stratified by study centre. The study participants will be assigned to either resuturing of the dehisced perineal wound preferably within 48 h of randomisation or expectant management (allowing the wound to heal by secondary intention). With the woman's agreement, a letter will be sent to her general practitioner confirming trial entry.

Interventions

Secondary resuturing is being compared with expectancy (healing by secondary intention). Both interventions will be undertaken following trial standardised procedures (not submitted but available from the trial team).

To ensure the standardisation of secondary resuturing, the trial team have provided recommendations for both the methods and materials to be used (table 1). These recommendations are based on clinical expertise and knowledge and will be continually reviewed if new evidence becomes available.

Due to the nature of the interventions, it will not be possible to blind outcome assessors, care providers or participants themselves. Assessment of perineal wounds following treatment allocation, at the agreed time periods, will be undertaken by independent practitioners (ie, not part of the research team); however, it will not be possible to blind participating women, operators and assessors due to the nature of the intervention. Women allocated to the control arm will receive expectant management (current standard intervention), with no additional concomitant care or interventions.

Data collection

Standardised PREVIEW questionnaires are based on those used and tested by members of the research team

Table 1 Methods and materials for resuturing

Methods	Standard surgical procedures for secondary suturing should be followed, including wound debridement if needed
Vaginal mucosa	Continuous technique
Muscle	Interrupted sutures
Skin	Depending on the length of the wound, the skin could be sutured by interrupted or subcutaneous sutures or left unsutured if the edges are approximated by suturing the underlying tissues
Materials	To ensure standardisation of materials, the PREVIEW Study team recommend that standard synthetic polyglactin 910 (gauge 2/0) suture material should be used as the material of choice

in other childbirth-related perineal trauma studies.[12 13] Participating women for the RCT will be reviewed at 2 and 6–8 weeks. The independent assessor will complete a perineal assessment questionnaire at each visit. For the secondary outcomes, all participating women in the RCT will be asked to complete a prepaid postal questionnaire at 6 weeks, 3 and 6 months following trial entry, respectively.

Data will be scanned into a bespoke database by the Market Research Group at Bournemouth University. By anonymising records and changing treatment allocation to a numeric code, the completed database will be supplied to the research team for analysis, carried out under the supervision of the trial statistician. In this way, analysis will be blinded.

In addition to the pilot RCT, a sample of women (n=12) who are participating in the RCT will be selected to represent age, parity, ethnicity and intervention. Indepth semistructured interviews will be conducted with written consent to capture information relating to their physical and psychological experiences following perineal wound dehiscence at 6–8 weeks following birth. The interviews will be taped, with permission, and transcribed.

Study outcome measures

Primary outcomes

- Proportion of women with a healed wound at 6–8 weeks following trial entry.

Secondary outcomes

- Pain at 6 weeks, 3 and 6 months following trial entry (randomisation)
- Dyspareunia at 6 weeks, 3 and 6 months following trial entry
- rates of breast feeding at 6 weeks, 3 and 6 months following trial entry
- woman's satisfaction with the aesthetic results of the perineal wound at 6 weeks, 3 and 6 months following trial entry.

Withdrawal from the PREVIEW Study

Participants may withdraw from the study at any time. Should they choose to withdraw, they will continue to be followed up, in line with current practice within the participating unit, but no further questionnaires will be sent. One reminder questionnaire will be issued to non-responders before they are deemed to have withdrawn. A record of the number of withdrawals will be kept and if applicable their reason for withdrawal.

Statistical issues

Sample size for the RCT

The current literature does not support a robust formal sample size calculation for the primary outcome of interest. One of the purposes of this pilot study is to collect data to inform a sample size calculation for a full-scale RCT. Three aspects of informing this calculation are to estimate (1) the recruitment rate, (2) attrition rate and (3) the proportion of women whose wound had healed at 6–8 weeks (the primary outcome). Hence, in estimating the sample size of this pilot study, we attempted to ensure a sufficient degree of precision of these estimates (precision defined as twice the SE).

A retrospective study at the host research site has identified that there were 117 women referred to the perineal care clinic with a dehisced perineal wound during a 4-year period (30 women/year). Hence, we estimate that there will be around 45 eligible women for recruitment per participating centre. Assuming that 45 women will be eligible per centre, with a take up rate of 80% and an attrition rate of 20% in four participating centres, we expect to recruit 144 women and 116 (58 in each arm) of these to complete the pilot study. This would allow for the recruitment rate in each site to be estimated with precision of ±12% (based on n=45), and overall recruitment rate to be estimated with precision ±6% (based on n=180). Loss to follow-up would be estimated with precision ±7% (based on n=144), and healing at 6–8 weeks (assumed to be around 50% from the retrospective study mentioned above) would be estimated to ±13% in each trial arm (based on n=58 per arm). Although the sample size is quite large for a pilot study, we feel that this is necessary in order for recruitment to start bedding down in each of multiple sites.

Estimating effect size is not a specific aim of this pilot, but nevertheless, it is still worth considering precision and power issues given the sample size of 116. Assuming that healing in the secondary intention group will be 50% at 6–8 weeks and that realistic percentages in the secondary resuturing group will be between 10% and 90%, the effect size for the primary outcome will be estimated with a precision of between ±15% and ±18%. This will be fed into deliberations regarding plausible effect sizes to be used for future sample size calculations. It is worth noting that with this sample size, the study will have 90% power to detect an increase in healing from 50% to 80% (assuming a 5% two-sided significance level).

As the definitive trial is likely to require many centres in order to meet sample size requirements, we may use this pilot to identify additional sites and also test out study procedures in those sites. Thus, the actual sample size might be larger than described here.

Statistical analysis for the RCT

Recruitment and attrition rates (overall and at each site) and proportion with healed wound at 6–8 weeks will be calculated, and precision of these estimates expressed using 95% CIs. A series of sample size calculations for a definitive RCT will be performed incorporating these interval estimates.

A statistical analysis plan for a full-scale RCT will be developed from and tested upon the data from this pilot

study. We will test out the practicalities of ensuring that the person analysing the data is blinded to group allocation.

Primary analysis will be undertaken on an intention-to-treat basis to limit the possibility of bias associated with women not receiving the intervention they were allocated. Strategies will be developed to ensure that data on primary outcome are as complete as possible (eg, reminder letters and phone calls).

Comparisons will be made between the interventions (secondary repair vs expectant management). Baseline characteristics of the comparative groups will be summarised using standard descriptive statistics. The primary outcome is the proportion of wounds healed at 6–8 weeks; this will be compared between the two groups using a logistic regression model that incorporates study site as a variable (since randomisation was stratified by site). Precision of estimates of effect size (ORs) will be summarised using 95% CIs. The analysis plan for other outcomes will also be developed taking into account the type and distribution of data (eg, logistic regression, multiple regression). If the amount of missing data seems problematic (eg, over 20%), we will assess the robustness of the results by data imputation in tandem with best- and worst-case sensitivity analyses. In addition to looking at each time point separately, we will also test a repeated measures approach to analysis to try and gain insight to whether effect sizes are changing over the course of follow-up (ie, looking at the interaction between intervention group and time). It is anticipated that this will be implemented using a multilevel (mixed) model for binomial or continuous responses as appropriate.[14] These models have the added advantage that they permit analysis of unbalanced repeated measures data, thus avoiding exclusion of participants with incomplete data. No additional a priori adjustment of covariates or subgroup analysis will be performed; these issues will be explored further in supplementary analysis as part of the development of the statistical analysis plan for the larger trial. No interim analyses are planned.

Qualitative analysis

Thematic analysis will be conducted using appropriate software such as N-Vivo. A sample of transcripts will be coded and analysed independently by two researchers and the emerging themes discussed to ensure reliability. While providing the researchers with an opportunity to research women's subjective experiences, the interviews will also offer valuable qualitative insight to aid understanding of the findings generated from the RCT.[15 16] Additionally, this phase will provide a window of opportunity to view women's unique experiences of an aspect of childbirth, which would otherwise not be known and can facilitate improvement in practice.[17]

In relation to the pilot RCT, capturing qualitative data on women's views of the impact of perineal wound infection on their well-being, will help to ensure that the definitive trial captures outcome areas that are relevant to women themselves. Likewise, it may help us to understand any barriers to participation before embarking on a full-scale evaluation.[18]

Patient involvement

Following guidance from INVOLVE,[19] two patient representatives have been recruited to assist with the design of study materials, including the information sheet, trial questionnaires and the qualitative interview schedule. They are also members of the trial steering committee (TSC).

Ethical considerations and safety committee

The PREVIEW protocol has been approved by the North Wales Research Ethics Committee (Central and East), reference number: 10/WNo03/16.

The conduct of the trial at each recruiting site including confidentiality and storage of all personal and research data will be in accordance with all applicable research governance regulatory requirements.[20–26] All recruiting maternity units will be required to sign a clinical trial agreement document detailing their commitment towards complying with the relevant laws, regulations, codes of practice and obligations to publication.

Site-specific and Research and Development approval is required for each recruiting unit and a Participant Identification Centre agreement is required from the Primary Care Trusts within the recruiting localities. The NIHR Primary Care Trust Research Network have also acknowledged their support for the study and have made a significant contribution towards communicating the study to Primary Care Trusts via individual Practice Managers within the locality of the recruiting sites.

A TSC will be convened to provide overall supervision of the PREVIEW Study and will adhere to the MRC's Guidelines for Good Clinical Practice.[24] Any deviations from the clinical trial agreement will monitored by the TSC who will decide whether further action needs to be considered.

An independent data monitoring ethics committee (DMEC) will be convened for the PREVIEW Study by the sponsor and will act as an advisory committee to the TSC. The DMEC will be the only body involved in the study that will have access to the comparative data. The DMEC will consist of a minimum of three members and will include a statistician and a clinician with expertise in the field of perineal care. The role of the DMEC will be to monitor trial data and make recommendations to the TSC on whether there are any safety reasons why the trial should not continue, including monitoring evidence for treatment harm, for example, serious adverse events (SAE).

The safety, rights and well-being of the trial participants are paramount. The DMEC will consider whether any interim analysis is necessary, will consider data from any analysis and considers requests for its release and will then advise the TSC.

A standardised operating procedure for the DMEC has been developed specifically for the PREVIEW Study based on MRC guidance, the template produced by the DAMOCLES Study Group and the ICH Harmonised Tripartite Guideline, for Good Clinical Practice.[24–26]

In accordance with NIHR Good Clinical Practice,[27] safety reporting guidance for a non-clinical trial of an investigational medicinal product including SAE has been made available for all recruiting sites. The guidance includes definitions of SAE; who the SAE should be reported to, when and how to report the SAE and what information will be need for the Research Ethics Committee, a copy of the National Research Ethics Service (NRES) SAE reporting form is also provided. Data regarding adverse events, other unintended effects of the trial interventions or protocol violations will be conveyed to the DMEC as and when necessary.

DISCUSSION

This pilot RCT addresses an area of clinical research that has been extremely neglected and has the potential of making a significant impact on women's health and well-being. The evidence gained from the study will inform a definitive RCT that will provide robust evidence of what is the best management of perineal wound dehiscence and hence be used by policymakers, clinicians, patients and the public to develop evidence-based best practice guidelines. This will potentially lead to significant improvements in perineal care and will help to reduce the short- and long-term morbidity experienced by women.

Author affiliations
[1]The Maternity Centre, University Hospital of North Staffordshire, Stoke-on-Trent, Staffordshire, UK
[2]Faculty of Health, Staffordshire University, Blackheath Lane, Stafford, UK
[3]Arthritis Research UK National Primary Care Centre, Primary Care Services, Keele University, Staffordshire, UK
[4]Clinical Research Unit, School of Health and Social Care, Bournemouth University, Bournemouth, Dorset, UK
[5]School of Clinical and Experimental Medicine, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK

Acknowledgements We thank Dr Roger Beech, Reader in Health Services Research/Director, Keele University Hub, West Midlands NIHR Research Design Service (RDS) and the RDS team for their advice and guidance towards formulating the research questions, the study design, methodology and analytical strategies, both quantitative and qualitative. We also thank Dr Darren Clement, R&D manager at the University Hospital of North Staffordshire, the host organisation for PREVIEW and the research teams at all recruiting sites for their support with the study.

Contributors All authors contributed equally to this work. LD, CK and KMI conceived the idea for the study. PT and LD will perform the statistical analysis for the study. LD is the PREVIEW Study coordinator and the lead research midwife for the study. She is registered as a PhD student at Staffordshire University, and the PREVIEW Study will form part of her doctoral studies. All authors contributed to the design of the study. PC provided qualitative advice and support. All authors helped to draft the manuscript and all authors read and approved the final manuscript.

Funding PREVIEW is funded by research grant from the National Institute for Health Research, Research for Patient Benefit (PB-PG-090920079) and sponsored by the University Hospital of North Staffordshire. The trial coordinator (LD) has also received a Doctoral Nursing Studentship award from the Smith and Nephew Foundation/Research into Ageing (RIA) Age Concern (2008–2011). The sponsor organisation in collaboration with the trial management group has overall responsibility for ensuring that the PREVIEW Study is conducted in accordance with the Department of Health Research Governance Framework for Health and Social Care.[23] The sponsor organisation will guarantee that there are appropriate arrangements in place: to initiate, manage and monitor the research; to finance the study and to report the outcomes of the research. The Chief Investigator (CI) and the trial steering committee have a contractual obligation to inform both the NIHR and RIA of any publications, which result from the research study. This relates to all publications generated from the research, including the scientific and lay press, abstracts and conference proceedings. The award holders also have a contractual obligation to submit an end of project report to the NIHR and RIA outlining the outcomes of PREVIEW. The report will detail a comprehensive overview of the work undertaken, summarise the research findings, any variation to the work outlined in the proposal or the research team and describe the next steps to patient benefit and the dissemination strategy. Additionally, the Research Investigators under the conditions of NHS Participant Identification Centre Agreements have a responsibility to share the learning from the research and provide the relevant Clinical Research Networks, Research Management and Governance Consortiums with: (1) the literature review from the research protocol, (2) interim findings from the research, when available and (3) a final report or summary of the research.

Competing interests CK and KMI run perineal repair workshops both nationally and internationally and have developed an episiotomy and second-degree tear training model with Limbs & Things, UK. They receive a small royalty fee that contributes towards women's health research funds.

Ethics approval Ethics approval was provided by the North Wales Research Ethics Committee.

Provenance and peer review Not commissioned; internally peer reviewed.

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Appendix 21: Cochrane Review

Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth (Review)

Dudley LM, Kettle C, Ismail KMK

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This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2013, Issue 9

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Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth (Review)
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[Intervention Review]

Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth

Lynn M Dudley[1], Christine Kettle[2], Khaled MK Ismail[3]

[1]Maternity Centre, University Hospital of North Staffordshire, Stoke-on-Trent, UK. [2]Staffordshire University, Beaconside, UK. [3]School of Clinical and Experimental Medicine, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK

Contact address: Lynn M Dudley, Maternity Centre, University Hospital of North Staffordshire, Newcastle Road, Stoke-on-Trent, Staffordshire, ST4 6QG, UK. lynn.dudley@uhns.nhs.uk.

Editorial group: Cochrane Pregnancy and Childbirth Group.
Publication status and date: New, published in Issue 9, 2013.
Review content assessed as up-to-date: 4 September 2013.

Citation: Dudley LM, Kettle C, Ismail KMK. Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth. *Cochrane Database of Systematic Reviews* 2013, Issue 9. Art. No.: CD008977. DOI: 10.1002/14651858.CD008977.pub2.

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ABSTRACT

Background

Each year approximately 350,000 women in the United Kingdom and millions more worldwide, experience perineal suturing following childbirth. The postpartum management of perineal trauma is a core component of routine maternity care. However, for those women whose perineal wound dehisces (breaks down), the management varies depending on individual practitioners preferences as there is limited scientific evidence and no clear guidelines to inform best practice. For most women the wound will be managed expectantly whereas, others may be offered secondary suturing.

Objectives

To evaluate the therapeutic effectiveness of secondary suturing of dehisced perineal wounds compared to non-suturing (healing by secondary intention, expectancy).

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 July 2013) and reference lists of retrieved studies.

Selection criteria

Randomised controlled trials of secondary suturing of dehisced perineal wounds (second-, third- or fourth-degree tear or episiotomy), following wound debridement and the removal of any remaining suture material within the first six weeks following childbirth compared with non-suturing.

Data collection and analysis

Three review authors independently assessed trials for inclusion. Two review authors independently assessed trial quality and extracted data. Data were checked for accuracy.

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Main results

Two small studies of poor methodological quality including 52 women with a dehisced and/or infected episiotomy wound at point of entry have been included.

Only one small study presented data in relation to wound healing at less than four weeks, (the primary outcome measure for this review), although no reference was made to demonstrate how healing was measured. There was a trend to favour this outcome in the resuturing group, however, this difference was not statistically significant (risk ratio (RR) 1.69, 95% confidence interval (CI) 0.73 to 3.88, one study, 17 women).

Similarly, only one trial reported on rates of dyspareunia (a secondary outcome measure for this review) at two months and six months with no statistically significant difference between both groups: two months, (RR 0.44, 95% CI 0.18 to 1.11, one study, 26 women) and six months, (RR 0.39, 95% CI 0.04 to 3.87, one study 32 women). This trial also included data on the numbers of women who resumed sexual intercourse by two months and six months. Significantly more women in the secondary suturing group had resumed intercourse by two months (RR 1.78, 95% CI 1.10 to 2.89, one study, 35 women), although by six months there was no significant difference between the two groups (RR 1.08, 95% CI, 0.91 to 1.28).

Neither of the trials included data in relation to the following prespecified secondary outcome measures: pain at any time interval; the woman's satisfaction with the aesthetic results of the perineal wound; exclusive breastfeeding; maternal anxiety or depression.

Authors' conclusions

Based on this review, there is currently insufficient evidence available to either support or refute secondary suturing for the management of broken down perineal wounds following childbirth. There is an urgent need for a robust randomised controlled trial to evaluate fully the comparative effects of both treatment options.

PLAIN LANGUAGE SUMMARY

Re-stitching broken down perineal (the area between the vagina and back passage) wounds compared with non-stitching

It is estimated that 350,000 women per year in the United Kingdom and millions more worldwide experience perineal stitches because of a childbirth-related natural tear or cut (episiotomy). Sometimes the perineal wound breaks down (opens up). This may be because it becomes infected, which could lead to systemic infection and sepsis. The current management of broken down wounds varies widely between individual health practitioners and hospitals. For most women the broken down perineal wound is left to heal naturally (managed expectantly). This is a slow process and it can take several weeks for the wound to heal completely resulting in persistent pain and discomfort at the perineal wound site, also possible urinary retention and defecation problems. The alternative is re-stitching. Due to the lack of research evidence, we do not know the best way to treat this type of complication. This review looked at randomised controlled trials of re-stitching broken down wounds compared with non-stitching. Two small studies were identified. One study, involving 17 women, showed a marginal tendency to improved healing in the women who were re-stitched, however, this evidence was not conclusive. In the other study involving 35 women, more women had resumed intercourse in the re-suturing group at two months. As the studies were small and of poor quality, it is not possible to draw conclusions about the best way to manage wound breakdown after childbirth. Therefore, there is an urgent need to conduct further studies to compare fully the benefits and risks of both treatments.

BACKGROUND

Approximately 350,000 women in the United Kingdom every year undergo perineal repair following childbirth to facilitate healing of the trauma site (Kettle 2002; McCandlish 1998; RCOG 2004). Despite the large numbers of women undergoing perineal repair and given that the postpartum management of perineal trauma, including the prevention of wound infection and assessing wound healing, are core components of routine maternity care (Gould 2007; NICE 2006; Steen 2007), there is limited research evidence available on the management and consequences of perineal wound

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dehiscence (also referred to as wound breakdown). It is apparent that perineal wound dehiscence both nationally and worldwide has not been a high priority either in practice or research and therefore current management is unlikely to be based upon robust evidence. Due to the lack of evidence-based clinical guidelines, clinical practice varies widely between individual practitioners and institutions.

There are some suggestions that the early closure of dehisced perineal wounds should be attempted in order to maintain perineal integrity (ACOG 2006; Hankins 1990; Monberg 1987; Ramin 1992; Uygur 2004); however, most dehisced perineal wounds are left to heal naturally by secondary intention (expectant management). Healing by secondary intention is a process whereby the dehisced area fills with granulation tissue that gradually contracts to bring the wound edges together; unfortunately this is a slow process and can take several weeks for the wound to completely heal (Boyle 2006; Thomas 1990).

Perineal wound dehiscence, which is commonly reported to be associated with infection (Gould 2007; Ramin 1992; Tharpe 2008), may lead to major physical, psychological and social problems if left untreated. Although maternal mortality is extremely rare in developed countries, an infected perineal wound is a potential route for systemic infection whereby sepsis and septic shock may ensue (Lewis 2007; Rotas 2007). Indeed sepsis has for the first time been identified as the leading cause of maternal mortality in the UK. The Centre for Maternal and Child Enquiries (CMACE) recently published their eighth Report on Confidential Enquiries into Maternal Deaths (CMACE 2011). The report revealed that during the 2006 to 2008 triennium, sepsis resulted in 26 direct maternal deaths with three further deaths classified as 'Late Direct Deaths' (occurring more than six weeks after delivery). Seven women died from sepsis following a vaginal delivery, including one woman with an infected perineum following a second-degree tear. The report clearly illustrates how healthy women with an uncomplicated pregnancy and delivery can become critically ill and die in a very short time (CMACE 2011). Gallop 2002 in a retrospective case report analysis revealed the death of a young 25-year-old mother five days postnatal, who died as a consequence of an overwhelming sepsis with a necrotising fasciitis, associated with an infected episiotomy site.

The morbidity associated with perineal wound dehiscence, can and does pose a serious threat to the general well being and quality of life of the mother causing a protracted recovery period, persistent pain and discomfort at the perineal wound site, urinary retention and defecation problems. These complications can potentially have a negative impact on the woman's relationship with her baby and interfere with breastfeeding (Sleep 1991). Moreover, perineal scarring can lead to dyspareunia (painful sexual intercourse) and psychological and psychosexual issues problems from embarrassment and altered body image (Hankins 1990; Ramin 1992; Steen 2007; Uygur 2004; Williams 2006). Consequently, this may be detrimental to the woman's relationship with her partner and other family members. Undoubtedly, the additional hospital appointments, delay in returning to work and corrective surgical procedures can be a source of financial burden both on the woman and the health service (Ganapathy 2008).

Perineal wound complications are feared by many pregnant and recently delivered women (Al-Mufti 1997; Bick 2010; Clements 2001). On occasions, some women are so traumatised by their experience of poor perineal management they request subsequent deliveries by caesarean section. Additionally, it is concerning that women who are pregnant for the first time are becoming increasingly worried about the consequences of perineal injury following childbirth and the associated morbidity. This may also be a contributing factor towards the increasing interest in elective caesarean section as a more 'attractive' alternative mode of delivery (Wagner 2000). Indeed, a survey conducted in 2001 reported that 31% of all women said they would prefer an elective caesarean section compared to vaginal delivery and astonishingly, 80% of these would prefer a caesarean section because of the fear of perineal damage (Clements 2001).

A Delphi survey of a cohort of women who previously sustained a degree of perineal trauma demonstrated that the most important outcome for women is fear of perineal wound infection and wound healing both at one week and two to four weeks postnatal. These surveys were carried out in the UK and subsequently repeated in Brazil with comparable results (Perkins 2008).

Description of the condition

A dehisced perineal wound following a spontaneous second-, third- or fourth-degree tear or episiotomy.

Definition of a dehisced perineal wound

Separation of sutured perineal skin, vaginal mucosa or the underlying perineal muscles.

Incidence of dehisced perineal wounds

The precise incidence of childbirth-related perineal wound dehiscence remains unknown; figures of 0.1% to 4.6% have been reported, dependent upon the degree of the initial trauma (Goldaber 1993; Ramin 1994).

The current classification of perineal trauma was modified by Sultan in 1999 (Sultan 1999) and has been adopted by the Royal College of Obstetricians and Gynaecologists (RCOG 2007) and the International Consultation on Incontinence since 2002 (Koelbl 2009; Norton 2002).

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Second-degree tear
Injury to the perineum involving perineal muscles but not the anal sphincter (RCOG 2007).

Episiotomy
A surgical incision of the perineum made by the midwife or obstetrician to increase the diameter of the vaginal outlet to facilitate the birth of the baby (Kettle 2012).

Third-degree tear
Injury to the perineum involving the anal sphincter complex (RCOG 2007).
3a: less than 50% of external anal sphincter (EAS) thickness torn.
3b: more than 50% of EAS thickness torn.
3c: both EAS and internal anal sphincter (IAS) torn.

Fourth-degree tear
Injury to the perineum involving the anal sphincter complex (EAS and IAS) and anal epithelium

Description of the intervention

Resuturing of the dehisced perineal wound compared with leaving the wound to heal by expectant management (secondary intention).

How the intervention might work

Traditionally, dehisced perineal wounds are managed expectantly, thereby allowing the wound to heal by secondary intention. This approach can result in a protracted period of significant morbidity for women. Therefore, some clinicians advocate secondary suturing and reported that early repair of perineal wound dehiscence is safe, effective and abolishes the prolonged period of disability and distress inherent with healing by secondary intention (Hankins 1990; Ramin 1992; Uygur 2004).

Why it is important to do this review

Currently there is wide variation in how practitioners manage perineal wound dehiscence. This variation is a result of the lack of robust evidence in support of any management strategy. Whilst mortality from perineal wound dehiscence is extremely rare, the impact of the morbidity associated with this complication is significant on women and their families. Therefore, we conducted this systematic review to evaluate the effectiveness of the management options offered to women who present with childbirth-related perineal wound dehiscence.

OBJECTIVES

The objective for this review was to evaluate the therapeutic effectiveness of secondary suturing of dehisced perineal wounds compared with non-suturing (healing by secondary intention).

METHODS

Criteria for considering studies for this review

Types of studies

- Randomised controlled trials investigating resuturing versus expectancy for dehisced perineal wounds (second-, third- and fourth-degree tears and episiotomy) following childbirth.
- Non-randomised, quasi-randomised, cluster-randomised, and cross-over trial designs were excluded.

Types of participants

All women with a dehisced perineal wound following primary repair of a spontaneous second-, third- or fourth-degree tear or episiotomy within the first two weeks following childbirth.

Types of interventions

Any secondary suturing of dehisced perineal wounds (second-, third- or fourth-degree tear or episiotomy), following wound debridement and the removal of any remaining suture material within the first six weeks following childbirth compared with non-suturing.

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All re-sutured perineal wounds were included irrespective of suture material.

Types of outcome measures

Primary outcomes

- Perineal wound healing at six to eight weeks.

Secondary outcomes

- Pain at six weeks, three months and six months.
- Dyspareunia at three to six months.
- Resumed intercourse within two months (**non-prespecified outcome**).
- Resumed intercourse by six months (**non-prespecified outcome**).
- Women's satisfaction with the aesthetic results of the perineal wound.
- Rates of breastfeeding (at six weeks and at six months).
- Rates of exclusive breastfeeding (at six weeks and six months).
- Maternal depression.
- Maternal anxiety.

Definition of wound healing

Wound healing is defined as the physiological processes by which the body both replaces and restores function to the damaged tissues (Flanagan 1996; Tortora G 1996).

Assessment of wound healing

Wound healing as described by the study investigator.

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (31 July 2013).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. weekly searches of Embase;
4. handsearches of 30 journals and the proceedings of major conferences;
5. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE and Embase, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

Searching other resources

We searched reference lists of retrieved studies, national and international guidelines and other publications identified when preparing this review.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Three review authors (Lynn Dudley (LD), Christine Kettle (CK) and Khaled MK Ismail (KMKI)) independently assessed and selected trials for inclusion in this review. It was not possible to assess the relevance of the trials blinded because the authors' names, institution, journal of publication and results were known when we applied the inclusion criteria. Disagreements were resolved by discussion until we reached a consensus. Reasons for exclusion of studies were documented.

Data extraction and management

We designed a data extraction form. For eligible studies, two review authors (LD and CK) independently extracted the data. Discrepancies were resolved by discussion or, if required, by consulting a third review author (KMKI). Data entry and analysis were undertaken using Review Manager software (RevMan 2011).

Assessment of risk of bias in included studies

Two review authors (LD and CK) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion or by involving the third review author (KMKI).

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(1) Random sequence generation (checking for possible selection bias)

We describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.
We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We describe for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether the intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.
We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

We tried to contact the trial authors for additional information regarding random sequence generation and treatment allocation concealment but were unsuccessful.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered studies to be at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.
We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.
We assessed the methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We state whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes.
We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found.
We assessed the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We describe for each included study any important concerns we have about other possible sources of bias.
We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings.

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Measures of treatment effect

Dichotomous data

For dichotomous data, we presented the results as summary risk ratio with 95% confidence intervals.

Continuous data

If we had found continuous data, we planned to use the mean difference if outcomes were measured in the same way between trials and the standardised mean difference to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

We only included randomised controlled trials in which the participants were individually randomised into the clinical trials. We did not include cross-over trials or cluster-randomised trials in this review.

Dealing with missing data

For included studies, we noted levels of attrition. We planned to explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and analysed all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if the I^2 was greater than 30% and either the T^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

In this version of the review, we were not able to explore possible publication bias using funnel plots as only two small studies contributed data to the meta-analyses.

We did not have access to the study protocols for the two included studies, therefore, they have been assessed as unclear for reporting bias as we were not sure whether all pre-specified outcomes were reported in the published papers.

Data synthesis

We carried out statistical analysis using Review Manager software (RevMan 2011). We were unable to combine the two trials in a meta-analysis. If there are suitable studies in future updates of this review, we will use fixed-effect meta-analysis for combining data where it seems reasonable to assume that studies are estimating the same underlying treatment effect: that is where trials are examining the same intervention, and the trials' populations and methods are judged to be sufficiently similar. If we suspect clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary, provided that an average treatment effect across trials is considered clinically meaningful. The random-effects summary gives an indication of the average range of possible treatment effects, and we will discuss the clinical implications of treatment effects differing between trials. If we do not think the average treatment effect is clinically meaningful, we will not combine trials.

If we use random-effects analyses, the results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis and investigation of heterogeneity

If substantial heterogeneity had been identified, we planned to investigate it using subgroup analyses and sensitivity analyses (RevMan 2011). We would have considered whether an overall summary was meaningful, and if it was, used random-effects analysis to produce it, however, due to the lack of studies and insufficient data, we did not carry out any subgroup analyses. If necessary, subgroup analysis will be conducted in future updates.

Sensitivity analysis

As only two small studies were included in this review, we did not carry out a sensitivity analysis for the primary outcomes. If necessary, sensitivity analysis will be conducted in future updates to assess the risk of bias associated with the quality of the included trials.

RESULTS

Description of studies

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Results of the search

The search strategy identified seven reports in total (three from the Cochrane Pregnancy and Childbirth Group's Trials Register and four from other sources). See Figure 1.

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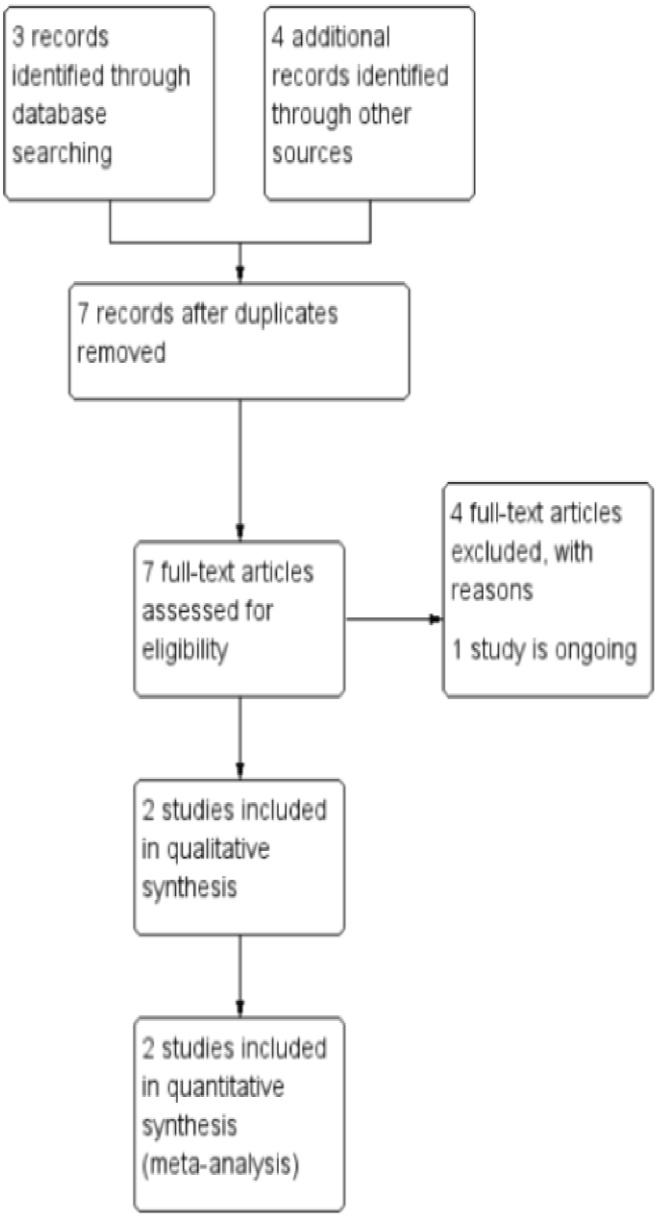
Figure 1. Study flow diagram.



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Included studies

We included the two studies by Christensen 1994; Monberg 1987 involving 52 women with a dehisced and/or infected episiotomy wound at point of study entry.

Setttings

Both studies were conducted within individual hospital settings in Denmark over 24 months (Monberg 1987) and 31 months (Christensen 1994).

Participants

The sample size for both studies was small and ranged between 17 (Christensen 1994) and 35 (Monberg 1987); all women had received an episiotomy with primary repair of the perineal trauma. The mean number of days from delivery to the confirmation of perineal wound breakdown in the trial by Monberg 1987 was 4.8 to 5.5 for both the intervention and the control respectively. No data were provided by Christensen 1994 regarding time from delivery to confirmation of perineal wound breakdown.

Interventions

Both trials compared secondary suturing versus non-suturing. In Monberg 1987, all women presented with a broken down perineal wound referred to as 'ruptured episiotomy'. All 35 women were then allocated to either group A, the experimental intervention or group B spontaneous healing. In the experimental intervention group, women were treated with Clindamycine and secondary suturing referred to as 'primary re-suturing.' Clindamycine was administered two hours prior to suturing and continuously for five days (300 mg three times a day). In the spontaneous healing group, women were treated according to the routine management of the department, which was detailed as cleansing the wound with chlorine and saline.

In comparison, in Christensen 1994 17 women presented with an infected episiotomy wound, however six of the 17 women presented with a wound infection that required incision and drainage. The remaining 11 women had wound breakdown referred to as 'with rupture'. Women were allocated into two groups: either the experimental intervention of incision, curettage and suture, also described as 'primary suture,' under antibiotic cover (Clindaycine), or the conventional treatment of incision and drainage. Of the 11 women presenting with a wound infection and wound breakdown, seven were allocated to the experimental intervention and four were allocated to the conventional treatment. Of the six women who presented with wound infection but no wound breakdown, one woman was allocated to the experimental intervention and five allocated the conventional treatment.

Outcomes

Measurement of the initial episiotomy was provided in one study (Monberg 1987) but no reference was provided in relation to wound healing or how healing was assessed. Whereas, Christensen 1994 referred to outcome measures of both primary and secondary healing, detailed as less than four weeks for primary healing and greater than four weeks for secondary healing respectively.

One of the studies included in this review (Monberg 1987) reported figures on the resumption of sexual intercourse in both groups at two and six months (a non-prespecified outcome measure) and dyspareunia at two and six months. This study also referred to the continuation of lactation and although no actual figures were provided, lactation continued in both groups.

Both studies identified length of hospital in-patient times: Christensen 1994 revealing the total number of women discharged from hospital less than and more than 48 hours following the operative procedure and Monberg 1987 revealing the number of days following complications until discharge in both the intervention and control group.

Excluded studies

We excluded four studies from this review; in all cases the reason for exclusion was that they were not randomised controlled trials (Arona 1995; Hankins 1990; Ramin 1992; Uygur 2004).

Risk of bias in included studies

The methodological qualities of the two trials included in this systematic review did reveal some inconsistencies. It was not clear if antibiotics were used in the expectant management group in either of the studies. Traditionally, antibiotics are used during expectant management, however, if antibiotics were not used in the control arms, this co-intervention could be a serious source for bias particularly in the absence of blinding.

A risk of bias summary is provided in Figure 2.

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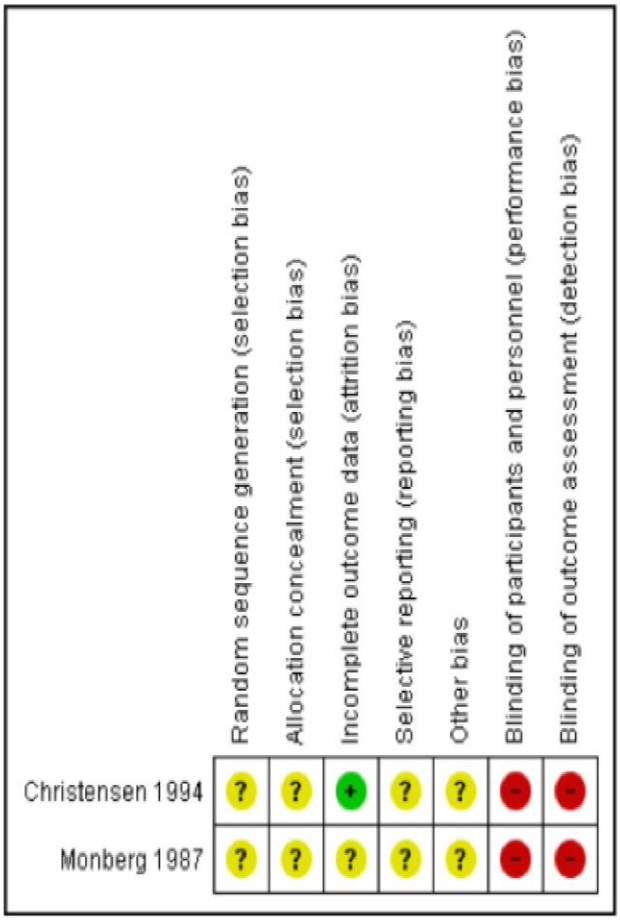
Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Both Christensen 1994 and Monberg 1987 revealed that treatment was by randomisation however neither trial described the methods used.

Blinding

No details were provided by Christensen 1994 or Monberg 1987 in relation to blinding of the interventions to either the clinicians or the participants. However, blinding of the outcome assessments would not have been feasible in either trial due to the obvious differences in the treatment groups. The difficulties of blinding clinicians to treatment allocations can be a potential source of bias when assessing outcome measures, particularly when women are assessed by the researchers themselves. All women in the trial by Monberg 1987 were examined by one of the authors with further control if necessary by the general practitioner and/or in the outpatient clinic.

Incomplete outcome data

Attrition was low in the In the trial by Christensen 1994, 20 women were asked to participate: 17 women were randomised and

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three withdrew before being allocated to a treatment group. One participant was reported as being unable to attend for the four-week review appointment. Outcome data were reported for all women included in the trial with the exception of one participant who was allocated the conventional treatment.

There were missing outcome data in the trial by Monberg 1987 for dyspareunia, particularly at the two-month assessment: no details were provided in relation to the missing data. Data were however complete for resuming sexual intercourse.

Selective reporting

There is an unclear risk of reporting bias for both included trials (Christensen 1994; Monberg 1987). Lactation was reported to have continued in both the intervention and control groups by Monberg 1987, however, no reference was made to the length of time women continued to breast feed.

Other potential sources of bias

Only Monberg 1987 revealed the technique and material used for the secondary repair, Vicryl 2/0 intradermally and in the subcuticular layer.

Inclusion criteria was not specified in either study and only Christensen 1994 described exclusion criteria: Chrons disease, ulcerative colitis and immunosuppressive treatment.

Effects of Interventions

We included two studies involving 52 women at point of trial entry.

Primary outcomes

Proportion of women with a healed perineal wound at six to eight weeks

Only the trial by Christensen 1994 presented data in a suitable format for inclusion in this analysis. Data were provided in relation to wound healing at less than four weeks although no reference was made on how healing was measured. This small trial demonstrated that there was a trend to reduced healing times in the secondary suturing group, however, this difference was not statistically significant, (risk ratio (RR) 1.69, 95% confidence interval (CI) 0.73 to 3.88, one study, 17 women: Analysis 1.1).

Secondary outcomes

Pain at six weeks, three months and six months

Neither of the trials included data in relation to pain at any time interval.

Resumption of sexual intercourse (non-prespecified outcome measure)

One of the trials included in this review (Monberg 1987), presented data on the resumption of sexual intercourse in both groups at two and six months. This was not an outcome prespecified in the protocol but one that the review authors felt was relevant to include in the analysis.

At two months, significantly more women in the secondary suturing group reported resuming sexual intercourse in comparison to the non-suturing group, (RR 1.78, 95% CI 1.10 to 2.89, one study, 35 women: Analysis 1.2). However there was no significant difference between groups at the six-month assessment. All women resumed intercourse by six months in the secondary suturing group and all but one woman resumed intercourse at six months in the non-suturing group, the last woman after six months, (RR 1.08, 95% CI, 0.91 to 1.28, one study, 35 women: Analysis 1.3).

Dyspareunia at three to six months

Only the trial by Monberg 1987 presented data relating to dyspareunia: assessed at two months and six months. At two and six months, dyspareunia was reported less frequently by women allocated to the secondary suturing group in comparison to women in the non-suturing group, however, these differences were not statistically significant , (at two months - RR 0.44, 95% CI 0.18 to 1.11, one study, 26 women: Analysis 1.4), (at six months - RR 0.39, 95% CI 0.04 to 3.87, one study, 32 women: Analysis 1.5).

Women's satisfaction with the aesthetic results of the perineal wound

Neither of the trials reported upon the woman's satisfaction with the aesthetic results of the perineal wound.

Rates of breastfeeding (at six weeks and at six months) and rates of exclusive breastfeeding (at six weeks and six months)

Only the trial by Monberg 1987 commented upon breastfeeding; no data were provided regarding rates of breastfeeding, although it was stated that lactation continued in both groups.

Maternal depression

Neither of the trials included data relating to maternal depression.

Maternal anxiety

Neither of the trials included data relating to maternal anxiety.

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DISCUSSION

The evidence from the two randomised controlled trials included in this review demonstrates that when compared with non-suturing of broken down perineal wounds, secondary suturing is a feasible alternative treatment option.

However we are unable to provide definitive evidence of benefits and risks associated with secondary suturing compared with non-suturing for broken down perineal wounds based on only two studies (Christensen 1994; Monberg 1987), particularly due to the methodological inconsistencies and outcome measures assessed. It was not clear if antibiotics were used in the expectant management group in either of the studies. Traditionally, antibiotics are used during expectant management, however, if antibiotics were not used in the control arms, this co-intervention could be a serious source for bias particularly in the absence of blinding.

The key issue is whether secondary suturing reduces the time taken to heal and only one study assessed this as an outcome measure (Christensen 1994). Secondary outcomes of pain; women's satisfaction with the aesthetic results of wound healing and maternal depression were not assessed as outcome measures by either study. Only Monberg 1987 assessed rates of dyspareunia at two months and six months.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to assess the benefits and risks of secondary suturing for broken down perineal wounds compared with non-suturing. There is an urgent need for a robust randomised trial to fully evaluate the comparative effects of both treatment options.

Implications for research

The review has highlighted the following areas that need further evaluation to guide the future clinical management of broken down perineal wounds.

- A robust randomised controlled trial to evaluate the effectiveness of secondary suturing compared with non-suturing for broken down perineal wounds, which addresses outcome measures that are important to women including pain, resuming sexual intercourse, dyspareunia, satisfaction with the aesthetic results of healing and the continuation of breastfeeding in both the short and long term.

- Research into women's personal experiences of perineal wound breakdown and the impact of this complication of childbirth upon themselves as a new mother and that of their newborn and families.

ACKNOWLEDGEMENTS

The Pregnancy and Childbirth Group (Liverpool) for their assistance and support during the preparation of this systematic review.

As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team) and the Group's Statistical Adviser.

The National Institute for Health Research (NIHR) is the largest single funder of the Cochrane Pregnancy and Childbirth Group. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR, NHS or the Department of Health.

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* *Indicates the major publication for the study*

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Characteristics of included studies *[ordered by study ID]*

Christensen 1994

Methods	Participants were allocated into 2 treatment groups. No methods of randomisation were provided. No details were provided regarding how the randomisation sequence was generated Outcome assessment - no details provided. 20 women following vaginal delivery with an episiotomy wound were asked to participate and 17 women were randomised
Participants	17 women were included in the study - no inclusion criteria specified 11 women had wound infection and wound breakdown. 6 women had a wound infection but no wound breakdown. Exclusion criteria - Chron's disease, ulcerative colitis, immunosuppressive treatment
Interventions	Intervention group (n = 8) Incision, drainage, curettage and suture under antibiotic cover. No specific suture technique or material used detailed (referred to as 'primary suture') 7 of the 11 women with wound infection and wound breakdown were allocated the intervention group 1 of the 6 women with wound infection but no wound breakdown was allocated the intervention group Control group (n = 9) Incision and drainage (conventional treatment, also described as 'open healing') compared with intervention 4 of the 11 women with wound infection and wound breakdown were allocated the control group 5 of the 6 women with wound infection but no wound breakdown were allocated the control group
Outcomes	Included in the analysis: Healing time. Time spent in hospital (inpatient). Recidivism (relapse/reoccurrence) of abscess. Vaginal reconstructive surgery.
Notes	Setting - Odense University Hospital. 3 women who were approached for inclusion did not want to participate 1 woman in the control group could not be contacted for assessment of wound healing Tables provided indicate an intention-to-treat analysis although not revealed in the paper There was no recidivism of abscess.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details provided.

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Christensen 1994 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	20 women were asked to participate in the study; 17 women were randomised, 3 withdrew before being allocated to a treatment group 1 woman from the incision and drainage group was unable to attend the 4 week follow-up assessment
Selective reporting (reporting bias)	Unclear risk	We were not clear whether all pre-specified outcomes were reported in the published papers
Other bias	Unclear risk	Not stated.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participant: no details provided. Clinician: no details provided.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Due to the obvious differences in treatments, the women and outcome assessors could not be blinded to the allocated intervention

Monberg 1987

Methods	Participants were randomised into 2 groups. No methods of randomisation were provided. No details regarding how the randomisation sequence was generated were provided 35 participants with an infected and/or ruptured episiotomy were included
Participants	35 participants (33 primipara) were randomised into 2 groups No exclusion criteria were provided.
Interventions	Intervention group A (n = 20) women had their episiotomy repaired (referred to as 'primary resuturing) and received Clindamycin 600 mg 2 hours prior to suturing and continuously for 5 days (300 mg 3 times a day) Group B (n = 15) women were treated in accordance with the routine management of the department: cleaning the wound with chloramine and saline, resulting in spontaneous healing
Outcomes	Included in the analysis: Healing time. Time spent in hospital (inpatient). Recidivism (relapse/reoccurrence) of abscess. Vaginal reconstructive surgery.

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Monberg 1987 *(Continued)*

Notes	Setting - Hvidore Hospital, Copenhagen, Denmark. Tables indicate intention-to-treat analysis although not stated in the paper All episiotomies examined for bacteria, unfortunately the authors reported that the results had been lost Method of repair described. Lactation continued in both groups but length of times not provided No losses to follow-up reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details provided.
Allocation concealment (selection bias)	Unclear risk	No details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Details unclear in paper.
Selective reporting (reporting bias)	Unclear risk	We were not clear whether all pre-specified outcomes were reported in the published papers
Other bias	Unclear risk	Not stated.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participant: no details provided. Personnel: no details provided.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Due to the obvious differences in treatments, the women and outcome assessors could not be blinded to the allocated intervention

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Arona 1995	Not a randomised trial. Case note review of 23 women who underwent early secondary repair of third- and fourth-degree perineal tears. 21 women had wound dehiscence following primary repair of a fourth-degree tear and 2 had wound dehiscence following primary repair of a third-degree tear. All repairs were successful with no subsequent wound dehiscence occurring

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(Continued)

Hankins 1990	Not a randomised trial. Early repair of episiotomy dehiscence was performed in 22 women with a fourth degree tear and 4 with a third-degree tear and 5 with a mediolateral episiotomy. Most of the women (n = 27) 1 year post secondary repair demonstrated excellent anatomical results and the women reported complete continence and normal coital activity
Ramin 1992	Not a randomised trial. Case note review of 34 women who underwent early repair of episiotomy dehiscence. Clinical follow-up was reported in 29 cases, 5 women were lost to follow-up. Most of wounds were healed completely in 2-3 weeks: 2 women had subsequent wound dehiscence
Uygur 2004	Not a randomised trial. A retrospective case note review including 37 women with episiotomy dehiscence. 12 women with episiotomy dehiscence were allowed to heal by secondary intention and 25 women underwent early secondary repair. 3 women from the re-suturing group had superficial separation of the skin edges, whilst healing was complete in the remaining 22 women

Characteristics of ongoing studies *[ordered by study ID]*

Dudley 2012

Trial name or title	Perineal resuturing versus expectant management following vaginal delivery complicated by a dehisced wound (PREVIEW)
Methods	Pilot and feasibility randomised controlled trial designed to provide preliminary evidence of the effectiveness of re-suturing versus expectant management for dehisced perineal wounds following childbirth, and to feed into the design and feasibility of a larger definitive trial.
Participants	Postnatal women referred to the perineal care clinics at the recruiting sites with dehisced perineal wound (spontaneous second-degree tear or episiotomy) that occurs within 2 weeks following childbirth
Interventions	Resuturing versus expectant management.
Outcomes	**Primary outcome** The proportion of women with a healed perineal wound at 6-8 weeks from the trial entry **Secondary outcomes** Pain at 2 and 6 weeks, 3 and 6 months following trial entry Dyspareunia at 6 weeks, 3 and 6 months following trial entry Rates of breastfeeding at 6 weeks, 3 and 6 months following trial entry Woman's satisfaction with aesthetic results of perineal wound at 6 weeks, 3 and 6 months following trial entry
Starting date	July 25th 2011.
Contact information	Lynn.dudley@uhns.nhs.uk
Notes	12 women who have participated in the randomised controlled trial will also be interviewed to explore their physical and psychological experiences following perineal wound dehiscence; assess the acceptability of the research plan and ensure that all outcomes relevant to women are included in the definitive trial

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DATA AND ANALYSES

Comparison 1. Suturing versus non-suturing for perineal wound infection/breakdown

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Wound healing within 4 weeks	1	17	Risk Ratio (M-H, Fixed, 95% CI)	1.69 [0.73, 3.88]
2 Resumed intercourse within 2 months	1	35	Risk Ratio (M-H, Fixed, 95% CI)	1.78 [1.10, 2.89]
3 Resumed intercourse by 6 months	1	35	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.91, 1.28]
4 Dyspareunia at 2 months	1	26	Risk Ratio (M-H, Fixed, 95% CI)	0.44 [0.18, 1.11]
5 Dyspareunia at 6 months	1	32	Risk Ratio (M-H, Fixed, 95% CI)	0.39 [0.04, 3.87]

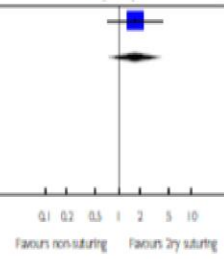
Analysis 1.1. Comparison 1 Suturing versus non-suturing for perineal wound infection/breakdown, Outcome 1 Wound healing within 4 weeks.

Review: Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth

Comparison: 1 Suturing versus non-suturing for perineal wound infection/breakdown

Outcome: 1 Wound healing within 4 weeks

Study or subgroup	2ry suturing n/N	Non-suturing n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Christensen 1994	6/8	4/9		100.0 %	1.69 [0.73, 3.88]
Total (95% CI)	**8**	**9**		**100.0 %**	**1.69 [0.73, 3.88]**
Total events: 6 (2ry suturing), 4 (Non-suturing)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.23 (P = 0.22)					
Test for subgroup differences: Not applicable					



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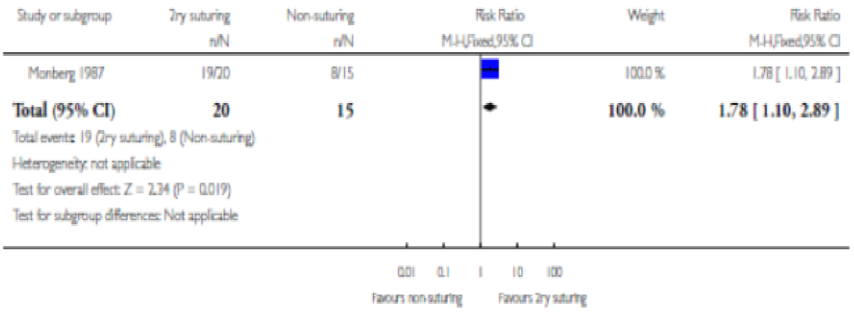
Analysis 1.2. Comparison 1 Suturing versus non-suturing for perineal wound infection/breakdown, Outcome 2 Resumed intercourse within 2 months.

Review: Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth

Comparison: 1 Suturing versus non-suturing for perineal wound infection/breakdown

Outcome: 2 Resumed intercourse within 2 months

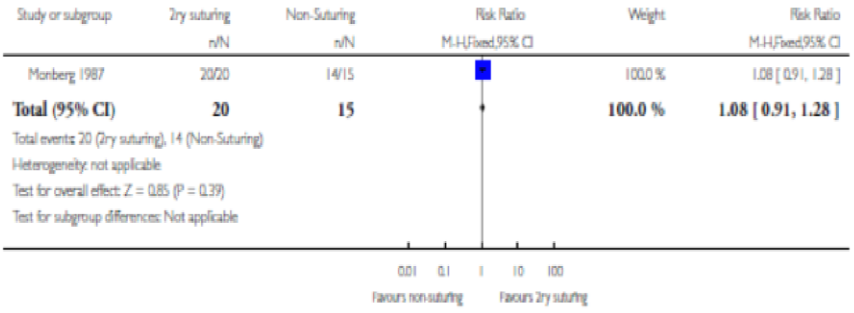


Analysis 1.3. Comparison 1 Suturing versus non-suturing for perineal wound infection/breakdown, Outcome 3 Resumed intercourse by 6 months.

Review: Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth

Comparison: 1 Suturing versus non-suturing for perineal wound infection/breakdown

Outcome: 3 Resumed intercourse by 6 months



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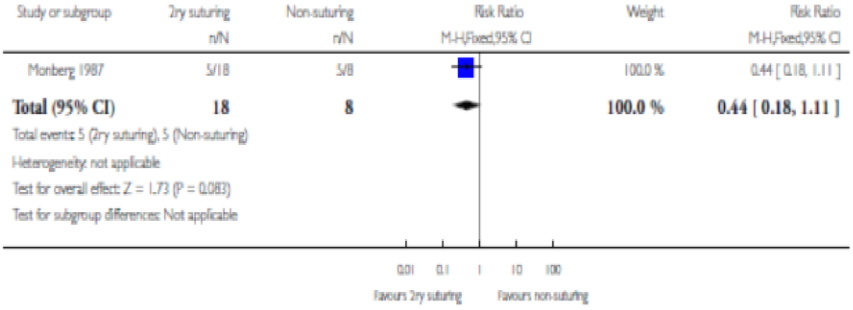
Analysis 1.4. Comparison 1 Suturing versus non-suturing for perineal wound infection/breakdown, Outcome 4 Dyspareunia at 2 months.

Review: Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth

Comparison: 1 Suturing versus non-suturing for perineal wound infection/breakdown

Outcome: 4 Dyspareunia at 2 months

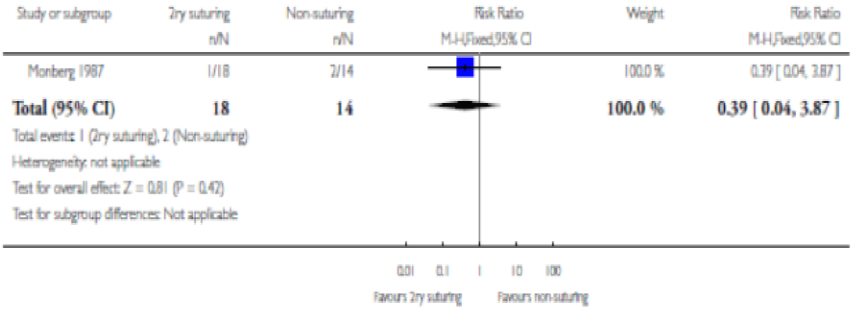


Analysis 1.5. Comparison 1 Suturing versus non-suturing for perineal wound infection/breakdown, Outcome 5 Dyspareunia at 6 months.

Review: Secondary suturing compared to non-suturing for broken down perineal wounds following childbirth

Comparison: 1 Suturing versus non-suturing for perineal wound infection/breakdown

Outcome: 5 Dyspareunia at 6 months



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CONTRIBUTIONS OF AUTHORS

Lynn Dudley (LD) and Christine Kettle (CK) conceived the original idea for the review. All three review authors LD, CK and Khaled MK Ismail (KMKI) critically appraised all papers for quality and eligibility independently. LD, CK and KMKI independently extracted the data and LD and KMKI entered the data onto the Review Manager software. All review authors agreed the final version of the review.

DECLARATIONS OF INTEREST

The authors of this review (LD, CK and KMKI) are conducting a randomised controlled trial 'The PREVIEW study' (perineal resuturing versus expectant management following vaginal delivery complicated by a dehisced wound) to evaluate the therapeutic effectiveness of resuturing dehisced perineal wounds versus healing by expectant management (secondary intention) (Dudley 2012). The contact person for this review is the Chief Investigator for the PREVIEW study. In the update of this review, two independent assessors who are not involved in the PREVIEW trial will conduct independent assessment of eligibility, risk of bias and data extraction for this trial.

Lynn Dudley is a recipient of a Doctoral Nursing Studentship award from the Smith and Nephew Foundation and Research Into Ageing (RIA) which has provided the funding for the trial and to prepare the Cochrane review. The Smith and Nephew Foundation and Research into Ageing do not have any financial interest in the conclusions of this review.

CK and KI run perineal repair workshops both nationally and internationally and have developed an episiotomy and second-degree tear training model with Limbs & Things, UK. They receive a very small royalty fee for input into the design of the model, which is administered by Keele University Office and Research enterprise and is used as part of their women's health research funds.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Smith and Nephew Foundation and Research Into Ageing (RIA), UK.

Lynn Dudley is a recipient of a Doctoral Nursing Studentship award from the Smith and Nephew Foundation and Research Into Ageing (RIA) which have provided the funding to prepare the Cochrane review.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Resuming sexual intercourse was a non-prespecified outcome measure in the protocol for this review; however, on reflection the authors felt that this was a relevant outcome measure to include for this review and subsequent updates.

Due to the lack of available studies and insufficient data relating to the prespecified outcomes, the authors were unable to carry out any subgroup analyses as planned. These will be conducted in future updates should more data become available.

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Appendix 22: Prevalence, pathophysiology and current management of dehisced perineal wounds following childbirth

Prevalence, pathophysiology and current management of dehisced perineal wounds following childbirth

Abstract

Each year, approximately 60 to 70% of women in the UK experience perineal suturing following childbirth, which equates to approximately 1000 women per day. The majority of sutured perineal wounds will heal fairly quickly by primary intention with minimal morbidity. However, for those women whose perineal wound dehisces (breaks down), the healing process takes considerably longer and is associated with increased morbidity. The exact incidence of perineal wound dehiscence is currently unknown; figures of 0.1% to 5.5% have been reported. A large proportion of dehisced wounds are managed expectantly (left to heal by secondary intention) whereas some are re-sutured during the early postpartum period. Currently, the management of dehisced wounds varies according to individual practitioner's preferences and hospital policy as there are no robust research evidence or clear guidelines to inform best practice.

Lynn Dudley
Midwife and Ph.D. Student
University Hospital of North Staffordshire

Christine Kettle
Professor in Women's Health
Staffordshire University

Khaled Ismail
Professor of Obstetrics and Gynaecology
University of Birmingham

Perineal trauma affects a vast amount of women worldwide; more than 60–70% of women per year in the UK alone need stitches to facilitate healing of a spontaneous tear or episiotomy (Sleep et al, 1984; McCandlish et al, 1998, Health and Social Care Information Centre, 2012), ensure good haemostasis and minimise the risk of infection (Royal College of Obstetricians and Gynaecologists (RCOG), 2004; Henderson and Bick, 2005). The postpartum management of perineal trauma, including the prevention of wound infection and the assessment of wound healing, is therefore considered a core component of routine midwifery care (National Institute of Health and Clinical Excellence (NICE), 2006; Steen, 2007; Bick, 2009).

Perineal wound infection and/or wound dehiscence can lead to serious consequences both in the short and long term. Deery (2011), reflecting upon her own midwifery career, acknowledged that examining the woman's perineum on a daily basis was an important part of the routine care plan. However, postpartum perineal care has not been given an adequate level of prioritisation (Bick, 2009; Bryson and Deery, 2009). There are even suggestions that this aspect of midwifery care has been superseded by the ever-increasing administrative and process driven demands expected of midwives in their everyday practice (Cattrell et al, 2005; Bryson and Deery, 2009). Moreover, there is a paucity of research evidence available on the immediate management and consequences of perineal wound dehiscence (Oldfield, 2010).

Definition of perineal trauma

Perineal trauma may occur either spontaneously during vaginal birth or when the midwife or obstetrician intentionally makes a surgical incision (episiotomy) to increase the diameter of the vulval outlet and facilitate delivery.

The current classification of perineal trauma was proposed by Sultan in 1999 (Sultan, 1999) and has been adopted by the Royal College of Obstetricians and Gynaecologists (RCOG, 2001), National Institute for Health and Clinical Excellence (NICE, 2007), and the International Consultation on Incontinence (Norton, 2002) *(Table 1)*.

Definition of wound infection, healing and dehiscence

Wound healing is the physiological processes by which the body replaces and restores function to damaged tissues (Flanagan, 1996); while wound dehiscence is a term used to describe the separation of a surgically closed wound (Oldfield, 2010). The perineal wound may be partially or completely dehisced.

Wound dehiscence following primary repair of a perineal tear or episiotomy may involve separation of the vaginal mucosa, the superficial perineal muscles (*bulbospongiosus* and *transverse perinei*) and sometimes the deeper perineal muscle (*pubococcygeus*). If a third or fourth degree tear is sustained, the external anal sphincter (EAS) and the internal anal sphincter (IAS) may dehisce or a recto-vaginal fistula may occur as a result of infection.

Currently there is no universal standard definition of perineal wound infection following

childbirth. According to the Centre for Disease Control/National Healthcare Safety Network (CDC/NHSN) the criteria for diagnosing an infected episiotomy are (Horan et al, 2008):

- Purulent drainage from the episiotomy
- Episiotomy abscess.

However, there is no reference made to infected second, third or fourth degree tears.

Prevalence of wound infection and dehiscence

Unfortunately, there is limited epidemiological data relating to the prevalence of either perineal wound infections or dehiscence. The exact incidence of perineal wound dehiscence is currently unknown; figures of 0.1% to 5.5% (Kaltreider and Dixon, 1948; Glazener, 1999) have been reported. While anecdotal evidence suggests that the number of women reporting perineal infections and dehiscence in the community is increasing, systems to track these complications following hospital discharge are lacking. Currently perineal wounds are 'monitored' by the community midwives and/or woman's GP and if necessary they are referred back to the maternity unit where they gave birth for review. It is imperative that before a true estimate of the problem can be established, that standardised criteria for diagnosing perineal wound infections are established.

Perineal wound dehiscence is commonly reported to be associated with infection, (Hankins et al, 1990; Goldaber et al, 1993; Gould, 2007; Tharpe, 2008). Wound infection prolongs the inflammatory phase of healing and contributes to delayed wound healing with an increase in granulation tissue and scar formation (Flanagan, 1996; Quick and Thomas, 2000; Boyle, 2006; Tharpe, 2008). The source of infection is considered to be either endogenous (vaginal flora) or exogenous (clinicians, visitors, equipment or the health-care environment) (Steen, 2007; Horan et al, 2008). Wound haematomas, which may present in the vulval, vaginal or sub-peritoneal areas (Bick, 2009) in addition to being a cause of wound dehiscence on their own, can provide an ideal medium for bacteria to colonise and multiply (Pudner and Ramsden, 2000; Oldfield, 2010).

A 3-month prospective audit by Johnson et al (2012) demonstrated that one in ten women who sustained a perineal tear at vaginal delivery that required suturing developed a perineal wound infection. The audit involved 409 women who sustained sutured perineal tears (first, second, third and fourth degree tears and episiotomies were included). Wound infection was defined as the presence of any two of the following markers: perineal pain, wound dehiscence or purulent vaginal discharge. A total of 341 (83%) women were contacted by telephone 21 days post-delivery and asked about markers for perineal wound infection and antibiotic use. Of the women contacted, 39 (11%) had a perineal wound infection based on the criteria of any two infection markers and 16 (5%) women had all three markers of wound infection. Prolonged rupture of membranes and instrumental delivery were significant risk factors for women with two and three markers of wound infection, respectively (Johnson et al, 2012).

Table 1: Classification of perineal trauma

Degree	Structures involved
First	Perineal or vaginal skin only
Second	Perineal muscles but not involving the anal sphincter
Third	Injury to the perineum involving the anal sphincter complex. This could be: • 3a: less than 50% of the external anal sphincter (EAS) thickness torn • 3b: more than 50% of the EAS thickness torn • 3c: Internal anal sphincter (IAS) torn
Fourth	Injury to the perineum involving the anal sphincter complex and the anal epithelium or rectal mucosa

Pathophysiology of wound healing

The majority of perineal wounds if repaired carefully will usually heal fairly quickly with no long-lasting morbidity. In the immediate period following childbirth the perineal area has optimal conditions to enable effective healing, these include the following:

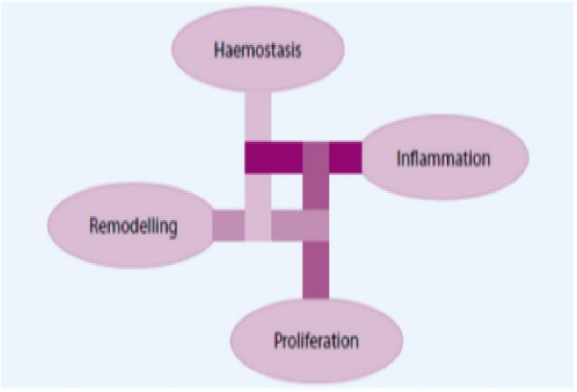

Figure 1. Phases of wound healing overlap and are interdependent on each other

- A favourable acidic pH level (approximately 4.5) in which organisms are unlikely to survive (Quick and Thomas, 2000)
- Moisture (Bryan, 2004)
- Warmth which encourages necessary leucocyte activity (Russell, 2000)
- An increased vascularity (Boyle, 2006).

Phases of perineal wound healing

Wound healing is regulated by a highly complex series of sequential, yet overlapping and interdependent chemical reactions which initiate, control or inhibit various factors (Flanagan, 1996; Boyle, 2006; Steen, 2007) *(Figure 1)*. However, it is not feasible to monitor the rate of wound healing or the effectiveness of wound care in the absence of a holistic approach to wound management or a lack of knowledge regarding the pathophysiology of wound healing and inability to differentiate between normal and abnormal characteristics associated with this process (Flanagan, 1996).

The phases of complete wound healing are commonly described as: haemostasis (not considered as a phase by some authors), inflammation, proliferation and remodelling (maturation) (Steen, 2007; Nobbs and Crozier, 2011) *(Figure 2)*.

Types of perineal wound healing:

Wound healing can be classified as primary, secondary and third intention also referred to as tertiary or delayed primary closure.

Primary intention

This is facilitated by the approximation of wound edges by primary suturing and in the absence of a 'dead space'.

Healing occurs without (or minimal) granulation tissue, contraction has a minor role, the epithelium migrates over the suture line and healing is primarily by connective tissue deposition with minimal scarring (Majid and Kingsnorth, 1998; Boyle, 2006).

Secondary intention

This occurs when there is a degree of gaping or dead space between the wound edges. Granulation tissue fills the area, which gradually contracts to bring the wound edges together. This is a protracted process that can prolong healing times (Majid and Kingsnorth, 1998; Oldfield, 2010), increase the potential for infection and scarring, and have a higher rate of complications than wounds that heal by primary intention (Boyle, 2006; Steen, 2007). Excessive collagen is produced when healing is delayed,

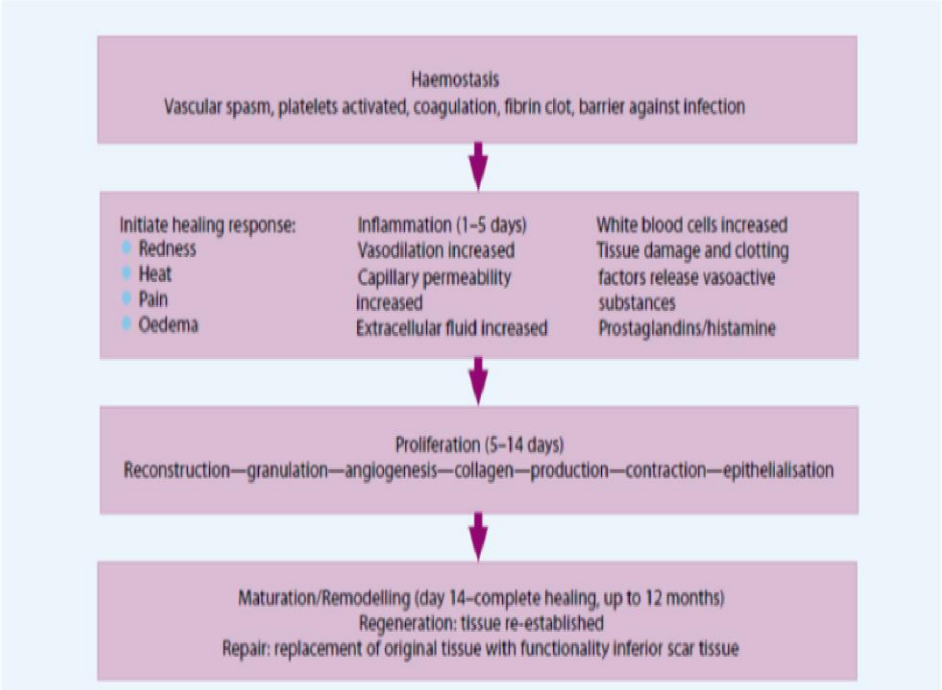

Figure 2. Phases of wound healing (adapted from Steen, 2007)

which may result in wound contracture, causing restrictive movement and deformity (Majid and Kingsnorth, 1998).

A surgical wound such as an episiotomy or a perineal tear which has dehisced following primary repair and is not re-sutured heals by secondary intention (managed expectantly).

Third intention: tertiary or delayed primary closure

Wounds are sometimes left open for several days to allow for oedema and/or infection to resolve and for exudate to drain prior to primary closure (Boyle, 2006; Vuolo, 2006). After several days the wound is then debrided (devitalised tissue removed) and surgically closed (Vuolo, 2006). It is important to note that midwives should liaise with the tissue viability team when managing wounds that are left to heal by third intention.

Risk factors associated with perineal wound dehiscence

In addition to infection, a retrospective case note study by Williams and Chames, (2006) demonstrated significant risk factors for perineal wound dehiscence as: prolonged second stage of labour (p=.001); operative vaginal delivery (odds ratio, 3.6; 95% Confidence Interval (CI): 1.8–7.3); episiotomy (odds ratio, 6.9; 95% CI: 2.6–18.7); third or fourth-degree tear (odds ratio, 3.1; 95% CI: 1.5–6.4) and meconium-stained liquor (odds ratio, 0.38; 95% CI: 0.18–0.84). Logistic regression analysis revealed the most significant factor being an interaction between operative vaginal delivery and episiotomy (odds ratio, 6.36; 95% CI: 2.18–18.57) (Williams and Chames, 2006).

Studies by Kindberg et al (2008) and Kettle et al (2002) have also demonstrated that the choice of suture techniques used for perineal repair may have the potential to contribute towards wound dehiscence. The study by Kindberg et al (2008) (n=495 women) comparing the continuous with the interrupted inverted suture technique reported a non-significant difference in wound gaping at day 10 (measured more than 0.5 centimetres) in the continuous group (30/198) compared with the interrupted inverted suture group (39/197) (risk ratio (RR) 0.77; 95% CI: 0.50–1.18). Total wound dehiscence was reported in two women in the continuous and four in the inverted interrupted suture groups.

Table 2. Factors affecting wound healing

Malnutrition	• Malnutrition in general can lead to reduced strength of the wound, increased wound dehiscence and increased susceptibility to infection and poor-quality scarring (Boyle, 2006; Gray and Cooper, 2001)
Obesity	• Adipose tissue is poorly vascularised and the consequential effects on oxygenation of the tissues and functioning immune response is thought to increase the risk of surgical site infections (NICE, 2008) • Obesity can mask an impaired nutritional state (Department of Health, 2002) • Being moderately or severely obese can increase the risk of perineal wound infection (Robinson et al, 2005)
Smoking	• Nicotine and carbon monoxide are known to have a damaging influence on wound healing by the vasoconstrictive effects and reduced oxygen carrying capacity of blood associated with smoking cigarettes (Bale et al, 2000; NICE, 2008). Even limited smoking can reduce peripheral blood flow to the wound but also decreases vitamins B, B6, B12 and C—vital for tissue regeneration (Flanagan, 1997)
Lack of sleep	• Sleep disturbances (experienced by virtually every new mother) may inhibit wound healing. Sleep encourages anabolism (the synthesis of complex molecules from simple ones) and wound healing includes anabolic processes (Boyle, 2006)
Stress	• It is believed that anxiety and stress can affect the immune system and thereby inhibit wound healing (Bale et al, 2000; Walburn et al, 2009) • Increased secretion of corticosteroids can inhibit the production and function of leucocytes (Workman, 1995)
Tissue hypoxia	• Hypovolaemia, hypothermia and vasoconstriction can all limit the oxygen carrying capacity to the tissues and may occur in the woman who has had a traumatic labour experience, for instance a major post partum haemorrhage • Too tight sutures may cause tissue hypoxia and delay healing (Kettle and Fenner, 2009)
Medical conditions	• Immunocompromised due to sepsis or malnutrition; specific disease process such as AIDS; renal or hepatic disease; or drugs such as corticosteroids can lead to a compromised ability to regulate growth factors and inflammatory and proliferative cells for wound repair (Gray and Cooper, 2001; Boyle, 2006; Burton, 2006)
Sub-optimal care	• Poor suturing technique • Retention of swabs (National Patient Safety Agency (NPSA), 2010)

While Kettle et al (2002) (n=1539 women) compared the continuous with the interrupted suturing technique and reported a significant reduction in wound gaping observed at 10 days in the continuous group (23/770) compared with the interrupted group (50/769) (odds ratio 0.46; 95% CI 0.29–0.74). Kettle et al (2002) reported that 3/771 women in the continuous and 1/771 in the interrupted suture group needed re-suturing up to 3 months postpartum (RR 3.00; 95% CI: 0.31–28.81).

There are, however, many factors that can compromise effective wound healing, and some of the complexities have only recently been realised; these are summarised in *Table 2*.

Understandably, due to the media portrayal of Methicillin-resistant *Staphylococcus aureus* (MRSA) and hospital acquired infections in recent years, women themselves have become fearful of wound infection and the subsequent consequences of poor healing (Jolley, 2008).

Maternal morbidity associated with perineal wound infection and dehiscence

Green et al (1998) revealed that perineal injury and stitches were reported by women as the worst thing associated with childbirth. Subsequent studies have also reported that perineal wound infection and the associated morbidity are feared by women (Al-Mufti et al, 1997; Clements, 2001; Perkins et al, 2008). A double iteration Delphi survey was conducted in the UK (2006) and Brazil (2007) to identify childbirth-related perineal trauma outcomes, deemed to be important by women (Perkins et al, 2008). These surveys consistently demonstrated that the highest ranked outcome was fear of perineal wound infection and delay in wound healing. Indeed, an outcome that appears to be prioritised by women across eclectic backgrounds and cultures worldwide.

Perineal wound infection and dehiscence may lead to major physical, psychological and social problems if left untreated. Moreover, morbidity associated with perineal wound dehiscence can and does pose a serious threat to the physical, psychosocial and sexual wellbeing of the new mother (Glazener, 1997). The extent of morbidity experienced will depend on the severity of the initial trauma and extent of the wound dehiscence. For many women morbidity *(Figure 3)* centres around persistent pain and discomfort at the perineal wound site, urinary retention, defecation problems, dyspareunia, and psychological and psychosexual issues from embarrassment and altered body image (Arona et al, 1995; Williams and Chames, 2006; Steen, 2007). The morbidity experienced may also have the potential to have a negative impact on the woman's relationship with her partner and other family members. Furthermore, the relationship with her newborn baby may become affected, and she may find difficulty in breastfeeding due to the distress caused by her perineal problems (Sleep, 1992).

Perineal wound infection and dehiscence is also a burden on health-care system resources, as quite often women who suffer this consequence of childbirth have to undergo corrective surgery, perineal refashioning, and excision of excessive scar tissue or other procedures associated with the management of perineal dysfunction (Ganapathy et al, 2008).

Furthermore, it is concerning that women who are pregnant for the first time are becoming increasingly worried about the consequences of perineal injury following childbirth and the associated morbidity (Pakenham et al, 2006). This too may be a contributing factor to the increasing interest in elective caesarean section as a more 'attractive' alternative mode of delivery (Wagner, 2000).

In addition, the potential for litigation with these cases must also not be underestimated; Chandraharan and Arulkumaran, (2006) site episiotomy wound breakdown and complications of perineal tears, including incontinence, fistulae and dyspareunia, as potential cause for medico-legal problems in obstetrics.

Management of dehisced perineal wounds

Over half a century ago two obstetricians reported that perineal wound breakdowns may be managed by early secondary repair once any infection had been treated (Kaltreider and Dixon, 1948). Surprisingly, it took some 40 years for clinicians to feel confident in their beliefs that the early closure of dehisced perineal wounds was both a feasible, safe option and should be attempted in order to maintain perineal integrity (Monberg and Hammen, 1987; Hankins et al, 1990; Ramin et al, 1992; Arona et al, 1995; Uygur, 2004; American College of Obstetricians and Gynaecologists (ACOG), 2006). However, in practice, due to lack of robust scientific evidence, some clinicians may offer re-suturing while most will leave dehisced perineal wounds to heal by secondary intention (expectant management).

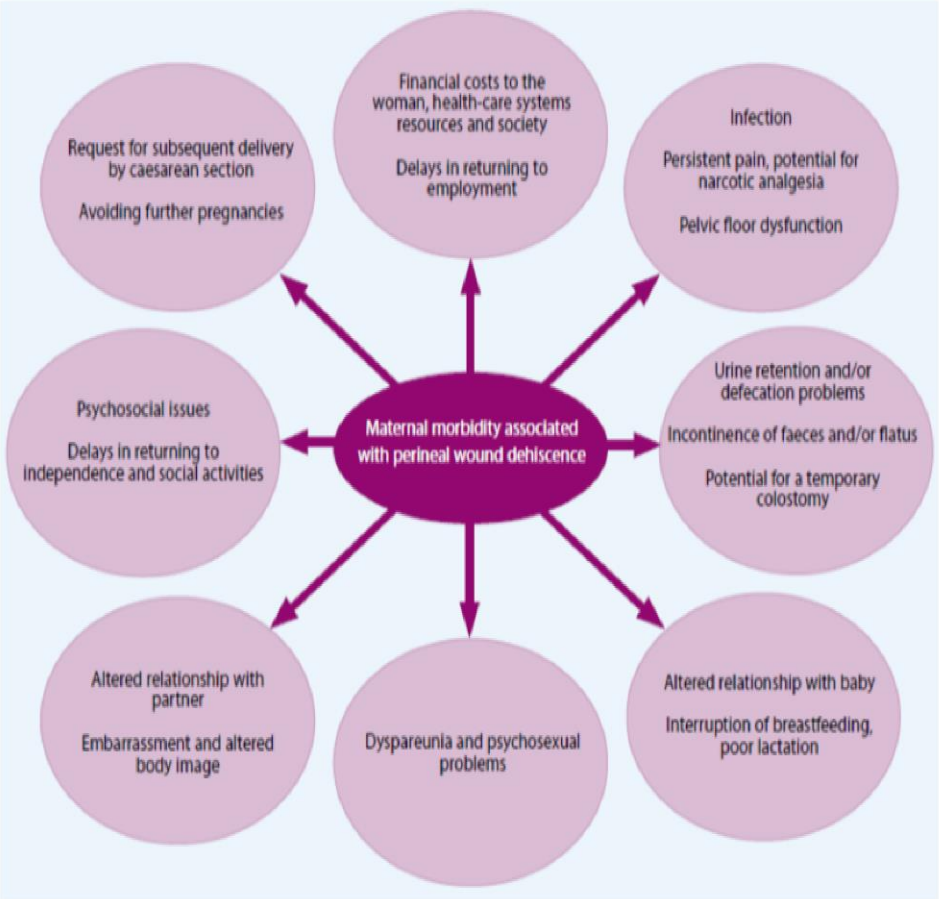

Figure 3. Maternal morbidity associated with perineal wound dehiscence

A recent systematic review of the literature found two small randomised controlled trials (RCT) that compared secondary re-suturing versus non-suturing (Monberg and Hammen, 1987; Christensen et al, 1994). While there are methodological weakness in both studies, a meta-analysis of results from the papers by Monberg and Hammen (1987) and Christensen (1994) demonstrated that early re-suturing is associated with a reduction in healing times, dyspareunia and earlier resumption of sexual intercourse (Dudley et al, 2013: awaiting publication).

Several retrospective studies have also concluded that with adequate preparation and antibiotic cover secondary perineal repair for wound dehiscence following primary repair of an episiotomy, second, third and fourth degree tears are a safe alternative to the expectant management commonly offered today (Hankins et al, 1990; Ramin et al, 1992; Arona et al, 1995; Uygur et al, 2004).

Promoting perineal healing and preventing wound dehiscence: The midwives' role

Midwives have a crucial role towards promoting wound healing and preventing both wound infection and dehiscence throughout the whole spectrum of maternity care. It is imperative that the key recommendations for practice are followed as detailed in the recent report from the Centre for Maternal and Child Enquiries (CMACE, 2011) and National Institute for Clinical Excellence Intrapartum and Postnatal guidelines (NICE, 2006; NICE, 2007) which include the following:

Antenatal

- Correct any systemic factors that may impair wound healing, such as anaemia
- Educate women on sensible eating to maintain a healthy body mass index (BMI) and promote wound healing

> Any signs or symptoms suggestive of infection, inadequate repair or wound dehiscence should be acted upon promptly and appropriately

- Provide smoking cessation advice and programmes where appropriate; women who continue to smoke should be aware that this may compromise wound healing.

Intrapartum

- Adhere to clinical practice guidelines for the management of the second stage of labour with particular reference to the length of this stage
- Follow clinical practice guidelines relating to the repair of perineal trauma which must encompass:
  - Timing of the perineal repair to minimise the risk of infection and blood loss
  - Rectal examination prior to commencing the repair to accurately assess the extent of the trauma and, following the repair, to ensure that suture material has not accidentally been inserted into the rectal mucosa
  - The use of an aseptic technique
  - The use of correct equipment, suture techniques and materials
  - Accurate documentation of the extent of perineal trauma and details of the repair
  - Swab and needle count prior to and following the repair
  - The administration of appropriate pain relief
  - Referral to more experienced practitioners for the suturing of complex trauma
  - The administration of antibiotic prophylaxis for the repair of third and fourth degree perineal trauma, to reduce infection and wound dehiscence
  - Provision of information for the woman regarding the extent of the trauma, pain relief, diet, hygiene, how to care for their perineal wound and the importance of pelvic-floor exercises.

Postnatal

- Inform all pregnant and recently delivered women about the risks, signs and symptoms of genital tract infection and how to avoid contamination of their perineum by washing their hands both prior to and after using toilet facilities and changing sanitary pads
- Inform women to take regular showers or baths; change sanitary pads regularly and keep the perineal area as clean and dry as possible
- Advise all women to ensure that their diet incorporates a varied range of food products to promote wound healing including a regular intake of foods rich in vitamin C and protein
- Advise all pregnant and recently delivered women to seek medical advice as soon as possible if they have any concerns about their general health and/or wound healing.

Assessing perineal wounds

Undoubtedly adequate clinical history and thorough examination are essential components of assessing any surgical wound. Examining perineal wounds necessitates the woman to adopt a position that facilitates inspection of the whole perineal area to ensure the efficient assessment of wound healing and the early detection of any signs of delayed healing (Bick, 2009). NICE (2006) recommends that at each postnatal contact, women should be offered a thorough perineal assessment if they have any concerns about their perineal wound, including perineal pain, discomfort or offensive odour. Any signs or symptoms suggestive of infection, inadequate repair or wound dehiscence should be acted upon promptly and appropriately. Wound swabs to identify causative organisms should only be taken if a perineal wound infection is suspected, as the routine swabbing of wounds will undoubtedly uncover bacteria (Patel 2007; Oldfield, 2010). Routine swabbing in the absence of clinical indicators of infection is neither helpful nor cost-effective (Patten, 2010). The practitioner should act in accordance with local guidelines regarding taking wound swabs, commencing antibiotics and seeking advice from the tissue viability team.

Signs and symptoms of wound infection:

Signs and symptoms of a wound infection may include one or more of the following:

- Abscess formation
- Increasing pain and/or tenderness
- Erythema
- Cellulitis (redness, heat, oedema and pain)
- Excessive exudate, change of colour of exudate (normal exudate is yellow in colour and is part of the normal healing process)

Table 3. Signs and symptoms of sepsis (may include one or more of the following)

- Pyrexia >38ºC (a normal temperature does not exclude sepsis)
- Hypothermia core temperature <36ºC is a significant finding that may indicate severe infection and must not be ignored
- Persistent tachycardia >100 beats per minute (BPM)
- Tachypnoea >20 breaths per minute is sepsis until proved otherwise
- Arterial hypotension (Systolic BP <90 mmHg (millimetres of mercury), Mean Arterial Pressure <70 mmHg)
- Acute oliguria (urine output <0.5 millilitre/kilogram per hour for at least 2 hours despite adequate fluid resuscitation)
- Leucopenia (white blood cell (WBC) count $<4x10^9$/l white blood cells/l is a significant finding that may indicate severe infection)
- Leucocytosis WBC count > $12x10^9$/l
- Arterial hypoxemia
- Elevated C-reactive protein >7milligram/l
- Serum lactate ≥4 millimoles/l is indicative of tissue hypoperfusion
- Coagulation abnormalities (International Normalised Ratio [INR] >1.5 or activated partial thromboplastin time [APTT] >60s)
- Thrombocytopaenia platelet count $<100x10^9$/l
- Hyperglycaemia in the absence of diabetes (plasma glucose >7.7 millimoles/l)
- Abnormal liver function tests and urea and electrolytes (Creatinine rise of >44.2µ millimoles/l. Sepsis is severe if creatinine level >176µ millimoles/l
- Diarrhoea and/or vomiting in a woman with any evidence of sepsis is a serious sign
- Severe lower abdominal pain and severe 'after pains' may be the result of bacterial toxins on the bowel wall. Ileus (absent bowel sounds)
- Significant oedema or positive fluid balance (>20 millilitre/kilogram over 24 hours)
- Altered mental status
- Decreased capillary refill or mottling
- Rash
- Offensive vaginal discharge (smelly suggests anaerobes; serosanguinous suggests streptococcal infection)
- Productive cough
- Urinary symptoms

(Harper, 2011: 92; RCOG, 2012: 10; Dellinger et al, 2013: 585)

Although leucocytosis (a high white cell count) and pyrexia are usual in sepsis, sepsis is sometimes accompanied by leucopenia or hypothermia which may mislead practitioners into underestimating the severity of the illness, losing valuable time before commencing appropriate treatment (Harper, 2011)

Investigating a suspected sepsis

- Full blood count, urea and electrolytes, liver function tests, full coagulation screen, C-reactive protein, serum lactate levels
- Blood cultures
- Arterial blood gases
- Swabs (vagina, wound if appropriate, throat or MRSA if status unknown)
- Urine, sputum, breast milk or stool sample for microbiology
- Any relevant imaging studies should be performed promptly in an attempt to confirm the source of infection

(Harper, 2011; RCOG, 2012; Dellinger et al, 2013)

- Odour
- Localised oedema
- Discolouration
- Dehiscence
- General feeling of malaise
- Pyrexia.

(Cutting and Harding, 1994; Flanagan, 1996; Boyle, 2006)

Sepsis

Sepsis is a systemic, toxic response to infection leading to severe sepsis and septic shock (severe sepsis plus hypotension not reversed with fluid resuscitation) (Dellinger et al, 2013).

Sepsis has been most recently defined as: 'the presence (probable or documented) of infection together with systemic manifestations of infection. Severe sepsis is defined as sepsis plus sepsis-induced organ dysfunction or tissue hypoperfusion' (Dellinger et al, 2013: 583).

Signs and symptoms of sepsis

Delays in recognition of sepsis, prescribing antibiotics and seeking consultant help were common findings in the 2011 CMACE report (CMACE, 2011).

Clinical signs suggestive of sepsis include one or more of the following: pyrexia, hypothermia, tachycardia, tachypnoea, hypoxia, hypotension, oliguria, impaired consciousness and failure to respond to treatment. It is important to remember that these signs, including pyrexia, may not always be present and are not necessarily related to the severity of sepsis (RCOG, 2012). Signs and symptoms of sepsis and recommended investigations are


Lucie Carter

Good hand hygiene is crucial in avoiding wound infection which could lead to sepsis

further detailed by Harper (2011), RCOG (2012) and Dellinger et al (2013) *(Table 3)*.

Regular observations of all vital signs (including temperature, pulse rate, blood pressure and respiratory rate) should be recorded on a Modified Early Obstetric Warning Score (MEOWS) chart (Harper 2011; RCOG 2012). Intravenous broad spectrum antibiotics should be administered within one hour of suspicion of severe sepsis, with or without septic shock (RCOG 2012; Dellinger et al, 2013). There must be an urgent referral to the critical care team in severe or rapidly deteriorating cases and early involvement of a consultant obstetrician. In addition, the expert advice of a consultant microbiologist or infectious disease physician should be sought urgently when serious sepsis is suspected (Harper, 2011; RCOG 2012; Dellinger et al, 2013).

Sepsis associated with perineal wound infection

Unfortunately for a very small number of women, perineal wound infection can have serious consequences and may in some circumstances prove fatal. Although maternal mortality associated with perineal trauma is extremely rare in developed countries, an infected perineal wound is a potential route for systemic infection whereby sepsis and septic shock may ensue (Lewis, 2007). Alarmingly, sepsis has been identified as the leading cause of maternal mortality for the first time in the UK since the *Confidential Enquiries into Maternal Deaths* report was introduced in 1952. The 2011 CMACE report revealed that seven women died from sepsis following a vaginal delivery, including one woman who's perineum became infected from a second degree tear—despite prompt referral to hospital and appropriate treatment, including maximum support in intensive care, she died a few days after delivery. Her blood cultures and perineal swabs grew *β-haemolytic streptococcus* Lancefield Group A (GAS). This was the most common pathogen identified in relation to sepsis; it is typically community based with 5–30% of the population asymptomatic carriers on the skin or throat (Health Protection Agency, 2004). It is very readily spread by person-to-person contact or by a droplet from an infected individual (Harper, 2011) and reinforces how crucial the advice is we give to women relating to hand and perineal hygiene. Steer et al, (2012) have recently published expert guidance for the prevention and control of group A streptococcal infection in acute health-care and maternity settings in the UK. They recommend that:

- Communal facilities, such as baths, bidets and showers, should be cleaned and decontaminated between all patients especially on delivery suites, postnatal wards and other high-risk areas
- Cases where there is significant discharge of potentially infected body fluids or high risk of shedding, mothers and neonates on maternity units, should be isolated until culture negative
- The isolation room, furniture, and equipment should be cleaned with detergent and water followed by hypochlorite at 1000 parts per million (ppm) daily (or combined detergent hypochlorite product)
- Pregnant women infected or colonised with GAS prior to admission should be treated and have this clearly documented in the maternity notes
- Antibiotics should be administered to mother and baby, if either develops suspected or confirmed invasive GAS disease in the neonatal period (first 28 days of life)
- Health-care professionals must adhere to strict hand hygiene policy. Visitors should be offered suitable information and facilities to be able to adhere to standard infection control practice, including good hand hygiene.

Future research

One study is currently underway looking at perineal re-suturing versus expectant management following vaginal delivery for

dehisced wounds, with the acronym 'PREVIEW' (Perineal re-suturing versus expectant management for dehisced wounds). This is a multi-centre pilot and feasibility RCT evaluating the management of perineal wound breakdown (Dudley et al, 2012). Further research studies such as PREVIEW have the potential to make a significant contribution towards answering the practice dilemma, for both clinicians and women, as to the best management of dehisced perineal wounds (to re-suture or not to re-suture). There is also a need to consider long-term follow up beyond 6 months in future studies. Other areas to consider are the methods and materials used for secondary re-suturing and the need for antibiotic prophylaxis for women considered at high risk of wound infection and dehiscence.

Conclusion

It is clear that the protracted morbidity of perineal wound infection and dehiscence, and its ongoing sequelae is a real problem experienced by women. In terms of prevalence it is difficult to quantify the true extent of the problem due to the fact that this data is not collated by individual maternity centres or GP practices. Furthermore, there is a definite lack of robust scientific evidence to guide the best management of dehisced perineal wounds for both clinicians and women alike. Further research work is needed to inform local and national guidelines. BJM

Key points

- Morbidity associated with perineal wound dehiscence can pose a serious threat to the physical, psychosocial and sexual wellbeing of the new mother
- Midwives have a crucial role in promoting wound healing and preventing both wound infection and dehiscence
- There are no robust research evidence or clear guidelines to inform best practice, and the management of dehisced perineal wounds varies according to individual practitioners' preferences and hospital policy
- There is limited evidence from small retrospective studies that secondary perineal repair is a feasible option when compared to expectant management
- Further robust research is needed to provide the definitive answer as to what is the best management of dehisced perineal wounds (to re-suture or not to re-suture)

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