Comparison of a single versus a four intradermal sterile water injection technique for the relief of lower back pain for women in labour: A mixed methods study.

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Statement of Authorship and Sources

This thesis contains no material published elsewhere or extracted in whole or in part from a thesis by which I have qualified for or been awarded another degree or diploma.

No parts of this thesis have been submitted towards the award of any other degree or diploma in any other tertiary institution.

No other person's work has been used without due acknowledgment in the main text of the thesis.

All research procedures reported in the thesis received the approval of the relevant ethics committees (where required) or a relevant safety committee if the matter is referred to such a committee.

I also certify that the thesis has been written by me. Any assistance that I have received in my research work and the preparation of the thesis itself has been acknowledged.

Signature of candidate

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"The warning hot wave of (labour) pain swept up her back, she entered a place where there was no time at all" (Lessing, 1970, p. 144)

"The (labour) pain in my back returned deafeningly. I closed my eyes but that shut me into a dark roaring world of pain. I groped through the shouting blackness…"(Banks, 1976, p. 273)

Acknowledgements

In 2009, I worked with a team of fellow midwives to introduce sterile water injections to our workplace; while reviewing the literature and developing the documentation I thought "there has to be a nice little RCT here somewhere" with the idea of trying my hand at some research and maybe writing a publication. This notion coincided with my colleague, Karen Wallace, circulating an email regarding research funding that was available, and the appointment of Sue Kildea as our Professor of Midwifery, whose first piece of advice was to link this to an academic degree. Seven months later I had funding for the trial and a scholarship to start a Masters of Philosophy which was soon upgraded to a PhD.

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Publications and conference presentations

This research has resulted in a number of publications and conference presentations, on which I have been first author.

Publications:

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Abstract

Background: Significant back pain is often experienced by women in labour and may increase the need for pharmacological pain relief, often with associated side effects including excessive sedation and restriction to mobility. Sterile water injections (SWIs) are a simple, safe, effective, non-pharmacological technique for relieving back pain in labour; however, the number of injections required to achieve optimal analgesia is unknown. Furthermore, administration of SWI causes a brief, but intense, pain which may influence the acceptability of the procedure to labouring women. There is limited data from previous trials on how women view SWI, and the benefits of this particular analgesic option, versus the pain associated with administration. No previous studies have examined how midwives regard the prospect of causing pain to labouring women; albeit to relieve pain. The aim of this research was to determine if a single injection of sterile water was clinically similar to four injections in terms of degree of analgesia and to examine the experiences of labouring women and midwives receiving, and administering, SWIs.

Design: Sequential, explanatory, mixed method design incorporating a randomised controlled non-inferiority trial and a descriptive qualitative study.

Participants and setting: Three hundred and five women, in labour at term, requesting analgesia for back pain were recruited from two metropolitan hospitals in Brisbane, Australia and participated in the randomised controlled trial (RCT) (SWITCh trial). For the qualitative phase, women were recruited from the RCT cohort and midwives from the participating sites, who had administered SWI during the trial, were invited to take part in the study.

Methods: Participants recruited to the RCT were randomly assigned to receive either one (n=147) or four (n=158) sterile water injections. Interviews were conducted with nine women who had received SWI and three focus groups were held with a total of 11 midwives with experience in administering SWI. Data for the quantitative and qualitative phases were collected and analysed separately, and the results synthesised.

Outcome measures: For the quantitative phase the primary outcome was the difference in self-reported pain measured using a visual analogue scale (VAS) between baseline and 30 minutes post-intervention. The clinically acceptable margin of difference was defined as

less than, or equal to, one centimetre on the VAS between the single injection (SI) compared to the four injection (FI) technique. Secondary outcomes included VAS score on injection and at 10, 60, 90 and 120 minutes post-intervention, analgesia use, mode of birth and maternal satisfaction. For the qualitative phase, the audio-recoded interviews were transcribed verbatim, read and re-read to identify key themes, independently coded by the researcher and a supervisor. Inconsistencies were reconciled and a final coding scheme agreed. Transcriptions were then uploaded to NVivo qualitative data analysis software (QSR International Pty Ltd. Version 8, 2009), and analysed thematically.

Findings: For the primary outcome of the quantitative phase, the mean difference in the pre and post-injection (30 minute) scores between two groups was -1.48 cm (95% CI -2.10, -0.86) in favour of the FI technique; however, the injection pain associated with the FI was significantly greater than that of the SI technique ($p<0.001$). There were no significant differences between the two groups in terms of other analgesic use, mode of birth or maternal satisfaction. The qualitative study identified a number of major themes including differences in the discourses between women and midwives on back pain in labour, the impact of the injection pain on the acceptability of the procedure, and the subsequent use of other analgesia.

Discussion: The finding that both SWI techniques produced a recordable reduction in pain was supported by women's accounts of the analgesic effects following the procedure. Although the FI technique was shown to be more painful than the SI, women were accepting of the injection pain of either technique, describing a no pain, no gain attitude. Midwives appeared to use their observations of overall benefit from SWI to overcome their reservations about inflicting pain. The study findings suggested that back pain in labour is not a widely discussed topic; findings also question the taken-for-granted association between the baby's position in the maternal pelvis and back pain.

Conclusion: The study demonstrated that the four injection technique was clinically more effective than a single injection; furthermore, the research suggests that both SWI techniques may have a role as a method of analgesia in labour, and that SWI is viewed by women and midwives as an acceptable and effective alternative analgesic strategy for back pain in labour.

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Abbreviations and Glossary

Abbreviations

CS   Caesarean section

CTG   Cardiotocograph

FI   Four injection

ITT   Intention to treat

NI   Non-inferiority

NRS   Numerical rating scale

OA   Occipito-anterior

OP   Occipito-posterior

PP   Per protocol

PSIS   Posterior superior iliac spines

RCT   Randomised controlled trial

SED   Sequential exploratory design

SI   Single injection

SWI   Sterile water injections

SWITCh   Sterile water injections techniques comparison (trial)

VAS   Visual analogue scale

Glossary

Antenatal	Occurring before labour and birth.
Augmentation	Artificially accelerating the progress of labour by rupturing the fetal membranes and/or the use of oxytocic drugs to stimulate the uterus.
Epidural	Injection of an anaesthetic agent into the space between the spinal column and the dura mater (a membrane surrounding the spinal cord) causing a loss of sensation to the lower part of the body.
Forceps	Surgical instruments designed to assist the vaginal birth of the infant without injury to infant or mother. The two forceps blades are introduced, one at a time, into the vagina and through the cervix permitting the fetal head to be grasped firmly but with minimal compression. Once in correct position the blades are articulated and traction is applied during a contraction.
Induction of labour	Artificial stimulation of labour contractions by rupturing the fetal membranes and/or the use of oxytocic drugs to stimulate the uterus.
Intradermal	Between the layers of the skin.
Intrapartum	Occurring during labour and birth.
Labour dystocia	A delay in the progress of labour involving an impediment to cervical dilatation and/or descent of the presenting part of the fetus.
Michaelis' rhomboid	A diamond shaped area of the lower back overlaying the sacrum. As there is no agreement in the literature how the phrase should be written (Michaelis or Michaelis'), in this thesis, the term Michaelis' rhomboid will be used.
Multiparous	A woman who has given birth to at least one infant greater than 20 weeks gestation.
Normal birth	Spontaneous in onset, low-risk at the start of labour and remaining so throughout labour and delivery. The infant is born spontaneously in the vertex position between 37 and 42 completed weeks of pregnancy. After birth mother and infant are in good condition. In normal birth there should be a valid reason to interfere with the

natural process. (World Health Organization, 1996, p. 4)

Nulliparous	A woman in her first pregnancy
Occipito-posterior	Where the occiput of the fetal skull is positioned towards the maternal spine
Occipto-anterior	Where the occiput of the fetal skull is positioned towards the maternal pubic bone
Postnatal	The period beginning immediately after the birth and extending for about six weeks.
Private insurance	Individuals who make financial contributions to health insurance companies to enable choice of consultant (medical specialists) and hospitals.
Public insurance	Public (taxpayer funded) health system enabling access to health care for all citizens which is free of charge at the point of delivery.
Regional analgesia	Blocking the passage of pain impulses through a nerve by injecting an analgesic drug close to the nerve trunk e.g. epidural and spinal anaesthesia.
Subcutaneous	Under the layers of the skin.
Vacuum extraction	A form of assisted instrumental birth where a small circular 'cup' is placed upon the fetal head. The air within the cup is removed to create a vacuum which adheres the cup to the scalp and allows the application of traction, during a contraction.

Chapter one: Introduction to the thesis

1.1   Overview

This chapter presents an introduction to the issue of back pain in labour and the role of sterile water injections (SWI) as an analgesic; both of which are explored in greater detail in the further chapters. The justification for the research is also outlined. The theories of pain are explored with particular reference to pain in labour, the differences between pain and suffering and cultural influences. The neuromatrix theory of pain is discussed as a conceptual framework for the research and, finally, the research questions and aim are detailed, followed by a summary of the structure of the thesis.

1.2   Back pain in labour and the use of sterile water injections

Almost one in three women in labour suffer from severe lower back pain (Melzack & Schaffeberg, 1987; Tzeng & Su, 2008). Clinicians often associate this with varying degrees of fetal malposition, particularly an occipito-posterior (OP) position (Simkin, 2010), as this is thought to cause pressure on pain-sensitive structures within the pelvis. Back pain in labour may also be referred pain (Ader, Hansson, & Wallin, 1991), where pain that originated in one part of the body is felt in another; hence pain from the cervix, uterus and surrounding structures is felt in the lower back. Characteristically, the back pain persists throughout the normally painless resting intervals between contractions (Tzeng & Su, 2008). It may be associated with greater use of pharmacological analgesia, including epidurals (Hutton, Kasperink, Rutten, Reitsma, & Wainman, 2009) which is correlated with a cascade of interventions and iatrogenic sequelae such as increased augmentation of labour, instrumental birth and urinary retention (Lieberman & O'Donoghue, 2002; Weiniger, 2006). Sterile water injections, administered into the lower back, have been demonstrated to provide analgesia with none of the aforementioned negative outcomes; hence their suitability for women wishing to avoid regional anaesthesia or labouring in localities where this service is not available (Hutton, et al., 2009). Administering SWI is inexpensive, low technology, safe and suitable for most maternity care settings (Hutton, et al., 2009). The injection of sterile water causes somatic and mechanical irritation resulting in a brief (15–30 seconds), but significantly painful, sensation. Relief of back pain follows almost immediately, may last for up to two hours and the procedure can be repeated a number of times (Martensson & Wallin, 2008). The

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physiology of the effect is thought to be related to the stimulation of ascending (gate control theory) (Melzack & Wall, 1965) and descending (diffuse noxious inhibitory controls) (Le Bars, Dickenson, & Besson, 1979) pain modulation systems. The most frequently used SWI technique consists of four intradermal injections into the skin surrounding Michaelis' Rhomboid over the sacral area (Reynolds, 2000) (refer to section 2.3.3 for a detailed description). Two clinicians, working in tandem, administer the injections concurrently.

The intensity of the injection pain associated with the use of SWI may negatively impact on the acceptability of the procedure to women (Fogarty, 2008; Martensson & Wallin, 2008). Hypothesising that one injection would result in less pain, two previous studies tested a single injection (SI) technique compared to a placebo and also reported a significant reduction in pain (Bahasadri, Ahmadi-Abhari, Dehghani-Nik, & Habibi, 2006; Kushtagi & Bhanu, 2009). No single injection technique (SI) trial had been designed to compare the analgesic outcomes with the four injection technique (FI) and hence it was not known if the two techniques provided similar levels of analgesia (Fogarty, 2008; Martensson & Wallin, 2008). There had been no qualitative studies exploring women's experiences of using SWI for back pain in labour and, similarly, there is no data on midwives responses to offering an analgesic intervention that causes brief, but intense, pain.

This thesis examines two techniques for the delivery of analgesia for back pain in labour using injections of sterile water; specifically a comparison of one versus four injections. The research incorporates accounts from women and midwives to provide additional and in-depth insights into the efficacy and value of both procedures.

1.3   Defining pain

The study of pain and pain relief provides a particular challenge to researchers. Although pain is a common, if not universal, experience that can be measured with reasonable precision and reliability, individual experiences and cultural input may influence a person's response to pain. This diversity in the experience of pain also presents challenges in establishing a definition of pain for research purposes. In everyday life the experience and role of pain may seem fairly uncomplicated; injury causes pain which generally prompts the individual into a protective and/or healing response. Hence pain, typically, has a sensory and affective component (Moseley, 2007). Physiologically, the sensation of pain is triggered by signals indicating tissue damage that is, in turn, detected by nociceptors (injury sensitive receptors) or

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a neuropathy which occurs following a disturbance of the function of these receptors (Chapman & Gavrin, 1993). These pain signals are transmitted through several neural pathways to multiple regions of the forebrain to produce a multi-dimensional interpretation of pain (Bushnell & Apkarian, 2006). The taxonomy of pain developed by the International Association for the Study of Pain (IASP) reflects this relationship:

> *An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage* (Loeser, 2011).

However, some authors have questioned how tissue may reach a state of potential damage i.e. between an undamaged and damaged condition, or if such a status is even possible (Wright, 2011). Furthermore, the experience of pain arising from the same source, or cause, may change if the pain persists over time as the pathways that transmit pain signals to the brain become sensitised. Likewise do areas within the brain that interpret the signal, leading to hyperalgesia (perception of pain increasing) and allodynia (non-painful stimuli registered as painful). In this case the relationship between pain and tissue damage becomes less relevant until the point that pain occurs, in the absence of ongoing tissue damage, and becomes the pathological state (Moseley, 2007). Hence, pain may not provide a direct indication of the tissue state with respect to actual damage (Moseley, 2007).

Early definitions of pain also focused on the subjective nature of pain:

> *Pain is whatever the experiencing person says it is, existing whenever the experiencing person says it does* (McCaffery, 1968, p 17).

The pain of others is observed through their subjective display and reporting of pain and these factors may be modified by the cultural, social, emotional and conceptual aspects of the individuals experience and the observers interpretation of pain (Chapman, 1977). The subjective and enduring nature of learned responses is articulated by the IASP:

> *Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life* (Loeser, 2011).

Other research confirms that the influence of pain experiences in early life may impact on sensory perceptions and processing of pain in later life (Wollgarten-Hadamek et al., 2009). Furthermore, words that are learned in association with pain can trigger pain processing areas

of the brain, either as verbal primes or during visualisations of situations involving pain (Richter, Eck, Straube, Miltner, & Weiss, 2010). Some authors have discussed how depictions of labour and descriptors of pain in advance, may subsequently influence women's perceptions in labour (Dick-Read, 1954; Mongan, 2005).

1.3.1   The neuromatrix theory

The experience of labour is recognised as being multidimensional (Trout, 2004) with labour pain being described as a:

> *complex, subjective, multidimensional response to sensory stimuli generated during parturition. Labor pain is a phenomenon embedded in the very nature of human existence and the relationships among us all. Unlike other acute and chronic pain experiences, labor pain is not associated with pathology but with the most basic and fundamental of life's experiences…*(Lowe, 2002, p. S16)

The concept that labour pain may not be connected with pathology, as suggested by the IASP taxonomy of pain, but rather as integral to life experience, is reflected in the neuromatrix model as described by Melzack (1999, 2001) which includes the role of evolutionary, inherited, and cultural influences on interpretations and responses to pain.

The neuromatrix theory presents a context whereby a genetically determined (inherited) response to pain is influenced by physiological stress systems, sensory inputs, cognitive reasoning, and previous experiences, to provide voluntary and involuntary (re)actions, communication and coping strategies or a *"neurosignature"* (Melzack, 2001, p. 1379).

The term matrix can be defined as *"something within which something else originates, takes form, or develops"* (Melzack, 2001, p. 1380); hence the neuromatrix theory proposes that although the brain is the centre for pain perception, the brain and central nervous system act as a unified system to produce a 'neurosignature' of pain for the whole body. Hence, the original noxious or painful stimulus is a single component and does not produce the neurosignature. Inputs to the neuromatrix arise from three processing networks: sensory-discriminative (noxious/painful stimuli); cognitive-evaluative (cultural and personal learning, expectation, anxiety); and motivational-affective (adrenalin/immune system response, endorphin release). Outputs from the neuromatrix occur through three responses: pain perception (cognitive, sensory and motivational); action programs (voluntary and involuntary

responses, social interaction and coping); and stress regulation (immune and endogenous pain modulation) (Melzack, 2001).

The neuromatrix theory redefines pain as one aspect of a multidimensional response when an organism perceives tissue (or itself) to be under threat and where the perceived level of threat determines the interpretation rather than the actual tissues state. This theory places pain within a broader physiological response which includes rapid changes in blood flow, the release of immune mediators and changes to voluntary muscle activity (Moseley, 2007). These changes are themselves affected by genetic and/or evolutionary influences on the synaptic architecture of the brain; the arrangement of neurological connections that govern the processing of stimuli and cultural and cognitive interpretations of both physiological and external environmental sensory data (Melzack, 2001). In the context of this research, the neuromatrix theory provides the basis for the assumption that to explore the effectiveness of an analgesic intervention, a quantitative measurement of pain such as a pain score, the personal experience of pain and pain relief both need to be considered. Encounters with, and the perceptions of, the clinicians administering the analgesia are also of importance.

1.3.2 The difference between pain and suffering

Psychological responses to pain and an individual's coping mechanisms may affect experiences of pain and/or suffering. Whereas pain can be described objectively in terms of noxious input to the nervous system, suffering may include subjective reactions such as fear, anxiety, depression and isolation (Loeser, 2001). Although it may amplify the sensation, pain alone may not be sufficient cause for suffering, whilst, conversely suffering may augment the intensity and experience of pain (Turk & Wilson, 2009). The distinction between the two appears to lie in the individual's interpretation of, and ability to manage, pain in their current circumstances. As such, suffering has been described as:

> *A complex negative affective and cognitive state characterised by perceived threat to the integrity of the self, perceived helplessness in the face of that threat, and exhaustion of psychosocial and personal resources for coping.* (Chapman & Gavrin, 1993, p 8)

The term suffering also has specific religious and cultural connotations, particularly in relation to childbirth pain and analgesia; these concepts will be discussed later in this chapter.

1.3.3   Should labour be painful?

While many women report severe pain in labour, others appear to experience little or none (Melzack, 1993); indeed there is much debate as to why normal physiological processes such as labour and birth should involve pain at all. Some theorists suggest that pain may have evolved to motivate behaviour (Wright, 2011) and; therefore, may act as a warning to the woman to seek a place of safety to give birth (Lowe, 2002). However, others argue that labour and birth are normal events and, as such, should not be painful but rather that pain occurs through social conditioning, expectation, ignorance and fear. A notable proponent of this explanation was Grantly Dick-Read, an English obstetrician (1890-1959).

Dick-Read developed his ideas about a possible relationship between fear and pain in childbirth after attending a birth in the slums of Whitechapel (London) in the 1930s. The birthing woman refused to allow him to administer chloroform and, following her infant's birth, remarked, *"It didn't hurt. It wasn't meant to, was it, doctor?"* (Dick-Read, 1954, p. 18). From this remark, and his observations of birth practices in other countries, Dick-Read proposed two questions:

> *Is labour easy because she is calm, or is she calm because her labour is easy? And conversely, is a woman pained and frightened because her labour is difficult, or is her labour difficult and painful because she is frightened?* (Dick-Read, 1946, p. 55).

Dick-Read theorised that fear had a physiological effect on the uterus which gave rise to pain and that when a woman (and her birth attendants) were calm, confident and relaxed, labour would not be painful. To this end, Dick-Read insisted that women be instructed in the facts of natural childbirth and relaxation and breathing techniques; he subsequently devised the first programme of antenatal classes. Dick-Read inspired the formation of the National Birthday Trust Fund, which later became the National Childbirth Trust; one of the largest independent providers of antenatal classes in the UK (National Childbirth Trust, 2012). Dick-Read was not without his critics; particularly within his own profession, some of whom viewed his theories as unscientific and accused him of creating a schism between women and their physicians (Caton, 1999).

Another proponent of painless childbirth was Marie Mongan, a hypnotherapist from the USA, who used Dick-Read's techniques for the birth of her own children and later developed

Hypnobirthing, which drew on techniques used in hypnosis. Like Dick-Read, Mongan considered that cultural conditioning was responsible for the pain experienced by women in labour and; therefore, pain could be eliminated by reconditioning the woman's subconscious expectations through the use of hypnotherapy techniques and education that reinforced her confidence and belief in her ability to give birth naturally (Mongan, 2005). The Hypnobirthing technique, and the use of hypnosis in labour more generally, has been gaining popularity and is also increasingly supported by empirical evidence suggesting that self-hypnosis techniques in labour reduces women's analgesic requirements and increases their feelings of autonomy and sense of self-control (Cyna, McAuliffe, & Andrew, 2004).

1.3.4   Cultural influences on labour pain

The notion of childbirth pain being related to, and defined by, cultural influences is also reflected in anthropological research which describes birth as a rite of passage integrating a series of rituals influenced by, and representative of, the individual woman's culture (Jordan & Davis-Floyd, [1978] 1993). Rites of passage typically have three phases: separation, where the previous state is discarded; transition, where the individual does not inhabit a recognised state; and re-integration, where the individual is recognised to be in a new state (Davis-Floyd, 1992, p. 18). During the journey from pregnant woman to mother the pain of labour may be viewed as the transitional phase. Within a society that emphasises the importance of science and technology, birth rituals such as epidurals are integral to modern obstetric practice. Such interventions may influence a shift in the woman's focus from herself and her own abilities, towards a reliance on technology and the medical system (Davis-Floyd, 1992). Although this viewpoint may acknowledge pain as an integral part of labour and women's social/psychological adaptations to motherhood, it also shifts control over the rite of passage, relocating it from the realm of personal experience to ownership and management by others. The different viewpoints and understandings of pain in general, and labour pain specifically, reflect the diversity of individual experience and culturally derived beliefs.

1.4   Research questions and aim

This research sought to answer two questions that are connected through the theoretical framework:

   i) For women with back pain in labour does a single, compared to four, sterile water injection technique provide clinically similar levels of analgesia?

ii) What are the experiences of women and midwives using sterile water injections for the relief of back pain in labour?

Therefore, the aim of this study was to: **compare a single intradermal SWI with the four injection technique in both the degree and duration of analgesic effect, and to explore the experiences of women and midwives using SWI.**

To address both of the research questions this study employed a mixed methods approach that combined quantitative and qualitative methodologies. The thesis is structured to reflect this approach.

1.5   The structure of the thesis

This thesis is divided into six chapters, including the Introduction. The remaining chapters are outlined below:

1.5.1   Chapter two: Literature review

The literature review is presented in five sections. The first section provides an overview of the history of analgesia for labour and birth, discusses the influences on the development of pharmacological analgesics, and medical and social responses that gave rise to non-pharmacological analgesics such as SWI. The second section describes and critiques the research into the development and use of SWI as an analgesic agent in labour, and other painful conditions, and examines variations in the techniques for delivering SWI. The third section describes the physiology associated with back pain in labour and the theoretical principles related to the analgesic effect of SWI. The fourth section explores the data from a small number of RCTs examining women's satisfaction with SWI and the role of analgesia more generally in women's expectations, and how this may impact on broader concepts such as control. The final section examines the role of the midwife in pain assessment and contrasts the development and uptake of SWI amongst midwives in Sweden, the USA and Australia, and the challenges involved in changing practice.

1.5.2   Chapter three: Research design

This chapter presents an overview of the relevance, benefits and challenges of using a mixed methods design with specific reference to the sequential exploratory approach used in this

study. The principles underpinning the randomised controlled non-inferiority design used in the quantitative phase (SWITCh trial) are introduced, including an explanation about the intervention and control groups, blinding strategies to reduce bias and data collection and analysis. The design of the qualitative phase is described in terms of sampling and recruitment, and data collection and analysis, with particular reference to approaches used for analysing focus group data. Finally, issues common to both phases of the study, such as ethics, validity and rigour, are discussed.

1.5.3 Chapter four: Analysis and discussion of the SWITCh trial

This chapter presents and analyses data from the quantitative phase; the SWITCh trial. The results for the primary and secondary outcomes are presented; as are findings from the postnatal questionnaire which explored levels of maternal satisfaction with the intervention including the best and worst aspects. In keeping with a sequential exploratory approach the outcomes specific to the quantitative phase are discussed with reference to the supporting literature.

1.5.4 Chapter five: Analysis and discussion of the qualitative study

This chapter presents the analysis of data collected from individual interviews with women and focus groups with midwives. Major themes and sub-themes were derived from the transcripts based on the frequency and strength of occurrence and relevance to the research questions. Themes included: the occurrence of back pain in labour; how the concept of SWI was introduced; the experience of the injection pain and the analgesic effect; and the views of women and midwives towards SWI. The themes are discussed in relation to the supporting literature.

1.5.5 Chapter six: Discussion and conclusions.

This chapter presents a synthesis of outcomes from both the quantitative and qualitative phases of the research project. The discussion draws on the key findings that contribute the body of knowledge surrounding SWI and these are presented with reference to the existing literature. The limitations of the research are also presented. The chapter concludes by outlining the implications for practice and recommendations for further research and practice development.

Summary

This chapter introduces the role of SWI in the relief of back pain in labour and reviewes the concepts of pain, pain in labour with reference to the cultural influences and the differences between pain and suffering. The neuromatrix theory was presented as the theoretical framework underpinning the research and the aims of the research and the research questions were provided. Finally the structure of the thesis was outlined.

The following chapter presents a brief history of analgesia in labour and the development of SWI as an analgesic. The literature pertaining to SWI and back pain in labour is described and critiqued and, finally, the influence of pain, and pain relief on the birth experience, and midwives role in pain assessment are discussed.

Chapter two: Literature review

2.1   Overview

This chapter is divided into five sections which describe and critique the relevant literature. The first section provides an overview of the history of pain relief in labour and birth, the early resistance to the use of pharmacological analgesia, the political movements in the USA and UK that influenced the development of pharmacological obstetric analgesia and the impact of the natural birth movement in developing non-pharmacological pain relief strategies for labour and birth. The second section presents a review of the literature pertaining to the development of SWI, as a form of analgesia, from the earliest use to the establishment of an efficacious procedure for relieving back pain in labour. The variations in SWI techniques are examined and the limitations of the current evidence are presented. (A summary of the studies reviewed is presented in Appendix 1). The third section examines the incidence and physiology of back pain in labour and outlines the principles of counter-irritation and theories of pain modulation. The fourth section reviews the research concerning women's experiences of SWI, the factors that influence their expectations and satisfaction with their birth experiences, with a particular focus on reported pain and analgesia use. The fifth section explores the use of SWI by midwives and the role of the midwife in assessing labour pain.

2.2   Analgesia in labour and birth: A brief history

2.2.1   The introduction of pharmacology to labour and birth

Throughout history, and across cultures, traditional healers, midwives and physicians have searched for, and experimented with, a number of agents for providing pain relief in labour. Heaton cites a recipe advocated by Zerobabel Endecott from 1677 entitled 'For sharpe and difficult travel in woman and child':

> *Take a Lock of Vergins haire on any Part of ye head, of half the Age of ye Woman in travill. Cut it very smale to fine Pouder then take 12 Ants Eggs dried in an oven after ye bread is drawne or other wise make them dry & make them to pouder with the haire, give this with a quarter of a pint of Red Cows milk or for want of it give it in strong ale wort.* (Heaton, 1946, p. 567).

In the nineteenth century bloodletting was advocated as a *"means of lessening the pains of parturition"* (Heaton, 1946, p. 567), as this was thought to depress the nervous system and therefore counteract pain. In 1847, James Simpson, a Scottish obstetrician, first used ether in childbirth for a woman whose pelvis had been deformed by rickets; although, he subsequently recognised that ether was both difficult to administer and reduced uterine activity (Caton, 1999). Later in the same year, after rendering himself and his colleagues unconscious during experiments, Simpson discovered the anaesthetic properties of chloroform (Woolcock, Thearle, & Saunders, 1997), which became increasingly popular following its administration by Dr John Snow to Queen Victoria in 1853 for the birth of her eighth child. The analgesic properties of nitrous oxide were also evident in the 1880s but as this provided only limited anaesthesia for instrumental births, it was less popular (Heaton, 1946). In 1902 Professor Richard von Steinbuchel began injecting labouring women with a mixture of morphine and scopolamine, a technique known in Germany as *Dammerschlaf* or dusk sleep. The procedure rapidly gained popularity in the USA and the UK where it was called twilight sleep (Barnett, 2005). Other methods were also trialled in the early twentieth century including Gwathmey's synergistic analgesia; a combination of morphine and magnesium sulphate administered by intramuscular injection, along with the rectal administration of ether (Heaton, 1946).

The introduction of epidural anaesthesia began in Germany. Surgeon August Beir and his assistant practised on each other using a mixture of cocaine and tap water to achieve an effective block although both men apparently suffered severe headaches for some days afterwards (Koller, Bier, & Pagés, 2009). Continuous spinal anaesthesia was first described by Henry Percy, the Dean of London Hospital, in 1907; however, it was not until the introduction of suitable epidural catheters in the 1940s and 1950s that the procedure was used in obstetrics (Koller, et al., 2009).

2.2.2   *Physiological pain and the curse of Eve: the case against the use of pharmacological analgesia in labour*

Prior to the development, and more widespread use, of anaesthetic agents in the early 1900s, the practice of providing analgesia to women in labour had long attracted opposition from religious, medical and political groups. In 1591, Eufame McCalyean and Agnes Sampson were burnt as witches in Edinburgh following accusations that, as a midwife, Sampson had used magical amulets to transfer McCalyean's labour pain to cats and dogs. The trial and

subsequent executions were used by the then reigning Scottish monarch, King James VI, to assert his authority over rivals and present himself as a defender of Protestantism (Defalque & Wright, 2004). Centuries later the use of chloroform, for the relief of labour pain, was also opposed by members of the medical fraternity and the clergy. The use of chloroform was not without risks and many physicians were also suspicious of the effects on labouring woman and the newborn infant, including concerns that it increased infection and haemorrhage. Most importantly, labour pain was considered an indicator of the normal progress of labour, as Nicolay Pirogoff, an eminent Russian scientist, remarked:

> *And finally, haven't midwives and parturients and indeed all others always viewed the agonies of delivery as an indicator of safety and a well-nigh holy accompaniment of childbirth?* (Pirogoff, 1847, pp. 3–4)

The safe administration of ether or chloroform required a high degree of skill as, in the hands of the inexperienced, death could occur rapidly; most likely as a result of the aspiration of vomit into the lungs (Defalque & Wright, 2004). Charles Meigs, an American Professor of Midwifery (the term obstetrics was first adopted in the early twentieth century) and a contemporary of Simpson, summarised the sentiment of many of his medical colleagues:

> *Should I exhibit the remedy for pain to a thousand patients in labor, merely to prevent the physiological pain. What sufficient motive have I to risk the life or the death of one in a thousand, in a questionable attempt to abrogate one of the general conditions of man (sic)?* (Meigs, cited by Caton, 1999, p. 28)

Some clergymen also opposed the use of analgesia with one declaring that:

> *Chloroform is a decoy of Satan, apparently offering itself to bless woman, but in the end it will poison society and rob God of the deep, earnest cries which arise in time of trouble for help!* (Woolcock, et al., 1997, p. 449)

The Christian religious opposition to pain relief in labour was founded on the biblical reference to the 'curse of Eve' which states that: *"in sorrow thou shalt bring forth children"* (Genesis 3:16). The argument was based on the interpretation of this text to mean that childbirth must necessarily involve pain and; therefore, the alleviation of it contradicted the scriptures (Woolcock, et al., 1997). Simpson argued that the use of the word sorrow was an

ambiguous reference to pain and the term could be interpreted to mean that women were to work (i.e. labour) during childbirth. This interpretation was supported by Rabbi Abraham De Sola in 1849, who stated that the Hebrew word *etzebh*, translated in the passage as sorrow, meant that through toil or labour, rather than pain, shall women bring forth children (Cohen, 1996).

In the decade following Simpson's discovery of chloroform, objections to obstetric analgesia quickly waned as its popularity and use increased. By 1857, further use of chloroform by Queen Victoria for the birth of her ninth child, barely raised comment (Caton, 1999).

2.2.3   *The influence of Western political movements on the development of pharmacological analgesia in labour*

The increase in use of obstetric analgesia coincided with, and was facilitated by, changing medical opinion and the major political movements of the late nineteenth century. The growing use of forceps as a solution to protracted labours, often associated with physical deformities resulting from dietary deficiencies causing rickets, prompted physicians to increase use of the new anaesthetic agents despite concerns over safety (Caton, 1999). Similarly, the rise of feminism, through the suffragette movement, viewed painful and poorly managed births as an impediment to the goal of equality (Caton, 1999). Around this time, access to, and administration of, analgesics such as chloroform, was restricted to physicians, resulting in a movement away from midwives as the lead professional attending women in labour (Woolcock, et al., 1997). However, this shift also had an effect on the provision of analgesia. As physicians generally only attended women at the moment of birth rather than throughout labour, analgesia was often withheld until either birth was imminent, or the forceps were applied, whereupon the woman was rendered unconscious (Caton, Frölich, & Euliano, 2002). Therefore even though pain relief was available, women had little say in the timing of administration.

In the USA, the use of twilight sleep (a combination of scopolamine and morphine) was advocated more persuasively by the burgeoning women's movement than by the medical profession, who viewed the technique as largely ineffective and expressed concerns about the side effects on the woman and the newborn. Under the influence of twilight sleep women frequently became disoriented and thrashed about; hence the recommendation that they be kept in darkened rooms with their eyes bandaged and ears occluded with wads of cotton to

reduce all sensory stimuli. To reduce the possibility of injury at the time of birth, women were then restrained and/or given a general anaesthetic (Wolf, 2002). Despite the limitations, twilight sleep was widely viewed by the general public as an effective panacea for the pain of labour. Its use was championed by the American feminist movement and a number of prominent and wealthy New York suffragettes established the National Twilight Sleep Association (NTSA) to promote the procedure and provide women with information that exalted the presumed benefits, with little or no mention of the risks. As support for twilight sleep by the feminist movement was as much about the politics of female equality as it was about the benefits of pain relief in childbirth, the campaign focused on the male dominance of the medical profession and rallied against their reluctance to use twilight sleep to:

> *Relieve one half of humanity from its antique burden of a suffering which the other half of humanity has never understood* (Caton, 1999, p. 139)

Rather than presenting an argument for safe and effective analgesia, the NTSA linked the use of twilight sleep with the political goals of emancipation, urging women to support the campaign and to "*hammer away with all your might. Emancipation day has come*". (Caton, 1999, p. 139). However, the use of twilight sleep came to an abrupt end with the death, in childbirth, of one of its most fervent supporters (Wolf, 2002)

Politics continued to play a part in the provision of pain relief in labour well into the 1950s. The National Birthday Trust Fund (NBTF), was established in the United Kingdom (UK) in 1927 to lobby for the extension of maternity services for poor women and a permanent solution to the relief of pain in childbirth (Caton, 1999). Aside from the upper classes, most women in the UK gave birth at home attended by midwives, so the NBTF viewed midwives as the most appropriate people to provide analgesia in labour. However, the use of chloroform and narcotics was restricted to doctors; although, the later development of the Minnitt machine, a portable device for administering a mixture of nitrous oxide and air, provided a possible solution to the administration of labour analgesia by midwives. In 1949, the NBTF supported a parliamentary bill to establish pain relief in childbirth as a legal right, based largely on the use of the Minnitt machine by midwives; the bill was defeated on economic grounds. However, in 1950, midwives in the UK were given the right to administer pethidine unsupervised by medical staff; although, it was known at the time that pethidine was more likely to sedate women that provide them with adequate analgesia (Barnett, 2007). Hence the

introduction of pethidine was an economic and political compromise and not solely related to clinical efficacy.

There was little or no attempt to ascertain the effectiveness or safety of the pharmacological agents employed; however, they did accommodate the growing use of forceps by physicians to expedite birth. To some degree they also served to fulfil political agendas such as the suffragette movement. Meaning, that labouring women and infants were subjected to risk through experimentation with largely untested chemicals and procedures to promote other societal objectives. Also the medical profession rarely asked their patients to voice an opinion on the efficacy of the treatments they provided, specifically their views on being rendered insensible or unconscious during labour and birth. This has contemporary relevance as the ongoing development of analgesic interventions must take into account the opinions and objectives of the labouring women as well as empirical evidence of effect.

Although the growing interest in natural birth may have influenced the progress of non-pharmacological pain relief methods, the development of SWI and other non-pharmacological analgesics, such as acupuncture, has not been immune to an assumption of benefit based on statistical inference of effect. Few of the published RCTs on the use of SWI, for example, included data relating to women's experiences of effectiveness.

2.2.4   *The rise of the natural birth movement and its influence on non-pharmacological pain relief*

By the mid 1930s the use of chloroform and forceps had become commonplace in an otherwise normal labour and birth. To illustrate this, Drife (2002, p. 314) cites a physician of the time commenting in a prominent medical journal that: *"I use chloroform and the forceps in every possible case, and have done so for many years"*. It has been suggested that this level of intervention may have contributed to the maternal mortality rate in the UK in 1935 being the same as it had been in 1840; however, calls for a more conservative approach led to numerous responses declaring that normal birth was not achievable for civilised women (Drife, 2002). Negative reaction to the technical and de-personalised approach of the obstetric profession was evident in the increasing popularity of the natural childbirth movement, a term coined by English obstetrician Grantly Dick-Read (1933) and which heralded his recognition as father of the movement. As previously stated, Dick-Read devised an approach to birth and motherhood that promoted the normality of birth and hence non-reliance on analgesic agents.

Dick-Read's philosophy of motherhood as a sacred calling was heavily influenced by his strong religious convictions, the English class system and the 'reformist eugenics' theories which promoted population growth in the middle classes as a means of providing a better quality of society (Moscucci, 2003). Dick-Read (1954) viewed natural birth as the seed for mother love which would transform society and abolish poverty and misery. Despite considerable, and often bitter, opposition from his medical colleagues, Dick-Read's ideas found favour with the public and were promoted through the NBTF (Moscucci, 2003). Kathleen Vaughan (1937), an obstetrician and contemporary of Dick-Read used her observations of women birthing in India to advance the three essentials of natural birth: a suitable pelvis; physical flexibility; and the use of a squatting position for birth. The natural childbirth movement was further developed through the work of Fernand Lamaze (1956) and the development of psychoprophylaxis, which was similar to Dick-Read's focus on the use of childbirth education, psychological preparation and breathing exercises, but without the religious and political connotations (Caton, 1999).

The establishment of the Royal College of Obstetrics and Gynaecology in 1947 coincided with a boom in post-war births in Western countries and a concentration of obstetric-led hospital care (Drife, 2002). Obstetric opposition to the natural childbirth movement contributed to the development of active management of labour; a strict regime focussed on the accurate medical diagnosis of labour, intervention, augmentation and control. Expounded by Dr Kieran O'Driscoll, an obstetrician practising in Dublin in the late 1960s, the premise of active management rested on labour lasting no longer than 12 hours as any prolongation past this point may *"cause permanent damage to a woman's personality"* (O'Driscoll, Stronge, & Minogue, 1973, p. 136). If birth had not occurred after 12 hours of labour a caesarean section (CS) was performed. The regime completely removed women from any participation or sense of control:

> It must be recognized that a primigravida, particularly with scant knowledge and no experience, is not qualified to make the crucial decision on which subsequent management depends. (O'Driscoll, Jackson, & Gallagher, 1969, p. 479)

The active management of labour regime was to become the basis for modern obstetric practice for the next 30 years; although, the 1970s saw a revitalisation of the natural childbirth movement as a reaction to the use of active management, fetal monitoring and birth in supine

and lithotomy positions (Mathews & Zadak, 1991). Although some of the ideas of the previous era, such as relaxation techniques and upright birthing positions, survived this new wave of the natural childbirth movement, there was a resurgence of feminism and consumerism which sought non-pharmacological alternatives to medical analgesics. Birth was seen as belonging to women who central to the choices about the care that they received, and how and where that care was provided (Mathews & Zadak, 1991). The champions of this era were French obstetricians Michel Odent and Fredrick Leboyer, both of whom espoused the use of water for labour and birth (Mathews & Zadak, 1991). Odent (1984) popularised water birth for pain relief in labour, while Leboyer (1974) recommended birth in tranquil surrounding; immediately submerging the newborn in water to counter the traumas of a traditional hospital birth.

The growing public interest in alternatives to the medical model of birth fostered the development of non-pharmacological alternatives for pain relief in labour, such as water immersion, transcutaneous electronic nerve stimulation (TENS), acupuncture and sterile water injections (Mathews & Zadak, 1991).

2.3   Sterile water injections as an analgesic agent

2.3.1   *The origins of sterile water injections*

Reference to the use of intradermal (also referred to as intracutaneous) injections of water (or saline) solutions to produce analgesia and anaesthesia first appeared in the literature at the end of the nineteenth century. Noted American surgeon, William Halsted (1885) reported achieving complete anaesthesia of the skin through cutaneous injections of water, as an alternative to cocaine-based agents, which were associated with toxic side effects (Ruetsch, Bajni, & Borgeat, 2001). Halstead (1885) noted that the area of analgesia did not extend past the area of the wheal, or bleb, created by the injection and the effect lasted beyond the time it took for the wheal to resolve. Although considered a suitable alternative to cocaine, the intense discomfort associated with administration was regarded as problematic (Anon, 1904). The synthesis of cocaine in 1891 led to the development of more conventional local anaesthetics in the late 1890s that offered more effective anaesthesia (Ruetsch, et al., 2001).

In the early 1900s, a solution containing sodium chloride, sodium sulphate and sterile water was used to treat the pain of sciatica (Launois, 1906). Four to six injections, varying in

anatomical depth, were administered over the areas of pain with the injections repeated on a daily basis, as needed. Although Launois (1906) did not report any specific data, he described the results as *"favourable"* and also recommended the method for relieving facial and intercostal neuralgia and lumbago.

Rose (1929) and Abrahms (1950) reported on the administration of intradermal injections of Novocaine, both abdominally and over the lumbar region, to relieve pain during the first stage of labour. Rose reported achieving significant analgesia effect; however, this was considerably diminished if the subcutaneous layer was infiltrated. Similar to injections of sterile water, local anaesthetics such as Novocaine resulted in a localised and intense pain and; therefore, may share a physiological mechanism with SWI.

2.3.2   Studies examining the efficacy of sterile water injections

The first randomised controlled, double blind study into the use of SWI to provide analgesia tested the procedure on thirty-two patients with renal colic pain compared to a control of normal saline injections (Bengtsson et al., 1981). The researchers recalled that the procedure had been used in a number of Danish urological departments since the mid-1960s after being described in Eastern European academic publications. The trial used four intradermal injections into the skin surrounding the area of pain and reported pain relief in 16 of the 18 patients receiving SWI. The analgesic effect was noticeable after one to two minutes and lasted from 90 minutes to four hours (Bengtsson, et al., 1981). French obstetrician Michel Odent also used sterile water injections to treat renal colic and labour pain and published one of the first commentaries on the subject (Odent, 1975).

Trolle, Hvidman and Guldholt (1986) cited the study by Bengtsson et al. (1981) as the basis for testing SWI on back pain for women in labour. The study treated 38 women in active labour (cervical dilatation equal to or greater than 4 cm) with injections of 0.1 ml of sterile water into four points surrounding the lumbar region of the lower back. A control group consisted of 38 women with back pain in labour who received no treatment. Prior to treatment allocation all women responded to questions regarding the intensity and localisation of their back pain, including scoring their pain on an ungraded Visual Analogue Scale (VAS). One hour following the intervention 30 women in the intervention group and 29 women in the control group replied to the same questions. Nineteen women in the intervention group reported a decrease in back pain compared with five women in the control group ($p<0.05$)

(Trolle, et al., 1986). The original article was printed in Danish; however an English translation does not mention if the allocation to treatment groups was randomised or non-randomised, or why a placebo was not considered for the control group. The study was referred to in the systematic review by Martensson and Wallin (Martensson & Wallin, 2008), but was not included in the review as it was deemed to be of low quality in terms of reported methodology.

A prospective cohort of 83 labouring women with back pain investigated whether the method described by Trolle et al. (1986) could be adopted as an alternative, or to complement, more common forms of pain relief (Lytzen, Cederberg, & Moller-Nielsen, 1989). In this paper the procedure was referred to as *"intracutaneous nocioceptive stimulation"* (Lytzen, et al., 1989, p. 341). Women participating in the study had not received pharmacological forms of pain relief prior to, or for one hour following, the intervention which consisted of the same number of injections and volume as described by Trolle et al., (i.e. four injections of 0.1 ml sterile water). Pain scores using a VAS were taken prior to, and at one hour following, administration. The mean total score for back pain prior to the intervention was 6.05 and one hour following the administration of SWI the mean score was 2.92 ($p<0.001$). Ninety-three per cent of women reported no back pain at one hour. Lytzen at al. (1989) states they found the duration of analgesia to be comparable to that experienced with pethidine and also provided the first detailed discussion regarding a possible physiological basis for the analgesic effect observed, citing pain modulation through the production of endogenous opioids, or the process of counter-irritation, as possible mechanisms. The authors concluded that the method has a place in obstetric analgesia; however, the study design was limited in its ability to clearly demonstrate a cause and effect.

The first randomised controlled trial (RCT) to include a double blind placebo group was conducted by Ader, Hansen and Wallin (1990) in Sweden. Forty-five pregnant women in the first stage of labour with low back pain were randomised to receive either four intradermal injections of 0.1ml of sterile water or four subcutaneous injections of isotonic saline as a placebo. Women participating had not received analgesia within three hours prior to being randomised. Twenty-four women were randomised to the treatment group and 21 to the placebo. Ader et al. (1990) noted that injections of isotonic saline are almost painless whereas injections of sterile water produce a brief but significant stinging sensation. In an attempt to

reduce the difference between the two treatments the injections were given during a uterine contraction; administering SWI during a contraction has since become standard practice. Blinding was achieved through the woman's primary midwife being absent from the room while a second midwife administered the injections. This midwife was under instruction not to discuss what kinds of injections were given or the woman's reaction to the treatment administered. The primary midwife returned to conduct the post-intervention pain scores, using a VAS at 10, 45 and 90 minute intervals. The midwife also recorded their own judgement of the analgesic effect of the treatment administered. At ten minutes the mean VAS score was found to be reduced in both groups, but the difference was more significant in the SWI group than the placebo group ($p<0.001$). The difference in mean VAS scores between the two groups was more pronounced at 45 minutes ($p<0.02$) and 90 minutes ($p<0.05$) in favour of the SWI group. Midwives also observed an analgesic effect more frequently in the treatment group than in the placebo group (17 versus 4, $p<0.001$). The study demonstrated that SWI produced an analgesic effect when compared to a placebo under randomised controlled conditions, and concluded that SWI appeared to be a simple and efficient method for alleviating back pain in labour (Ader, et al., 1990). The study was limited in that the authors did not indicate how the sample size was determined, the power of the study to determine the result, or how dropouts and missing data, if any, were managed.

The largest RCT to date on SWI using a four injection technique (Trolle, Moller, Kronborg, & Thomsen, 1991) included a sample of 272 women in labour with severe back pain. The sample size was sufficient to provide detection of at least 15% difference in pain scores between the two groups with a power of 90% (study group n=141, control group n=131). Treatment randomisation was achieved through identically labelled ampoules of either sterile water or isotonic saline that were randomly mixed then numbered and the attending midwife administered the injections using the next numbered ampoule. Visual analogue pain scores were taken prior to, and at one and two hour intervals following, administration. Unlike previous trials, women who had used other analgesia, such as pethidine and/or nitrous oxide inhalation prior to randomisation, were included in the study. Pain scores for women who had received pharmacological analgesia were not analysed or presented separately to determine if this influenced their scores and hence it could be argued that allowing the concurrent use of pharmacological analgesia during the time that the VAS was measured reflected a more realistic clinical situation. Mean pain scores, prior to administration, were similar for both

groups (83 mm SWI versus 81 mm placebo). After one hour; however, a significant difference between the mean pain scores was observed; 29 for the SWI group and 76 for the placebo group ($p<0.001$) and this remained at two hours: 53 SWI versus 82 placebo ($p<0.001$). The study reported no difference between the two groups in the use of analgesia following the intervention, nor in the rates of instrumental birth. Rates of labour dystocia requiring oxytocic augmentation were also similar between the two groups. However, the study did report a significantly lower CS rate in the SWI group compared to the placebo group (4.2% versus 11.4%, $p=0.5$). This study presents the strongest evidence to date of the efficacy of SWI to relieve back pain in labour. Unlike previous studies women were offered other forms of pharmacological analgesia, such as nitrous oxide inhalation and intramuscular pethidine (75 mg) prior to, or following, SWI.

These early studies contribute to the evidence supporting the clinical efficacy of SWI. As some of these studies (Bengtsson, et al., 1981; Trolle, et al., 1986) were not available in English, the significance of SWI as an emerging analgesic alternative may have been impacted to some degree by language bias i.e. the broader exposure and impact of English language articles to influence practice. Three of the studies reported in English (Ader, et al., 1990; Lytzen, et al., 1989; Trolle, et al., 1991) were later summarised by Reynolds (1994), who provided the first practical guide to the procedure and, on the basis of existing evidence, established the four intradermal injection technique as the accepted method for SWI. However, in the studies reviewed by Reynolds (1994), there were slight variations in how the four injection sites were determined. Subsequent studies have used variations in anatomical depth, volume of water injected and, particular to this study, the number of injections used. These variations in techniques are discussed in the following section.

2.3.3   *Establishing the anatomical position of the injection sites for the four injection technique*

The early studies demonstrated the efficacy of SWI in providing analgesia for back pain in labour and established the four injection intradermal technique as the norm. They described anatomical points at which the injections were given; however, they varied slightly in each study. For example, Bengtsson et al. (1981) described a particular rhomboid pattern (a geometrical diamond shape characterised by adjacent sides of equal length and angles) for the position of the four injections in relation to skeletal anatomical structures such as the iliac

spines and the lumbar and thoracic vertebrae. Trolle et al. (1986) based their study on the work of Bengtsson et al. (1981) and referred to the four injection sites as bordering the region of the sacrum. The first reference to anatomical landmarks as the site for the procedure was made by Lytzen et al. (1989) who used the posterior superior iliac spines (PSIS) as the initial position for the first two injections. The third and fourth injections were placed approximately three centimetres below and one centimetre medially to form a rhomboid pattern corresponding with Michaelis' Rhomboid; an anatomical region bound by the right and left PSIS, the spinous process of the fourth lumbar (L4) vertebrae and the upper part of the anal cleft (Schünke, Schulte, Ross, Schumacher, & Lamperti, 2006) (Figure 2.1). In this study the anatomical positions of the four injections as described by Lytzen et-al. (1989), were used.

First injection point;
Posterior superior
iliac spines (PSIS)

Second injection points; 3 cm
below and 1 cm medial to the
PSIS
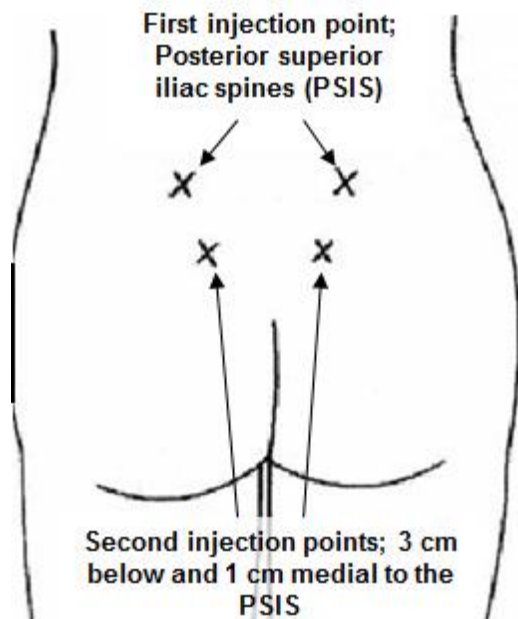
Figure 2.1: Anatomical position of injections based on Lytzen et al. (1989)

Dahl and Aarnes (1991) used the sacral area as a guide and asked women to define the borders of the painful area; these were used as the indicators to position the injections. Dahl and Aarnes (1991) also used between two and four injections; however, no direct comparison of the difference was reported. All trials reported an analgesic effect from SWI regardless of the position of the injection sites, which may indicate that precise anatomical positioning is not essential to the analgesic effect (Fogarty, 2008). As such, other factors associated with the

administration, such as the injection pain, may play a more pivotal role in triggering the analgesic response.

2.3.4   The single injection technique

Particularly relevant to the SWITCh Trial, this section discusses two trials that investigated the single injection technique to relieve back pain in labouring women. The initial trial (Bahasadri, et al., 2006) used an RCT design to compare SWI to a normal saline control in 100 labouring women in Iran. This study was also the first to use a calculated sample size based on a 30% reduction in pain scores with a power of 90% at a significance level of 0.05. Bahasadri et al. (2006) chose the subcutaneous route and used a single injection technique with a volume of 0.5 ml. The single injection was used in order to reduce the pain associated with the procedure and was given at the point, or area of the back, that women indicated was the most painful. There were differences used to determine pain scores between this and previous trials. Bahasadri et al. (2006) used a 'faces' rating scale instead of a VAS, citing varying degrees in education in the sample population as problematic and rendering the VAS too difficult to administer. However, it was noted, in a systematic review, that the rating scale published in the paper used a starting point of one, which differed slightly from that used in the trial, which started at zero (Fogarty, 2008). Bahasadri et al (2006) reported a significant reduction in pain scores for SWI compared to the normal saline group (p=0.01); however, they stressed that the trial was not designed to test the analgesic effect of a single versus four, injections.

Kushtagi and Bhanu (2009) largely repeated the methodology used by Bahasadri et al. (2006) using the same sample size and the single injection technique, but using a fixed anatomical point, the centre of Michaelis' Rhomboid, as the site for the injection. They reported a reduction in pain of 50% at 45 minutes following the single SWI, which they cited as being less than the 73% reduction from pre-injection VAS scores reported by Martensson and Wallin (1999) using a four injection technique. However, in the trial by Kushtagi and Bhanu (2009), the post-injection pain assessments were recorded by the investigators and not persons independent of the research; therefore, bias cannot be excluded. As the two trials (Bahasadri, et al., 2006; Kushtagi & Bhanu, 2009) using the single injection technique produced slightly different results from trials using the four injection technique, this reinforced the need for a study specifically designed to compare the two techniques.

The efficacy of the single injection technique had also been previously studied in Iran for patients with renal colic pain, who were recruited to an RCT comparing SWI to a normal saline placebo (Ahmadnia & Younesi Rostami, 2004). A single intradermal injection of 0.5 ml was administered at the most painful point and this trial reported a mean reduction from a pre-treatment VAS of 9.9 cm to 1.02 cm at 60 minute (*p*=0.000). This equates to a 90% reduction in pain suggesting that a single injection using a greater volume may increase the degree of analgesia. However, there are obvious differences in the pain associated with renal colic compared to labour that extend beyond similarities in VAS scores. Specifically, back pain often constitutes only one element of labour pain and although it may be relieved, the contraction (abdominal) pain generally persists. Therefore, VAS scores from the use of SWI in labour may be influenced by unrelieved contraction pain and; hence be scored higher. In comparison, the pain of renal colic is localised and unaccompanied by other pain; therefore, any analgesic response may be more readily perceived and result in a lower VAS score.

Similar to studies investigating the four injection technique, the three aforementioned studies involving a single injection also reported a statistically significant difference between the intervention and control groups. It is not possible to make any direct comparison of the two techniques from these studies due to differences in research design, data measurement, analysis and reporting. Therefore, it remains plausible that a single injection may offer analgesia that is clinically as good as four injections. As previously discussed, reducing the number of injections may have benefits for labouring women in terms of a reduction in procedural discomfort and also for midwives in offering a simpler and faster technique. Hence a comparison of the analgesic effects of the single and four injection techniques is the main focus of this research.

2.3.5   *Injection pain associated with sterile water injections*

The intense pain associated with the SWI, which lasts for about 20 to 30 seconds, is consistently described throughout the literature and has been discussed in studies conducted outside the field of obstetrics. For example, Byrn, Borenstein, and Linder (1991), reported the use of intradermal SWI on ten patients with whiplash syndrome. They found that although the treatment resulted in a reduction in pain and an increase in mobility in all cases, the intense pain associated with the injections was reported as very unpleasant for the patients, particularly when repeat injections were required. The pain associated with the injections has

been depicted as being like that of a *"wasp sting"*, a description cited in the literature (Byrn, et al., 1991; Byrn et al., 1993; Martensson & Wallin, 2008). Byrn et al. (1993) repeated their initial study (Byrn, et al., 1991) using subcutaneous injections and reported that these were less painful; however, they offered no data to support this assertion. In a preliminary evaluation, Peart et al. (2006) reported that, women in labour with back pain and a VAS score of less than seven may find the pain of the injections unacceptable compared with the resulting analgesia. Similarly, in an RCT comparing SWI to other types of analgesia for back pain in labour, participants in the SWI group, who had higher VAS scores for pain prior to treatment, were more likely to use the procedure again in a subsequent labour than women with lower initial VAS scores.

Reynolds (1994), notes that some maternity practitioners advocate administering the injections during a uterine contraction to mitigate the intensity of the pain. Other studies also described this approach (Dahl & Aarnes, 1991; Kushtagi & Bhanu, 2009; Martensson & Wallin, 1999; Wiruchpongsanon, 2006) either to reduce the effect of the stinging sensation or to mask differences between the sterile water and normal saline solutions, which is associated with markedly less pain. Dahl and Aarnes (1991) noted that, based on VAS scores, the injection pain of sterile water increased the pain of a contraction by eight%.

A study comparing skin pain in humans following injection of water-soluble substances (Lindahl, 1961) found that hypotonic distilled water was considerably more painful than isotonic saline (4.05 versus 1.33 pain intensity units) and the duration of the pain lasted about 40 seconds, compared with eight seconds for saline.

Two systematic reviews of the SWI research (Fogarty, 2008; Martensson & Wallin, 2008) commented on the impact of the injection pain on the acceptability of the procedure to women in labour. Results showed that the intense pain of the injections discourages women from requesting repeat injections or considering using SWI in future labours. Prior to the current trial, it was not known if the use of a single injection would result in significantly less pain compared to the more commonly used four injection technique and would; therefore, increase acceptability.

2.3.6   Intradermal versus subcutaneous injections

Martensson and Wallin (1999) undertook a three arm RCT comparing the effect of intradermal SWI (n=33), subcutaneous SWI (n=33) and a subcutaneous normal saline placebo (n=33). The aim of the study was to determine if the analgesic effects were similar and if the subcutaneous route was less painful than the intradermal route; the sample size was estimated *a priori* based on a previous study (Ader, et al., 1990). Based on VAS scores, no differences were reported between the two treatment groups, compared to the placebo, in terms of analgesic effect. To elucidate differences in pain associated with administration, women were asked to rate their pain using the VAS at two minutes following the injections. No differences were reported between the two treatment groups; however, as women were able to use inhalational analgesia (Nitrous Oxide) during the administration of the injections this may have masked any difference between the two groups (Martensson & Wallin, 1999). The study authors also commented that the injections were given at the height of a contraction and thus, women may not have been able to distinguish the pain of the injection from the pain of a contraction. Interestingly in this study, more women stated they would use the intradermal injections again in subsequent labours, than those receiving the subcutaneous injections.

In another study, Martensson (2000) used a crossover design involving 100 healthy non-pregnant female volunteers to once again attempt to determine if the subcutaneous route was less painful than the intradermal. Participants were randomised into two groups, one group receiving sterile water intradermally and the other subcutaneously; VAS scores of the injection pain were taken following administration. One week later the participants returned and received the opposite to what they had previously been administered. The women rated the pain from the intradermal method higher than the subcutaneous method (mean 60.8 versus 41.3, $p<0.001$) and hence the authors concluded that the subcutaneous route was less painful than the more commonly used intradermal route. However, it was highlighted that there may be differences transferring the results from a non-pregnant group of women without pain to a pregnant group experiencing pain. Despite this finding the intradermal route appears to be the most commonly used technique in research, as evidenced by five out of the seven recent trials (Gao, 2008; Martinez Galiano, 2009; Peart, et al., 2006; Saxena, Nischal, & Batra, 2009; Wiruchpongsanon, 2006). The majority of midwives in Sweden, the USA and Australia also reported using the intradermal route in clinical practice (Lee, Martensson, & Kildea, 2012; Martensson, McSwiggin, & Mercer, 2008a; Martensson & Wallin, 2006).

2.3.7   Variations in the injected volume for the intradermal technique

A number of studies have varied the volume of sterile water injected at each site. Often, visual assessment, by the clinician, of the bleb resulting from the injection is used to determine the actual volume of sterile water injected. Hence, the range in volume is used to overcome any variations in technique. For example, an Australian study (Peart, et al., 2006) recruited a prospective cohort of 60 women in labour, with back pain, from two hospitals and injected between 0.1 ml and 0.5 ml into each of the four points surrounding Michaels' Rhomboid. Similarly, another study (Saxena, et al., 2009) used 0.5 ml of sterile water in an RCT involving 100 pregnant women in India. Both studies stated they used the larger volume to overcome any difficulties encountered by the clinicians or variations in determining the anatomical sites when administering the injections. The resulting pain scores were consistent with previous studies using more rigid injection volumes; however, as the scores were not reported in relation to the amount of sterile water injected, neither study could demonstrate any greater duration of analgesia related to the increased volume.

A non-randomised trial examining the effectiveness of SWI in Spanish women (Martinez Galiano, 2009) used a small volume of 0.05 ml to 0.1 ml in the four injection sites and reported a decrease in pain scores following the treatment. The investigators describe duration of analgesia of 60 to 90 minutes although only scores for the first 10 minutes post SWI were reported. Variations in injected volume also occur in clinical practice. A cross-sectional study of Australian midwives using SWI, reported considerable variation in injected volume amongst clinicians ranging between 0.1 ml and 0.5 ml (Lee, et al., 2012). In summary, as with the variations in tissue depth (intradermal versus subcutaneous), there is insufficient evidence to determine if differences in the volume of sterile water injected at each site impacts upon the efficacy of analgesia, i.e. if there is a dose-related effect and, if so, the minimal volume required to initiate the analgesia.

2.3.8   The systematic reviews of clinical trials on sterile water injections

A number of systematic reviews have been published in this field, the first of which was undertaken by Martensson and Wallin (2008) who reviewed six trials taking place between 1990 and 2006 (Ader, et al., 1990; Bahasadri, et al., 2006; Labrecque, Nouwen, Bergeron, & Rancourt, 1999; Martensson & Wallin, 1999; Trolle, et al., 1991; Wiruchpongsanon, 2006). Each trial was scored using the Jadad scale (Jadad, et al., 1996) which rates the quality of

RCTs from zero to five, based upon the reporting of randomisation, blinding, withdrawals and dropouts; all the trials included in the review scored three or more. Martennson and Wallin (2008) reported a 60% reduction in pain scores following SWI in all trials compared to control groups with the effect lasting for up to two hours. However, as the review included the single injection study by Bahasadri et al. (2006) the review authors questioned if the number of injections influenced effectiveness of the analgesia.

A second systematic review (Fogarty, 2008, p. 159) evaluated the same six trials as Martennson and Wallin (2008), commenting that all trials had been published in *"reputable and well respected"* journals. Fogarty noted, in particular, the reduction in CS rates reported by Trolle et al. (1991) and concluded that, as the results of the single injection trial (Bahasadri, et al., 2006) had compared favourably with those from the four injections trials, further research was required to determine any benefit of four over a single injection.

A systematic review and meta-analysis (Hutton, et al., 2009) evaluated eight trials published between 1990 and 2009 (Ader, et al., 1990; Bahasadri, et al., 2006; Kushtagi & Bhanu, 2009; Labrecque, et al., 1999; Martensson, Stener-Victorin, & Wallin, 2008b; Martensson & Wallin, 1999; Trolle, et al., 1991; Wiruchpongsanon, 2006). The trials were assessed using a modified Jadad Scale (1996) and all but one trial (Ader, et al., 1990) was rated as high quality trials. The primary outcome for the meta-analysis was CS. The reviewers reported the CS rate in the SWI group as 4.6% and 9.9% in the comparison groups (n=828) (RR 0.51, 95% CI: 0.30, 0.87) and suggested explanations for this effect such as SWI providing increased parasympathetic uterine tone, and/or increased relaxation of the pelvic muscles, promoting the normal mechanism of fetal rotation and descent. The review also examined differences in pain scores at time intervals of 10–30 minutes, 45–60 minutes and 90–120 minutes; a significant reduction in pain scores for SWI groups was reported compared to placebo or comparison groups (Hutton, et al., 2009).

A Cochrane Review (Derry, Straube, Moore, Hancock, & Collins, 2012) of seven SWI trials (n=766) using blinded controls of normal saline (Ader, et al., 1990; Bahasadri, et al., 2006; Kushtagi & Bhanu, 2009; Martensson & Wallin, 1999; Saxena, et al., 2009; Trolle, et al., 1991; Wiruchpongsanon, 2006). Although all the trials reported a statistically significant difference in mean VAS scores between treatment and control groups, the review authors, citing previous work by Moore (2005), highlighted that many of the trials did not report

statistical aspects, such as normal distribution of VAS data which may affect the clinical generalisation of the results. (For a detailed description of the relationship between normal distribution and VAS data please refer to the Research Design chapter). The review authors also concluded that the trials were too heterogeneous to enable a meta-analysis; although, Hutton et-al. (2009) did in fact conduct a meta-analysis on a number of the included trials (Martensson, et al., 2008b; Martensson & Wallin, 1999; Trolle, et al., 1986; Wiruchpongsanon, 2006) using Mantel–Haenszel fixed-effects modeling to account for significant levels of heterogeneity, that did report a significant analgesic effect for SWI. To prevent against further heterogeneity in future SWI RCTs, Derry et al. (2012) established a benchmark for clinically relevant outcomes, including a percentage reduction in pain (≥50% and ≥30%) and maternal satisfaction and used this for the basis of their review. However, as no previous SWI RCTs had examined these outcomes, the authors concluded that there was little robust evidence that SWI was effective for the relief of back pain in labour and recommended that further research was needed to establish the clinical efficacy of SWI using the reporting criteria outlined in the Cochrane review.

2.3.9   *Limitations of published clinical trials on sterile water injections*

The four published systematic reviews revealed a number of limitations in the published RCTs on SWI (Derry, et al., 2012; Fogarty, 2008; Hutton, et al., 2009; Martensson & Wallin, 2008). The trials generally had small numbers of participants and only one trial (Bahasadri, et al., 2006) reported a sample size calculation based upon a reduction in pain scores. Two trials reported sample sizes *a priori* (Kushtagi & Bhanu, 2009; Martensson & Wallin, 1999). Design aspects such as allocation concealment and blinding were not reported in three trials (Ader, et al., 1990; Trolle, et al., 1991; Wiruchpongsanon, 2006) which may have led to bias. Only one trial (Bahasadri, et al., 2006) reported completed data for all time-based outcomes such as VAS scores. Trials reporting missing data did not provide details on drop-outs.

It is worth noting that a number of the early SWI trials predate the establishment of the Consolidated Standards of Reporting Trials (CONSORT) Statement, which was first published in 1996 (Begg et al., 1996).

There is remarkable consistency in the outcomes of the trials with regards to the analgesic effect in the experimental groups compared to placebo and other interventions. However, the limitations noted nonetheless detract from the robustness of the evidence and may account for

the differences and difficulties in acceptance of the procedure between midwives and other clinicians. The four aforementioned systematic reviews all highlighted the need for further high quality trials and, of relevance to this study, the comparison of a single versus four injection technique (Fogarty, 2008; Martensson & Wallin, 2008).

2.3.10 Sterile water injections compared to other forms of analgesia

A small number of studies have compared SWI to other pharmacological and non-pharmacological forms of analgesia commonly available to labouring women. A prospective study (n=1024) recorded women's assessment of pain and response to SWI, nitrous oxide inhalation, pethidine, and paracervical (local anaesthetic injected into the vagina below the cervix) or epidural blocks (Ranta et al., 1994). Assessment of pain was determined by pre and post-analgesia VAS scores taken during the latent, active, transitional and third stages of labour. Women also completed a questionnaire regarding their pain experience on the third day postpartum. The researchers reported that only epidural blocks significantly reduced pain scores across all phases of labour. On day three SWI was rated as comparable to pethidine and better than nitrous oxide in terms of pain relief. Within this same study pain comparisons were not restricted, or necessarily related to, back pain although it can be reasonably assumed that only women with back pain requested and received SWI. All women involved in the study were monitored throughout their labours by continuous cardiotocograph (CTG) restricting them to a supine position. This may well have increased their pain and analgesic requirements as studies at the time indicated that an upright position and unrestricted ambulation significantly decreased analgesia requirements in labouring women (Flynn, Kelly, Hollins, & Lynch, 1978), and specifically those with back pain (Melzack, Bélanger, & Lacroix, 1991).

An RCT compared a four point SWI of 0.2 ml per injection to 75 mg of diclofenac sodium (a non-steroidal anti-inflammatory drug) intramuscularly and a third placebo control group of normal saline, in 119 participants with renal colic pain (Sigirci et al., 2005). Pre-treatment pain VAS scores were above eight in all three groups. At all time points prior to 120 minutes, patients in the SWI group recorded lower pain scores from those in the diclofenac sodium group. Notably at five minutes the difference was 2.1 (SWI) versus 8.3 (diclofenac sodium) (*p*=0.001). Patients in the placebo group who reported no analgesia effect after 30 minutes (n=40) were treated with either of the interventions. The authors concluded that SWI was

superior to diclofenac sodium in rate of onset, quality and duration of analgesia for patients with renal colic pain.

One RCT compared SWI to other routinely used forms of non-pharmacological pain relief for back pain in labour. Labrecque, et al. (1999) randomly assigned 34 women with low back pain in labour to either SWI, trans-electrical nerve stimulation (TENS), or standard care. Standard care was defined as low back massage, followed by immersion in a whirlpool bath or liberal mobilisation, depending on the woman's preference. Sterile water injections consisted of four injections of 0.1 ml into the lumbo-sacral area, based on a description of the technique by Reynolds (1994) using the posterior superior iliac spines as the reference points. The primary outcome was the intensity and unpleasantness of the back pain, determined by VAS at 15, 60, 90, 120 and 180 minute intervals. Women in the SWI group rated their back pain significantly lower than the TENS group (p=0.003) and the standard care group (p=0.001). No differences in epidural use or birth outcomes were noted between the three groups; however, this may have been due to the small sample size. Acupuncture was compared to SWI in a study involving 128 women in spontaneous labour at term experiencing at least three contractions every 10 minutes. (Martensson, et al., 2008b). The inclusion criteria required that women had not received any other pharmacological analgesia in the ten hours prior to randomisation to either acupuncture or SWI, and they were stratified by parity. The locations of acupuncture points were based on current clinical practice; the injections sites for SWI were based on the areas where the women felt their pain most intensely. As such, the use of SWI was not restricted to back pain. The SWI technique consisted of four to eight subcutaneous injections of 0.5 ml of water. Pain scores were assessed, by VAS, immediately before and at 30 minute intervals up to 180 minutes. The researchers reported that SWI provided greater pain relief than acupuncture (p=0.001) and a greater degree of relaxation (p=0.001). There were no significant differences in requirements for additional pain relief. Martensson et al. (2008b) commented that the reduction in the VAS score was less pronounced in the SWI group than in previous studies and that this may be related to the use of SWI for labour pain other than back pain. Separate pre and post-treatment scores for abdominal or back pain were not reported. The theory that SWI may be more effective for the relief of back rather than abdominal labour pain is further supported by the results of another non-randomised study comparing SWI to dry needling (where needles were inserted into the skin but no injection given) (Dahl & Aarnes, 1991), in which SWI was used to relieve both

abdominal and back pain. The numbers of women reporting at least a 50% reduction in pain was greater in those who received SWI for back pain (69.7%) than abdominal pain (26.9%). The reason for the difference in effect between the two anatomical sites was uncertain.

These studies indicate that SWI compares favourably to other forms of non-pharmacological pain relief, such as acupuncture, TENS, water immersion, massage and unrestricted ambulation for the relief of back pain in labour. The procedure may also be comparable to the use of intramuscular pethidine, diclofenac sodium and inhalational nitrous oxide for the relief of back pain. Such findings support continued inquiry into SWI as an effective analgesic strategy.

2.3.11 Studies not reporting pain relief from sterile water injections

Not all studies involving SWI for pain relief have favoured the intervention. An RCT (n=117) investigating the use of SWI in myofacial pain syndromes, compared to normal saline, found no difference in rates of analgesia between the two groups (Wrege & Brorsson, 1995). Each participant received 0.5 ml injected intradermally at identified trigger points. The researchers reported that patients found the sterile water injections significantly more painful than the normal saline group (*p*=0.001) and although they reported a statistically significant reduction in pain on rotation of the cervical spine (touching shoulders to chin) (*p*=0.05), this was a secondary outcome measure. Although the sample size may not be sufficient to support the generalisation of this result, the study does imply some limitations on the types and/or locations of pain that SWI may be effective for.

2.4   Back pain in labour

2.4.1   Incidence and causes of back pain in labour

A small number of studies have examined the frequency and causes of back pain in labour. An early study (Melzack & Schaffeberg, 1987) asked 46 women in early labour (cervical dilatation of 2–3 cm and contractions less than five minutes apart) to complete the McGill Pain Questionnaire (MPQ), rating the quality and intensity of pain using a list of descriptors. Fifteen women were asked to track their labour pain by turning a knob on a hand-held box that recorded the output on a polygraph; their contractions were simultaneously recorded on a CTG. The results indicated that there were three types of labour pain that were characteristically different from each other: abdominal contraction pain (96%); intermittent

low back contraction pain (74%); and continuous low back pain (33%). The highest pain levels recorded by the polygraph occurred when women had low back contraction pain superimposed upon continuous low back pain. When this combination occurred the women described the contraction pain as *"riding on"* the continuous back pain and as being unrelenting and exhausting. Melzack and Schaffelberg (1987) reported that the causes of continuous low back pain in labour are uncertain and likely to be multi-factorial.

A prospective cohort study of 93 Taiwanese low risk women in labour at term reported that 75.3% of participants experienced low back pain during labour with 45.7% being continuous (Tzeng & Su, 2008). The severity of pain was determined with a self-reported VAS resulting in scores varying between 36.6 and 76.2 (using a 100 mm VAS). The most common area for back pain was the lumbar region, most likely occurring in the latent and early active phases of labour.

2.4.2   Is back pain in labour normal?

There is little evidence to demonstrate whether, considering the relative frequency of occurrence, back pain in labour represents a normal or abnormal variation of labour pain. Some authors (Leap, Dodwell, & Newburn, 2010a) have proposed that normal labour pain will occur to a degree that most women are able to bear without the need for pharmacological analgesia, and that severe or abnormal labour pain, requiring analgesia, may be indicative of pathology including malposition of the fetus. Some studies have also suggested a relationship between severe labour pain and CS birth (Hess, Pratt, Soni, Sarna, & Oriol, 2000); however, no studies have yet distinguished between back pain, abdominal labour pain and birth outcomes such as an increased need for epidural analgesia or CS.

2.4.3   Factors associated with back pain in labour

A number of factors have been associated with back pain in labour; however, not all studies have reported the same association. An early study exploring correlations between low back pain in labour, menstrual pain and back pain before and during pregnancy, found an association between women who experienced back pain during menses and during labour (Melzack & Belanger, 1989). This study also found a strong association between a history of back pain and the occurrence of back pain in pregnancy, but not in labour. A review of studies that explored risk factors for back pain in pregnancy found general agreement with the association with previous back pain (Ansari, Hasson, Naghdi, Keyhani, & Jalaie, 2010). The

aforementioned study of Taiwanese women (Tzeng & Su, 2008) also found a statistically significant association between high body weight and back pain in labour. Although the authors did not define parameters for body weight, they stated that this may be a cultural phenomenon as Taiwanese women are generally encouraged to gain weight during pregnancy and cited local data indicating that 80% of pregnant Taiwanese women are overweight (Tzeng & Su, 2008). This study reported an association between back pain in pregnancy and the occurrence in labour, contradicting the findings of Melzack and Belanger (1989); no other studies have examined this relationship. The correlation between the experience of back pain during menses and labour may indicate a similar underlying neurological pathway of referred pain (Melzack & Belanger, 1989).

The occipito-posterior (OP) fetal position has also been reported to be a cause of back pain in labour (Reynolds, 2000). The OP position nearly always includes some degree of deflexion of the fetal skull away from the most advantageous position, presenting a larger diameter as it enters and progresses through the maternal pelvis; causing delay in descent of the fetal head during labour and reduced contact with the cervix. Therefore, the OP position is often associated with labour dystocia, characterised by slow progress in the first and second stages of labour and increased pain (Kjaergaard, Olsen, Ottesen, Nyberg, & Dykes, 2008; Selin, Wallin, & Berg, 2008). One systematic review (Fogarty, 2008) noted the universal agreement amongst researchers that the OP position was a common contributing factor to back pain in labour, although one study (Melzack & Belanger, 1989) found no such correlation.

A cohort study used serial ultrasound scans to determine the changes in fetal position in labour (n=1562) (Lieberman, Davidson, Lee-Parritz, & Shearer, 2005). Ultrasound scans of fetal position were undertaken at enrolment to the study, four hours later, at insertion of epidural and after the participants had progressed further than eight cm cervical dilatation; the fetal position at birth was also noted. At enrolment 24.0% of fetuses were in the OP position compared to 26.9% in the occipito-anterior (OA) position and 36% of fetuses were in an OP position at some point during labour. The study authors did not report any association between back pain in labour and OP position, with almost equal numbers (28% vs 26%) of participants reporting back pain in labour with an OP and an OA position respectively. The study did report a strong association between epidural use and OP position at birth (RR 4.0, 95% CI 1.5, 10.5). In a review of the literature on OP position, Simkin (2010, p. 64) describes

the association between OP position and back pain as a *"prevailing concept"* held by many clinicians and childbirth educators, which is often used as the basis for action and advice related to relieving pain and anticipating that the fetus will rotate to a more favourable OA position. Simkin (2010) observes that this approach may exclude women with a fetus in an OP position who do not experience back pain and questions the validity of this long held belief, which concurs with the findings of Lieberman et al. (2005).

The lack of congruence between the causes for back pain in labour may indicate that the origin is indeed multi-factorial. Individual women's variances with respect to physiology, pain perception and tolerance, and the unique phenomenon of referred pain, may contribute to the variance.

2.4.4   Neurophysiology of referred back pain in labour

Referred pain has been defined as *"pain felt at a site remote from the site of origin/stimulation"* (Arendt-Nielsen & Svensson, 2001, p. 11). Referred pain has specific features including: a time delay between the original pain or stimulation; the development of referred pain and; that referred pain is often located in adjacent neural segments. The pathway of referred pain is also not bi-directional, i.e. the stimulation of the area of referred pain does not, in turn, produce pain at the original site (Arendt-Nielsen & Svensson, 2001; Laursen, Graven-Nielsen, Jensen, & Arendt-Nielsen, 1997). The following section describes the neurophysiology of referred back pain.

Pain impulses from the uterus and cervix are transmitted to the spinal cord by thinly myelinated A-delta fibres and smaller visceral non-myelinated C fibres, carried in the sympathetic pathways and communicating with the posterior roots of the T10, T11, T12 and L1 nerves to the spinal cord (Bonica, 1979). The cutaneous branches of the T10–L1 nerves are large myelinated A-beta fibres that supply the skin at a lower level, between L2 and S1 (Bonica, 1979). Compared to the larger myelinated A-beta fibres, nerve impulses travel more slowly along the A-delta and C fibres due to the reduced or absent myelin sheath. A-delta and C fibres specifically carry pain nerve impulses whereas A-beta fibres are not usually associated with transmission of pain information (Godfrey, 2005). The three types of fibres all converge in the dorsal horn of the spinal cord (Trout, 2004).

The precise mechanism for referred pain remains unclear although a number of theories have developed to explain the phenomenon (Laursen, et al., 1997), generally revolving around either the convergence, or bifurcation, of neural structures (Arendt-Nielsen & Svensson, 2001; Graven-Nielsen, Arendt-Nielsen, Svensson, & Staehelin Jensen, 1997; Laursen, et al., 1997). The convergence facilitation, or central sensitisation, theory originally described by Mackenzie (1893), suggests that an afferent stimulus to the spinal cord from a localised area, such as the uterus and cervix, could create an irritable focus in the dorsal horn of the spinal cord causing abnormal afferent somatic impulses perceived as referred pain (Arendt-Nielsen & Svensson, 2001; Laursen, et al., 1997). This theory supports the observation of the time delay in the development of referred pain as stimulation of the slower nocioceptive A-delta and C fibres would build up and essentially *"feedback"* through the faster multi-sensory A-beta cutaneous fibres.

During labour there is significant distension of the lower segment of the uterus and stimulation of pain sensitive structures in the pelvic cavity. Bonica (1979) identified five possible causes of referred back pain in labour: traction and pressure on the adnexa; stretching of the parietal peritoneum and surrounding structures; compression and stretching of the bladder, urethra and rectum; compression and stretching of ligaments, fascia and muscles of the pelvic cavity resulting in muscle spasm and vasospasm; and pressure on one or more roots of the lumbo-sacral plexus. The latter produces severe pain in the lower back that is referred by the cutaneous branches (Melzack & Belanger, 1989). Therefore, to relieve referred back pain, analgesia should be centred in the area of L2–S5 (Bonica, 1979). This corresponds with the area of Michaelis' Rhomboid. Hyper-stimulation or counter-irritation of the A-beta fibres such as would be achieved through the injection of sterile water at a point surrounding Michealis' Rhomboid, may affect the mechanism of referred pain, essentially producing referred analgesia (Trolle, et al., 1991).

A study by Laursen et al. (1997) found that application of a topical anaesthetic cream to the skin area of referred pain significantly reduced the perception of pain, indicating that referred pain may depend on input from large peripheral myelinated nerves. Rose (1929) and Abrahms (1950) used intradermal infiltration of local anaesthetic across the abdomen and lower back to relieve the pain of labour, indicating that elements of this are referred through the nerves servicing the skin covering the abdomen.

2.4.5   Counter irritation and theories of pain modulation

Of two pains occurring together, not in the same part of the body, the stronger weakens the other. (The aphorisms of Hippocrates) (Wolff & Hardy,. 1947, p. 167)

Counter-irritation has been an important method of pain relief employed by physicians for centuries and has been described as the phenomenon of reducing pain caused by one stimulus through the application of a second (noxious) stimulus (Melzack, 1975b). Anthero, in the reign of emperor Tiberius, was apparently cured of gout after stepping onto a live torpedo, an electric fish of the ray family (Wand-Tetley, 1956). More conventional methods of counter-irritation such as the application of heat and cold, vibration and massage have been used to provide analgesia (Gammon & Starr, 1940) and are still commonly used by midwives and birth attendants to relieve pain in labour. Each of the systematic reviews acknowledge that there is general agreement within the studies supporting SWI, that the analgesic effect is based on either counter-irritation as described by the gate control theory (Melzack & Wall, 1965) or the theory of Diffuse Noxious Inhibitory Controls (DNIC) (Le Bars, et al., 1979).

2.4.6   The gate control theory

The gate control theory of pain transmission (Melzack & Wall, 1965) describes how pain can be modulated at the level of the spinal cord. The theory identifies the portion of the dorsal horn called the substantia gelatinosa, an area consisting of densely packed cells that extends the length of the spinal cord, as the functional unit responsible for modulating the transmission of nerve impulses from peripheral fibres to the cells of the spinal column. Essentially acting as a gate that remains open to the normal and constant transmission of nerve impulses from the A-delta and C nerve fibres, these small myelinated and unmyelinated fibres adapt slowly to noxious stimuli, dominating the receptor cells within the substantia gelatinosa holding the gate open. When a noxious stimulus is applied to the skin the larger and faster A-beta fibres are stimulated; this stimulus produces a disproportionate increase in large over small, fibre activity. Depending on the severity and duration of the stimulus, more receptor cells are recruited to receive impulses from the A-beta fibres which closes the gate to the smaller, slower nerve fibres (Melzack & Wall, 1965). The three types of nerves all converge at the same neural segment.

The gate control theory also explains neurological function and the ability of the central nervous systems ability to exert central control over the excitability of the nerve cells that transmit information about pain. This central control is determined by genetic and sensory influences (Melzack, 1999) and is mediated through the gate control system (Melzack & Wall, 1965; Wall, 1978). The original theory was limited by lack of knowledge about neurological anatomy and physiology (Wall, 1978) and although revisions have since occurred, the basic premise of the theory remains unchanged; i.e. that the gate, allows transmission of noxious stimuli and is influenced by thresholds of input and impulses descending from the brain (Dickenson, 2002; Wall, 1978). The original paper by Melzack and Wall (1965) outlined the therapeutic implications of the theory and the basis for subsequent research; that the control of pain could be achieved through selectively stimulating large fibre input, as occurs with the injection of hypotonic sterile water.

2.4.7 *Diffuse Noxious Inhibitory Controls*

Diffuse Noxious Inhibitory Controls (DNIC) refers to the inhibition of the transmission of noxious or painful nerve impulses in the dorsal horn of the spinal column by a noxious or painful stimulus applied to a region of the body remote to the stimulus (Le Bars, et al., 1979; Morgan & Whitney, 1996). The physiology of DNIC has been suggested as the neural basis for counter-irritation (Le Bars, et al., 1979). Although the analgesic effects of counter-irritation have been demonstrated to be most effective when applied to the skin directly over, or in close vicinity, to the pain (Gammon & Starr, 1940), the premise of DNIC is that modulation of pain can be stimulated by counter-irritation applied to any part of the body, no matter how remote from the affected area. The DNIC consists of a complex supraspinal loop that responds to the stimulus of competing A-delta and C peripheral nerve fibres. Noxious or painful stimuli are transmitted to the subnucleus reticularis dorsalis in the medulla of the brain stem. Stimulation of this area produces inhibition of wide, dynamic range, neurons in the spinal cord (Westlund, 2005).

The actual mechanism of DNIC is unknown but is likely to involve production of neuro-chemicals and endogenous opioids, such as endorphins, which may be dependent on the type of noxious stimulus. For example, a recent animal study by Wen et al. (2010) compared DNIC responses, stimulated by either an electrical or chemically-induced pain stimulus, and found only those induced by chemicals were reversible by a narcotic antagonist (naloxone).

As DNIC only applies to stimuli from the smaller A-delta and C nerve fibres, it is independent of the segmental stimulation of larger A-beta fibres as described in the gate control theory. Hence, the effect is mediated supraspinal to the dorsal horn and is considered a descending inhibitory response.

Gate control theory and DNIC have been considered as explanations for the analgesic effects of counter-irritation generally, and SWI specifically. Both theories illustrate the complex processes involved in the transmission and perception of pain and the self-modulating abilities of the neurological system. Although neither theory is conclusive or complete, each acknowledges other influences such as personal and cultural experiences (Melzack, 1999), ethnicity, gender and age (van Wijk & Veldhuijzen, 2010).

2.5   Women, back pain in labour and sterile water injections

2.5.1   Women's experiences with sterile water injections

Only a small number of the studies investigating the analgesic benefits of SWI in labour reported data on participants responses to questions regarding the effectiveness of SWI and whether they would consider using SWI as an analgesic in a subsequent labour (Labrecque, et al., 1999; Lytzen, et al., 1989; Martensson & Wallin, 1999; Trolle, et al., 1991). Most of these studies used closed question response scales reported as secondary outcomes; which the small sample sizes of these studies further limited the generalisation of the results, which are summarised in Appendix 2.

One study (Lytzen, et al., 1989) asked participants (n=83) whether they considered the analgesia derived from SWI to be sufficient in both the first and second stages of labour. Participants were also asked if they would use SWI for their next labour. Most participants indicated that they found SWI to be effective in the first stage (78%) compared with the second stage of labour (53%). The study authors indicated that a small number of women received repeat injections but not the stage of labour at which this occurred. It would have been interesting to know if women who found SWI effective in first stage labour reported equal or less effect in second stage. The majority of participants (80%) also indicated they would use SWI again in a subsequent labour. It was not reported if the survey tool had been piloted or validated prior to use, which may limit the generalisation of any conclusions drawn. Nevertheless, the study concluded that the method was well accepted by the participating

women. Similarly, in their trial comparing SWI to a normal saline placebo, Martensson and Wallin (1999) also questioned the effectiveness and women's intention to use SWI in the future and reported similar results to those of Lytzen et al. (1989); however, 58% of participants receiving the placebo also indicated they would use that intervention again. Another RCT (Trolle, et al., 1991) also asked women if they would use SWI in labour again; fewer women in this study indicated yes (69%) and, again, half (50%) of the participants who received the placebo also indicated an intention to use this again. As a placebo, normal saline is known to produce a mild and brief analgesic response, which may account for the number of women indicating an intention to re-use this intervention. Labrecque et al. (1999) compared SWI (n=10) to TENS (n=12) and *"standard care"* (water immersion, massage and unrestricted ambulation) (n=12) and found that even though SWI was more effective in relieving back pain, only a small proportion (n=4, 40%), would use SWI again due to the discomfort associated with the injections. The low number of participants indicating an intention to re-use SWI may reflect some degree of disappointment in being allocated to the one of three interventions that would involve injections and discomfort. Similarly, this response may be observed in the numbers of participants recruited to the trial during the 15 month recruitment period; the study authors noted that of the 304 women eligible for inclusion, only 34 participated in the study.

Only one study specifically asked women to rate their satisfaction with the use of SWI and describe some aspects of their experience (Peart, et al., 2006). This prospective cohort study (n=60) included a questionnaire that was offered to women two days following birth; fifty-two women (87%) completed it. The questionnaire asked women to rate their satisfaction with SWI in terms of the pain relief provided on a four point scale from *"very satisfied"* to *"very dissatisfied"*; women were also asked to comment on the best and worst aspects of their SWI experience. Of the women who responded, 47 (90%) indicated they were *"satisfied"* or *"very satisfied"* with the pain relief provided by SWI; the lack of side effects made the method an attractive option (Peart, 2008). However, many women commented on the pain associated with the procedure, with those women who were dissatisfied remarking that the pain outweighed any benefits, particularly if the analgesia they experienced was inadequate. Fogarty (2008) also theorises that the pain associated with the administration of SWI may deter women from considering the procedure in future labours.

Based on results of a pilot study,Peart, et al. (2006) also postulated that due to the significant discomfort associated with the administration of SWI, a minimum level of labour related back pain should be present, below which SWI may be viewed as too painful and hence as outweighing any benefit; a minimum VAS score of seven which has been demonstrated to equate to severe pain (Collins, Moore, & McQuay, 1997).

However, each of the trials detailed in Appendix 1 defined the level of back pain required prior to participation in the trial differently, with only Trolle et al. (1991) and Martensson and Wallin (1999) describing the level of back pain required as severe. If recruitment had involved women with lower levels of back pain, this may have affected the reported level of analgesic benefit and women's desire to use again in a subsequent labour.

Despite the significant body of research investigating the effectiveness of SWI to provide relief from back pain in labour, the reported experiences of women comprised only a relatively small part of these studies. The available data suggests that many women are accepting of the procedure and the experience is sufficiently positive to suggest use in a subsequent labour. The brief but significant discomfort associated with the procedure; however, has been highlighted as a deterrent with a sizable proportion of women rejecting the treatment in future, despite satisfaction with the analgesic effect (Fogarty, 2008; Martensson & Wallin, 2008). This raises questions about why women may choose such a form of analgesia, what might influence them to use the procedure again and recommend it to others. To date, there have not been any qualitative studies that have examined in more detail the experiences of women in labour using SWI, as the aim of most studies to date have been to demonstrate analgesic effects in trends, frequencies and statistical significance. That qualitative approaches do not provide data to validate interventions in scientific terms (Al-Busaidi, 2008) may explain the dearth of qualitative research into SWI. This does not detract from the usefulness and validity of qualitative research to explore and describe the impact of pain and analgesic interventions and other factors on the birth experience. The following section reviews the literature specific to the relationship between women's expectations and experiences and subsequent satisfaction with labour and birth.

2.5.2 *Women's expectations, experiences and satisfaction of birth*

Childbirth experiences including, measurements of satisfaction are complex and multidimensional, with women reporting satisfaction with some aspects of their experience

and dissatisfaction with others (Hodnett, 2002). An early study suggested that a woman's memories of her experiences may be influenced by her personal sense of control, how she coped with pain, the birth environment, her perceptions of support, encounters with midwives, carers and other health professionals, the level of intervention and her sense of involvement in the decisions made about her care (Bramadat & Driedger, 1993).

In a systematic review of 137 studies investigating women's experience of childbirth, Hodnett (2002) observed that most studies which included measures of experience and satisfaction were based on either fulfilment or discrepancy theories. Fulfilment theory measures satisfaction based upon outcomes to the exclusion of expectations or preferences. Discrepancy theory measures satisfaction based on the difference between the experience or outcome and prior expectations and preferences (Bramadat & Driedger, 1993).

Hodnett (2002) noted that most studies did not clearly differentiate between expectations or preferences. The notion of expectation was typically based on what was known to be available within a service or model of care and preferences reflected a woman's individual wishes, independent of any service limitations (Hodnett, 2002). This understanding of expectation has been observed in women's responses to questions about their birth experiences as suggested by the refrain *"what is, must be best"* (Porter & Macintyre, 1984, p. 1197), i.e. women assume that whatever service is being provided has been well designed and is the best available. Therefore expectations and satisfaction will be based on what is available rather than other possible preferences. Hodnett (2002) concluded however, that a woman's sense of control, involvement in decision making, and her relationship with care providers, was independent of, and indeed overrode, any impact from factors such as environment, model of care or degree of medical intervention.

A more recent systematic review of studies examining women's expectations and experience of pain in labour (Lally, Murtagh, Macphail, & Thomson, 2008) also identified control and involvement in decision making as key themes. A study of Jordanian women, which sought to document different aspects of women's childbirth experiences, found the majority of participants indicated that they were dissatisfied with their experience as they perceived that they had little control over decision making during childbirth (Oweis, 2009). This supports an earlier study (Bramadat & Driedger, 1993) that suggested that women will measure their experiences of birth against standards and expectations that represent a personal view of

acceptability instead of an objective benchmark. This suggests that there is a level of maternity care that reflects a normal expectation of decency and respect, regardless of whether the care is provided in advanced or developing health systems.

A report by Peart (2008), based on an earlier study (Peart et-al., 2006) (n=60), commented on the sometimes complex nature of women's experiences of SWI. They frequently remarked on how painful the procedure was; however, many women (90%) stated that they were satisfied with the effect and would readily use the procedure again in a subsequent labour. As the procedure of SWI was being used within the participating units for the first time, women would have had few expectations although indicating a preference for SWI in a future labour suggests a positive experience. However, as previously discussed, women (n=10) in the study by Labrecque et al. (1999) were much less likely to consider using SWI again despite the pain relief it provided;. possibly related to being randomised away from other preferred alternatives such as TENS and water immersion that did not involve any initial discomfort. This may illustrate that the relationship between what is expected, what is preferred and the actual components of the experience are often complex and contradictory (Bramadat & Driedger, 1993; Hodnett, 2002; Lumley, 1985; van Teijlingen, Hundley, & Rennie, 2003)

2.5.3   Women's sense of control and participation in labour

The complex nature of the birth experience and the often contradictory relationships between different elements involves a composite process of evaluation and interpretation by women. Bramadat and Driedger (1993) describe women taking a *"step back"* and making a measured evaluation of their experiences. Although quantitative approaches may provide information about larger samples using instruments that can be tested for reliability and validity; limited choice, short answer and fixed scale questions limit the depth of data that may be gathered (Howell & Concato, 2004; Redshaw, 2008). The use of interviews, including focus groups with open ended questions, provided opportunities for women to respond and express a wider scope of feelings and experiences; hence interviews may elicit richer descriptions of women's birth experiences (Howell & Concato, 2004).

As previously stated, the systematic reviews by Hodnett (2002) and Lally et al. (2008) identified control and participation in decision making as key components of a woman's birth experience. To investigate the role of control during labour, a questionnaire was provided to 1146 women one month prior, and six weeks following, birth (Green & Baston, 2003). The

researchers pointed out that, across previous studies there has yet been no clear definition or concept of what constitutes control which they defined in terms of the following three concepts: internal control, referring to control over one's body and behaviour; internal control, with respect to contractions related to pain and pain relief; and external control, or control over what was done by others. This was also equated with involvement in decision making (Green & Baston, 2003). The authors concluded that women's perceptions about the degree of external control had the most enduring impact on childbirth experiences.

Other qualitative studies provide insight into the meaning and significance of control for labouring women. In a phenomenological study of 14 women (Halldorsdottir & Karlsdottir, 1996), the metaphor of a journey to encapsulate the birth experience was used. The study identified internal and external control as a key part of preparing for, and participating in, the labour and birth journey. Women's sense of control contributed to their feelings about thetransition to motherhood and sense of accomplishment. Another study of eight postnatal women, which also used a phenomenological approach (Gibbins & Thomson, 2001), identified women's feelings of control as major contributors to a positive experience, even when the actual experience differed from expectations. Four qualitative studies exploring women's experiences of labour, birth and pain, conducted at two Alternative Birth Care centres (ABC) in Sweden, employed either a phenomenological or hermeneutic approach (Lundgren, 2004). The researcher acknowledged that women using the ABC centres represented a particular demographic and; therefore, may demonstrate a higher level of participation and confidence in managing their birth experience (Lundgren, 2004). As such, the findings from the four studies may not be representative of women accessing standard models of maternity care although the author concluded that the women's sense of self trust and feelings of control positively affected their experiences and transitions to motherhood.

The relationship between the midwife and the labouring woman has also been shown to have a significant impact on a woman's feelings and perceptions of control, particularly with regards to her experiences of pain (Bluff & Holloway, 1994; Gibbins & Thomson, 2001; Green & Baston, 2003; Leap, Sandall, Buckland, & Huber, 2010b; Lundgren, 2004). Women may view the relationship as shared with the midwife providing advice and decisional support (Raynes-Greenow, Roberts, McCaffery, & Clarke, 2007) and trusting the midwife to guide them through labour on their own terms (Berg, Lundgren, Hermansson, & Wahlberg, 1996).

When the midwife was perceived as supportive and inclusive, the woman's sense of control was higher than if the midwife was seen as being unhelpful and not supportive. A recent study (Dietsch, Shakleton, Davies, McLeod, & Alston, 2010), that examined the experiences of Indigenous women birthing in a non-Indigenous setting away from their home communities, found that when power and control were negatively skewed in favour of the care provider, the effect equated to bullying. This not only impacted upon women's birth experiences but also negatively affected their ongoing psychological and physical health.

The perception of internal and external control is supported and enhanced by the relationship between the woman and the midwife (Bluff & Holloway, 1994; Gibbins & Thomson, 2001; Green & Baston, 2003; Leap, et al., 2010b; Lundgren, 2004). As control will often include a woman's reaction to pain and/or the use of analgesia, this adds an extra dimension to the relationship between woman and midwife. The midwives knowledge of, and preferences for various analgesic strategies and the assessment, information and advice regarding analgesia provided, may either support or threaten a woman's sense of control.

Further threats to an individual's sense of control can arise from the pain incurred in labour and/or the side effects of some forms of analgesia (Halldorsdottir & Karlsdottir, 1996; Mander, 1992). Medications such as narcotics and sedatives may cause dizziness, drowsiness and disorientation, impacting on a woman's ability to be involved in decision making and to respond to the physical demands of labour (Mander, 1992).

2.6   Midwives and sterile water injections

2.6.1   *Midwives assessments of pain in labour*
Although pain is essentially a personal and subjective experience, midwives assist women to make choices by providing information about analgesia. This inevitably involves assessment and interpretation of the woman's pain.

Specific to the literature on SWI, studies by Ader et al. (1990) and Martensson and Wallin (1999) asked midwives caring for women who participated in their studies, to assess the analgesic effects of the interventions, thereby suggesting that midwives had already assessed their pain prior to the use of SWI. In the trial by Ader et al. (1990) the midwives assessments demonstrated a significant difference between the two treatment groups; however, no attempt was made to correlate the results with the VAS scores provided by the women. Martensson

and Wallin (1999) also asked midwives to evaluate the effectiveness of the treatments but found no statistical difference between the pain reduction reported by both women and midwives.

Other studies that have compared the assessment of pain by both midwives and women have reported mixed results. A cohort of 78 women in labour and 28 birth suite midwives who were asked to complete a questionnaire following labour and birth (Bradley, Brewin, & Duncan, 1983) found that midwives consistently under-estimated the pain experienced by women. Another study (Baker, Ferguson, Roach, & Dawson, 2001) asked 13 labouring women and nine birth suite midwives to complete the short form of the Magill Pain Questionnaire (SF-MPQ) every 15 minutes following admission until the women were no longer able to hold a pen and mark responses to the questions. The results indicated that at mild to moderate levels of pain, the scores from both women and midwives correlated well, however midwives underestimated pain which women described as severe. Another study (Sheiner et al., 2000) that asked two obstetricians and 14 midwives to complete VAS scores for women (n=255) in active labour, also completed the VAS prior to receiving any analgesia. The researchers reported that while clinicians accurately assessed pain in 50% of women, they, either underestimated or overestimated it in the remainder. This study was conducted in Israel and involved women from a number of culturally diverse groups. The researchers reported that the wider the cultural gap between the labouring woman and the attending clinician, the less accurate was the assessment of pain. Finally, drawing from data generated by a national sample of women (n=6,459) birthing in one week in National Health Service (NHS) hospitals in the UK, Rajan (1993) also stated that only 52% of women and care providers (obstetricians and midwives) were in agreement with reported levels of pain.

One explanation for the discrepancy described in these studies may be that clinicians are comparing a particular woman's pain to that of other women previously encountered, whereas for the woman the experience will be unique (Bradley, et al., 1983). Rajan (1993) also noted that there was greater congruence between women and midwives over the assessment of the effectiveness of analgesia, than pain. This suggests that a reduction in pain may be easier to assess than a pre-existing level of pain. Further, Ludington and Dexter (1998) highlighted that as the intensity of pain increases as labour progresses; women constantly redefine their

perception of the highest level of pain, whereas there is no similar impetus for clinicians to alter pain parameters in their own assessments.

A small number of qualitative studies have also explored the experience of pain in labour from the midwives' points of view. One such study (McCrea, Wright, & Murphy-Black, 1998) used observations of midwives' behaviours during interactions with labouring women requesting analgesia to describe three types of behaviours from midwives: the *"cold professional"*; the *"disorganised carer"*; and the *"warm professional"* (McCrea, et al., 1998, p. 177). The cold professional provided objective information to women requesting analgesia options; however, this approach involved a 'do to' attitude rather than working 'with' women. The disorganised carer took a more social approach and gave information which was haphazard and inconsistent, based on opinion and experience. The warm professional worked with women as well as providing adequate and appropriate information; emotional support, presence and closeness were hallmarks of this approach. The authors concluded that personal qualities as well as professional expertise defined the midwives' responses to the woman's pain. They also acknowledged that, although the study used an appropriate methodology, the small sample size limited the generalisation of the findings. Also, there was no capacity within the study to determine any relationship between clinical outcomes and levels of maternal satisfaction, compared to the identified types of behaviour.

The theme of the *"anchored companion"* was explored by Lundgren and Dahlberg (2002, p. 155) using a phenomenological approach. The anchored companion had respect for, and a responsibility to act within, the woman's ability. Essentially, the midwife uses active listening, mutual participation and trust to guide women's responses to pain. In another study, Vague (2004) described the midwife as an interpreter of the woman's language of pain who needed to formulate a plan of care, and that the more accurate this interpretation, the more satisfied the woman will be with the management of her pain. In describing the process as *"leaping ahead"* and *"leaping in"* Vague (2004, pp. 23-24) viewed midwives as anticipating the needs of women and preparing the way i.e. as the midwife taking a more direct role in the woman's labour.

These studies present a number of common themes: the role of the midwife as a potentially supportive presence during labour; a delicate balancing act of pre-emption and appropriate response within the context of the individual woman's birth experience; and the midwives'

own knowledge and beliefs. Midwives may interpret the pain of labour as an obstacle to be overcome through the provision of analgesia (Rajan, 1993) or as part of a journey and transition that ultimately empowers the woman with feelings of accomplishment (Leap, 2000; Lundgren & Dahlberg, 2002).

In addition to the pain of labour, there may be pain or discomfort associated with clinical procedures. However, there is a dearth of literature on how midwives view any discomfort they cause women from routinely administered procedures. Despite the discomfort associated with the use of SWI, no studies have yet explored the midwives attitudes towards causing such pain. Vaginal examination is an intrapartum procedure that is recognised as being unpleasant for women, but which is also routine clinical practice. The associated discomfort may be rationalised by practitioners by the imperative for clinical assessment; however, it may be equally perceived as a demonstration of control over women in labour (Bergstrom, Roberts, Skillman, & Seidel, 1992; Stewart, 2005). Using euphemisms and referring to themselves in the plural ('we' instead of I) to describe the examination, clinicians may experience a sense of disembodiment during the procedure. Ritualistic, processes such as hand washing and donning of gloves may assist in removing any emotional response to a clinical procedure that may involve pain or discomfort (Bergstrom, et al., 1992; Robinson, 2001).

2.6.2 *Midwives knowledge and use of sterile water injections*

Three papers reporting on the results of surveys that were conducted with midwives from the United States of America (USA) (Martensson, et al., 2008a), Sweden (Martensson & Wallin, 2006) and Australia (Lee, et al., 2012) sought to determine the level of knowledge and use of SWI amongst midwives. The Swedish survey, which specifically sought to compare the indication and level of use for both SWI and acupuncture, was distributed to 956 midwives who were asked about use of SWI and acupuncture during labour care. Five hundred and sixty-five midwives (59%) returned questionnaires. Sterile water injections and acupuncture were used by all midwives; however, there was a preference for acupuncture over SWI. The woman's wishes and the midwives own clinical experiences were considered to be the most important criteria for information and recommendations about the two procedures. Midwives were also asked what they would choose for their own labour and birth; this correlated with their individual choice of method in clinical practice, which was a preference for acupuncture.

This gives an indication of the complex process between assimilation of knowledge, practice and personal belief. The prevalence of reports on procedures such as SWI and acupuncture in the literature and instructional texts available to midwives, may also influence preferences. Martensson and Wallin (2006) cite a number of sources available to Swedish midwives and women that list acupucture as a suitable analgesic in labour but make little, or no, reference to SWI despite the procedure being taught to Swedish midwives as standard care

In the USA study (Martensson, et al., 2008a), questionnaires were randomly sent to a sample of members of the American College of Nurse Midwives (ACNM) (n=450). One hundred and thirty-two questionnaires (29%) were completed and returned. Twenty-six per cent of the responding midwives stated that they had knowledge of, or had used, SWI in their practice. Eighty-one per cent of the midwives not using SWI, had no training or experience in the procedure, but expressed an interest in accessing relevant information. Additional reasons for not using SWI ranged from institutional prohibition based on a perceived lack of evidence to support efficacy and safety, and a concern about the pain of the procedure compared to the possibility of poor analgesic effect. The survey identified a number of misconceptions held by some respondents based on a lack of knowledge about the procedure and mechanisms of action.

The Australian survey (Lee, et al., 2012) was distributed, via email, to members of the Australian College of Midwives (ACM) (n=4700) and CRANA*plus* (n=454), a professional organisation for remote area practitioners. A small number of participants may have been members of both organisations. Nine hundred and seventy participants (19%) responded to the survey. The sample size was sufficient to be representative of midwives who were members of the ACM but may not be representative of Australian midwives nationally. Results suggested that SWI was not being used by a majority of midwives (42.5%), but similar to the USA survey, many of the midwives not using SWI (90%) expressed an interest in doing so. Lack of access to information, training and practice guidelines were cited as common reasons for not using SWI. Overall, 32.2% of participants indicated that they had experienced resistance to the use of SWI from other midwives and/or medical colleagues.

These studies indicate that there are barriers, in terms of access and assimilation of knowledge about SWI, that affect the availability of the procedure in practice; the midwife's personal and professional beliefs are additional factors. The studies were not designed to report on the

experiences of midwives using SWI as an analgesic strategy, nor how midwives integrate knowledge and their experiences of providing care in labour.

Summary

The chapter was divided into five sections. The first section reviewed the history of obstetric analgesia including early resistance, the influences of Western politics and the impact of the natural birth movement on the development of non-pharmacological analgesic for labour pain. The second section examined the literature on SWI from the earliest references to the use of intradermal injections as a method of pain relief in renal colic, to the adaptation of its use in labour. The studies that established the efficacy of the procedure were reviewed and the variations in the technique in terms of anatomical position and depth, volume of fluid injected and, central to this study, the number of injections used. This section also considered the systematic reviews on SWI, outlined the limitations in the current research and evidence base, and established the rationale for this present study. The third section explored the physiology of back pain in labour and referred pain, and examined the underlying causes. The gate control and DNIC theories of pain modulation were summarised as possible explanations for the underlying physiology of the analgesic effect produced by SWI.

The latter two sections established SWI as a legitimate basis for the relief of back pain in labour and offer theories for the associated physiology. They also highlight the considerable variation in the technique, which in turn has raised questions about the number of injections required to achieve an analgesic effect. Particular to this study is the issue identified in the systematic reviews by Martensson and Wallin (2008) and Fogarty (2008) regarding the need for a comparison between the single and four injection techniques to determine if both techniques can provide similar levels of analgesia.

Studies on SWI that had included data on maternal satisfaction were detailed in the fourth section. Also discussed within this section were the complex relationships between women's expectations, birth experiences and satisfaction, with particular reference to pain and analgesia. These aspects and the interactions between women and midwives, explored in qualitative studies, provide the rationale for further exploring the experiences of back pain in labour and the use of SWI from the perspectives of the labouring women and midwives.. There have not been any qualitative studies to date that have investigated these outcomes,

hence the importance of this study. The final section examined how midwives assess pain and the effect of analgesia, particularly in relation to the use to SWI; however, data in this area is very limited. No studies specific to the role and experience of midwives using SWI have been conducted, including how midwives acquire, integrate into practice, and rationalise, the use of SWI. The following chapter details the design and methodology used in the research project.

Chapter three: Research design

3.1 Overview

The previous chapter examined the literature pertaining to the research topics. This chapter details the research design and is divided into four sections. The first section describes the research questions, and the relevance, benefits and challenges of a mixed method design. The second section provides an outline of the randomised controlled trial design with regard to the benefits of the approach, defining the control and intervention groups and the control of bias through blinding. Aspects particular to this study with regard to non-inferiority design and the analysis of VAS data are discussed. The third section details the methodology that was employed in the qualitative arm of the trial, which explored the experiences of SWI from the perspectives of labouring women and administering midwives. The design of the study is detailed in terms of sampling, recruitment, consent, data collection and analysis. Finally, issues common to both phases of the mixed methods design, such as ethics and the concepts of validity and rigour, are discussed.

3.2 The mixed methods design

The overall aim of this research was to explore two questions that arose from the literature review:

i) For women in labour with back pain, does a single SWI, compared to a four injection technique, provide similar levels of analgesia?

ii) What are the experiences of women and midwives using SWI for the relief of back pain in labour?

The first question required a quantitative approach as it sought measurable results that will define categories that can be applied to all subjects within the study and be applicable beyond the study (Winter, 2000). The second question required a qualitative approach as it sought to understand individual experiences rather than report outcomes that may be representative of the wider population. The quantitative results may demonstrate the benefits of one technique over the other, in a statistical sense, although if the procedure is not seen as useful and beneficial by those who are using it, the relevance of the procedure is questionable. The qualitative analysis aimed to flesh out and offer greater clarity and relevance to the

quantitative findings, by providing opportunities for participants to explain how they perceived the intervention, and their motivation and rationale. This approach may also assist in explaining any anomalies and provide insights into practice issues not otherwise captured.

Mixed methods research has been described as a framework for collecting and analysing quantitative and qualitative data that is integrated at some point in the research process, to provide a greater understanding of the research question(s) (Ivankova, et al., 2006). Mixed methods research has been criticised for being methodologically unsound as it attempts to blend opposing paradigms of inquiry (Holmes, 2006), often relegating qualitative research to a secondary position (Howe, 2004). However, Creswell (2011) and Bergman (2011) argue that the paradigms are not mixed as much as amalgamated, or linked at a specific point that supports the final design; therefore, the conventions of each paradigm remain essentially intact. Creswell (2011) notes that a number of mixed methods designs emphasise qualitative inquiry over quantitative; this is largely a decision informed by the researchers approach to the research topic. Moreover, Creswell (2011) argues that mixed methods research potentially elevates the role of qualitative research, providing greater legitimacy through broader exposure and association with quantitative inquiry although this may be viewed as a positivist take on qualitative research. A number of specific designs are detailed within the broader description of mixed methods design, often dependent on the stage in the research process when the two methods are blended. As the results of both approaches will be blended to synthesise the final discussion, a sequential explanatory mixed methods design (SED) was employed, involving a two-stage mixed methods approach where the quantitative phase precedes the qualitative stage. The qualitative phase; however, is designed to be of specific relevance to the quantitative phase and both samples are drawn from the same group of participants. Both phases are analysed separately and the results integrated (Creswell & Plano Clark, 2007). This design has a number of advantages: the structure is straightforward for a single researcher to carry out as the phases are conducted consecutively; data analysis and results are conducted and presented separately; and the design normally preferences the quantitative phase (Creswell & Plano Clark, 2007). The SED design; however, also presents a number of challenges and decisions for the researcher. Namely, the time involved in conducting two periods of data collection and analysis, the sequence of the various research processes and identifying the point of integration, and the overall weighting of each phase in

the final synthesis (Ivankova, et al., 2006). The research sequence and integration for this study are presented in Figure 3.1.
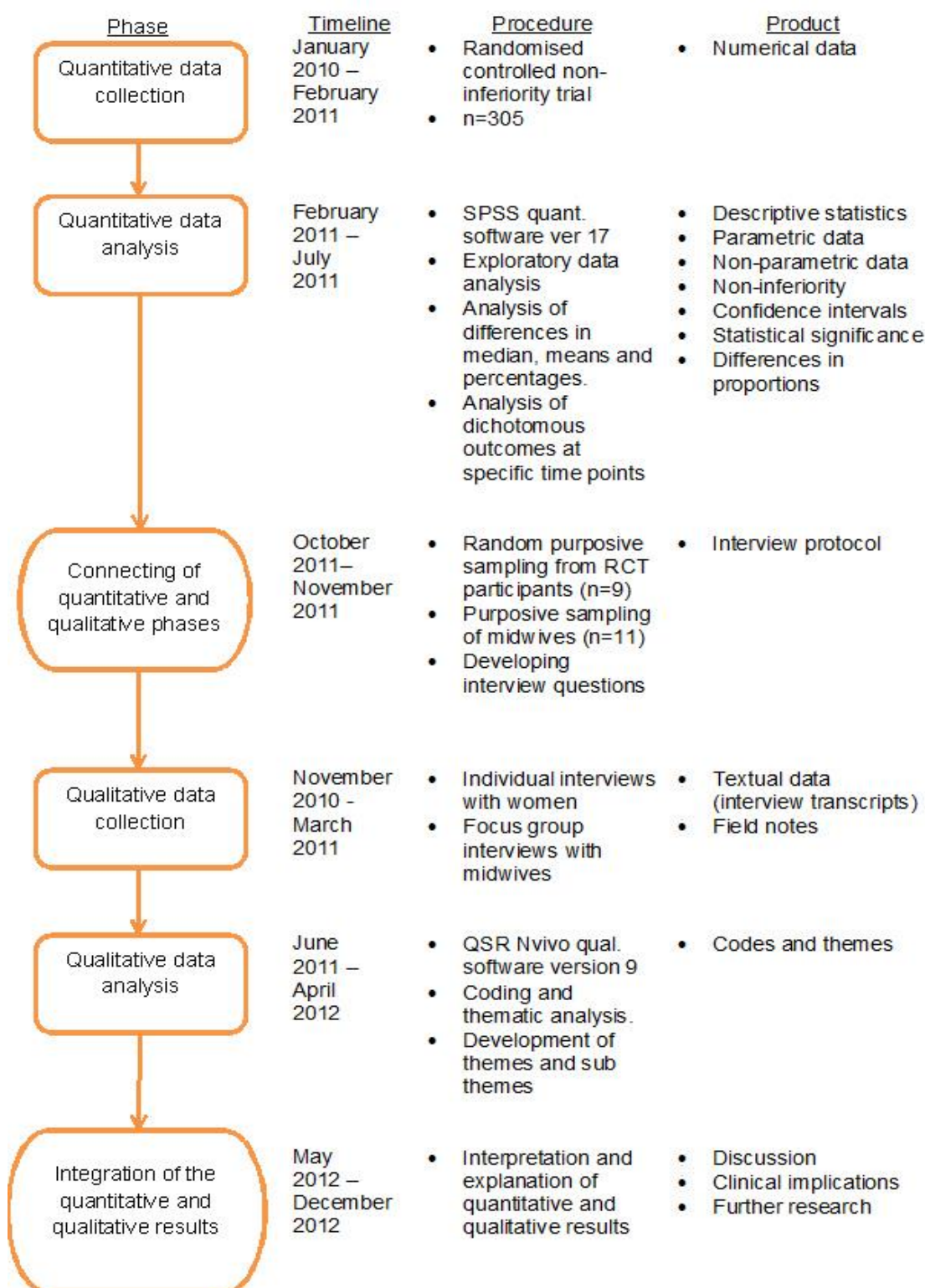
Figure 3.1: Model of sequential explanatory design procedures (adapted from Ivankova, Creswell, & Stick, 2006)

3.3   Quantitative phase: The SWITCh trial

3.3.1   Aim and research question

The aim of this phase of the study was to compare a single intradermal SWI technique with the standard four injection intradermal technique in the degree and duration of analgesic effect. Specifically, the research was directed at addressing the following question: for women in labour with back pain, does a single sterile water injection technique, compared to the standard four injection technique, provide comparable levels of pain relief?

3.4   Randomised controlled trial design

3.4.1   Introduction

This phase used a randomised controlled, non-inferiority design to compare the effects of the two techniques. Randomised controlled trial (RCT) design has been described as the ideal study design to answer questions related to health care interventions (Jadad, 1998) and hence was considered appropriate for this study. Randomisation refers to the allocation of participants to one of a number of study groups, by chance alone, to reduce selection bias (Piantadosi, 2005). The process of allocation is not determined or influenced by clinicians, researchers or participants; rather it follows predefined rules that are particular to the study (Jadad & Enkin, 2007). Random allocation ensures that any baseline differences that participants may have, known or unknown, are likely to be similar in each of the treatment groups prior to any comparison. Therefore, any resulting differences between the two groups can be more confidently attributed to the allocated treatment (Jadad & Enkin, 2007; Piantadosi, 2005).

3.4.2   Randomisation

Procedures for randomisation may include simple randomisation, where treatment is allocated on the basis of a sequence of randomly generated numbers. This may result in a difference in the numbers of participants allocated to each group at any particular point in the trial. Another form is blocked randomisation, where each *"block"* contains a specified number of assigned treatments within which a number of permutations may occur. For example, a block of two treatments (A, B) may be AABB of which variations may be ABAB, or BBAA and so forth. Block randomisation ensures that there are equal numbers of participants assigned to each

treatment at any point during the trial and also reduces the chance that the order of randomisation may be predicted (Jadad & Enkin, 2007; Piantadosi, 2005). For this study, both simple and block randomisation were used; the rationale for this decision, discussed later in this chapter. Although randomisation is considered to be the gold standard in terms of quantitative research design, as it distributes variables equally across treatment groups, it is not without its critics. Grossman and MacKenzie (2005) for example, argue that randomisation may produce a false sense of homogeneity, particularly if the sample size is small in comparison to the number of demographic or clinical variables within the trial population.

3.4.3   Control and intervention groups

The control group consists of participants drawn from the same population as the intervention group, and are similar in every respect except that they do not receive the intervention. Therefore, any difference between the two groups can be related to the intervention (Cluett, 2006). Usually the control group receives either no treatment, a placebo treatment that has no active effect, or a standard treatment that is offered routinely (Cluett, 2006). The use of a placebo group will assist in determining whether an intervention has an effect that is superior to no treatment but it will not determine if that effect is equal to, better, or worse than, an existing treatment (Jadad & Enkin, 2007).

3.4.4   Blinding

Assessment bias may occur when either the participants or personnel assessing the treatment effect are aware of which intervention was used (Jadad & Enkin, 2007). Blinding, or masking, means that all personnel connected to the study, including participants and researchers, remain unaware of which treatment has been administered to whom. The process of blinding thus minimises assessment bias (Piantadosi, 2005; Wang, Nitsch, & Bakhai, 2006). Ideally, a double blind design would be used where neither participants, clinicians or researchers are aware of the assigned intervention. Inadequate blinding in trial design can lead to an exaggeration of the effect of the intervention over the control (Jadad & Enkin, 2007; Schulz, Chalmers, Hayes, & Altman, 1995). It was not possible to double blind this study as the participants may have been aware of the number of injections they received however, to minimise bias in the recording of the pain scores, the primary midwife was absent from the room while two other midwives, not directly involved in caring for the woman, administered

the intervention. This approach has been used previously in two SWI trials (Ader, et al., 1990; Martensson & Wallin, 1999).

3.4.5   Non-inferiority design

The majority of RCTs are superiority trials that aim to determine if a new treatment is better than a current standard treatment or a placebo (Allen & Christopher, 2007). Where two treatments have both previously been shown to be superior to a placebo, and/or in cases where the use of a placebo may be unethical or impractical, a non-inferiority design can be used to determine if one treatment is no worse than the other (Miller, Neate, & Wang, 2006; Scott, 2009). In previous RCTs, both the single and four SWI techniques have been demonstrated to be superior to placebos (Hutton, et al., 2009). As the aim of this study was to compare the clinical impact of the two techniques, a non-inferiority design was considered the most appropriate. The interventions in non-inferiority designed trials usually comprise a new treatment and an active comparator, or a treatment currently in use. In relation to this trial, the single injection was the new treatment and the four injection technique was the active comparator.

The preferred statement of hypothesis in RCT design is the null hypothesis, where it is assumed that there is no difference between the control and intervention. Hence the null hypothesis places the onus on the intervention to be proven (Cluett, 2006), and is accepted if it cannot be rejected statistically in favour of the intervention. However, as the non-inferiority design is attempting to show that two active treatments are similar in effect, starting from a hypothesis that there is no difference may lead to bias and adoption of an inferior therapy (Piantadosi, 2005). Therefore, non-inferiority trial design reverses the focus of the null hypothesis and states that the treatments are different. The null hypothesis is not proven if the measured effects of the two treatments lie within a specified non-inferiority margin (Kaul, 2006). Within non-inferiority design the sample size must be sufficient to test the clinically relevant margin (Piantadosi, 2005), which is based on what would be considered to be clinically relevant, with any difference outside this range indicating that the difference between the two treatments is unacceptably large (Miller, et al., 2006). The sample size calculation and justification for this trial is detailed later in this chapter.

Non-inferiority trials may also include a placebo arm (Miller, et al., 2006), which was considered for this trial but not included for the following reasons. Namely, the placebo used

in previous trials was normal saline, which is virtually painless when injected, and the literature suggests that the absence of any discomfort during injection would likely alert women and their care providers to the use of a placebo, which may alter their behaviour and choices regarding analgesia and participation in the trial (Fogarty, 2008). A placebo may be omitted from NI trials when both treatments have been demonstrated to be superior in placebo controlled studies (Wang, et al., 2006). The inclusion of a third placebo arm would have complicated this trial with regard to blinding, therefore as both treatments used in this trial had previously been tested against placebos and found to be superior, a placebo group was not used.

3.4.6 *Intention to treat analysis*

The intention to treat (ITT) approach to analysis of any participant population is the most valid approach in RCT design as it adheres to randomisation procedures and ensures that participants randomised to a particular arm are analysed in that group, regardless of which treatment was actually received or any failures to comply with the treatment or protocol. In ITT analysis, participants who have received the alternate treatment to that which they were assigned to or a different treatment, or who violated the protocol, dropped out or have missing data, may make the two groups seem more similar than they actually are, and; therefore, any differences between the groups can be more confidently assigned to the intervention (Jones, Jarvis, Lewis, & Ebbutt, 1996). The ITT analysis reduces the chances that the null hypothesis, of no difference between the two treatment groups, is rejected, or of a type one error occurring (Piantadosi, 2005). A type one error would state that a difference exists where in fact it does not. Accepting the null hypothesis when it is actually incorrect, leads to a type two error where no difference exists, when in fact it does. Intention to treat analysis also strengthens the chance of participants' characteristics, that cannot be controlled or measured, are equally distributed between groups (Montori & Guyatt, 2001).

However, an issue with non-inferiority design is that ITT analysis may lead to an increased risk of a type one error, or falsely claiming non-inferiority (Piaggio et al., 2006). This may lead to an inferior treatment being accepted as non-inferior as a result of participants moving from one intervention to another, significant protocol violations, or missing data from dropouts (Kaul, 2006; Miller, et al., 2006).

3.4.7 Per protocol analysis

A per protocol (PP) analysis is an alternative to ITT analysis. It is restricted to participants who fulfil the trial protocol in terms of eligibility, intervention, and outcome assessments and participants are analysed by the treatment they actually receive and not what they were randomised to receive (Miller, et al., 2006). Therefore any trend towards similarity between two treatments, resulting from crossover between treatment groups, is avoided. Excluding data that may be related to protocol violation, and missing data possibly resulting from a reduced efficacy of either the new treatment or the comparator, may bias the result in either direction, causing a type one or a type two error (Miller, et al., 2006).

To address the issues between ITT and PP analysis in non-inferiority design, some authors have recommended that PP analysis is also conducted alongside ITT to provide a more robust conclusion, if both methods support the non-inferiority (D'Agostino, 2003; Miller, et al., 2006). Others (Wiens, 2007) argue that the benefits of ITT analysis continue to outweigh the PP approach. In this study, both the ITT and PP results are reported.

3.4.8 Hypothesis

The predefined non-inferiority margin was chosen *a priori,* based on the minimal clinically (i.e. not statistically) significant difference in the VAS scores for severe pain of 10 mm (Kelly, 2001). Thus the margin was defined as + or -1 cm on the 10 cm VAS scale, with greater than 1 cm (or 10 mm) indicating a clinically significant difference in perceived pain. Therefore, the null hypothesis would be *"treatment is inferior"* and the alternative hypothesis that *"treatment is non-inferior"*.

H_0: Difference between the four intradermal SWI and single intradermal SWI is ≥ 1 cm on the 10 cm VAS.

H_A: Difference between the four intradermal SWI and single intradermal SWI is < 1 cm on the 10 cm VAS.

3.5 Method of investigation

3.5.1 The setting

The trial was conducted at two metropolitan tertiary maternity units in Brisbane, Queensland; referred to in this document as Site One and Site Two respectively.

Each site provides maternity services for discrete populations of the city and surrounding suburbs, with the Brisbane River providing a natural geographical divide between north and south. In 2008 the population of Brisbane was 1,676,389, of whom 23.6% were born overseas, with Europeans, New Zealanders and peoples from Southern and Northern Asian countries comprising 51% of the inner city Brisbane population. Persons identifying asAboriginal or Torres Strait Islander currently make up 1.7% of this population. These statistics indicate a high degree of multiculturalism within the target population (Australian Bureau of Statistics, 2008).

Site One has approximately 10,000 births per annum, divided almost equally between public (uninsured) and private (insured) women. Site Two has an annual birth rate of approximately 5,000 women, the vast majority being public admissions. Staffing and labour management practices are similar at both sites.

Both sites offer women choices of obstetric and midwifery models of care. Site One has four community based Midwifery Group Practices (MGP) that offer continuity of care from a known midwife throughout the antenatal, intrapartum and postnatal periods. A Young Women's Group Practice is included which provides care specifically for women less than 21 years of age. Site One also offers midwifery antenatal care with a known midwife through the onsite antenatal clinic. Site Two has a long established birth centre, with birth centre midwives offering continuity of care through two midwifery teams. The birth centre offers water births and is in close proximity to, although physically separate from, the birth suite.

The SWI procedure was introduced to Site One by a team of midwifery facilitators, lead by the researcher, as part of a clinical fellowship designed to facilitate evidence-informed practice in the clinical setting. Sterile water injections had been used routinely in clinical practice for approximately twelve months prior to commencement of the trial.

Recruitment had already commenced when midwives from Site Two approached the research team to discuss their possible involvement in the trial. Sterile water injections were subsequently introduced to Site Two specifically in conjunction with this research project. As conduct of the trial at Site Two needed to strictly adhere with the established trial protocol, an introductory period to provide adequate staff education and ensure stakeholder liaison was required. Prior to the commencement of recruitment at Site Two, training sessions covering

the administration of SWI and trial processes were provided to a group of clinical midwives identified as *"trial champions"*. The role of these midwives was to support the conduct of the trial, through providing on-going training sessions, in conjunction with the research team, and to act as a project resource for staff. Individual competency in SWI administration was assessed by either the researcher or one of the trial champions. A training tool, including multimedia content, was developed by the researcher and was available online at both sites. A research procedure manual was placed in the handover areas and information folders containing material detailing the recruitment and data collection processes were also made available in each birth room at both sites. As the trial champions generally took on a clinical leadership role rather than providing direct clinical care, they were available to obtain consent from potential participants and administer the intervention with another midwife.

3.5.2   Restriction of women's access to sterile water injections at Site Two

Only women who consented to participate in the trial were able to receive SWI at Site Two. This restriction was imposed by the clinical leaders prior to the commencement of the trial on the grounds that the procedure was novel and unknown within the clinical setting and that the relevant clinical policy review committees had not reviewed the evidence nor developed an appropriate policy. It was understood by the stakeholders that trial participation by Site Two would provide an opportunity to introduce SWI under conditions specified within the trial protocol. Following the conclusion of the recruitment phase, a clinical procedure for SWI manual was developed and SWI was subsequently made available to all women on request.

A number of midwives at Site Two questioned whether it was ethical to restrict access to a procedure on the basis of inclusion in an RCT. Orentlicher (2005) argues that offering treatment only when the participant agrees to participate in research is ethical when such studies involve a comparison of therapies that have proven clinical benefit. As both interventions are supported by placebo controlled trials, it was considered thus ethical to offer women access to SWI only within the trial conditions.

3.5.3   Study population and eligibility criteria

The study population included any woman seeking analgesia for lower back pain during labour (VAS ≥7), at either Site One or Site Two, who met the eligibility criteria.

Participants eligible for the study were defined as women who met the following criteria:

- Term pregnancy (between 37 and 42 weeks).

- Singleton pregnancy.

- Fetus in a cephalic presentation.

- First stage of labour (spontaneous or induced).

- No previous analgesia.

- Back pain assessed by VAS as ≥7.

Participants ineligible for this study were defined as women who met one or more of the following criteria:

- Pregnancy <37 weeks.

- Multiple pregnancy.

- Fetus with a malpresentation (e.g. breech, transverse).

- Second stage of labour.

- Pharmacological analgesia prior to SWI.

- Back pain assessed by VAS <7.

- Any complications of pregnancy or labour (e.g. bleeding, diabetes, hypertension).

- Unable to personally provide consent. (e.g. women who required but were unable to access an interpreter and those who required consent to be provided by a parent or guardian)

3.5.4   Control group

Participants randomised to the control group were given SWI, using the standard four injection intradermal technique into the skin surrounding Michaelis' Rhomboid over the sacral area (Appendix 3). Anatomically, the injections were administered in the following manner; two simultaneously over each posterior superior iliac spine (PSIS) followed by two simultaneously, 3 cm below and 1 cm medial to the PSIS (Figure 3.2). As minor discrepancies or changes to the anatomical position or alignment of the four injections have not been shown to impact on analgesic effect (Duff, 2008), it was not expected that minor deviations from the described anatomical placement of the injections would affect clinical outcome or reported VAS scores.

First injection points; Posterior superior iliac spines (PSIS)

Second injection points; 3 cm below and 1 cm medial to the PSIS
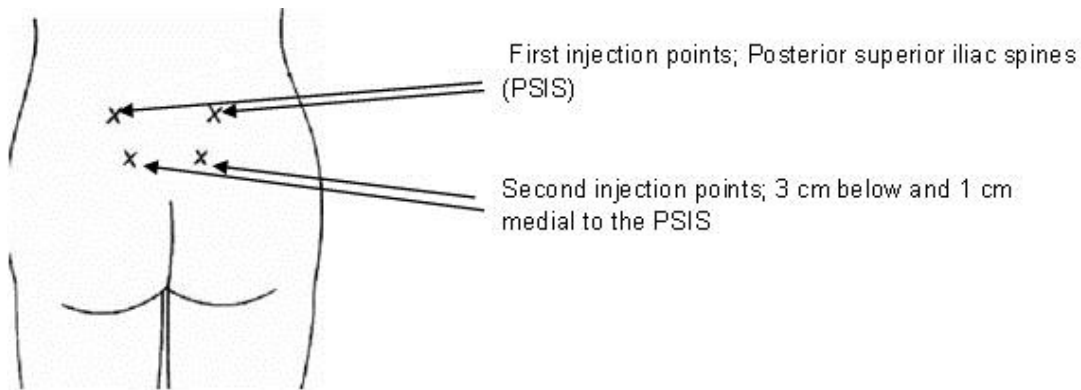
Figure 3.2: The four injection technique

3.5.5 *Differences in injection technique from previous single injection trials*

The injected volume for the SI technique in this trial was 0.1 ml using an intradermal approach. The intradermal approach was used for both the SI and FI techniques as this is the most common technique used in practice (Fogarty, 2008; Martensson & Wallin, 2008) and the technique in use at Site One. Both SI trials injected into the subcutaneous layer using 0.5 ml of sterile water. An RCT comparing both the intradermal and subcutaneous approaches found no difference in terms of analgesic effect therefore it was considered unlikely that the difference in anatomical depth between the intradermal and subcutaneous techniques would affect the outcome of the trial (Martensson & Wallin, 1999).

3.5.6 *Intervention group*

Participants randomised to the intervention group were given SWI using the single injection intradermal technique. The anatomical site for the single injection was over the single most painful point as indicated by the woman (Figure 3.3) (Appendix 4).
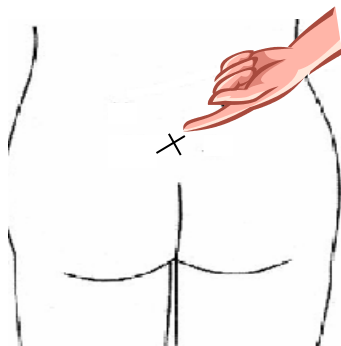
A woman indicates or points to the most painful point or central point of back pain

Figure 3.3: The single injection technique

3.5.7   Outcome measures

Previous studies have used time intervals varying between 30 and 45 minutes as the primary point for measuring the VAS score following administration of SWI, with durational endpoints at 60 to 120 minutes (Hutton, et al., 2009). Results indicate that the peak of analgesic effect begins at 30 minutes post intervention (Fogarty, 2008). Therefore, to provide a narrow, predefined and comparable non-inferiority margin, the 30 minute time interval was selected as the primary endpoint in this study. Time-based secondary outcomes were measured at 30 minute intervals, for two hours, following injection.

Primary outcome:

Pain measured by VAS at 30 minutes post-intervention

Secondary outcomes include:

i)   at least 50% and/or 30% difference between pre and post-injection self-reported pain scores at 10, 30, 60, 90 and 120 minutes

ii) level of administration discomfort associated with SWI procedure (measured by VAS at 10 minutes post SWI)

iii) subsequent analgesia use (pharmacological and non-pharmacological)

iv) mode of birth

v)   likelihood to use again with subsequent labour

vi) patient satisfaction with analgesic effect.

3.5.8   Sample size

A sample size of 133 in each group was required to achieve 90% power to detect non-inferiority using a one-sided, two-sample t-test. The margin of equivalence is ≤1 cm on the 10 cm VAS and the true difference between the means is assumed to be 0 cm. The significance (alpha) of the test is 0.025, and data drawn from populations with a standard deviation (SD) of ±2.5 on the VAS. The SD was conservatively estimated from results reported in a recent meta-analysis of SWI studies (Hutton, et al., 2009). As consent and randomisation occurred in birth suite, attrition was expected to be minimal. However, a 20% attrition rate was nonetheless factored into the sample size to account for cases of withdrawal such as precipitate birth or emergency caesarean section prior to the assessment of the primary outcome. Thus a total of 320 participants were required; i.e.160 in each treatment group.

3.5.9 Recruitment of participants

Trial participation was invited by disseminating information to pregnant women at antenatal clinics, antenatal education classes and birth suites, at both sites. As women returned to the antenatal clinic in the third trimester (36 weeks at Site One and 30 weeks at Site Two), they were routinely provided with information regarding the trial (Appendix 5). This strategy allowed women time to consider the use of SWI, and their possible participation in the trial, alongside any decisions regarding alternative analgesic use. Further information, including a video demonstrating the four injection technique, was available for women to access at the specifically designed trial website; the Internet address was detailed on the participant information form.

The original intention was to recruit the sample solely from Site One at an estimated rate of 20 to 30 participants per month; however, over the first three months only 15–20 women per month were recruited. The addition of the second site compensated for the reduced recruitment rate and increased the likelihood of completion within the expected timeframe.

3.5.10 Consent

Women consented to participate in the trial on presentation to birth suite in labour. A trial investigator was available, via mobile phone, to provide support for midwives or trial champions undertaking the consent and other trial processes, and to promote continuity in processes and trial fidelity across the two sites. The consent tasks did not significantly increase the workload of the midwifery team leader as on average one to two eligible women per day agreed to participate in the trial. (The consent form is provided in Appendix 6).

Women were able to withdraw consent at any time (i.e. before, during or after the procedure and/or before completing a postnatal questionnaire) or request alternative methods of analgesia. Two participants declined to continue in the trial following consent and hence did not receive the intervention.

3.5.11 Randomisation and allocation concealment

Women presenting to the birth suite requesting SWI, who meet the eligibility criteria and consented to participate in the study, were randomly assigned to one of the two treatments. For Site One, the randomisation schedule was prepared using a computer-generated list of random numbers. Allocation to either the control or intervention arm was undertaken by the

midwifery team leader selecting the next in a series of pre-prepared opaque sealed envelopes. The envelopes were prepared by a research assistant under the supervision of a senior research officer at Site One, who was independent of the research team. The envelopes were arranged sequentially to aid in the tracking of data and documentation. A separate process of block randomisation was undertaken for Site Two, using similarly prepared opaque sealed envelopes. This process ensured that, given the expected smaller numbers of participants, equal numbers of participants were randomised across both arms of the trial. The envelopes were kept in a locked cabinet and the key was held by the midwifery team leader for each shift ensuring that randomisation was possible 24 hours per day.

3.5.12 Blinding

Following consent, the midwifery team leader obtained and opened a trial envelope and, with the assistance of another midwife not involved in the woman's care, administered the SWI using the technique detailed in the envelope. The two midwives were present throughout the procedure regardless of the SWI technique outlined. Following administration of the intervention the injection site was covered with a hypoallergenic opaque dressing to prevent visualisation of the number of injections administered. The midwife caring for the woman was absent from the room while the SWI procedure was administered and then invited to return. All participants were requested not to discuss with the midwife providing care the SWI intervention to which they had been allocated.

3.5.13 Pain measurement

All previous SWI trials have used some method of subjective self-reported pain assessment, typically the VAS (Ader, et al., 1991; Labrecque, et al., 1999; Martensson & Wallin, 1999; Trolle, et al., 1986). The VAS is comprised of a single line anchored at 0 cm by the words *"no pain"* and at 10 cm by the words *"worst possible pain"* (Figure 3.4). The participant is invited to make a mark on the line corresponding to their perceived level of pain, which is then measured from the no pain end of the scale, to obtain a numerical score. The VAS scale has been demonstrated to have a high degree of validity and reliability as a quantifiable measurement of pain (Downie et al., 1978; Price, McGrath, Rafii, & Buckingham, 1983; Revill, Robinson, Rosen, & Hogg, 1976).
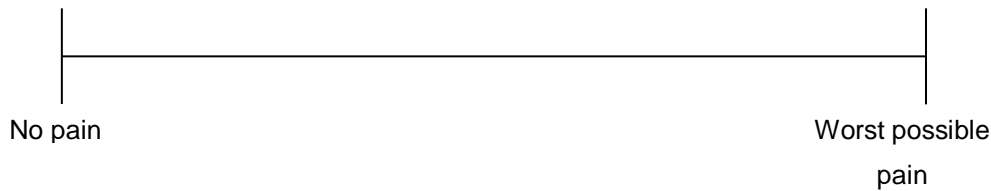
Figure 3.4: Visual Analogue Scale

Other trials (Kushtagi & Bhanu, 2009; Martinez Galiano, 2009; Peart, et al., 2006) have used variations of the VAS that could be graphically or verbally delivered, such as the Numerical Rating Scale (NRS). The NRS, which is divided into centimetre segments from zero to 10, can also be anchored by descriptors (Figure 3.5), and has been validated for use in acute pain settings (Bijur, Latimer, & Gallagher, 2003). The NRS has the advantage of being easier to administer in situations where participants' visual, cognitive and motor functions may be compromised (Bijur, et al., 2003; Holdgate, 2003).
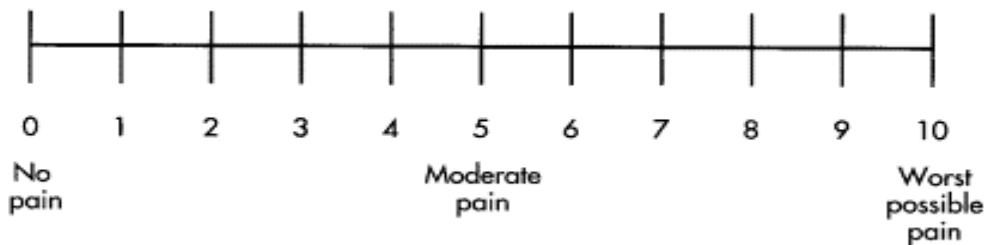
Figure 3.5: The Numerical Rating Scale

The VAS has been correlated with the NRS and the two have been considered interchangeable in clinical use and terminology; the NRS is typically viewed as a variation of the VAS, hence the term VAS was used to describe the instrument used in this study (Bijur, et al., 2003; Downie, et al., 1978; Waterfield, 1996; Williamson, 2005).

In this study, a paper version of the VAS requiring the participant to make a mark was anticipated to have some practical problems regarding administration in the birthing rooms, where water immersion and showers are frequently used by labouring women. The increasing level of pain experienced by women as labour progresses may also impair their ability and their motivation for completing a written scale (Ludington & Dexter, 1998). For these reasons a waterproof graphical NRS version of the VAS, that could be administered visually and verbally, was used to measure pain scores.

With reference to pain rating scales such as the VAS or NRS, it was important to establish if the score equated with moderate to severe pain and at which point a change in score indicated a clinical difference in perceived pain. One study (Collins, et al., 1997) concluded that a score between three and six (30 mm to 60 mm) would indicate moderate pain, whereas a score of seven (70 mm) or more would indicate severe pain. This correlates with the observation by Peart et al. (2006) with regards to women in labour with severe back pain. Furthermore, Kelly (2001, p. 206) reported that, for severe pain, the minimal clinically significant difference in VAS scores that indicated a change equivalent to *"a little better"* or *"a little worse"* was 10 mm, and this was statistically consistent with changes in lesser degrees of pain. Overall, linear pain rating scales have been shown to provide ordinal data that remains consistent with increasing and decreasing levels of pain (Kelly, 2001; Myles, Troedel, Boquest, & Reeves, 1999).

A limiting factor associated with the VAS may occur when measuring differences between different types of pain that occur concurrently, such as abdominal and back pain, and the injection pain associated with SWI. If a woman rates her labour pain towards the *"worst pain imaginable"* and then experiences a significantly greater pain, there is not the scope within the instrument to rate the pain beyond this fixed endpoint (Bergh, Stener-Victorin, Wallin, & Martensson, 2009). Additionally, the woman's interpretation of the maximum level of pain, *"worst pain imaginable"*, may be expected to change as the intensity of labour progresses (Wei, Leng, & Siew, 2010). Therefore the experience of the injection pain may be perceived, or rated, as greater in the early stage of labour when other concurrent pain may be less severe.

3.5.14 Data collection

Following randomisation the attending midwife documented the following data:

- Woman's unit record number (URN).
- Gravity and parity.
- Gestation (recorded in weeks and days).
- Onset of labour (spontaneous or induced).
- Findings of last vaginal exam and time performed.
- VAS score and time collected.
- Time of administration of SWI.

Following administration of SWI the following data were recorded:

- VAS related to discomfort felt during the procedure.
- VAS related to analgesia effect at 10 minutes.
- VAS related to analgesic effect at 30 minute intervals up to two hours post-procedure.

At Site One the following data were extracted from the obstetric database by the research midwife following birth:

- Age of participant.
- Educational level.
- Booking weight and body mass index (BMI).
- Mode of birth.
- Time of birth.
- Any other analgesia used (pharmacological and non pharmacological).
- Model of care (at presentation in labour. e.g. midwifery group practice).
- Infant feeding intention.

The obstetric databases at Sites One and Two varied slightly in the data items routinely collected. As separate data collection forms were generated for the randomisation process for Site Two, they were amended to account for these differences. All completed data forms were returned to a securely locked cupboard; they were also de-identified and entered into a password protected electronic database. Identified data collection forms were kept in locked storage according to the Site One research department policy for data storage. Data collection forms at the second site were stored in a locked cupboard and collected by the chief investigator on a fortnightly basis. Electronic data were provided to the chief investigator in a password protected Microsoft Excel spreadsheet.

The following self-reported data were sought from women within 48 hours following birth via a questionnaire administered by the research assistant:

- Perceived satisfaction with SWI administration.
- Perceived satisfaction with SWI analgesic benefit.
- Likelihood to use again with subsequent labour.
- Likelihood to recommend SWI to others.

3.5.15 Data collection tools

The intrapartum data collection tool was adapted from a document that had been in use since the SWI procedure was introduced to Site One; therefore it was familiar to midwives collecting the data at this site.

3.5.16 Data entry

Data entry commenced in January 2010 and continued as trial recruitment progressed. Data were entered by the researcher into a password protected Microsoft Access Database (Microsoft Corporation 2007 Version 12) specifically designed for the trial by the Research Department at Site One. The database incorporated a data dictionary that provided default values for the majority of the data fields. Missing data were recovered through chart audits conducted by the researcher, where possible.

3.6 Data analysis

3.6.1 Data analysis plan

Data were analysed using SPSS for Windows, (Rel. 17.0.1. 2008. Chicago: SPSS Inc.). Data for continuous outcomes were initially analysed using the Shapiro-Wilk test and assessed visually using histograms to determine parametric or non-parametric distribution. Mean differences and 95% CIs are given for VAS data; means and standard deviations (SDs) are use to describe other normally distributed continuous variables. Medians and interquartile ranges (IQR) are provided for non-parametric data. Where the sample size is less than 100 percentages are reported as whole numbers only (Lang and Secic, 2006). Categorical variables, such as parity and onset of labour, were analysed using the chi-squared test. For differences of two proportions, for example analgesic use between groups, a two tailed Z test was performed. The relative risks (RRs) are provided for dichotomous data, such as mode of birth outcomes, and 95% confidence intervals (CI) are given. Relative risk is recognised as an appropriate method for reporting treatment effects in RCTs as this method, through expressing probability, reflects an intuitive understanding of risk (Simon, 2001). Relative risk is also considered an accurate representation of treatment effect in RCTs (Groenwold, Moons, Peelen, Knol, & Hoes, 2011). Data with normal distribution were analysed using a t-test; non-parametric data were analysed using the Mann-Whitney U test. Data were analysed on an ITT basis and as previously discussed, per protocol (PP) analysis was also conducted to validate the results of the primary outcome (Scott, 2009; Wang, et al., 2006). In line with the

recommended format for clinically relevant outcomes detailed in the Cochrane review (Derry, et al., 2012), VAS outcomes have also been reported as dichotomous outcomes for pain relief of an at least 50%, or 30%, difference between pre and post-injection pain scores at 10, 30, 60, 90 and 120 minutes. Demographic and other baseline characteristics are also reported to assess comparability between groups; however, formal statistical testing was not carried out to assess differences. The level of statistical significance was set at 0.05.

3.6.2 Missing data

It was envisaged that not all women would provide complete VAS data for the two hour data recording period as birth, subsequent analgesic use (epidurals) or other unforseen clinical events, would interrupt the data collection and result in missing data. As previously indicated, the sample size calculation included allowance for an attrition rate of 20%. Only one previous RCT on SWI (Bahasadri, et al., 2006) published complete data and although available data were analysed, missing data were not replaced by imputation. As this approach may lead to bias during an ITT analysis, baseline data for participants who did not complete all VAS scores will be explored in the analysis to determine the generality of these outcomes (Altman, 2009).

3.6.3 Analysis of non-inferiority

The primary aim of the quantitative phase was to determine if the SI is non-inferior to the FI based upon a comparison of VAS scores prior to, and 30 minutes following, treatment. The mean difference would thus need to fall within a clinically relevant non-inferiority margin of less than one centimetre.

An accepted approach to the analysis of non-inferiority is a hypothesis testing framework where the null hypothesis of inequality is rejected in favour of the alternative hypothesis of equality based on a single sided *p* value of less than 0.025 (Kaul, 2006). Interpretation may also be based upon the corresponding lower limit of a two sided 95% CI (Lesaffre, 2008; Piaggio, et al., 2006). The lower limit of the CI is usually interpreted as the degree of inferiority to the standard treatment (EMA., 2005; Scott, 2009). That is, non-inferiority is demonstrated if the lower limit of the CI is greater than, or outside, the designated NI margin (Miller, et al., 2006). However, non-inferiority trials are more common in pharmaceutical testing where the use of the lower CI is required to avoid a type one error where a treatment may be erroneously viewed as non-inferior, particularly in the absence of a placebo (Hung,

2003). The standard approach to interpretation of superiority trials involves both statistical significance and clinical relevance (EMA., 2005). Hence, Piaggio (2006) recommends that both sides of a 95% CI should be reported and taken into consideration. Therefore, in the interpretation of non-inferiority, if the point estimate and lower limit of the CI fall outside the non-inferiority margin, and some portion of the upper CI falls within the non-inferiority margin, although the treatment fails the test of non-inferiority, the treatment is not absolutely inferior (Miller, et al., 2006).

Figure 3.6 outlines possible scenarios for the outcome of the data analysis based on the pre-defined non-inferiority margin. Error bars indicate 90% CIs. If the CI is completely to the left of zero, the treatment is inferior (scenario A). Scenarios C and D indicate non-inferiority as the CI lies within the specified margin; scenario E would indicate superiority. An inconclusive result (scenario B) is unlikely as the sample size is sufficiently powered to provide a result.
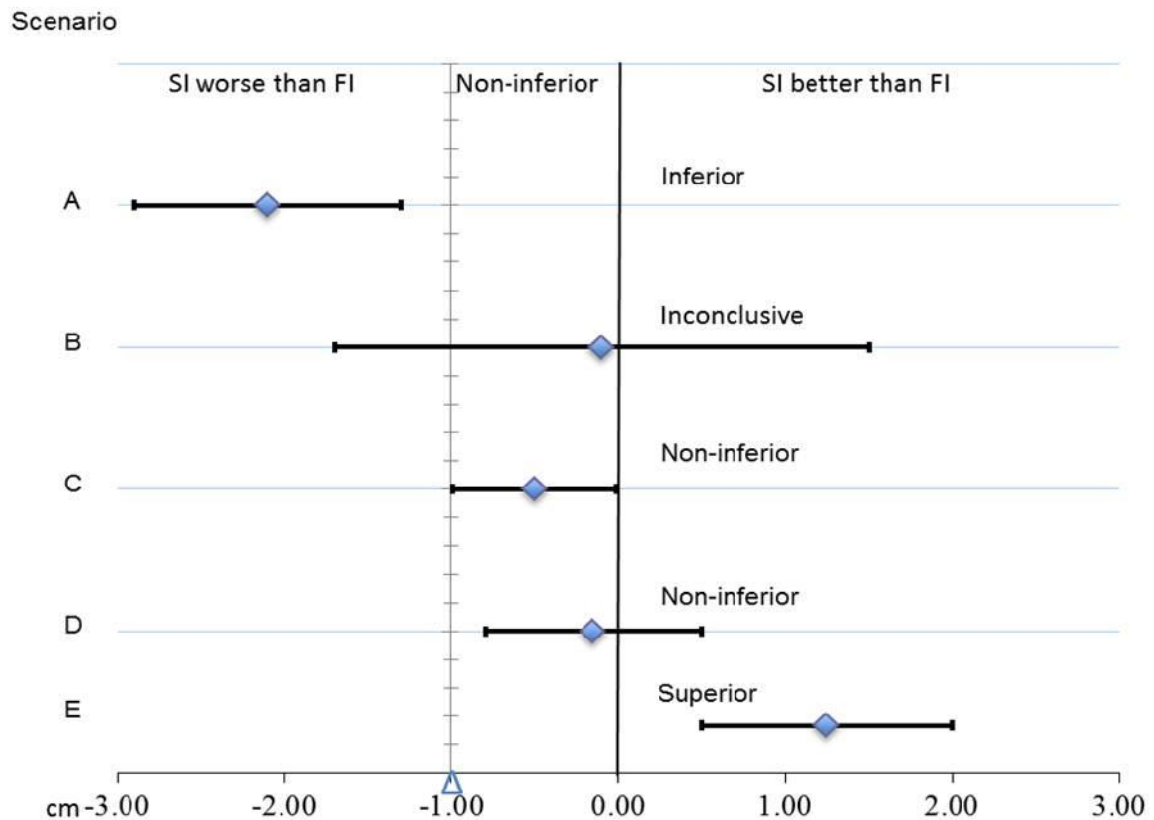
Figure 3.6: Possible scenarios for the outcome of primary analysis (adapted from Piaggio, 2006).

3.6.4 Statistical analysis of Visual Analogue Scale data

Controversy exists regarding the most appropriate statistical test for VAS data (Dexter & Chestnut, 1995; Mantha, Thisted, Foss, Ellis, & Roizen, 1993). Parametric tests that assume a normal distribution of data are more sensitive to differences between groups, and produce CIs that are narrower and arguably more clinically relevant. However, they may produce false positive results in data that are not normally distributed by more than a modest degree (Mantha, et al., 1993). Non-parametric tests, which are based on the rank order of data, are problematic in terms of producing CIs, as there is no accepted process for determining CIs from non-parametric data (Nakagawa & Cuthill, 2007). A number of authors (Dexter & Chestnut, 1995; Ludington & Dexter, 1998; Mantha, et al., 1993; Myles, et al., 1999) have advocated the use of parametric tests for the analysis of VAS data. However, Dexter and Chestnut (1995) point out that if greater than 16% of participants rank their pain at the extreme ends of the scale (either 0 or 10) then the distribution of the data would be outside the limits for parametric testing to return an accurate and meaningful result based on the assumption of normal distribution. Therefore, if more than 16% of women from this study, in either group, return a VAS score of zero a parametric test is not suitable for analysing the raw VAS data to report on the primary outcome.

Visual analogue scale data that is either positively or negatively skewed may be transformed to a more normal distribution (Maxwell, 1978), achieved, for example, through logarithmic, square root or arcsine transformation, although Dexter and Chestnut (1995) advise that any such transformation may also reduce differences between means which may then limit the potential of a parametric test to detect a difference. Alternatively, the difference between the pre and post-intervention scores may be calculated to present a change in pain levels with the pre-score as a baseline. Mantha (1993) also advocates for the average change in pain levels to be calculated.

Finally, some studies have demonstrated the relationship between mean VAS scores and a dichotomous description of the same data as the number or proportion of participants who achieved 50% pain relief (Moore, McQuay, & Gavaghan, 1996; Moore, Moore, McQuay, & Gavaghan, 1997). The presentation of VAS data as a dichotomous variable has the advantage of being clinically intuitive (Derry, et al., 2012; Moore, et al., 1996).

3.6.5 Statistical analysis of secondary outcomes

A number of relevant secondary outcomes were identified within the trial protocol (Appendix 18) for data collection and analysis. The analysis of secondary outcomes may have particular relevance in non-inferiority trials, if the outcome of the primary end point is inconclusive (Pocock, 2003), or provide support for the conclusions drawn from the primary end point (Moyé, 2003).

The test for non-inferiority was only applied to the primary outcome; however, for the secondary VAS outcomes, the results are also presented in relation to the non-inferiority margin to maintain a consistent comparison of clinical effect. Standard inferential statistical tests were applied to the secondary endpoints. In this study these data items included the VAS scores of injection pain and back pain recorded at 10, 60, 90, and 120 minutes post injection. Visual analogue scale data were collected on women who received repeat injections (n=19) which were given using the four injection technique as further randomisation and blinding was not possible.

Other secondary exploratory outcomes included subsequent analgesic use, both pharmacological and non-pharmacological, within the two hour VAS data collection period and during the remainder of the labour and mode of birth (including birth position and labour duration). However, the secondary outcomes were not specifically powered to detect differences and are; therefore, exploratory. Clinical differences in outcomes that are parametric will be drawn from, and presented, as CIs. The use of CIs to present clinical significance in secondary outcomes has the added advantage of presenting the effect size. This range of information contributes to the precision of the difference given the limited sample size (Nakagawa & Cuthill, 2007). No *p* values are reported in tables where secondary outcomes are parametric data. For non-parametric data and in comparison of differences in proportions where the cell frequency was less than five, and where a binomial test was performed, *p* values are used to explore the outcomes. The analysis of data from the postnatal questionnaire is described later in this chapter.

3.6.6 Subgroup analysis

A subgroup analysis may be defined as an analysis of a particular outcome undertaken within a subgroup of participants defined by baseline characteristics (Wang, Lagakos, Ware, Hunter, & Drazen, 2007). Subgroup analysis may be undertaken to determine if treatment effects

and/or trial conclusions vary according to the baseline factor. However, due to the smaller sample size, results of subgroup analyses are more prone to false positive results and applicability to larger populations is questionable (Dijkman, Kooistra, & Bhandari, 2009). Six subgroup analyses were undertaken on the data on a post hoc basis, i.e the analysis was not planned in the original trial protocol, but was undertaken to explore hypotheses presented in the literature. The subgroup analyses undertaken concerned pharmacological analgesic based on parity, non-pharmacological analgesic use, labour duration, the relationship between body mass index (BMI) and back pain, and characteristics of participants who reported no effect from SWI. Differences in timing of epidural use following SWI were also explored. The same approach to statistical analysis was used as for the secondary outcomes.

3.6.7 Protocol violations

Women who gave birth or elected to have pharmacological analgesia after the collection of the primary measure (VAS score 30 minutes post-injection), but before the completion of the secondary outcomes (VAS up to 120 mins), were included in the trial. Women who gave birth or elected to have pharmacological anaesthesia prior to the collection of the primary outcome measure were included in the ITT analysis.

In the event that women experienced no relief from the single injection and requested the four injection technique, they remained within the study, and their data were analysed according to ITT principles.

3.7   The postnatal questionnaire

3.7.1 Data collection

On the first postnatal day participants were invited to complete a questionnaire regarding their satisfaction with the pain relief they experienced; the best and worst aspects of SWI, whether they would use SWI again and/or would recommend it to other pregnant women. Women who elected for early discharge directly from birth suite were mailed a questionnaire with a reply paid envelope, or responses were taken over the phone by the research midwife.

The postnatal questionnaire (Appendix 9), based upon a similar tool used in a prospective cohort study of women using SWI, was adapted and used with the permission of the authors (Peart, et al., 2006). It consisted of five questions related to women's perception of, and satisfaction with, SWI. Two open-ended questions asked women to describe the best aspects

(what they liked most) and the worst aspects (what they liked least) about using SWI. A third question asked women to rate their satisfaction with the pain relief provided by SWI on a five point Likert scale ranging from *"very dissatisfied"* to *"very satisfied"*. Two questions required a yes/no response: whether women would consider using SWI again in a subsequent labour and; whether they would recommend the procedure to other women.

3.7.2   Analysis

Initial analysis examined differences in demographic data between women completing the questionnaire and those who did not. Chi-square tests were used for categorical variables such as group allocation, level of education, parity, model of care and onset of labour. Data on BMI and cervical dilatation prior to administering SWI were not normally distributed, therefore a non-parametric test, Mann-Whitney U, was used. The Student's *t*-test was used to determine differences in age. Responses to the satisfaction scale and questions concerning the likelihood of using the intervention again, or recommending it to other women, were analysed using a Chi-square test. A simple content analysis categorised responses to the open-ended questions, which are presented in the SWITCh Trial Results chapter as a percentage of the responses to the questionnaire although not all women provided responses to these two questions.

3.7.3   Summary of quantitative phase design

This section outlined the purpose and rationale for the randomised controlled non-inferiority design. Specifically, how the characteristics of non-inferiority design suited the stated objective of examining the single and four SWI techniques to determine if they are comparable. The trial methods, in terms of consent, treatment allocation, blinding, data collection, analysis, and the training of midwives, were also discussed. An overview of the postnatal data collection tool and analysis were provided.

The methodology for the qualitative phase of the project is reviewed in the following section.

3.8   Qualitative phase

3.8.1   Introduction

As the aim of this component of the study was to describe women's and midwives' experiences of using SWI, a qualitative research methodology was most appropriate. The approach is also consistent with a sequential explanatory mixed methods approach (Creswell

& Plano Clark, 2007). Qualitative research can be described as a set of descriptive, interpretive and material practices or methods that bring meaning to events in terms of the people that experienced them (Denzin & Lincoln, 2011). In doing so, qualitative studies attempt to present a rich in-depth account of phenomena from the perspective of the participant (Sandelowski, 2000b). Hence, qualitative research employs a wide range of empirical methods, such as interviews, observations, and analyses of historical and/or contemporary texts, including social media. Qualitative researchers may employ a range of descriptive and interpretive practices, often interconnected, to analyse their data (Denzin & Lincoln, 2011).

3.8.2   *Qualitative design*

The broad nature of qualitative research may result in the final design of the study only becoming apparent as the study progresses and adapts to the realities and perspectives of those involved, including the researcher (Polit & Beck, 2004). This is a conscious process of observation, reflection, questioning and decision making that reflects an *"epistemological reflexivity"* (Dowling, 2008, p. 747). A number of specific theoretical approaches, including phenomenology, were considered for this part of the study; however, the nature of the data and the relationship between the qualitative and quantitative components of the study suggested a broader, more flexible and adaptive approach. It is acknowledged that using a well established approach such as phenomenology or grounded theory may add an immediate sense of epistemological validity to the qualitative research project; however, authors such as Sandelowski (2000b) and Braun and Clarke (2006) point out that many qualitative designs share a common underlying approach to methodology and analysis. As such, the shared and foundational approach to design and analysis, carries a long-standing theoretical validity that, because of its broad applicability, is often overlooked or rebranded as more recognisable methodologies such as phenomenology. Hence, the approach taken here is based on the fundamentals of descriptive qualitative research and thematic analysis, which have their origins in a naturalistic approach (Braun & Clarke, 2006; Sandelowski, 2000b). This involves researching with natural settings, to ensure data are generated with minimal manipulation of variables, and hence reflect the participants' everyday environments (Sandelowski, 2000b). Naturalistic enquiry also preferences the research question over pre-existing theory and, as previously discussed, the eventual research design is emergent and not bound to a particular theoretical perspective (Guba & Lincoln, 1982).

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The specific aspects of my approach, including participant recruitment, data collection and analysis, will be discussed later in this chapter.

3.8.3   Reflexivity

An essential difference between quantitative and qualitative research is the role and positioning of the researcher in relation to the research (Guba & Lincoln, 1982). Within an RCT, randomisation, blinding and allocation concealment are designed to eliminate bias that may otherwise occur as a result of interactions between participants and researcher that may influence the data and analysis (Jadad, 1998). In qualitative research the researcher is integral to and has an influence on, all aspects of research activities; not only data collection and analysis. As far as possible the researcher places themselves within the participant's world and the resulting data inevitably includes interactions between the two (Winter, 2000). However, if the process of interaction between participant, data and researcher is not made transparent through a process of reflection, then it may be difficult for readers to judge if the analysis has been authentically drawn from the data and is justified (Lambert, Jomeen, & McSherry, 2010). Reflexivity can be broadly defined as a continuous process of increasing the researcher's self-awareness, active engagement, and ongoing explanation of the possible influences they have on the research project (Walsh & Downe, 2006). The process requires the researcher to consider, and describe, their personal and professional beliefs and agendas (Dowling, 2008; Kingdon, 2005). Triangulation may contribute to reflexivity through comparing different data sources to identify patterns of convergence, or to corroborate the analysis and interpretation (Mays & Pope, 2000). Koch and Harrington (1982, p. 888) observe that the process of reflexivity also involves the *"many voices"* that may influence the researcher, which need to be recognised and acknowledged.

Both the quantitative and qualitative phases of this research evolved from discussions with colleagues, supervisors and labouring women. Initially, I collaborated with other midwives to take on the clinical and political challenges involved with introducing SWI to the workplace; a process that highlighted the need for further research. A personal desire to learn about research processes led to the establishment of the quantitative trial and the eventual expansion of the project into an academic pursuit, starting with enrolment in a Masters program and progression to a PhD. Academic supervisors reviewed, challenged and encouraged my ongoing critique associated with data analysis, while labouring women constantly challenged

my priorities and assumptions. Identifying a research question is inevitably driven by a degree of familiarity with the topic and a desire to know more (Savin-Baden, 2004). Throughout my professional life I have variously been a clinician, educator and now a novice researcher, with each role bringing particular views and questions to my work. As a clinician the practical aspects of SWI and the effects on the labouring woman take precedence; as an educator, the professional aspects of training, communication, and establishing the evidence for the procedures are important; while as a researcher, the practice and rigor of research and the generation of theory and knowledge are key. Within the context of this study, each of these three perspectives influenced how data were viewed and analysed; similarly, these viewpoints evolved as the research progressed.

There are any number of specific and personal characteristics such as gender, age, ethnicity etc. that may influence the interaction between researcher and participant, the data collected during interviews and the process and interpretation of data analysis. Two personal aspects may have influenced the qualitative study: my gender and my relationships with my midwifery colleagues. As a male working in a predominantly female profession, caring for women in labour may raise assumptions and/or expectations regarding the role of males in midwifery and health care more generally. This in turn may influence how participants respond to being interviewed by a male, especially where this concerns intimate events, such as childbirth. In a review of qualitative studies that used cross-gender interviewing (Broom, Hand, & Tovey, 2009), the authors observed that cross-gender interviews (e.g. males interviewing females) were influenced not only by perceptions of gender roles but also familiarity with the topic and the initial stance taken by the interviewer. Therefore a male midwife interviewing women on the subject of pain relief in childbirth presents not only as male but also as someone with detailed background knowledge (but not personal experience) of the topic. Secondly, as a clinical midwife who worked on the same birth suite as most of the participating midwives, I was positioned in the role of an insider, which can be advantageous in terms of fitting in and having existing knowledge of the topic, but it may also carry a number of assumptions and expectations about the responses which will be provided. Burns et al. (Burns, Fenwick, Schmied, & Sheehan, 2012) discuss the importance of maintaining a middle ground when midwives engage in midwifery research and using reflexivity to constantly explore the researcher's stance.

3.8.4   Sampling

Random purposive sampling was used to recruit participants for the qualitative study. Purposive sampling refers to the deliberate selection of participants who have the requisite knowledge or experience to speak to the topic (Holloway & Wheeler, 1996). However, within a mixed method design, where there was a large potential population (i.e. labouring women with back pain who received SWI) identified in the quantitative phase, it is possible to draw randomly from this group (Sandelowski, 2000a). Similarly, there were a large number of midwives at both sites who participated in the use of SWI within the context of the quantitative study from which to draw a sample.

Sample size in qualitative research is determined by the purpose and type of the research question(s) and to the degree of heterogeneity between participants although there are no precise criteria to determine either aspect (Polit & Beck, 2006). The women in the quantitative study could be considered a homogenous group, as they all received SWI for back pain in labour, with approximately half receiving either one, or four, injections. Similarly midwives could be considered homogenous in that they all provided SWI to labouring women, albeit with differing levels of experience in SWI administration and midwifery practice generally. As the midwives participating in this study worked in birth suite during the time the SWITCh trial was taking place, it is reasonable to assume that they had knowledge and experience of either (or both) the single and four injection techniques. The final sample size for a qualitative study may be determined by the point of data saturation, that is, the number of participants required to reach a level where no new themes arise from the data. Holloway and Wheeler (1996) offer a broad guide to sample sizes, although they acknowledge that this may be affected by elements such as the topic and methodology. For the qualitative phase of this study a sample size of 10 women and 10 midwives was determined as appropriate with the final sample consisting of nine women and eleven midwives.

3.8.5   Participants

Postnatal women from both sites were invited to participate in the study based on the inclusion criteria: having previously participated in the SWITCh trial and; able to provide written consent. Women who were excluded from the SWITCh trial were also excluded from participation in this phase of the research.

Midwives who worked in birth suite, at both sites, and had experience of using SWI during the SWITCh trial, were invited to participate in the qualitative phase.

3.8.6   Recruitment and consent

Following ethics approval from the Human Research Ethics Committees (HREC) at both sites, an invitation to participate in this phase of the study was offered to women who had participated in the SWITCh trial. An information sheet (Appendix 10) was offered to women by a research assistant at the time of the administration of the postnatal survey for the SWITCh trial. The research assistant was a midwife; therefore, women had an opportunity to ask questions of a suitably qualified person. At this time women were informed that, if after reading and understanding the information, they were interested in participating in the second phase, they could provide contact details to the research assistant who passed them to the researcher. The researcher then contacted the participant to provide a detailed explanation regarding the processes and expectations, including consent and the use of recorded interviews. Prospective participants were provided with a consent form (Appendix 11) immediately prior to interview. Nine women participated; seven from Site One and two from Site Two. The difference in numbers was largely related to the difference in the number of women being recruited to the SWITCh trial at each site.

An invitation to participate was also distributed to midwives in the form of an information sheet which was emailed via employee email accounts at both sites (Appendix 12). The researcher's email address and phone number were provided. Midwives interested in participating contacted the researcher and were offered a detailed explanation of the processes and expectations involved, including the use of recorded interviews (Appendix 13). Written consent was sought immediately prior to interviews (Appendix 14). Eleven midwives were recruited and three focus groups were held; two at Site One (n=4, n=3) and one at Site Two (n=4).

3.8.7   Data collection

Data were collected through individual, face to face interviews with women and focus groups with midwives. Interviews are a common means of data collection in qualitative research because they enable the researcher to explore experiences from the view point of the participant (Bluff, 2006). Burgess (1984, p. 84) describes qualitative interviews as *"conversations with a purpose"*, where, unlike structured questions and answers, a semi-

structured approach uses themes and topics aligned to the research aims to guide questions throughout the course of an interview. Bluff (2006) advocates a semi-structured approach with questions related to the research agenda that allow participants to express what is important to them, while remaining sufficiently flexible to explore unanticipated areas of interest. Semi-structured interviews should offer a limited number of prompts or open-ended questions to encourage the participant to discuss their responses at length (Smith, Larkin, & Flowers, 2009).

Individual interviews with women took place in their homes. This was their preferred venue, mostly because it minimised the inconvenience of travelling with a newborn infant and provided a naturalistic setting to conduct the interview. The interviews were conducted at a time mutually agreed by the researcher and the individual participant. They lasted between 30 and 60 minutes and a prompt sheet was used to facilitate questions (Appendix 15).

Qualitative data from midwives were obtained through focus group interviews using a semi-structured format. A focus group is an interview typically involving three to 10 people that focuses on a specific topic. Focus groups provide a number of advantages over individual interviews, including the provision of a safe forum for discussion that potentially encourages a greater degree of spontaneity, and provides a rich data set (Bluff, 2006; Sim, 1998). Midwives typically use birth stories, narratives and anecdotes to share information, reflect on practice and offer mutual support (Leamon, 2009). A focus group therefore provided a naturalistic setting for midwives to discuss their experiences of using SWI.

Some authors advise that the size of the focus group should be large enough to generate a good discussion but small enough to allow participants the time and opportunity to contribute their own perspectives (Smith et al., 2009). The focus groups for this study were limited to three or four midwives. The smaller group size supported in-depth discussion and provided opportunities for participants to express their views; again a semi-structured format was used to prompt discussion. The focus groups, which were facilitated by the researcher with notes made by a second person (academic supervisor), lasted between 40 and 60 minutes. Prior to the focus group commencing, ground rules were discussed (Appendix 16) and midwives were asked to complete a brief questionnaire that requested demographic data (Appendix 17).

3.8.8   Thematic analysis

Thematic analysis was the method chosen to undertake analysis of the qualitative data. It is generally acknowledged that there are no universal procedures for analysing qualitative data; however, the selected approach needs to be consistent with the overall methodology (Polit & Beck, 2004). Thematic analysis can be described as a widely used, and essentially foundational, method for *"identifying, analysing and reporting patterns (themes) within data"* (Braun & Clarke, 2006, p. 79). Accordingly, a theme can be defined as a statement or concept that captures and brings meaning to a pattern of responses within a data set. Themes are often described as emerging from the data although this may overlook the position and potential influence of the researcher (Braun & Clarke, 2006; DeSantis & Ugarriza, 2000). Two approaches to thematic analysis have been described; inductive, where the themes are strongly linked to the data and; theoretical, where the analysis is linked to a particular theoretical approach (Braun & Clarke, 2006). In keeping with the methodology adopted in this study, an inductive approach was used.

3.8.9   Analysing of focus group data

Focus groups may produce data that are different from that gained from individual interviews. The group interaction potentially provides insights, similarities and differences based on the opinions and experiences of the individual members (Morgan, 1997) that are responded to, and considered, in real time. Data may be provided in the form of stories and anecdotes with the group dynamics permitting the researcher to witness how interactions function in a particular social setting (Kitzinger, 1994). Focus group data presents a number of challenges for analysis, especially with respect to single versus multiple voices, potentially resulting in complex levels of analysis (Duggleby, 2005; Kidd & Parshall, 2000). Group interaction may also impact upon whether themes are representative of the group, or rather strongly held individual viewpoints that are then accepted, or echoed, by others (Kidd & Parshall, 2000). There are no specific methods for analysing the dynamics of focus groups (Wibeck, Dahlgren, & Öberg, 2007); however, Kitzinger (2005) advocates that, where possible, sections of the discussion may be presented to illustrate how individual voices interact within the group to contribute to the identified theme. Similarly, Duggleby (2005) describes a method where themes are identified from individual data and then compared with interaction data to provide greater depth in the analysis.

3.8.10 Data analysis

All one-on-one interviews and focus groups were audio recorded and transcribed by a third party and verified by the researcher. Transcripts were read a number of times to identify broad themes. These primary themes were then clearly defined, for example:

1. Pain: descriptions and accounts of **all** experiences, inclusive of physical/emotional etc and regardless of timing i.e. from earliest memory to present.

   Data were then coded to sub themes for example:

   i) Pain associated with previous pregnancy, birth and postnatal period; pain related to previous pregnancy/birth, inclusive of/from previous injury/experience and back pain.

   ii) Back pain associated with this labour: accounts, impact and descriptions of pain which specifically includes the lower back area.

The process was iterative as all data were read and re-read to identify potential themes of relevance to the research question. Data were independently coded by the researcher and a supervisor. Inconsistencies were reconciled and a final coding scheme agreed. Transcriptions were then uploaded to NVivo qualitative data analysis software (QSR International Pty Ltd. Version 8, 2009), and analysed thematically. Themes and definitions were reviewed against the text to ensure that they accurately reflected the data entered. A process of collapsing and merging of subthemes then occurred before the final thematic structure emerged.

3.8.11 Presentation of findings within the text

The results of the data analysis are presented thematically in the Analysis of Qualitative Data chapter. De-identified extracts from the data were selected to reflect the meaning of each theme in relation to the research question and the extant literature. Focus group conversations and interactions have been included in the extracts, where appropriate. Although extracts and quotes are used to illustrate the essence of the themes, the process involves selection by the researcher, and is therefore also representative of the researcher's interpretation of the quote in the context of the data and the research question.

The following conventions are used in the presentation of interview data in this chapter:

i) Extracts/quotes from participants are distinguished by italicised text.

ii) Clarifications within the quote (e.g. descriptions, indefinite articles, moments of pause or laughter) are presented as normal text within parentheses (...) and the characters *[…]* indicate where quotes have been edited for clarity.

In keeping with the conventions of qualitative research, contributions from participants remains in their language and may include grammatical errors and outdated terminology.

3.9   Issues in mixed methods design

3.9.1   *Rigour and validity in mixed methods research*
The issue of validity and rigour in a mixed methods design is a subject of ongoing debate (Onwuegbuzie & Johnson, 2006); not least because the language and description of validity and rigour are generally grounded in assumptions about either quantitative or qualitative paradigms (Winter, 2000).

3.9.2   *Validity in quantitative research*
As quantitative research attempts to break down and measure a phenomenon into restrictive sets of outcomes that can be applied to all participants, both within, and outside of, the study, the investigator is required to distance themselves from the data and research process to avoid influencing these outcomes (Sale & Brazil, 2004; Winter, 2000). Therefore, the concept of validity in quantitative research is designed to demonstrate the independence of the research enterprise from the researcher, and the observance of an identified research process through adherence to a defined set of rules (Sale & Brazil, 2004). These rules aim to demonstrate the validity of research findings in terms of internal and external validity, reliability and objectivity. As the quantitative arm of this study used an RCT design, validity was promoted through the use of the Consolidated Standards of Reporting Trials (CONSORT) Statement specifically required for non-inferiority design (Piaggio, et al., 2006).

3.9.3   *Rigour in qualitative research*
he concept of rigour in qualitative research continues to be the subject of considerable debate (De Witt & Ploeg, 2006; Rolfe, 2006; Walsh & Downe, 2006). Many researchers credit Lincoln and Guba (1985b) as providing the first standardised framework for assessing the rigour of qualitative research under the criteria of credibility, transferability, dependability and confirmability. These criteria were further developed for nursing research by Sandelowski (1986) and Beck (1993). However, others (Koch, 1996; Rolfe, 2006) argue that it is not

possible to have a singular approach to rigour in qualitative research as the different methodologies each have specific approaches and goals that cannot be assessed or evaluated against a single set of criteria. Broadly, there appear a number of re-occurring themes within discussions about rigour such as the need for a clear theoretical framework (Annells, 1999; Crist & Tanner, 2003; De Witt & Ploeg, 2006; Koch, 1996) and congruence between the chosen methodology and the research question (Koch, 1996; Rolfe, 2006). A clear decision trail that allows the reader to easily see the analytical processes used by the researcher is also viewed as essential (Annells, 1999; De Witt & Ploeg, 2006; Koch, 2006; Walsh & Downe, 2006). These themes were further detailed in the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (Tong, Sainsbury & Craig. 2007). Moreover, some authors suggest that the quality of report writing is an important element in accurately conveying the experiences of the participants for the reader (Annells, 1999; De Witt & Ploeg, 2006; van Manen, 1997).

3.9.4 Combining rigour and validity in mixed methods design

Some authors (Onwuegbuzie & Johnson, 2006; Sale & Brazil, 2004) have advocated the use of a combined language and description of validity in mixed methods research. This essentially matches the expectations of validity in both paradigms, based on the framework of Lincoln and Guba (1985a, 1986). For example, internal validity is aligned with credibility, external validity with transferability, reliability with dependability and objectivity with confirmability. The essential purpose of this process for both quantitative and qualitative designs is to present the transparency of the research process so that the quality of the research, and the outcomes, can be assessed by consumers of research (Onwuegbuzie & Johnson, 2006).

3.9.5 Ethical issues

All phases of the study were approved by the Australian Catholic University Human Research Ethics Committee (HREC), and the governing HREC at each participating site (Appendix 20).

This study conformed to the principles of the *"Declaration of Helsinki"* (World Medical Association, 2008), first developed by the World Medical Association (WMA) in 1964 and since regularly reviewed and amended. The statement outlines the ethical principles for medical research involving human subjects.

3.9.6   Potential risks

The four injection SWI technique had been used routinely at the Site One birth suite for 12 months prior to the start of the trial. During this time no adverse events or reactions had been reported. Moreover, no adverse events, including allergic or systemic reactions to the procedure had been reported in the literature, other than the brief stinging sensation immediately following administration (Fogarty, 2008). Therefore, no additional risks for women participating in the study were expected.

As labour and birth experiences may contain both positive and negative memories for participants, potential for distress through the recall and discussion of stressful or traumatic events was acknowledged. Prior to interview, all participants were advised they could end the interview at any time without question. Participants who expressed distress during an interview could be offered referral to existing hospital supports at each site, such as the patient advocate and pastoral care representatives. During the data collection period participant distress was not detected and hence, no referrals were needed.

3.9.7   Project management

Project management was overseen by a research team, chaired by the author and consisting of midwifery and obstetric clinicians, midwifery academics and researchers from both sites. The research team met regularly during the project development phases; regular contact and progress reports continued throughout the project.

3.9.8   Confidentiality and data security

Several methods were employed to ensure participant anonymity was maintained and individual identity protected from unauthorised parties. Identified data collection forms were kept in locked storage, according to the Site One guidelines for data storage. Through allocation of a study code, which was also entered on the data collection forms, data were de-identified and entered into a password protected database. Data entry and storage, both paper and electronic, were stored and maintained as specified by Site One (Data and Record Management for Clinical Research) for a period of not less than 15 years.

An ethical issue identified for focus groups is the threat to breach of confidentiality. This may occur from information revealed to the group as well as the researchers, or may stem from issues that arise as a result of group interactions (Smith, 1995). This was addressed through

the discussion and agreement of ground rules before the commencement of each focus group that highlighted individual respect and the right to decline further participation or elaboration on particular points of discussion. As far as I am aware, no breaches of confidentiality took place during, or following, the focus groups.

It was also acknowledged that a midwife participating in the focus group may reveal an event, or knowledge of an event, that may have implications for practice and safety. Should this occur, the researcher would seek advice and support from the principal academic supervisor and the issue discussed with the chair of the relevant HREC. No such incident arose during the focus groups.

3.9.9   Data Safety Monitoring Board

A Data Safety Monitoring Board was not established for this trial, as there had been no adverse events reported in any previous trial of SWI. The trial was thus considered to be low risk. A senior obstetrician at each site agreed to act as a clinical monitor to investigate any adverse events that might have been associated with the trial. This process was approved by the HREC at each site. Only one incident was reported involving a participant who experienced an episode of syncope two hours after administration of the intervention. This was investigated by the clinical monitor and found to be unrelated to the trial.

3.10   Summary

This chapter was divided in four sections. The first section discussed the sequential explanatory mixed methods approach as it applied to this project. The second section presented an overview of the RCT design with particular reference to the aspects of the design that are adapted to establish non-inferiority. The third section discussed the qualitative methods used, detailing the processes for data collection and thematic analysis, with consideration given to the analysis of focus group data. Finally, the concept and application of validity and rigour within a mixed methods design was explored.

The following chapter presents the data and analysis for the quantitative phase of the study.

Chapter four: Results of the SWITCh trial

4.1   Overview

The previous chapter provided an overview of the research design for the mixed methods approach to the study. This chapter examines the results of the analysis of the SWITCh trial data. The results for the primary and secondary outcomes are presented and issues relevant to the findings are discussed. The chapter also presents findings from the postnatal questionnaire which explored levels of maternal satisfaction with the intervention; responses to the open-ended questions illustrate the participant's perceptions about the best and worst aspects of the intervention. Outcomes specific to the quantitative phase are discussed in reference to the supporting literature. As outlined in the Introduction chapter of the thesis, areas of interest from both the quantitative and qualitative phases are explored in the Discussion chapter.

4.2   Sample

Over the period of the study, (January 2010 to February 2011), 352 women were eligible for inclusion in the trial; 44 women declined to participate, 32 received SWI outside of the trial, one was excluded as an interpreter could not be located and, on two occasions, midwives were unavailable to perform the intervention. Therefore, a total of 305 women were randomised to the trial; 215 women at Site One and 90 at Site Two (Figure 4.1).
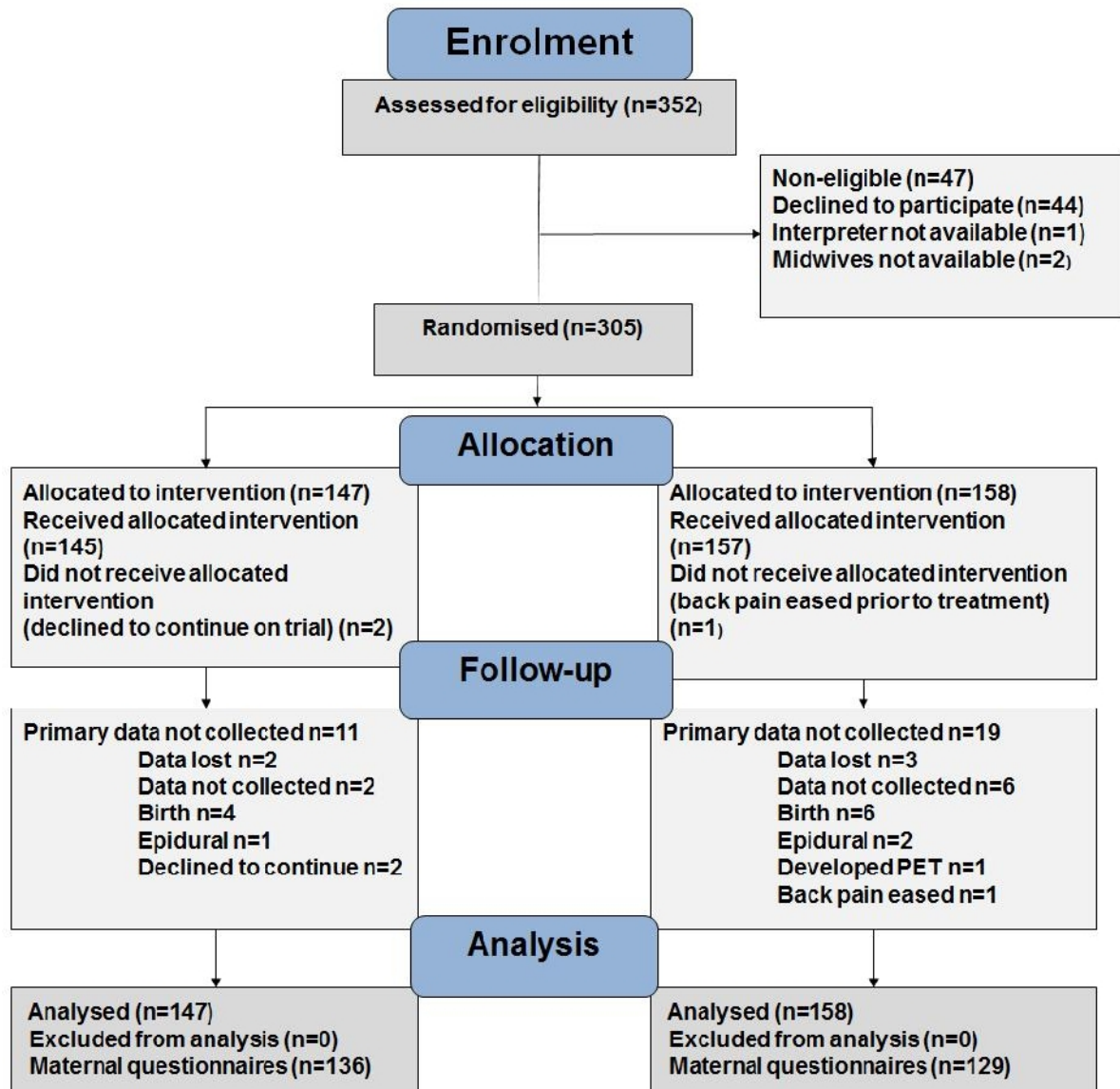
Figure 4.1: Participant allocation and flow

4.3   Baseline characteristics

Baseline characteristics of participants from Site One and Site Two were compared to determine if both cohorts were similar. There were no significant differences between the participants recruited at the two study sites (Table 4.1), except for privately insured women who were only provided for at Site One.

Table 4.1: Comparison of baseline characteristics at each study site

	Site One n=215	Site Two n=90	*p*
Treatment group allocation	SI 104 (48.4)/ FI 111 (51.6)	SI 43 (47.8)/ FI 47 (52.2)	0.92
Age: mean (SD)	27.98 (5.16)	28.81 (4.45)	0.18
BMI: median (IQR)	23.3 (20.5/26.7)	24.0 (21.3/26.4)	0.13
Tertiary education	119 (55.3)	58 (64.4)	0.07
Nulliparous	158 (73.5)	66 (73.3)	0.97
Gestation: median (IQR)	40 (39/40)	40 (39/40)	0.10
Spontaneous onset of labour	173 (80.5)	79 (87.7)	0.06
Cervical dilation prior to randomisation: median (IQR)	4 cm (3.0/5.0)	4 cm (3.0/5.0)	0.62
VAS score of back pain prior to randomisation: median (IQR)	8.00 (7.7/9.0)	8.00 (8.0/9.0)	0.52
Private insurance	37 (17)	nil	

Values are number (%) unless otherwise indicated.

Following randomisation, baseline characteristics between the two groups were similar, (Table 4.2). Twenty-four women (16%) in the SI group received their antenatal and intrapartum care from a private obstetrician compared to 12 (7%) in the FI group. Insurance status was not identified as a factor likely to effect the perception of pain or pain relief (Dannenbring, Stevens, & House, 1997; Fridh, Kopare, Gaston-Johansson, & Norvell, 1988; Halldorsdottir & Karlsdottir, 1996) and; therefore, was unlikely to influence the primary outcome. In keeping with a contemporary approach to baseline characteristics, an analysis of significance was not performed as the imbalance occurred by chance and was not shown to impact upon the analysis of the primary outcome (Pocock, Assmann, Enos, & Kasten, 2002; Senn, 1994). This approach was also used for the baseline characteristics of participants who did not complete all the VAS scores.

Table 4.2: Baseline characteristics following randomisation

	SI n=147	FI n=158
Age: mean ±SD	28.8 (5.03)	27.6 (4.87)
BMI: median (IQR)	25 (20.9/26.7)	24 (20.7/26.1)
Tertiary education	94 (64.4)	88 (56.1)
Private insurance	24 (16.0)	12 (7.0)
Nulliparous	107 (72.7)	117 (74.0)
Gestation: median (IQR)	39.6 (39.0/40.0)	39.5 (39.0/40.0)
Spontaneous onset of labour	118 (80.2)	136 (86.0)
Cervical dilatation: median (IQR)	4 cm (3.0/5.0)	4 cm (3.0/5.0)

Values are number (%) unless otherwise indicated

The mean (SD) age of participants was 28.8 (5.03) in the SI group and 27.6 (4.87) in the FI group which is consistent with other studies conducted in countries of a similar economic standard such as Canada and Northern Europe (Ader, et al., 1990; Labrecque, et al., 1999; Martensson, et al., 2008b; Martensson & Wallin, 1999).

Seventy-four per cent of the sample was nulliparous women which is also similar to all previous RCTs, where nulliparous women consisted of 60–75% of the total sample, suggesting that back pain in labour is more common in nulliparous women. Nulliparous women typically comprise approximately 40% of the Australian pregnant population (Li, McNally, Hilder, & Sullivan 2011). The mean cervical dilatation of participants prior to randomisation was four centimetres in both groups, also aligning with all previous RCTs (3–5 cm). There was no difference in cervical dilatation at randomisation with regards to parity (median 4 [IQR 3.0/5.0] *p*=0.25*)*, which supports the observation that back pain in labour is a feature of the late-latent, to early-active stage of labour.

Anatomically, the transition from the latent to the active phase of labour occurs when the cervix is between three and five centimetres dilated and fully effaced (thinned). At this point the fetal head normally rotates, flexes and descends further into the pelvis. This process increases pressure on the cervix, the lower segment of the uterus and surrounding structures which may produce referred pain in the lower back (Bonica, 1979). As greater resistance would exist in the un-stretched tissues of nulliparous women, compared to multiparous

women, noxious stimulation of nerve fibres arising from these structures over a prolonged period of time may explain the increased back pain reported by this group

4.4   Incomplete data

Data for the primary outcome was not collected from 30 participants (SI n=11; FI n=19) (Figure 4.1). An allowance for 20% attrition following randomisation was factored into the sample size as stated in the Research Design chapter; the actual rate of attrition at the measurement of the primary outcome was 10%. The reasons were: lost data (SI n=2; FI n=3); VAS scores which were ceased by some midwives on participants when protocol violations were noted i.e. prior use of pharmacological analgesia (SI n=1; FI n=6); preterm labour (SI n=1); pre-VAS scores less than seven (FI n=1); and a diagnosis of pre-eclampsia (FI n=1). Two participants declined to continue with the trial (SI n=2) and the back pain eased for one woman prior to injection (FI n=1). Ten women gave birth (SI n=4; FI n=6) and three women received epidurals (SI n=1; FI n=3) prior to the 30 minute VAS score. The loss of this data did not impact on the required sample size of 133 participants in each group and is not shown, as the baseline characteristics for these participants did not differ substantially from the overall group. All other data was collected from all these participants and included in the ITT analysis.

Some participants did not complete all the VAS measurements. The main reasons for incomplete data in both groups were birth (SI n=31; FI n=28) and insertion of epidural (SI n=22; FI n=17). Data collection was also ceased on women when they: entered the second stage of labour (SI n=3; FI n=6); received pharmacological analgesia (SI n=2; FI n=4); received repeat SWI (SI n=2; FI n=2); when they were transferred out of birth suite in early labour (SI n=4; FI n=6); and when no reason for ceasing the data collection was recorded (SI n=8; FI n=9). One hundred and fifty-three women (53.6%) completed all the VAS data. Reasons for incomplete scores are detailed in Table 4.3.

Table 4.3: Number and percentage of women who did not complete all VAS scores and reason

Reason	Group SI n=142 FI n=152	10	30	60	90	120	Total of each reason VAS not completed
				Time in minutes post SWI			
Birth	SI	4(2.6)	1(0.7)	10(7.0)	13(9.1)	3(2.1)	31(21.8)
	FI	5(3.2)	5(3.2)	6(3.9)	11(7.2)	7(4.6)	28(18.4)
Second stage	SI	-	-	3(2.1)		-	3(2.1)
	FI			3(1.9)	3(1.9)		6(3.9)
Epidural	SI	-	1(0.7)	7(4.9)	7(4.9)	7(4.9)	22(15.4)
	FI		2(1.3)	5(3.2)	5(3.2)	5(3.2)	17(11.1)
Other analgesia	SI	-	-	-	2(1.4)	-	2(1.4)
	FI				2(1.3)	2(1.3)	4(2.6)
Repeat SWI	SI	-	-	1(0.7)	1(0.7)		2(1.4)
	FI			-	-	2(1.3)	2(1.3)
Transfer out of birth suite	SI	-	-	1(0.7)	3 (2.1)		4(2.6)
	FI			-	1(0.6)	4 (2.6)	6(3.9)
No reason given	SI	-		6(4.2)		2(1.4)	8(5.6)
	FI		1(0.6)	-	2(1.3)	4(2.6)	9(5.9)
Total number of women to complete VAS scores at each time interval	SI	138(97.1)	136(95.7)	108(76.0)	82(57.7)	70(49.2)	72(50.7)
	FI	147(96.7)	139(91.4)	125(82.2)	10(65.7)	83(54.6)	69(45.3)

Values are number (%) unless otherwise indicated

The baseline data from participants who did not complete all the VAS scores differed from those who did in terms of parity and onset of labour although there was no clinical difference in other baseline characteristics (Table 4.4). More multiparous than nulliparous women did not complete the VAS scores and the main reason for this was birth within the two hour data collection period. This difference may impact upon the generality of the pain score results at the 120 minute point.

Table 4.4: Baseline characteristics of participants with missing VAS data

	SI n=78	FI n=75
Age: mean ± SD	28.9 (5.04)	27.8 (4.98)
BMI: median (IQR)	23.0 (20.7/26.1)	23.0 (21.5/27.6)
Tertiary education	49 (63)	38 (51)
Private insurance	15 (19)	6 (8)
Nulliparous	48 (61)	48 (64)
Gestation: median (IQR)	40.0 (39.0/40.0)	40.0 (39.0 40.0)
Spontaneous onset of labour	59 (75)	67 (89)
Cervical dilatation: median (IQR)	4 cm (3.0 5.0)	4 cm (3.0 6.0)

Values are number (%) unless otherwise indicated

The median VAS score prior to randomisation in both groups was eight; there was no difference in this score between the two intervention groups ($p=0.52$) and this score was not affected by parity ($p=0.53$).

4.5 Primary outcome

The VAS scores were not normally distributed so were unsuitable for a comparison of means; therefore, the difference between the VAS scores was used as this data was found to be normally distributed. The analysis of non-inferiority is based on the lower range of a 95% CI, as detailed in the Research Design chapter. The mean difference in pre and-post injection scores at 30 minutes, between the single and four injection groups, was -1.48 cm (lower range of 95% CI -2.10, -0.86), which is outside the clinically significant non-inferiority margin of -1 cm (Δ). Figure 4.2 illustrates the CI in relation to the line of non-inferiority, for the primary outcome: VAS score at 30 minutes post-injection. To facilitate comparison, results for VAS scores at other time intervals are also presented in relation to the NI line, although this data was not tested for non-inferiority.
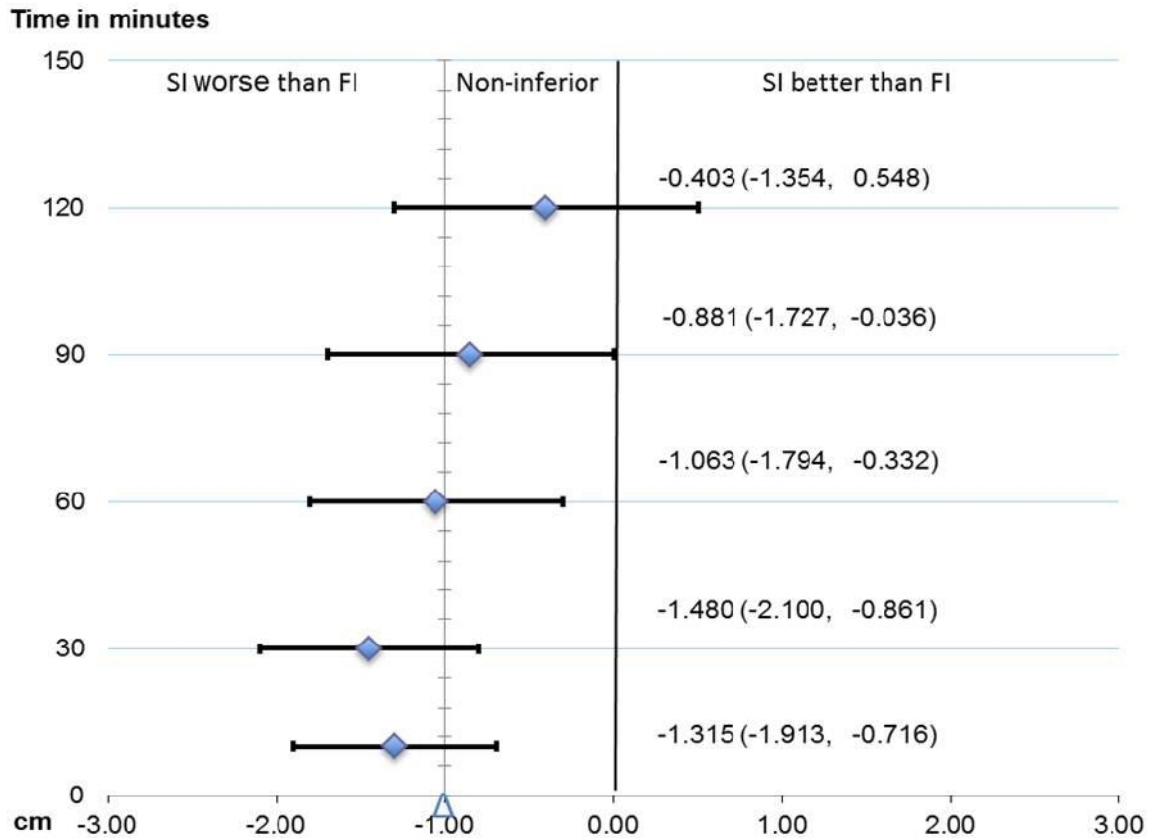
Figure 4.2: Observed treatment difference for primary (30 minutes) and secondary outcomes of single, versus four, injections at different time intervals
(Primary outcome of non-inferiority based on lower range of 95% CI at 30 minutes: Δ defines line of non-inferiority)

4.5.1 Per protocol analysis

A per protocol (PP) analysis was also conducted to provide a more robust interpretation for the NI outcome. The PP analysis demonstrated a difference of 1.51 cm (lower range of 95% CI -2.13, -0.89). This supports the outcome demonstrated in the ITT analysis.

The results of the trial indicate that the single injection technique failed the test of non-inferiority compared to the four injection technique. With regards to the testing of the stated hypothesis, the null hypothesis of a difference between the two treatment groups is not rejected.

A failed test of non-inferiority, based on a single-sided CI, does not automatically imply that the experimental treatment is inferior to the control. The test for inferiority is based on the two-sided CI (Miller, et al., 2006; Wang, et al., 2006). In this study the two-sided CI for the primary outcome did contain some positive values in the non-inferiority range; therefore, it

remains plausible that the true treatment effect lies within the clinically significant margin. Hence, the test for inferiority between the SI and FI is inconclusive.

4.6   Analysis of secondary outcomes

A number of relevant secondary outcomes were identified in the trial protocol, as detailed in the Research Design chapter; however, these outcomes were not specifically powered in the study and therefore the results must be viewed as exploratory.

4.6.1   Injection pain

Women in the single injection group rated the injection pain (median [IQR]) (8.0 [7.0/9.0]) lower than women in the four injection group (9.0 [8.0/10.0]) (Figure 4.3). The difference in reported pain from the two techniques was statistically significant ($p<0.001$) in favour of the SI technique. Similar levels of injection pain for the FI technique were reported in one study (Martinez Galiano, 2009) where participants (n=32) rated the VAS of injection pain (9.2) higher than that of the back pain (8.4). Only one other study using a FI technique (Martensson & Wallin, 1999) recorded VAS scores of treatment pain and found that women rated the injection pain (median VAS=7.7 cm) at a similar level as the back pain (median VAS=7.6 cm). However, in this particular study, women were able to use nitrous oxide inhalation during SWI administration which the researchers acknowledge may have reduced, or at least masked, any perceived difference. Neither of the two studies using the SI technique (Bahasadri, et al., 2006; Kushtagi & Bhanu, 2009) reported VAS scores of injection pain, however, Bahasadri et al. (2006) cite the rationale to test a single injection was a potential reduction in injection pain.

4.6.2   Differences in pre and post-intervention Visual Analogue Score

The difference in VAS scores between groups was clinically significant at 10, 30, 60 and 90 minutes; however, this trend was not evident at 120 minutes (Table 4.5).

Table 4.5: Mean differences between pre and post-injection VAS scores at different time intervals

Time post injection	SI		FI		
	n=	Mean ± SD	n=	Mean ± SD	Mean difference (CI 95.0%)
10 minutes	138	4.30 ± 2.66	147	5.62 ± 2.47	-1.31 (-1.91, -0.71)
30 minutes	136	4.07 ± 2.74	139	5.55 ± 2.46	-1.48 (-2.10, -0.86)
60 minutes	108	3.59 ± 2.92	125	4.66 ± 2.73	-1.06 (-1.79, -0.33)
90 minutes	82	3.16 ± 2.86	100	4.04 ± 2.88	-0.88 (-1.72, -0.03)
120 minutes	70	3.04 ± 2.85	83	3.45 ± 3.05	-0.40 (-1.35, 0.54)

The FI technique achieved a reduction in back pain of 70%. This is similar to reductions in pain levels, between 30 to 45 minutes post-injection, of 64–70% which was observed by other studies that compared the four injection technique to normal saline placebos (Martensson & Wallin, 1999; Saxena, et al., 2009; Trolle, et al., 1991; Wiruchpongsanon, 2006). When the SI technique was used, pain levels were reduced by 51%. This result is almost identical to that reported in the two single injection trials (Bahasadri, et al., 2006; Kushtagi & Bhanu, 2009) where both reported a 50% reduction in pain at 45 minutes.

The systematic review of SWI by Derry et.al (2012) recommended the presentation of VAS data in dichotomous format to display the number of women who had achieved at least 50%, or a minimum of 30%, reduction in pain as this format may be clinically easier to interpret although previous SWI trials have not reported data in this format. In this study, proportionally more women experienced a 50% or more (Table 4.6), or a 30% or more (Table 4.7), reduction in pain following injection up to 60 minutes post-intervention. This suggests that the FI technique is clinically more effective in terms of analgesia than the SI and supports the primary outcome.

Table 4.6: Number and percentage of participants with differences in pre and post-injection VAS scores of equal to, or greater, than 50%

Time since injection	SI		FI		Mean difference %	95% CI
	n=	≥ 50% n %	n=	≥ 50% n %		
10 min	138	75 (54.3)	147	107 (72.8)	-18.4	-29.4, -7.4
30 min	136	68 (50.0)	139	102 (73.3)	-23.3	-34.5, -12.2
60 min	108	48 (44.4)	125	75 (60.0)	-15.5	-28.2, -2.8
90 min	82	31 (37)	100	49 (49)	-11.1	-25.5, 3.1
120 min	70	27 (38)	83	36 (43)	-4.8	-20.4, 10.8

Values are number (%) unless otherwise indicated. Where group size is <100, % presented in whole numbers only

Table 4.7: Number and percentage of participants with differences in pre and post-injection VAS scores of equal to, or greater than, 30%

Time since injection	SI		FI		Mean difference %	95% CI
	n=	≥ 30% n %	n=	≥ 30% n %		
10 min	138	96 (69.5)	147	128 (87.0)	-17.5	-26.9, -8.1
30 min	136	93 (68.3)	139	117 (84.1)	-15.7	-25.6, -5.8
60 min	108	69 (63.9)	125	95 (87.9)	-12.1	-23.8, -0.3
90 min	82	43 (52)	100	64 (64)	-11.5	-25.8, 2.7
120 min	70	35 (50)	83	45 (54)	-4.2	-20.0, 11.6

Values are number (%) unless otherwise indicated. Where group size is <100, % presented in whole numbers only

4.6.3   Duration of analgesia

Median VAS scores from both groups over the two hour data collection period were plotted to assess the duration of analgesic effect (Figure 4.3). At 60 minutes post-treatment the FI group maintained a 50.0% reduction in pain from the original pre-injection baseline, whereas the SI group had reduced to a 37.5% reduction. Only one other RCT using a four injection technique (Wiruchpongsanon, 2006) measured VAS scores at 60 minutes and reported a reduction of pain of 71.0%; however, the sample size was quite small (n=15).

The median VAS scores recorded at 90 minutes equate to a 25% (SI) and 37% (FI) reduction from baseline VAS scores. This level of analgesia was maintained at 120 minutes, although at this time point the difference between the two techniques remained unchanged and was not likely to be of clinical significance (Figure 4.3). Two previous RCTs (Martensson & Wallin, 1999; Saxena, et al., 2009) using the four injection technique reported pain reductions of 33–

35% at 90 minutes. Two studies that recorded VAS scores at 120 minutes following a four injection technique reported a 25–36% reduction. None of the single injection RCTs recorded VAS scores after 45 minutes (Bahasadri, et al., 2006; Kushtagi & Bhanu, 2009).

Figure 4.3: Median VAS score for each group, including pre-injection, over two hours
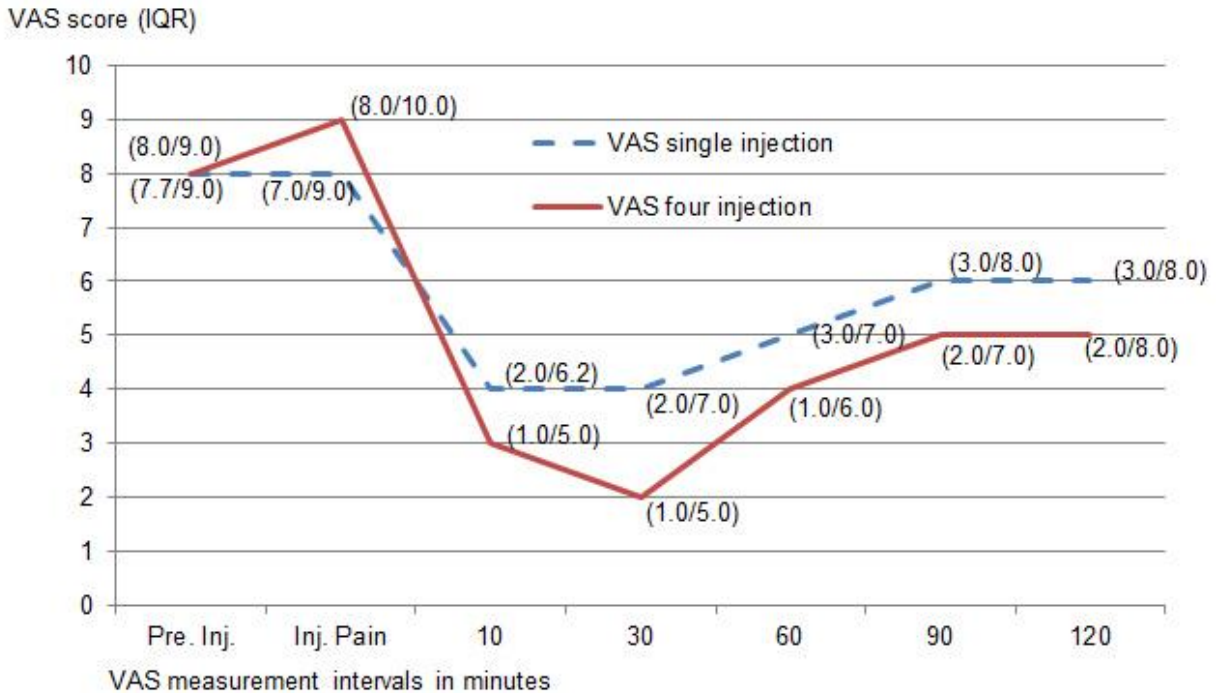
The VAS scores recorded in the SWITCh trial support the results of other SWI RCTs using both the single and four injection techniques. Although our trial demonstrated the analgesic effect of both techniques, the results indicate that the FI technique is clinically more effective in terms of quality and duration of analgesia provided. The results also suggest that these effects may be related to the number of injections, indicating a dose related response. However, the FI was not four times better than the SI, indicating that if a dose relation does exist it is not proportional.

4.6.4   Characteristics of sterile water injection analgesia

The rapid onset of analgesia following SWI was noted in this, and previous, studies (Martensson, et al., 2008b). By the first post-injection VAS score at ten minutes both techniques had reduced women's perceived pain by 50% with the four injection technique proving to be the more effective, this difference was more evident at 30 minutes post injection. However, after 90 minutes the difference in effect was diminished although a

degree of analgesia was still being provided for both. The speed of the analgesic response followed by a gradual diminishing of effect may indicate the differing ascending and descending pain modulating systems stimulated by SWI (Martensson, et al., 2008b). Also, as the injections are given directly over the most painful area of the back, there are likely to be segmental interactions involved in the ascending pain modulation. As detailed by the gate control theory (Melzack & Wall, 1965), the sudden noxious stimulation of the larger somatic A-beta fibres produces the initial rapid reduction in pain as the neural gate is blocked to the visceral A-delta and C fibres. Simultaneously, descending pain modulation systems may be stimulated involving the release of endogenous opioids as described by Diffuse Noxious Inhibitory Control (DNIC) (Le Bars, et al., 1979) and Heterotopic Noxious Conditioning Stimulations (HNCS) (Sprenger, Bingel, & Büchel, 2011). The effect of descending pain modulation may contribute to the duration of the analgesia.

However, one premise of descending systems, such as DNIC, is that modulation of pain can be stimulated by counter-irritation applied to any part of the body remote from the original site of pain. The analgesic effects of counter-irritation methods such as SWI have been demonstrated to be most effective when applied to the skin directly over, or in the vicinity of, the pain (Gammon & Starr, 1940). This is further illustrated by the observation that SWI into the lower back has no apparent effect on abdominal contraction pain. Such features of the analgesia provided by SWI indicate the physiological mechanism for the analgesia provided by SWI remains uncertain and is undoubtedly an area for further research.

4.6.5 Repeat sterile water injections

Nineteen women requested repeat injections of sterile water (SI n=10, 6.7%; FI n=9, 5.7%). All women received the four injection technique, as repeating the initial treatment group may have impacted upon blinding and was; therefore, considered not feasible. The median pre-injection VAS score for the repeat injections was 8.00 cm. The mean difference between pre-injection and thirty minutes post-injection VAS scores was 4.89 cm (95% CI 3.58, 6.21). Although the cohort was small (n=19), the difference suggests that repeat injections can re-establish the analgesic effect.

A recent case study (Martensson, 2010) described a woman who was enrolled in an RCT comparing SWI to acupuncture for both abdominal and back pain (Martensson, et al., 2008b). The woman received up to eight injections on four consecutive occasions, for a total of 30

injections during her labour. On each occasion the VAS score was >60 mm prior to treatment and 25–35 mm 30 minutes post-injections. Early studies into the effect of counter-irritation as a means of non-pharmacological analgesia (Gammon & Starr, 1940) demonstrated that periodic application of the counter-irritation was effective in producing analgesia, as was demonstrated in both this and our study.

4.6.6   Differences in anatomical depth and injection volume

The intradermal approach, as outlined in the Research Design chapter, and the injected volume of

0.1 ml of sterile water, used in this trial, differ from the previously reported single injection RCTs (Bahasadri, et al., 2006; Kushtagi & Bhanu, 2009) which used a subcutaneous injection of 0.5 ml. Despite the variation in anatomical depth and volume, all three trials reported similar reductions in pain at 30–45 mins (50% reduction from baseline VAS score). Similarly the median VAS scores reported in this trial for the FI group at 30 minutes was similar to that reported by Martensson and Wallin (1999) at 45 mins (median [IQR], 2.00 [1.0/5.0] versus 2.00 [0.4/6.0] respectively) and supports their conclusions that there was no difference in analgesic effect between the use of intradermal or subcutaneous injections.

4.6.7   Pharmacological analgesia

Pharmacological analgesic use was reported for the two hour period following the intervention, while the VAS scores were being recorded, and for overall analgesic use during labour and birth. There was no significant difference in the use of analgesia between the two treatment groups in the two hours following the injection(s) (Table 4.8). Nitrous oxide gas was the most frequently used analgesic during the first two hours following administration (SI 48.2%; FI 31.4%). More women in the SI group received an epidural during the two hours following the intervention (12.8%) compared with the FI group (7.0%), though the numbers were small. A small number of women, not reported in Table 4.8, used a combination of pharmacological analgesics during this period such as nitrous oxide combined with either narcotics (SI n=8, 5.4%; FI n=8, 5.0%) or epidural (SI n=5, 3.4%; FI n=1, 0.6%).

Table 4.8: Difference in total pharmacological analgesia use during the first two hours following intervention:

Type of pharmacological analgesia	SI n=147	FI n=158	Mean difference% (95% CI)
No analgesia used	71 (48.2)	83 (52.5)	-4.2 (-15.4, 6.9)
Nitrous oxide Inhalation	57 (38.7)	54 (34.1)	4.5 (-6.2, 15.4)
IM/IV narcotics	12 (8.11)	18 (11.4)	-3.2 (-9.8, 3.4)
Epidural	19 (12.8)	12 (7.6)	5.3 (-1.4, 12.1)

Values are number (%) unless otherwise indicated

Almost half the women, in both the SI (48.2%) and FI (52.5%), did not use any other form of pharmacological analgesia during the initial two hours following treatment. This suggests that the analgesia provided by either SWI technique was considered by these participants to be adequate.

Seventeen per cent of women in the SI group and 20% in the FI group did not use any pharmacological analgesia during their labour (Table 4.9). Overall there was no difference in analgesic use between the two groups during labour. Nitrous oxide inhalation was the most frequently used analgesia by 64.0% of women in the single injection group and 59.5 % of women in the four injection group. Epidurals were used by 41.5% of women in the SI group and 44.3% of women in the FI group. The difference in epidural use between the two treatment groups was not clinically significant (Table 4.9). Nitrous oxide gas and epidural were the most frequently used combination of pharmacological analgesics used by women during the course of labour (SI n=28, 19%; FI n=30, 19%).

Table 4.9: Difference in proportions of pharmacological analgesia use during labour:

Type of pharmacological analgesia	SI n=147	FI n=158	Mean difference% (95% CI)
No analgesia used	25 (17.0)	32 (20.3)	-3.2 (-11.9, 5.4)
Nitrous Oxide Inhalation	95 (64.0)	94 (59.5)	5.1 (-5.7, 16.0)
IM/IV Narcotics	28 (19.0)	35 (22.1)	-3.1 (-12.1, 5.9)
Epidural	62 (42.1)	70 (44.3)	-2.1 (-13.2, 8.9)

Values are number (%) unless otherwise indicated

Only two previous SWI studies have reported on other analgesia use in labour (Ader, et al., 1991; Martensson, et al., 2008b). The trial by Ader et al. (1991) comparing SWI to normal saline injection, and Martensson et al. (2008b) comparing SWI to acupuncture found no difference in pharmacological analgesic use between the groups compared. In both studies nitrous oxide was the most commonly used pharmacological analgesic. Epidural use in the SWITCh trial (SI 41.8%; FI 44.3%) was similar to that reported by Martensson et al. (2008b)

The combination of back pain and contraction pain may result in pain greater than normal (abdominal) labour pain (Melzack & Schaffeberg, 1987). Currently no studies exist that have examined the differences in analgesic demands or requirements between women who do, and women who do not report back pain in labour. Therefore, it is difficult to determine if the use of SWI has, or should have, any impact on epidural use since this may be increased in women with back and contraction pain compared, to women with contraction pain only.

4.6.9   Birth outcomes

The rates of normal vaginal birth (NVB) were 65.3% in the SI group and 62% in the FI group (Table 4.10). This is slightly less than the Australian national average rate of 68.5% (Li, et al., 2011). In both groups nulliparous women (55.4%) were less likely to have an NVB than multiparous women (85.2%). There were no clinically significant differences in modes of birth between the two groups.

Table 4.10: Mode of birth and relative risk for the two groups

Mode of birth	SI n= 147	FI n=158	RR (95% CI) Reference group = vaginal birth
Normal vaginal	96 (65.3)	98 (62)	1.00
Ventouse	21 (14.3)	26 (16.5)	0.91 (0.68,1.22)
Forceps	7 (4.8)	7 (4.4)	1.10 (0.55,1.73)
Caesarean section	23 (15.6)	27 (17.1)	0.93 (0.69,1.25)

Values are number (%) unless otherwise indicated

Obstructed labour was the most frequently cited indication for instrumental (ventouse or forceps) and CS birth in both groups; accounting for 30 (60%) of all CS births. Thirty two per cent of CS births (n=16) were performed for non-reassuring fetal heart. One woman in the SI group and two women in the FI group had a CS birth for unexpected breech presentation in labour.

4.7 Sub group analysis

A number of sub group analyses were undertaken to explore areas of interest arising from the literature. As described in the Research Design chapter, results of sub group analyses are not generalisable to larger populations.

4.7.1   Parity and use of pharmacological analgesia

Although there was no difference in the pre-injection VAS scores between nulliparous and multiparous women (median 8.0 [IQR 8.0 / 9.0]*),* parity was a factor in overall epidural use with 51% (114/224) of nulliparous women receiving an epidural compared to 13.5% (11/81) of multiparous women (RR 0.56 95% CI 0.48; 0.66). There was a considerable difference with regard to parity in the non-use of pharmacological analgesia, with 13% of nulliparous women (30/224) not using pharmacological analgesia compared to 33% (27/81) of multiparous women (RR 0.46 95% CI 0.32; 0.66). Nulliparity has been associated with epidural use in other trials; however, other factors such as the practice culture and environment in birthing units can also contribute to uptake (Le Ray, Goffinet, Palot, Garel, & Blondel, 2008; Schytt & Waldenström, 2010). The SWITCh trial was conducted in tertiary centres with ready access to an epidural service; in other centres, where access is not so readily available, the use of epidurals, is likely to be lower.

4.7.2   Non-pharmacological analgesia use

There were differences in the reporting of non-pharmacological analgesic strategies between the two sites with Site One providing data on categories such as breathing, visualisation and hypno-birthing that was not recorded at Site Two. Eight categories were identified as being reported in a similar manner at both sites, and only these categories were analysed (Table 4.10). Women may also use more than one non-pharmacological strategy during the course of their labour or in combination, such as using a birth ball in the shower. In the choice of non-pharmacological analgesia, 27% of women in the SI group received massage during labour (40/148) compared to 17% (27/157) of women in the FI group. Similarly, 43% (64/148) of women in the SI group used a birth ball during labour compared to 31% (49/157) in the FI group. Although the differences in massage and birth ball use between treatment groups were notable, the timing of use is unknown, i.e. prior to or following SWI; therefore, it cannot be ascertained if this was in any way related to the intervention. No previous SWI studies have reported on non-pharmacological analgesic use.

4.7.3   Body mass index and back pain

Eighty seven per cent of women (n=235) had a body mass index (BMI) of less than 30 and 13% of women (n=34) recorded a BMI of 30 or greater. There was no difference in median VAS scores of back pain reported prior to randomisation based on BMI $\geq$ 30 (median 8 [IQR 8 / 9]) (p=0.93 Mann-Whitney U test). Few studies have been conducted on the incidence of back pain in labour and associated factors. Although one study (Tzeng & Su, 2008) suggested that an increased BMI at admission in labour was associated with back pain; however, data from our study does not support this finding.

4.7.4   Timing of epidural use

The time duration between treatment with SWI and receiving an epidural was different between the two groups (p=0.006 Mann-Whitney U test). For women in the SI group the median time between SWI and epidural was 2:35 hours (IQR 1:30 / 3:52) and for the FI group 3:49 hours (2:05/6:19). No previous SWI studies had reported differences in timing of epidural use.

Table 4.11: Differences in non-pharmacological analgesic use between groups

Type of non-pharmacological analgesia	SI n=147	FI n=158	Mean difference% (95% CI)
No analgesia	9 (6.1)	12 (7.5)	-1.4 (-7.1, 4.1)
Aromatherapy	4 (2.7)	4 (2.5)	[##]p=0.91
TENS	3 (2.0)	4 (2.5)	[##]p=0.76
Massage	40 (27.2)	27 (17.1)	10.1 (0.8, 19.4)
Heat packs	35 (23.8)	31 (19.6)	4.1 (-5.0, 13.4)
Water immersion	24 (16.3)	21 (13.3)	3.0 (-4.9, 11.0)
Shower	73 (49.7)	81 (51.3)	-1.6 (-12.8, 9.6)
Birth ball	64 (43.5)	49 (31.0)	12.5 (1.7, 23.3)

Values are number (%) unless otherwise indicated ##binomial test

The shower was the most frequently used form of non-pharmacological analgesia with 49.7% of women (73/148) in the SI group and 51.3% in the FI group. Water immersion in a bath was used by 24 women (16.3%) in the SI group and 21 (13.3%) in the FI group. The policy governing the use of water immersion differed at each site. At Site One, water immersion was generally available to all women with no identified risks in pregnancy, whereas at Site Two,

water immersion was only available to women attending the birth centre and not the birth suite. Although more women from Site Two used water immersion (26%) than Site One (8.8%), there were no differences in the use of other non-pharmacological strategies between the two groups (Table 4.11).

4.7.5 Labour duration

The overall duration of labour was similar in both treatment groups (Table 4.12). The length of both the first and second stages was longer for nulliparous women than that for multiparous women. The median length of labour for nulliparous women was seven hours in the SI group and six hours and forty-nine minutes in the FI group. For multiparous women in the SI group the median length of labour was four hours and fifty-two minutes compared to four hours and forty-nine minutes in the FI group. Similarly there was no difference in the median length of second stage between treatment groups.

Table 4.12: Labour duration

	SI	FI
Nulliparous first stage	7:00 (3:40/10:25)	6:49 (3:39/10:55)
Nulliparous second stage	0:52 (0:06/2:10)	0:57 (0:15/1:44)
Multiparous first stage	4:52 (2:30/7:49)	4:49 (2:51/8:08)
Multiparous second stage	0:14 (0:07/0:31)	0:13 (0:06/0:39)

Time format hh:mm; and values median (IQR)

Measurement and comparison of labour duration is problematic as there is no precise definition for the onset of labour and interpretation may differ considerably between women and midwives (Gross et al., 2009). In this study the onset of labour was drawn from the obstetric database at both sites, which is completed by the attending midwife who may, or may not; take into account the woman's perception of when her labour began. Interestingly, a prospective comparison of labour duration in women who received SWI (n=35) and women who did not (n=307) found that the length of the first stage of labour was two hours longer in the women who had received SWI (Tandberg, 1990). However, other RCTs have not reported any difference in labour duration between SWI and placebo groups (Martensson & Wallin, 1999; Wiruchpongsanon, 2006).

4.7.6 Women reporting no analgesic effect from sterile water injections

No effect from SWI was defined as participants who reported a difference in pre and 30 minute post-VAS scores of one or less. The rationale for this is based on the same assumption

that was used to determine the non-inferiority margin; that a change in VAS score of more than 1 cm indicated a change in level of pain (Kelly, 2001).

Of the 275 women reporting VAS scores at 30 minutes following either treatment, 33 women reported VAS scores of 1 cm or less. More women in the SI group (n=27, 19.9%) reported no effect than those in the FI group (n=6, 4.3%). Women who did not report any benefit from SWI did not differ in terms of age, BMI, gestation, onset of labour or mean cervical dilatation, prior to treatment. However, they were more likely to be nulliparous (n=28, 84% versus n=174, 71.9%). The CS rate in the group reporting a <1 cm change in VAS was 27.3% (n=9) compared to 14% for participants reporting a >1 cm change in VAS (n=35).

4.8   Responses to the postnatal questionnaire

4.8.1   Sample

Eighty-seven per cent of women completed the postnatal questionnaires, 136 women from the SI group (85%) and 129 women (82%) from the FI group. Only one woman in the SI group and one in the FI group did not provide comments to the open-ended questions. Women who completed the questionnaire were more likely to be older, have received the single injection and be uninsured (accessed public care). There were no statistically significant differences in BMI, level of education, onset of labour, or cervical dilatation prior to intervention between women who did, or did not, complete the questionnaire (Table 4.13).

Table 4.13: Demographic data of responders to postnatal questionnaire compared to non-responders.

		Responder n=265	Non-responder n=40	*p=*
Treatment group	SI	136 (51.3)	11 (27)	0.00
	FI	129 (48.7)	29 (72)	
Age: mean (SD)		28.4 (4.950)	26.7 (4.947)	0.03
BMI: median (IQR)		23.1 (20.8/26.1)	23.9 (20.8/28.4)	0.41
Tertiary level of education		166 (62.6)	16 (40)	0.05
Nulliparous		197 (74.3)	27 (67)	0.36
Public insurance		240 (90.6)	29 (72)	0.00
Spontaneous onset of labour		219 (82.6)	35 (87)	0.44
Cervical dilatation prior to treatment: median (IQR)		4.00 (3.00/5.00)	4.00 (3.00/5.00)	0.70

Values are number (%) unless otherwise indicated

4.8.2   Satisfaction with pain relief

There was no statistically significant difference in the number of women who reported being *"very satisfied"* with either technique (*p*=0.08). More women in the FI group (36%), compared to the SI group (27.4%), responded that they were satisfied with the level of analgesia experienced. Sixteen women in the SI group (11.9%), compared with six women in the FI group (6.6%), responded that they were *"very dissatisfied"*. Overall there was no statistical difference in responses between the two groups (Figure 4.4).
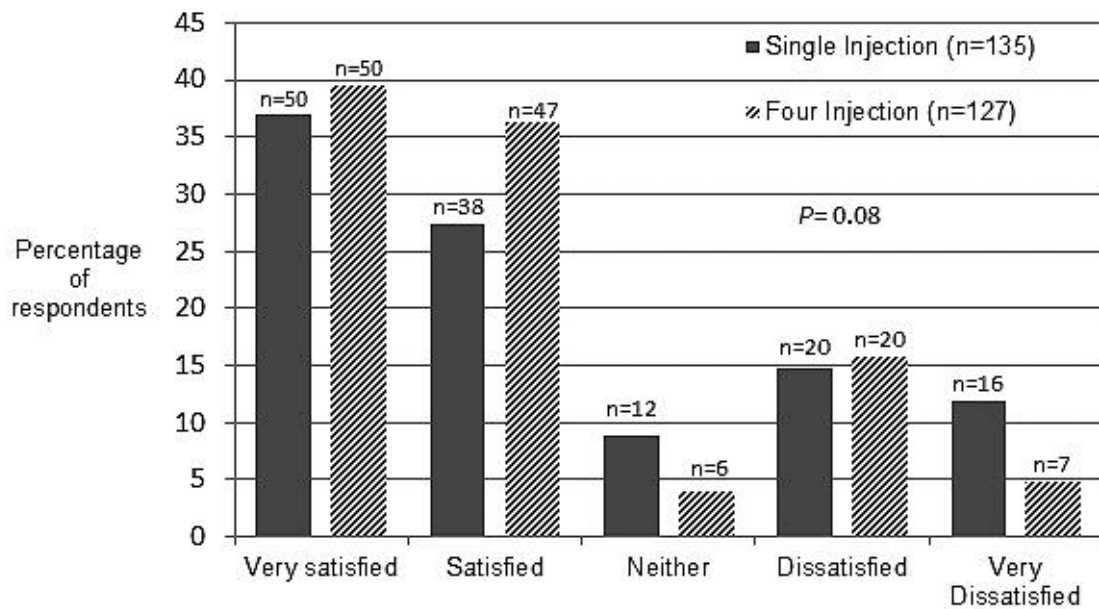
Figure 4.4: Satisfaction with SWI

4.8.3   Likelihood to use again or recommend

Ninety one women (67.4%) in the SI group indicated that they would use the technique again, as did 89 women (69.3%) in the FI group. Similarly, 105 women in the SI group (77.8%), compared to 101 women in the FI group (79.5%), indicated that they would recommend the procedure to other women. The overall differences between the two groups were not statistically significant and absolute differences were small (Figure 4.5).
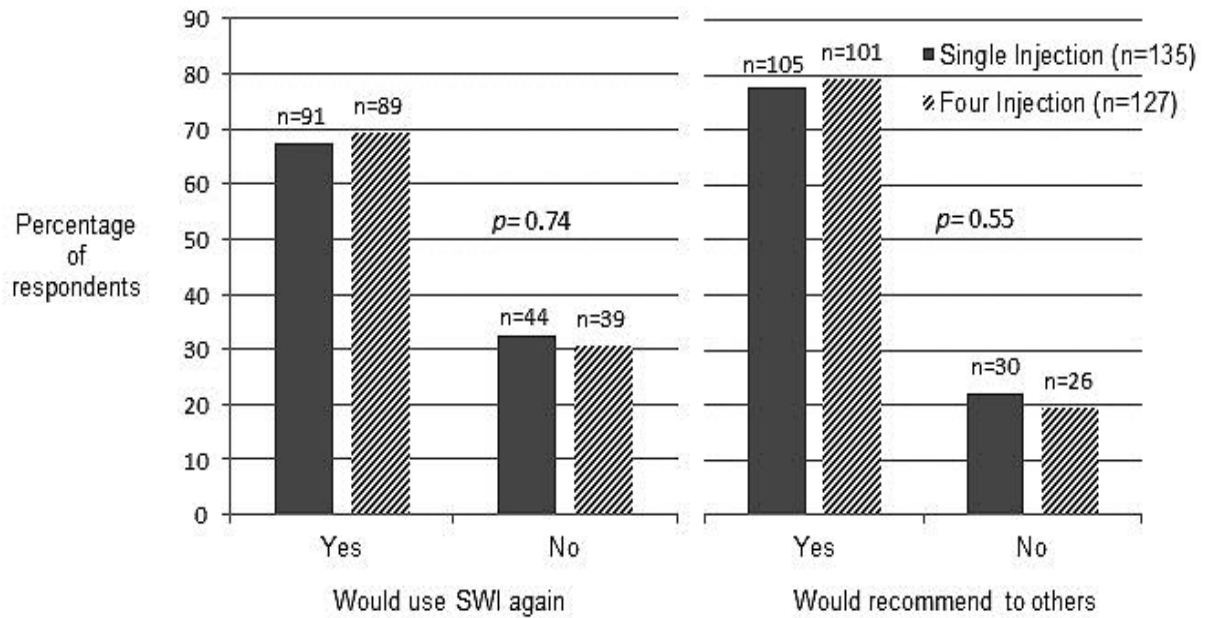
Figure 4.5: Likelihood would use SWI again or recommend to others

There was no difference in the median [IQR] VAS score for injection pain in treatment groups between women who were *"very satisfied"* or *"satisfied"* and those who were *"very dissatisfied"* or *"dissatisfied"* (SI 8.0 [7.0/9.0]; FI 9.0 [8.0/10.0]); would, or would, not use SWI again (SI 8.0 [7.0/9.0]; FI 8.0 [8.0/10.0]), and would, or would not, recommend SWI to other women (SI 8.0 [7.0/9.0]; FI 8.0 [8.0/10.0]). However, the mean difference in VAS scores at 30 minutes was significantly different in women reporting being *"very satisfied"* or *"satisfied"* and those *"very dissatisfied"* or *"dissatisfied"* (SI 2.67 95% CI 1.66, 3.69; FI 2.32 95% CI 1.30, 3.36). Similarly, the mean difference in VAS scores was also significantly different in women who would, or would not, use SWI again (SI 1.37 95% CI 0.44, 2.29; FI 2.00 95% CI 1.05, 2.93) and women who would, or would not, recommend SWI to other women (SI 1.76 95% CI 0.67, 2.85; FI 1.62 95% CI 0.57, 2.68).

4.9 Short answer questions

The postnatal questionnaire asked women to respond to two short answer questions regarding their experience of the intervention. Specifically the questions asked:

 i) what was the best aspect about using SWI

 ii) what was the worst aspect about using SWI?

Two hundred and sixty-five women responded to both the open-ended questions; 136 (51.3%) from the SI group and 129 (48.7%) from the FI group. Two women in the SI group (1.5%) and two women in the FI group (1.6%) answered only one question.

The responses to these two questions were analysed using content analysis process as outlined by Smith (2000). Responses were read to identify coding units based on reoccurring themes, before being coded to categories that were not mutually exclusive (i.e. participants may refer to more than one aspect of their experience and; therefore, responses may appear in more than one category). Numbers of respondents and percentages for each treatment group are given for each coding category and verbatim de-identified quotes have been selected to support the statistical data.

4.9.1 The best aspect of using sterile water injections

One hundred and twenty-three women (46%) commented that the pain relief they experienced following SWI was the best aspect; a substantial reduction in lower back pain was specifically mentioned. A considerable difference between treatment groups was noted with 53 women (39%) from the SI group compared with 70 women (54.3%) from the FI group commenting on this aspect:

> *No lower back pain experienced after the injection took effect.* (No: 18 FI)

> *It gave back pain relief when it was needed the most. It was great during my contractions.* (No: 107 FI)

> *It did what it was supposed to do back and hip pain relief. It was great.* (No: 164 SI)

> *Full back pain relief.* (No: 188 SI)

The speed at which SWI took effect was commented on by 66 women (25%) and was reported as being one of the best aspects of the procedure. The almost instant onset of pain relief was cited by 36 women (26.5%) in the SI group and 30 women (23.3%) in the FI group:

> *The injection was swift and the relief came as soon as the sting subsided.* (No: 44 SI)

> *It took away the back pain very quickly.* (No: 67 SI)

> *The best aspect would be that it takes the pain away in no time.* (No: 96 SI)

> *As soon as I had the injections my back pain went away almost immediately.* (No: 198 FI)

The non-pharmacological nature of the intervention and the absence of side effects were highlighted by a total of 28 (10.6%) respondents. This represented 14% (n=19) of the SI group and seven % (n=9) of the FI group:

> *Natural pain relief with no side effects.* (No: 166 SI)

> *No side effects for baby was the best reason for giving it a go.* (No: 121 SI)

> *Non drug method of pain relief.* (No: 88 SI)

> *Chemical free option for pain relief.* (No: 147 FI)

Thirteen women (5%) commented on the positive impact that SWI had upon their ability to cope with labour enabling them to remain active and avoid an epidural. This group consisted of five women (5%) from the SI group and eight women (6%) from the FI group:

> *Brilliant—saved having an epidural.* (No: 494 SI)

> *I was able to move around a lot more easier to keep contractions getting stronger.* (No: 413 SI)

> *Took away back pain and helped me concentrate on contractions.* (No: 76 (FI)

> *It enabled me to complete a natural labour and continue to be active through the delivery of my baby. I am sure that without SWI I would have needed an epidural and then possibly further intervention.* (No: 451 FI)

Sixteen women commented positively on the duration of the pain relief following administration of SWI. This consisted of the same number of women (n=8; 6%) in each of the two treatment groups:

> *It made my pain stop fully for up to two hours.* (No: 189 SI)

> *It relieved the back pain in labour for about three or four hours.* (No: 61 FI)

Overall 34 women (13%) commented that, although the SWI provided only a short duration of pain relief, they nonetheless rated this as a positive aspect. Women were evenly divided in both the SI (12.5%) and FI (13.2%) groups:

> *It did relieve my back ache for a short period of time.* (No: 54 SI)

> *Relief of back pain for half an hour during first stage of labour, which was great.* (No: 167 SI)

> *There was no pain for 10–15 minutes which was quite relieving.* (No: 152 FI)

Not all women reported a positive aspect to the SWI procedure; this was generally associated with the absence of pain relief. Overall, 25 women (9%) reported no analgesic effect following the injection. More women in the SI group (n=15; 11%) than the FI group (n=10; 8%) experienced no pain relief:

> *Nothing, it stung like buggery and the contractions kept coming stronger. Did not help the back pain either.* (No: 405 SI)

> *Baby born 20 minutes after injection, no best aspect or benefit at all.* (No: 458 SI)

> *Had heard it would ease back pain, no real benefit, could not define a best aspect.* (No: 431 FI)

4.9.2   The worst aspects of sterile water injections

The pain experienced by women associated with the administration of the injections was the most commonly cited *"worst aspect"* of SWI. Seventy four per cent (n=197) of respondents commented on this feature. This consisted of 69% of women from the SI group (n=94) and 52% from the FI group (n=103):

> *Hurt an awful lot. My partner says I made the worst noise of the whole labour when the SWI went in.* (No: 95 SI)

> *The injection pain, wasn't prepared for how painful it was, even after being warned.* (No: 180 SI)

> *It was like a current in the body when it was given, very painful.* (No: 209 FI)

A small number of women (n=10; 3.8%) commented that the brief period of pain that was experienced was insignificant compared to the degree of analgesia produced:

> *The pain at the injection site but it was temporary and well worth it.* (No: 151 FI)

> *Was painful when injected but minor pain in the scheme of things.* (No: 198 SI)

Although experiencing only a short duration of analgesia was previously described as a positive aspect, it was also reported as a negative aspect by 30 women (11%). This effect was evenly distributed between the two groups: 10% (n=14) of women in the SI group and 12% (n=16) in the FI group:

> *But after about 20–25 minutes I was having the same back pain I was earlier before taking SWI.* (No: 146 FI)

> *Did not last as long as I would have liked.* (No: 152 SI)

Similarly, some women stated that the analgesia wearing off was the worst aspect of their experience. This observation was expressed by 12 women (4.5%); four from the SI group (2.9%) and eight from the FI group (6.2%).

Experiencing little or no pain relief was cited by 23 women (9%). More women in the SI group (n=19; 14%) indicated that the SWI provided no pain relief compared to the FI group (n=4; 3%):

> *Unfortunately I did not get any pain relief at all.* (No: 1 SI)

> *It didn't work—no relief and pain remained at the same level.* (No: 52 SI)

Three women in the FI group (2%) stated that the relief of their back pain increased their awareness of their "front" or contraction pain

> *It made me realise all the front pain I was going through.* (No: 417 FI)

Not all women reported a *"worst aspect"*, with 17 women (6%); 12 (9%) of the SI women and five (4%) of the FI group, commenting that they could not find a negative aspect to SWI:

> *There wasn't any worst aspect about using SWI.* (No: 73 SI)

> *None.* (No: 42 FI)

The results of the short answer questions are consistent with those reported by Peart (2008) where quality of analgesia and speed of onset were rated highly as positive aspects and the lack of side effects a strong motivating factor for use. Similarly, Peart (2008) reported that

women became dissatisfied with SWI when the pain of the injection overshadowed any perceived benefit, or where the pain relief was considered inadequate.

4.10   Summary

This chapter presented the results of the data analysis of the quantitative phase of the SWITCh trial. An overview of the study sample and baseline characteristics was provided. The analysis approach to the VAS data provided clinically significant results in line with the intention of the non-inferiority design. The SI technique failed the test of non-inferiority in comparison to the FI technique; therefore, the null hypothesis was accepted:

Secondary outcomes including pre and post-injection VAS scores, analgesic use, birth and neonatal outcomes were analysed and the data were presented within the chapter. The analysis of the postnatal questionnaire regarding satisfaction with the analgesia, intention to use again or recommend to other women, and answers to short answer questions concerning best and worst were detailed.

The following chapter presents findings from the qualitative phase of the study.

Chapter five: Qualitative findings

5.1   Overview

The previous chapter presented the results of the SWITCh trial. This chapter presents the analysis of data collected through individual interviews with women and focus groups with midwives who participated in the quantitative phase of this (SWITCh) trial. Five major themes and a number of subthemes were derived directly from the data based on the relevance to the research question and the frequency and strength of occurrence within the transcripts. The five themes present data from the combined perspectives of women and midwives. Raw data are presented as de-identified quotes to illustrate the accompanying text which is referenced to the supporting literature with some discussion included in this chapter.

5.2   Back pain in pregnancy and labour

5.2.1   Midwives' perspectives

The association between back pain and fetal OP position is a dominant discourse in pregnancy and labour for which there is little empirical evidence (Simkin, 2010). Regardless, the concept tends to be presented to women by care providers, as the primary cause of labour-related back pain. Data from this study suggests that women also, perhaps unsurprisingly, believe these factors are related.

Analysis of data from focus group discussions with midwives highlighted a number of other possible causes for back pain in labour including fetal position, maternal position and physiology, reduced mobility in labour and referred pain:

> *All the nerves are linked. Women feel period pain in their back. Some women don't have a posterior baby and they still have horrific back pain.* (laugh) *Sometimes it's because they are stuck on their back in the bed.* (Sarah, midwife seven years)

> *I think we were always trained that it was OP positions; often it can be referred or positional.* (Alexandra, midwife eight years)

Empirical evidence supports the observation that back pain in labour is not exclusive to women with an OP position, but may also be related to a tendency for women to labour in bed

(Melzack, et al., 1991) or to women with a history of menstrual pain (Melzack & Belanger, 1989). Differences in racial characteristics, with respect to female pelvic anatomy, were also discussed with midwives suggesting that an android pelvis, common amongst women of African descent, not only increases pain, but also increases the tendency for *"posterior babies"*:

> *African women seem to have bad back pain more in my experience. I think it's their android pelvis shape.* (Marilynn, midwife 10 years)

> *They* (women of African descent) *keep their* (baby's) *head high for so long don't they? You don't know if that has an impact on back pain. Labouring with that high head. They may have more posterior babies. Back to that chestnut.* (Sarah, midwife seven years)

These comments imply knowledge and hypothesising drawn from midwives personal observations and clinical experience. They also demonstrate a process of reflection between learned knowledge, such as pelvic anatomy, and that gained from the everyday practice of caring for labouring women (Hunter, 2008). The midwives' observations of a racially related association between pelvic shape and OP position are supported by radiological evidence, with one study suggesting that women of African descent are indeed more likely to have a pelvic shape associated with an OP position (Sizer & Nirmal, 2000). Although midwives may correctly hypothesise a relationship between race, maternal pelvic shape and OP position, extrapolating this concept to include an increased likelihood of back pain is not supported by a later radiological study which disputed this relationship (Lieberman, et al., 2005). Nonetheless, the enduring notion of the concept is evident amongst clinicians; as Sarah comments: *"Back to that chestnut"*.

In another focus group Carmen and Deena suggested that back pain in labour may reflect a pre-existing cause:

> *Some people come into labour having already, they already have back pain for some, some reason and maybe it's never been investigated.* (Carmen, midwife 30 years)

> *Some women have had an injury in the past. Some people have had back pain all through their pregnancy.[…] Those* (babies) *in posterior positions cause a lot of back*

pain. One of the main reasons is the baby's position I guess. (Deena, midwife 20 years)

Although, both midwives mention other pre-existing causes for back pain, Deena's final comment reiterates the dominance of the OP position as the primary cause.

The widespread and largely unquestioned acceptance of the OP position/back pain discourse may affect the information and care that is provided to women, especially during labour. Kirstie describes how she encourages women to mobilise:

> *As one of the givens* (with back pain) *is that the baby is in the posterior position so you just try and do a bit more to try and get them* (labouring women) *up and mobile and educate them on what exactly is going on.* (Kirstie, midwife five years)

Kirstie emphasises the importance of *"educating"* women; of providing them with information and possible solutions to their back pain, which she assumes is related to fetal malposition. As the information she provides is supported by her authoritative position as a midwife and clinician, women in her care are likely to accept, without question, the association she makes between back pain and OP position.

During pregnancy, women may attend antenatal classes or otherwise access information about the theory of Optimal Fetal Positioning (Sutton & Scott, 1995) which advocates particular exercises and postures to prevent babies from assuming an OP position. Marilynn suggests that for women who followed such advice, the occurrence of back pain in labour may result in subsequent negative feelings:

> *Sometimes they* (labouring women) *feel bad because they did all the special exercises and movements and they were unsuccessful.* (Marilynn, midwife 10 years)

Alexandra and Marilynn explore the idea of the OP position being a modern malady, associated with a reduction in women's physical activity, an increase in the use of technology and a negative effect on women's posture:

> *I remember when I worked in the labour ward in the early 90s, I don't remember people reporting as much back pain. I think more sitting occupations, more I don't*

> *know, um* (pause) *more information age, more technology, more less uprightedness.* (Alexandra, midwife eight years)

> *More years on the couch I would say.* (general laughter) (Marilynn, midwife 10 years)

Midwives discussed other contemporary lifestyle issues such as an older age at conception, and a tendency towards *"weight problems"* associated with an increasingly sedentary lifestyle:

> *Because we are seeing more older women having their first baby. And what sort of lifestyle you had before, flexibility, all of that comes into it. Because if you have weight problems, you are less active, who knows.* (Alexandra, midwife eight years)

> *Fitness.* (Karleen, midwife three years)

There is evidence to show that maternal age (>35 years) and obesity are separately associated with increased rates of interventions and complications during labour (Lampinen, Vehviläinen-Julkunen, & Kankkunen, 2009; Sebire et al., 2001). Research also suggests an association between obesity and back pain generally (Leboeuf-Yde, 2000) and in labour (Tzeng & Su, 2008). Also, back pain in non-pregnant populations has been reported more frequently by those who lead more sedentary lifestyles (Heneweer, Vanhees, & Picavet, 2009) which suggest lifestyle factors may be as important as the baby's position. This observation was confirmed by a midwife in another focus group:

> *I think how fit you are too. I think if you are unfit, have a bad posture your abdominal muscles are slack, if you are not a healthy specimen, you are probably going to cop more back pain.* (Holly, midwife 25 years)

Comments regarding sedentary lifestyles, being unfit and having weight problems, may be suggestive of a moral judgement that privileges fitness and health in women's ability to labour successfully; in particular without the back pain they, and their clinicians, associate with an OP position. However, obese women are considered to be at higher risk of pregnancy and birth related complications, such as diabetes, hypertension, labour dystocia and stillbirth, (Kerrigan & Kingdon, 2010; Salihu et al., 2007), which may affect choices such as model of care and increase the need for pre-emptive intervention (e.g. induction of labour). Although back pain in labour is not a high risk indicator, it may be linked by clinicians to such

complications as labour dystocia, particularly when there may be other concurrent risk factors e.g. obesity.

Women may typically derive expectations of their labours, and labour pain, from a range of sources including female relatives and friends, the media, Internet and childbirth educators. Changes in family sizes and living arrangements, have reduced opportunities for women in Western cultures to learn about childbirth from traditional sources such as female family members (Karkada, Noronha, & D'souza, 2010); hence they may rely more on alternative sources. Media stories tend to dramatise childbirth (Handfield, Turnbull, & Bell, 2006), whereas the information provided by childbirth educators, although possibly viewed as more trustworthy, may have limited appeal because of the didactic formats in which they are often delivered (Sylvia, 2010). Women may also base their expectations on contradictory and/or out-dated information, or they may express preferences for interventions not available locally. When labour pain is subjectively different from their expectations, women's views about their needs for analgesia may be changed. Kirstie suggests:

> *In the instance when we* (the woman and her carers) *were aiming for a natural birth but then* (she) *experienced this back pain I think then they* (woman) *start to think* (pause) *well what have I got myself into? No one ever talked about this back pain. So then* (they) *start to think well, maybe I do need pain relief.* (Kirstie, midwife five years)

Kirstie also observes that the presence of back pain may initiate a reappraisal of women's original plans to achieve a natural birth. As the type and location of labour pain may not be made explicit in the information accessed by, or provided to, women their expectations may substantially underestimate the reality (Lally, et al., 2008). Kirstie goes on to suggest that the physiological and psychological effects of the difference between expectations and reality may increase women's sense of uncertainty and fear which may then interfere with labour processes, including hormonal release:

> *I think that if women experience bad back pain and it's unexpected they can have a sense of fear, that it's not supposed to feel like this and that may inhibit with their whole hormone release system as well.* (Kirstie, midwife five years)

By reducing stress responses to pain and promoting a sense of calm, hormones, such as oxytocin, play a vital role not only in uterine function, but also in maternal adaptation to labour and birth (Leng, Meddle, & Douglas, 2008). By contrast, situations producing fear and stress initiate the release of adrenalin which has long been known to interfere with the process of normal labour and birth by negatively affecting the action of oxytocin (Garrett, 1954). Therefore, the release of adrenalin in response to fear may not only affect the progress of labour but also women's ability to cope with labour pain. The experience of unexpected pain may heighten the sensation or perception of that pain, setting up a cyclical physiological response of pain, fear, more intensely felt pain and greater fear of further pain with escalating effects or consequences for normal hormonal activity.

Factors that would otherwise assist women to cope with labour pain may also be affected by the unrelenting presence of back pain. Sarah suggests that women may cope better if they experience a resting phase between contractions that offers a relatively pain free period:

> *It's often debilitating because it* (back pain) *doesn't go away between contractions as well. You know people can cope when they get a break but they* (women) *just don't have a rest from that continuous back pain.* (Sarah, midwife seven years)

Continuous back pain removes the normally occurring pain free periods between contractions. There is thought to be a distinct difference between the experiences of pain that may occur with, and without, suffering, as discussed in the Introduction chapter. In this context, the term suffering differs with cultural/religious associations, as the distinction between normal labour pain and suffering occurs when there is a loss of confidence and personal resources to cope with pain (Lowe, 2002). The pain of labour may be ameliorated by positive feelings of empowerment and achievement compared with suffering which involves negative emotions that may range from a sense of helplessness to perceptions of personal threat (Simkin & Bolding, 2004). The shift from the normal pain of labour, which women generally are able to cope with, to suffering pain that exceeds capacity and causes distress, may be challenging for midwives objective:

> *I feel really sorry for them. I feel sorry for them anyway, which I shouldn't, it's not about sympathy. But it's a bit of a rip-off getting back pain.* (Alexandra, midwife eight years)

Early discussions about the role of labour pain described it as *"pain with a purpose"* (Kitzinger, 1978, p. 119); as associated with a task that has a defined start and end point (Melzack, 1993). Hence, midwives may regard the pain of labour positively, viewing their role as primarily supportive rather than necessarily intervening to relieve pain. However, when labour pain exceeds women's expectations and coping abilities, it may be viewed negatively, and the midwife's response may shift to feelings of compassion and sympathy, and a need to relieve the woman of her pain and suffering. It has been suggested that a woman's ability to cope with the pain of labour may be dependent on the confidence that her primary carer has in her ability to do so (Lundgren & Dahlberg, 1998). Hence, a change in the attitude of a primary carer, such as a midwife, may lead to a loss of confidence in women and a shift in both their expectations about, and experiences of, labour pain and analgesic requirements.

5.2.2   Women's perspectives

The dominance of the OP position as a unitary and uncontested explanation for back pain in labour was also reflected in the data provided by women. Perhaps unsurprisingly, women's ideas were influenced by the information they received from maternity care providers during pregnancy and labour:

> *Well, apparently he* (baby) *was laying reverse. His spine was on my spine so that's what the midwives, the obstetrician, told me why I was experiencing pain. Because he was facing the wrong way.* (Bea, first baby)

In describing the baby's position as *"facing the wrong way"*, something out of the ordinary and possibly pathological, is suggested. Odette describes a similar scenario:

> *My priority at the time was my back pain, because for some reason that was just what was just throbbing the most. Whether or not it was his position or* (pause) *the doctor from upstairs, the one who examined me in the wards, said she was concerned that he had actually turned around. His back was against my back and that could be the reason why I was having so much back pain. I honestly don't know.* (Odette, third baby)

These explanations, and women's inferences of a pathological cause for their back pain, are likely to be ascribed greater significance by the authoritative position of the care provider

(Jordan, 1997). In this scenario, the credibility of the information provided to Bea and Odette is reinforced not only by the professional/authoritative position of midwives and obstetricians, but is also likely to be influenced by the hospital environment in which these encounters took place.

Odette's statement: *"I honestly don't know"*, suggests that she is unconvinced by the doctor's explanation, perhaps because she recalls a midwife giving her a similar explanation for the back pain she experienced in her first pregnancy:

> *With my first son, Sam, he actually was facing the wrong way until right at the very end, because every appointment that I had they kept saying, no he's still facing the wrong way. [...] Maybe you should do some more exercises where you're on all fours. [...] So that's why I was sort of in the pool a bit. I was lying, like, on my tummy a lot in the pool floating and stuff, wondering if that was going to help. And I was worried, Oh, what's going to happen if he doesn't move and things like that, so then I sort of looked that up* (on the internet) *and they said, Oh most babies move at the last little bit and I was like, Oh well, it's that'll probably happen, that's OK.* (Odette, third baby)

The OP position is generally understood to require remedial treatment; however, without the immediate imperative of labour, Odette has the time to seek out, and assess, other sources of information (e.g. from the internet) that provide a different view; that the fetus may change position spontaneously. She is then reassured, not by her maternity care providers, but by the results of her own information-seeking strategies. The internet is increasingly used by women as a source of antenatal information, independent of that provided by care providers (Larsson, 2009). Odette's information seeking efforts provide a sense of autonomy that may be felt as part of the responsibility of being pregnant (Luyben & Fleming, 2005), and may be viewed as expression of individual agency, i.e. the capacity to act and consider the meaning of one's actions (Murphy-Lawless, 1998).

Kerry also emphasised the relationship between her baby's position in pregnancy and the back pain she experienced in labour:

> *And that* (back pain) *also caused problems in the pregnancy because she* (baby) *ended up being posterior and I wasn't able to sit in the optimal positions for you know, when you're in labour, to try to get the baby in the right position. I had to lay down a lot*

> *and I think that's why in the end she was posterior because I had a lot of trouble with mobility and things with the pain.* (Kerry, first baby)

Through the use of words such as *"posterior"* and *"optimal positions"*, Kerry has incorporated technical language into her explanation. With a blending of lay and technical terminology, Kerry attributes the (posterior) position of her baby to her own inability to adopt the recommended optimal positions that she understood may have corrected this perceived malposition.

The plethora of information now available through an ever expanding array of media sources exposes women to medical language, which may once have distinguished an expert from a lay person, are increasingly merged (Kangas, 2002). However, Prior (2003) observes that there is not always congruence between technical/expert and lay terms, hence a hybrid language may emerge conferring a range of different, and possibly contradictory, explanations. Therefore, although the same words may be used the information conveyed may be prone to distortion or misinterpretation.

The experience, recollection and interpretation of pain is intensely personal, typically involving a process of stepping back and evaluating against expectations and previous encounters with painful events (Bramadat & Driedger, 1993). During interviews for this study, women provided detailed descriptions of their experiences of labour pain. Sometimes differentiating between *"back"* and *"front"* (contraction) pain:

> *I knew it was a contraction but I wasn't getting any contractions around the front, it was only this really, really bad lower back pain. A real intense, sort of, take-your-breath-away pain, where you sort of almost gritted your teeth and had to really control your breathing. It was a very intense pain, yeah, central, low, but quite, quite unlike anything I've ever experienced before to tell you the truth.* (Luci, third baby)

Although Luci has two previous experiences of labour pain, her story indicates that the back pain associated with her third labour required new strategies for coping, such as controlled breathing. Odette also described the back pain associated with the labour of her third baby as different to her previous experiences:

> *I felt my spine was being squished sort of thing. It was a very specific point in my back, it just felt like it was being squashed or something. It was just quite intense. It's the worst pain I've ever had actually.* (Odette, third baby)

Odette's description of a localised point in her back being *"squashed"* is similar to the description given by Kerry, in labour with her first baby:

> *It was a really hard, dull pain. It wasn't like a zapping or a pinch or anything like that, it was like someone was trying to break your bone by putting pressure on it and that's what it felt like. It feels like that there's that much pressure that the only thing it can do is explode* (laughs). (Kerry, first baby)

The sensation of pressure was a common theme in women's descriptions, distinguishing back pain from the front pain more commonly associated with labour. In an early study of labour pain women differentiated back and front contraction pain; describing back pain as *"riding on"* the normal abdominal contraction pain, and that the combination elevated the experience to *"excruciating levels"* (Melzack & Schaffeberg, 1987, p. 903). The experience of back pain completely absorbed women's focus:

> *I mean, as I said it's a whole body thing. [...] It's your whole back and it overrides everything else that's sort of going on and stuff, because all that you can think about is that damn back pain. Yes I must say it was really, really horrible.* (Siobhan, third baby)

Siobhan describes her pain as all consuming, overriding everything else that was going on in her mind and body. Bea describes how her back pain impacted on her ability to move about freely:

> *Because all the pain was in my back there was not much I could do apart from just standing. I tried sitting for a little while, then standing. I couldn't walk around, I couldn't bend over, I couldn't have a shower so I just stood there and had to deal with the pain. [...] I just stood there. I just stood there for hours in one spot.* (Bea, first baby)

Bea's back pain severely limited her ability to take remedial action, such as walking about or being in the shower. Restriction of free movement also affected women's psychological

responses to labour. In the following quotation Kerry describes withdrawing mentally to help her cope with the pain:

> *I couldn't be as active as I wanted to be because of the* (back) *pain and therefore it affected me mentally and there were times where I really had to sort of go deep within myself and remind myself what it was all for. [...] It can be very tormenting on your mind, your thought process too.* (Kerry, first baby)

Women frequently suggested that their back pain challenged their plans to be active during labour, resulting in physical and mental withdrawal. This mirrors earlier research where women described withdrawing to a *"private world"* which acted to shield them from feelings of vulnerability and provide a sense of seclusion (Halldorsdottir & Karlsdottir, 1996, p. 52).

Women sometimes used metaphors, describing their back pain as:

> *Like being kicked in the back by a donkey constantly. Just, you know, being kicked constantly. Never going numb, just constantly being kicked. That's what it felt like. Yeah, all the time, it did not go away at all.* (Bea, first baby)

Bea emphasises being kicked repeatedly to illustrate pain which is intense and unrelenting. Camila also used analogies with familiar objects to describe her pain:

> *Kind of like someone having a rope or a belt around that sort of area right round the front and the back and just pulling it as tight as they could.* (Camila, first baby)

These descriptions illustrate the continuous nature of back pain that was a common feature of women's memories of their labours.

The descriptions of back pain in this section were provided by women in labour with a first and subsequent term pregnancy. Regardless of parity, their accounts shared some similar characteristics, with no element particular to either nulliparous or multiparous women. Ongoing studies in this area suggest that while parity may affect perceptions of pain at different stages of labour, the overall intensity appears to be similar (Capogna et al., 2010; Gaston-Johansson, Fridh, & Turner-Norvell, 1988; Lowe, 1987).

5.3   Introducing sterile water injections to the clinical area

5.3.1   Women: "It's just water"; "it wasn't a drug"

The use of water in labour (e.g. warm baths and hot showers) is typically associated with relaxation and an analgesic effect. However, the combination of water associated with the medically orientated image of an injection may set up contradictions, and challenge clinicians and women's ideas about what constitutes an analgesic substance (Reynolds, 1998). The following section presents data on the rationales, motivations and expectations of women receiving and midwives administering, SWI.

Women were asked about their impressions when they were first presented with information regarding SWI:

> *I mean it's* (SWI) *natural. It's just water. There's nothing else in it. There's not chemicals, there's no, nothing like that kind of thing, you know, with the drugs and the pethidines and all that kind of stuff. […] So I thought why not give it a go?* (Siobhan, third baby)

Siobhan differentiates the effects water, being chemical free and natural to pethidine which has been used as an obstetric analgesic since the 1940s, and which has long been associated with altering women's cognitive functions, perceptions and decision-making abilities as well as having negative effects on neonates (Anderson, 2011).

Women sought to balance their experiences of pain, and pain relief, without resorting to (pharmacological) *"drugs"*:

> *I thought, wow, that's interesting that they've got at least something there, you know there's something to fall back on. So I guess it gives you a little bit of relief that you, if you are in that much pain and you don't want to take drugs, that you've got that there, to us, if you really need it.* (Kerry, first baby)

> *The attraction was that it would take away some of the pain and that it was sterile water, it wasn't a drug. You know, so I could still experience everything but without you know, a certain degree of the pain.* (Sherelle, first baby)

The desire to both experience and control pain may appear contradictory, although this may also reflect women's understanding about the complexity of pain which they perceive as integral to the birth experience. A number of authors have discussed labour pain as a rite of passage that conveys important personal values to women and may even play a role in the physiological adaptation to labour, birth and the transition to motherhood (Davis-Floyd, 1992; Leap & Anderson, 2008). However, Lally et al. (2008) cautions that there may be disparity between desire and expectation; women may desire one experience, i.e. coping with pain without recourse to *"drugs"*, but also expect that pharmacological analgesia may be necessary. Such contradictions may reflect the need to balance personal desire for a natural birth and achieving mastery over labour pain, and a realisation that pain relief may be inevitable. It is interesting to note that in the previous quotes both Kerry and Sherelle discuss using SWI for pain in general terms and not specifically for the relief of back pain. In the SWITCh trial, the fact that SWI was offered only when women reported back pain, may have been lost within the broader discussion about women's desire for effective non-pharmacological pain relief in labour.

Margarite compares SWI with her views about epidurals:

> *I mean if you'd said this* (SWI) *would reduce your back pain from 10 to two and its potentially as bad for you as an epidural, and is going to take a month to recover and affect your ability to breastfeed and all that sort of stuff, I wouldn't have done it. I would have just put up with pain. But given that there was no, no side-effects, why wouldn't you give it a go?* (Margarite, first baby)

Margarite expresses concerns about the potential side effects of epidurals, stating that in her choice of analgesia, the ability to recover quickly, care for, and feed her infant were important considerations. This also suggests that analgesic options must be congruent with women's views of birth and the requirements of early motherhood; hence the desire to avoid the side effects associated with pharmacological analgesics can be a significant and motivating factor in the choice of SWI (Peart, 2008).

Some women expressed doubts about the ability of water to relieve intense pain:

> *To be honest with you, I wasn't expecting a lot. I really wasn't. It's water, you know, and water's good for you I know. But when you are, you know, thinking about the*

> *intensity of the pain and all of that kind of thing you just don't think that water is going to make any difference at all.* (Siobhan, third baby)

As a method of pain relief, water may be viewed as something that is applied externally to the skin, for example, in terms of hot or cold through the use of compresses, or immersion in a bath. Hence, perceptions about the effectiveness SWI may be limited by commonly held beliefs about the use of water therapeutically. Whilst Odette is able to contemplate *"injecting water"*, she is unconvinced about its effectiveness for relieving her pain:

> *I thought, you're injecting water, OK, how effective would that be? So I have to admit I was a bit of a sceptic.* (Odette, third baby)

Pharmacological analgesia is typically viewed in terms of substances that are injected or taken into the body to produce a specific effect; there is an anticipation of reliability and effectiveness, compared to expectations about non-pharmacological methods. The fact that sterile water is injected suggests that the procedure and effects may be invested with expectations similar to those held for pharmacological products.

Women were offered printed information about SWI between 32–36 weeks gestation by midwives working in the hospital antenatal clinics. However, it was not until the midwife drew Siobhan's attention to SWI in the context of a discussion about pain relief in labour that she considered this option:

> *One of the midwives, they gave me a flyer, a pamphlet, well, a piece of paper with some information on it. But to be honest with you I didn't pay it much attention and I think it was brought up again with the midwife as well and she said, Did you read up on the sterile water, because we were talking about pain relief and all of that kind of thing. So I'm like, well you know, I've heard about it a couple of times now.* (Siobhan, third baby)

The provision of information leaflets alone, even when these are evidenced based and commercially produced to a high standard, does not necessarily facilitate informed choice and decision making in pregnancy and childbirth (O'Cathain, Walters, Nicholl, Thomas, & Kirkham, 2002); perhaps because printed information may remain largely invisible unless reinforced by discussion (Stapleton, Kirkham, & Thomas, 2002). Information may need to

come from a variety of sources and in various formats, and over a period of time, to allow women to reflect on what may be relevant for them. Types of, and approaches to, pain relief may influence women's choices, with practices that are seen to be endorsed by care providers more likely to be regarded positively (Stapleton, et al., 2002).

Kerry indicates that she first heard about SWI in her antenatal classes:

> *I heard about them* (SWI) *in the antenatal classes. Because all of us wanted to go through a natural process of labour. We didn't want any drugs. She* (midwife) *said that there was this procedure where they inject water under the skin.* (Kerry, first baby)

Antenatal classes may present women with opportunities to explore new concepts and consider how these may be regarded by other pregnant women. However, this may depend on how information is presented, either encouraging group discussion and participation or silencing questions and reinforcing the policies of the institution (Nolan 2009). Kerry reported that there was a general desire amongst women attending her antenatal classes to pursue a natural birth process without recourse to drugs, (i.e. pharmacological analgesia). As pre-existing ideas and expectations may influence the consideration of new ideas, procedures that are in alignment with an individual's expectations, may have greater appeal and be more easily incorporated into birth choices. Conversely, Machin and Scamell (1998) suggest that new information which is radically different is less likely to be assimilated into existing personal belief systems. Hence, information regarding analgesic options such as SWI may appeal more readily to women actively seeking alternative, non-pharmacological, strategies to support a natural labour and a normal vaginal birth.

Women's first encounters with information about SWI may influence their interpretation and decision making processes. Despite attempts by the research team to disseminate information antenatally, some women reported that they were first informed about SWI when they were in labour:

> *It wasn't until I phoned in labour that I'd heard about it. Yeah, the midwife there she said, if you're interested we have the sterile water injections, and I'm like, well, you know, what are they? She explained quite briefly over the phone what it was and I've just gone, you know what? If it helps I'll give it a try.* (Luci, third baby)

Discussions with partners and other support people, regarding the need for assessment of labour progress and analgesia may trigger women's initial contact with midwives. These negotiations between labouring women, their support persons and midwives may leave women feeling indecisive (Eri, Blystad, Gjengedal, & Blaaka, 2010); hence the offer of analgesia may provide an uncomplicated course of action. Bea confirms that once in hospital, the views and opinions of partners and other support people may have influenced her decisions:

I said to Jim (partner)*, Oh my back hurts, and he actually said have a look at this* (information on SWI)*, and that's when I read it, or I tried to read it in between pain. Then the midwife suggested it. [...] Then Jim said, well if it's going to ease your pain maybe you should just give it a go, and I thought, I'll try it. Oh anything to get rid of this pain.* (Bea, first baby)

The experience of pain may necessitate immediate action, limiting women's ability to adequately process information, with the result that additional information offered by a clinician may have greater influence (Carlton, Callister, & Stoneman, 2005). The need for analgesia, and the influence of persons in relationships of trust and power, may impact upon labouring women's expressions of capacity and their ability to fully consider all the available options. Capacity requires that a person be able to understand, retain and consider information, and communicate an informed decision, although pain is known to impact upon women's ability to freely provide consent in labour (Jackson & Cox, 2011). Hence, decisions may be based more on the need for immediate pain relief rather than a balanced consideration of information and the various options.

5.3.2   Midwives: "It's just water. How's that gonna work?"

Midwives also discussed their initial reactions to administering SWI. In the following quote, Kirstie reiterates the *"freaky"* notion of producing an analgesic effect through injecting water under the skin:

I think when you hear about it, it sounds, I don't know if you can use the word scary but sounds (pause) *like, a bit freaky. For two reasons: you are using needles under the skin and it's just water, so it's just sounds too simple too work.* (Kirstie, midwife five years)

Kirstie's comment reiterates the work of Reynolds (1998) who commented that the simplicity of the SWI procedure may challenge clinicians' perceptions about effective pain relief, with some relating the level of complexity associated with a procedure, or the restrictions placed upon administration, with the degree of analgesia provided. For example, the relative intricacy and skill associated with procedures such as epidurals, or the controlled access to narcotics, may inflate the expectation for analgesic effect.

The invasive aspect of SWI, through the use of needles, also attracted comment from midwives contributing to focus groups discussions. Hanna discusses the issue of using a needle and causing pain versus the potential for SWI to reduce the likelihood of women requiring an epidural, with all the associated side effects:

> *There's the invasive thing that the needle does hurt a little bit. But if that gets someone through their labour and it means that they can go without having other interventions like epidurals which, with all the things attached with epidurals can cause complications, yeah why not, give it a go, see if it works.* (Hanna, midwife 14 years)

A study of Australian midwives use of SWI (Lee, et al., 2012) reported that some viewed the procedure as invasive and did not support the practice, or were suspicious about the analgesic effects. This illustrates that midwifery practitioners have diverse beliefs about methods of pain relief and there is often considerable debate about what constitutes analgesia. Leap and Anderson (2008) discuss two different paradigms regarding labour pain and recourse to analgesia: the normality of labour pain where pharmacological analgesia should be used sparingly and then only to relieve pain associated with pathology such as malposition and; the relief of pain where the perceived benefits of pharmacological analgesics outweigh any associated side effects. Hanna's use of SWI to *"get someone through their labour"* would thus be situated within the paradigm that accepts the liberal use of pharmacological analgesia, lessening the overall experience of birth for women (Leap & Anderson, 2008, p. 43).

In another focus group midwives revealed their initial scepticism about the effectiveness of SWI:

> *I thought it was going to have like a placebo/psychosomatic effect. I thought she was going to go, Oh yeah, it actually, it feels a bit better.[…] Didn't think it was going to work. Was a bit dubious.* (Sarah, midwife seven years)

> *That was the same for me. I was a bit sceptical.* (Marilynn, midwife 10 years)

Sarah suggests that the placebo effect, derived from the Latin *I shall please*, may produce an analgesic effect through altering expectations and conditioning. The placebo effect involves a complex process of interactions between the participant and the clinician which typically begins with a mutual desire for symptom change, perhaps influenced by varying degrees of empathy and reassurance (Finniss, Kaptchuk, Miller, & Benedetti, 2010). Placebos may produce not only a neurobiological response through the release of endogenous opioids, but have also been demonstrated to reduce neurological activity in pain-sensitive areas of the brain, thereby altering the experience of pain at a physiological level (Wager et al., 2004).

Karleen echoes the words of women in saying that *"it's just water"* and questions the physiological process. Carolyne is also unsure of her views about the physiology behind SWI:

> *Mmm, it's just water. I mean* (pause) *how's that gonna work?* (Karleen, midwife three years)

> *I couldn't believe* (it) *myself when I heard it initially. So I just was so curious to see how effective it is. And still it is hard to comprehend the physiology of pain relief. I know it's blocking the nerves and things but how. How? I've heard something else about theory of gate control, so I was wondering how it works [...] when I saw it practically I understood what's the effect.* (Carolyne, midwife five years)

After witnessing the effects of SWI Carolyne recalls the gate control theory (Melzack & Wall, 1965); her personal experience of SWI thus reinforces the theoretical aspects of the procedure. Although midwives had been provided with information regarding the evidence base for SWI, their scepticism illustrates how clinicians may still rely upon their own observations and experiences before accepting new procedures into practice (Gerrish, Ashworth, Lacey, & Bailey, 2008).

The use of SWI was a new concept and a new skill for many midwives, requiring information and training before incorporation into practice. Like other health care professionals, midwives may respond to the introduction of a new procedure based on a number of factors, such as the relevance to their personal practice, the quality of the learning experience, peer pressure, policies and institutional directives. The positions adopted by institutions and the views of

senior clinicians about new procedures may also influence uptake. Kirstie discussed the contrasting attitudes to SWI between her university lecturers and colleagues in her workplace:

> *I heard about it at uni [...] They* (university lecturers) *told us all about it and explained how it works and explained the whole physiology behind it but basically said, just go with whomever you are working with and see if they do it. I entered into a workplace where no one had ever heard of it before I knew what it was, and then it was just disregarded because you need someone else there to do your injections points and no one really knew what you were doing, so it just kind of got lost in the system.* (Kirstie, midwife five years)

Veeramah (2004) observed that some midwifery practitioners may be constrained by the pressures of heavy workloads or institutional barriers in their desire to implement new practices. Studies examining the introduction and use of SWI by midwives have reported resistance from both medical and midwifery colleagues, perhaps reflecting conflicts in their respective understanding about SWI, the available evidence, and views about what constitutes appropriate analgesia (Lee, et al., 2012; Martensson, et al., 2008a). Reviews of research evidence that support SWI use (Fogarty, 2008; Hutton, et al., 2009; Martensson & Wallin, 2008), and those that question the clinical efficacy and benefits for women (Derry, et al., 2012; National Institute for Health and Clinical Excellence, 2007), may also result in an uneven acceptance by professionals involved in providing maternity care:

> *Years ago, when was it first started? Melbourne or somewhere. [...]We had midwives who had worked there and wondered why we weren't using it here.* (Deena, midwife 20 years)

Clinicians familiar with, and accepting of, the use of a procedure in one institution may feel a degree of frustration when the same procedure is not accepted or used in another. This may result in negative feelings when practitioners relocate and lose skills acquired in their previous employment.

Arianne discusses a situation where a midwife performed SWI in a clinical setting when there was no policy or guideline to support its use:

(Midwife) *did one and there was no policy out and* (pause) *got into trouble for it.* (Arianne, midwife 25 years)

Midwives work within the boundaries of organisations and/or agencies, such as professional registration authorities, that exert control over the limits of their practices. This helps to ensure the delivery of a consistent level of care that can be measured against specific standards; it also informs risk management strategies. However, it may equally limit the uptake of new knowledge and practices, despite supporting empirical evidence, until they are described within policies and guidelines. In Australia, the development and implementation of policies is often a process undertaken by individual hospitals and may be constrained by the necessity for each to assess and present supporting evidence, and translate that evidence into clinical practice. This factor, together with limited access to appropriate training, has been highlighted by midwives as a serious constraint in the uptake of SWI into clinical practice (Lee, et al., 2012).

5.4   Sterile water injections and pain associated with administration

5.4.1   "It's like a bee sting": Midwives and women's discussions about injection pain

The most notable and widely discussed side effect of SWI is the associated injection pain. Discussions between midwives and women must not only facilitate an exchange of information, but in the case of SWI, establish a language to describe pain. Women's experiences of pain are likely to be affected by how the midwife presents information, including the choice of words and the emphasis placed on particular aspects of the SWI procedure. Research suggests that pain receptor areas of the brain may be activated by trigger words and/or descriptions of pain that then act as verbal primers for perception (Eck, Richter, Straube, Miltner, & Weiss, 2011; Richter, et al., 2010). During the focus groups the midwives discussed how they presented the injection pain to women in their care; references to everyday phenomena and language that emphasized the brevity of the sensation were common:

> *I say it's going to really, really hurt and it's like a bee sting. […] it doesn't last long.* (Deena, midwife 20 years)

> *I say it's like a bee sting but it's quick and it's done.* (Hanna, midwife 14 years)

> *Yeah, I say it's like a bee sting. I don't elaborate too much.* (Holly, midwife 25 years)

> *I just say it will be a sharp sting for a minute and then it's gone.* (Carmen, midwife 30 years)

A bee sting is a common concept in Western cultures, describing an intense and unexpected pain, as illustrated by the famous quote from boxer Mohammed Ali: *"sting like a bee"* to describe his boxing style. Midwives often used the imagery of a bee sting to convey the sensation and duration of the injection pain, a reference they were likely to have heard during their training in SWI by the author of this thesis, who cited publications that contained comparisons to bee and wasp stings (Byrn, et al., 1993; Martensson & Wallin, 2008; Reynolds, 1998). The above quotes also illustrate how similar descriptions of pain may nonetheless convey other information including that related to intensity and duration. Deena associates the bee sting with pain that will *"really, really hurt"* together with the brief nature of the intervention; similarly, Hanna emphasises the brevity of the sensation, by advising that it is *"quick and it's done"*. Other midwives used more colloquial references to insect bites, adapting language to local circumstances:

> *I say look, I'm not going to lie to you this really stings like a bull ant bite. It's really nasty and you are going to try and jump off the bed and* (then) *it should be all gone.* (Sarah, midwife seven years)

Although Sarah uses the analogy of a bull ant bite, a large aggressive ant common in Australia, the use of familiar imagery is similar to that of a bee sting, as the sting from both insects cause intense pain. However, the use of such descriptors relies on assumptions that midwives and women share similar understandings of pain and a familiarity with the points of reference. Arianne however, cautions against the use of words such as sting because women may not have previously encountered this sensation:

> *My issue is that some people describe it as a stinging sensation. I think it's more than a stinging sensation. It's very intense pain, just a short period but more than stinging. I tell them it hurts like anything. But it's short lasting. I don't want to tell them it's like a bee sting because if you've never been stung by a bee how do you know.* (laughter). (Arianne midwife 25 years)

Perceptions and experiences of pain, and the use of descriptors such as stinging, may also be culturally specific (Callister, 2003) and carry different meanings which may be lost for women from different backgrounds. Early research in this area referenced a number of additional descriptors for stinging such as tingling, itching and smarting (Melzack, 1975a).

Karleen and her colleagues used the VAS pain rating scale to provide a basis for describing the intensity of the injection pain:

> *If they* (women) *are telling me it's 8/10* (VAS score) *back pain at the moment with their contractions, I tell them the injection is going to be 11/10 just for that 30–60 seconds and then it will be all gone. But I do let them know it's going to be a little bit more painful than what they are currently experiencing but then it's all gone.* (Karleen, midwife three years)

Karleen empathises that the intensity of the injection pain may temporarily exceed the woman's back pain but mitigates this by reassuring her that it will be brief. Later in the focus group she reported that her observations of women's reactions to the injection pain have influenced the way in which she presents information:

> *I do compare, and that's probably why I come into knowing what to say to her, the next woman. Because maybe I didn't describe that pain as well as I should have and you know, there is that time that you feel bad because maybe you didn't pre-warn her enough about how much it's going to sting.* (Karleen, midwife three years)

The way in which information is provided may affect the acceptability of the procedure. For some women, the intensity of the injection pain may be such that they are discouraged from considering repeat doses of SWI (Fogarty, 2008; Martensson & Wallin, 2008). Kirstie stresses the importance of presenting information to women in such a way that they are appropriately and adequately prepared:

> *The women who say that the pain from the injections like far outweighs what they could have experienced and they don't want it again because that was too much.* (pause) *I think that comes down to preparing the women for what it's really going to be like.* (Kirstie, midwife five years)

The subjective nature of pain, and the varying but generally increasing intensity of pain associated with labour, means that definitive, realistic, and individualised explanations may be difficult to provide.

Some women suggested that the explanations provided by midwives underestimated their actual experiences of the pain associated with the injections:

> *They said it was like getting a bee sting. It was probably worse than a bee sting. […]It was more like a wasp sting.* (laughing) *Yeah, a wasp sting that lasts for 10 seconds, yeah* (laughing). (Kerry, first baby)

> *I guess I'm surprised it was a bigger sting than I thought I thought it would be. Like they sort of said it would be a bee sting and I'm like, this is not a bee. It's a, yeah much bigger than a bee.* (Odette, third baby)

Conversely, other women agreed with midwives' descriptions:

> *Like a bit of a bee sting in my back, but as soon as they done what they had to do the pain went.* (Camila, first baby)

> *It was like yeah OK, then it does feel like a bee sting.* (Siobhan, third baby)

Siobhan thought midwives sometimes over emphasised the injection pain:

> *But I must say they talk up the pain you know, Oh this is really going to hurt, you really are going to feel this, but only for short time you know, and stuff like that. […] To be honest that first lot it was nothing really. It was, Oh yes the bee sting but nothing to what they said. […] I was expecting a hell of a lot more than what was actually there.* (Siobhan, third baby)

However, midwives indicated that they would feel responsible if they underestimated this aspect of the procedure and had not sufficiently prepared women in their care. As the relationship between midwives and women is widely viewed as being based on trust and confidence (Halldorsdottir & Karlsdottir, 1996), a significant discrepancy between expectation and actual experience could impact negatively. Some women preferred to receive an exaggerated description of the injection pain as a means of preparing themselves:

> *I want them to tell me to prepare for the worse pain then I will set my mind, cause I'm that kind of person. If you tell me this is what it's going to be, and if it's more than that, I should be able to prepare myself.* (Monika, first baby)

Siobhan's and Monika's reflections reiterate the difficulties for midwives attempting to tailor their descriptions of the injection pain to the needs of individual women. Using analogies that have some familiarity and relevance for both staff and women may be helpful in preparing women for the pain associated with the procedure; however, as previously noted, constraining imagery to culturally specific descriptions, such as a bee/wasp sting, may exclude women who are unfamiliar with such images. Furthermore, midwives could not rely on parity as an indicator for preparation as multiparous women appeared no different from their primiparous peers in their experiences of injection pain.

5.4.2   *"No pain no gain": women's reactions to additional pain*

When labouring women request analgesia, the likelihood of further, and worsening, pain needs to be balanced against the prospect of relief. Some women considered their experience of the injection pain very positively against the analgesic effect provided:

> *Doesn't matter about that 30 seconds of pain or whatever it was, because within a minute, I was, felt relief from my back pain. […] So yeah, I would say that outweighed you know, because no pain no gain, sort of thing.* (Odette, third baby)

> *You know short term pain for a longer term relief which was good. […] the intense pain of the needle lasted such a short time. […] I would say that's nothing in comparison to the effectiveness and speed that it takes.* (Luci, third baby)

The phrase *"no pain no gain"* is a popular and widely understood notion with strong religious and cultural connotations suggesting that rewards are gained through hardship and suffering (Morris, 2005). In this sense, the pain and reward metaphor may be applied to birth as a whole, through the sense of triumph and accomplishment associated with the completion of a personally challenging journey (Halldorsdottir & Karlsdottir, 1996; Leap & Anderson, 2008). However, women's achievements in labour may draw little recognition from a society that values technology and safety over the many personal accomplishments that may be associated with normal birth (Klein et al., 2006).

Bea describes how the idea of adding more pain to her existing labour pain affected her:

> *The midwife had said look it really hurts, […] it will be worse than what you're feeling now. And I went, Oh I don't want to feel any worse than what I'm feeling now, so I think I got that into my mind. […]I think that's just fear grabbing hold of you when I was trying to be so confident through the whole process and not expecting for* (the) *whole labour process being so painful and then when I was hit with this bullet, this is going to hurt too, well I thought, I don't want to have any more pain.* (Bea, first baby)

An unknown degree of additional pain, superimposed on the existing and unrelenting pain of labour, may trigger women to doubt their ability to labour and give birth unaided; this may be amplified for primiparous women. In addition, there may be negative effects on self-confidence and self-esteem related to the fulfilment of personal expectations, and the expectations of others (Nilsson & Lundgren, 2009). The experience of labour pain has already exceeded Bea's expectations; hence the need for pain relief is the imperative that drives her acceptance of the brief episode of pain associated with SWI:

> *Well through the whole labour I didn't really yell or squeal but I did when I got the injection, so yeah, it was probably the worst pain out of all of it but it lasted the least amount of time so it was bearable. […] After five seconds it went away and all the pain was relieved. […] I did feel a lot better with it.* (Bea, first baby)

Bea describes the injection pain as the *"worst pain out of all"* but subsequently reconsiders this as *"bearable"* because of the positive analgesic effect she experienced.

As detailed in the Literature Review chapter, clinicians frequently administered the injections during a contraction to mask or distract from the injection pain accompanying SWI. The relationship between the timing of the SWI injections and the pain of contractions also affected women's experiences of the injection pain. Bea used her contraction pain, reinforced by the visual representation on the cardiotocograph (CTG) screen to distract her:

> *It was while I had the contraction, so I was focussed on the contraction and not that* (injection). *But I knew it was happening. You know your brain knew that you were*

getting a needle in your back even though you were looking at the (CTG) *screen and you knew you were having a contraction.* (Bea, first baby)

The combination of using a cognitive focus (a CTG screen) simultaneously with a physical sensation (contraction pain) to distract from a painful stimulus (injection pain), has been demonstrated to provide a greater pain modulating response than just physical counter-irritation alone (Moont, Pud, Sprecher, Sharvit, & Yarnitsky, 2010). Distraction and counter-irritation techniques are also amongst the oldest recognised forms of analgesia and have been discussed since the time of Hippocrates (Wolff & Hardy, 1947).

5.4.3 *"We're not used to doing that": midwives' reactions to causing pain*

Midwives typically focus on supporting women through the pain of labour. Therefore, causing a brief but nonetheless significant, degree of additional pain may be seen as counter-intuitive; as contrary to normal practice. This may be especially so for midwives administering SWI for the first time, as reflected by the following quotes from Alexandra and Sarah:

And then the girl really screamed and abused me. I felt really bad and I was relieved when it worked really well, but I still felt a bit sad that I hurt her so much. Because we're not use to doing that. We're not use to hurting people and I felt quite bad. She almost looked at me like I lied about it. (Alexandra, midwife eight years)

Bit shocked about how much she screamed and jumped off the bed. But then you think, got to do this. But then two minutes later, she's your best friend ever and you think well it's worth it. And then women say it's worth it and they ask for another lot three hours later. (Sarah, midwife seven years)

These accounts illustrate the dilemmas facing midwives in causing women additional pain, albeit to relieve a more severe pain. Later in the same focus group discussion the midwives reflected on how their opinions had developed and changed over time:

Well you feel pretty bad about torturing somebody if it (SWI) *doesn't work. I don't think we would love it as much if it doesn't work so miraculously. We wouldn't be willing to cause that intensity of pain if it* (VAS score) *went from a nine to an eight. If*

there was that much pain for a little bit of difference then I don't think we'd love it really. (Sarah, midwife seven years)

It has to be that level of goodness to inflict pain on people, definitely. We aren't really good on tough love. (Alexandra, eight years)

Alexandra refers to midwives not being good at *"tough love"*, a popular expression that evokes images of stern treatment underpinned by a sense of social, moral and/or professional judgement and responsibility. The term is also associated with paternalism and control, perhaps best illustrated in an Australian context by politically conservative policies aimed at controlling already disadvantaged groups such as Indigenous persons and young single mothers (Mendes, 2009). As such, the metaphor of tough love does not sit well with the broader view of relationships between labouring women and midwives being based on mutual trust and shared power (Kirkham, 2011). Alexander's reference to a *"level of goodness"* suggests that the acceptability of the procedure may be challenged by the pain midwives inflict through the injections. Midwives generally agreed however, that the pain they caused was not necessarily a barrier to them suggesting SWI to women in their care, especially those wanting to pursue a natural course of labour, i.e. without recourse to pharmacological analgesia:

Especially those women that want a natural course of labour. They know that this benefit will outweigh the pain. (Carolyne, midwife five years)

When you've seen it work and you've seen the results you know you've just got to get through that little bit and help the women through that short period of pain. (Kirstie, midwife five years)

Getting women *"through"* the pain of labour is viewed as integral to the midwife's role in supporting women to achieve a normal birth, although Crabtree (2008) suggests the concept remains ill-defined, largely constructed by the attitudes of care providers and influenced by institutional and risk management policies, and fiscal concerns. Procedures such as SWI and epidurals may be included or excluded from definitions of normal birth, depending on the viewpoint of the care provider and/or their employing institution. Definitions may also be influenced by competing priorities, including the influence of professional bodies such as

midwifery and obstetric colleges, compared to hospitals that may focus more on the mitigation of risk in order to avert legal proceedings.

Midwives contributing to this study largely viewed SWI as congruent with their definition of normal birth, not least because of expectations that it assisted in avoiding the cascade of interventions associated with pharmacological analgesia:

> *I guess if you know that you are going to save them pain in the long run, if it works well for them then it's worth it in my mind. And if it means that it's going to stop them having something else that's going to cause a cascade of intervention, then it's probably worth it.* (Deena , midwife 20 years)

Simkin and Ancheta (2011) observed that timely and appropriate use of midwifery skills can prevent the need for medical interventions, increasing the likelihood of a normal birth. For many midwives in this study the injection pain associated with SWI was placed within the context of prioritising normal birth and hence was incorporated into the concept of supporting women in labour. However, midwives noted that for some women the analgesic effect did not compensate for the injection pain:

> *Some say that no matter how bad this pain gets, I will never have that* (SWI) *again. (Marilynn, midwife 10 years)*

Kirstie explores this further:

> *I think for some women that intense short pain that is from the injections is just too much and scares them into getting it again. But I also think that's experienced a lot more from women who are in early stages of labour. […]When back pain is really bad because they are in really good labour, that intense feeling of pain from the sterile water doesn't seem to be as bad.* (Kirstie, midwife five years)

As Kirstie observes, women's reactions to the injection pain may reflect their (early) stage of labour. Labour is recognised as a dynamic process where the level and intensity of pain increases as labour progresses, requiring women and midwives to constantly reassess their interpretations of pain (Ludington & Dexter, 1998). Hence, the experience of additional injection pain may be relative to the pain of labour at the time. As previously noted, women

with back pain which is reflected in a VAS score of six or lower, may be more likely to object to the pain of SWI compared with those who rated their back pain higher (Peart, et al., 2006).

5.5 The analgesic effect of sterile water injections

5.5.1 Women's accounts

Women's accounts of the analgesic effect of SWI not only described the degree of pain relief but also the time between administration and the onset of effect. Only one woman reported a substantial delay between receiving the injection and the onset of analgesia:

> *After 10 minutes or 20 minutes. Yes, 10 minutes, my back is starting to feel well. Cause when they put in the injection my back isn't reacting straight away.* (Monika, first baby)

However, for many women the onset of pain relief was almost instantaneous:

> *Look, in all honesty it was pretty much instantaneous because they said, after I had the injection, they said we want to wait for another contraction just to make sure it's working and to make sure you're OK and things like that. […] So it was yeah, it was immediate.* (Luci, third baby)

Siobhan also described her continuous back pain as abating as soon as the injection pain eased:

> *Nearly instantly. Pretty much instantly. Like I think if it hadn't have had that stinging sensation when you actually have it you would notice it a lot quicker. But once that stingingness goes and all that kind of thing, you notice, Oh god that's right, now the back pain's gone. It pretty much, is nearly instantaneous which is brilliant, that's what you want.* (Siobhan, third baby)

Siobhan's comment, that the rapid onset of pain relief was what she wanted, reflects the observation that the time delay between the procedure and the onset of relief may influence women's impressions of the overall analgesic effect. When a woman experiences a degree of pain that triggers a request for analgesia, there is almost certainly a sense of urgency about the timing of the request and need for early onset of pain relief; the longer the duration, the less

positive women's recall of their experience of the analgesic effect is likely to be (Collis, Davies, & Aveling, 1995; Moore, 2009).

The quality of pain relief generally encompasses a number of distinctive characteristics including the speed of onset, perceived effectiveness and duration of effect. That said, there is no single measure or definition for assessing the overall quality of a particular analgesic in individuals (Moore, 2009). Both primiparous and multiparous women described similar experiences with respect to rapid onset:

> *Brilliant, absolutely brilliant. [...] I was expecting, you know, maybe a little bit of dullness but I wasn't expecting it to go. And it literally went. Like there was no back pain, nothing at all. Brilliant.* (Siobhan, third baby)

> *I thought it would take some of the pain away but it was a lot better than what I actually thought it would be. I thought that I'd still have a fair bit of pain there but it took a lot away on that side.* (Camila, first baby)

Although Siobhan and Camila's expectations were exceeded by their actual experiences, there may be differences between conscious expectations and subconscious conditioning that affects the experience of analgesia (Benedetti et al., 2003). Subconscious conditioning may arise from assumptions that whatever procedure is being offered by the clinician has been well designed and is the best available, referred to otherwise as *"what is, must be best"* (Porter & Macintyre, 1984, p. 1197). Subconscious conditioning may also arise as a result of conversations between women and midwives that precede the SWI procedure. For example, women may subconsciously select aspects of the conversation they perceive as relevant to their immediate desire for pain relief, while midwives may emphasise aspects they consider most appropriate or relevant to the woman's course of labour and/or desire to avoid medical interventions and achieve a normal birth. Hence differing conclusions may be drawn from the same conversation based upon the desired outcome.

In describing their experience of pain relief some women referred to their VAS pain scores:

> *You can still feel it in the back but it, it really relieves the pressure feeling, really relieves it, so you can still feel it happening. I would say that the pain would go from an eight down to a two, yep.* (Kerry, first baby)

However not all women reported experiencing good analgesic effect from SWI. In the following quote Margarite describes her disappointment:

> *I think I said I might have been a* (VAS score) *nine or 10 to start with and with and I stayed around that to an eight or so may be dropped by one possibly but maybe not the two that I was hoping for. […] It didn't work for me but the thought of it, like the hope that it would work, was very good.* (Margarite, first baby)

Margarite also drew on her experience of VAS scoring to quantify her experience of the analgesic effect. Despite her disappointment, she continued to emphasise her aspirations: that the effect of SWI would be *"very good"*. This illustrates the complex relationship between expectation and individual experience of analgesia.

Sherelle was also disappointed with the degree of pain relief she experienced:

> *Well I was expecting, you know, a lesser degree of pain. I was still expecting some pain, I wasn't expecting the whole pain to go away. But yeah, I was expecting there to be less pain and there wasn't.* (Sherelle, first baby)

As in other SWI trials (Martensson & Wallin, 1999; Trolle, et al., 1991), the SWITCh trial also noted that between five and 10% of women receiving SWI will experience little or no pain relief and this is regardless of parity and other confounders.

Women's recall of the duration of the analgesic effect appeared to be distorted by the effect of labour:

> *Looking back I think it was round about the two hours that it lasted. It could have been give or take half an hour either side I don't really remember. It felt like it only lasted five minutes, but by the time I looked at the clock it was a lot longer. The time was a big blur*. (Bea, first baby).

> *It lasted quite a while from what I remember. […] Time went so fast.* (Camila, first baby)

In a qualitative exploration of women's of childbirth experience, women described being in a world of their own, where their sense of time was altered or lost altogether (Halldorsdottir & Karlsdottir, 1996). Fox (1989) also discussed women's perceptions of time as being derived

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from the rhythms associated with labour and birth, in contrast to quantifiable chronological measurements. If time distortion in labour is part of a natural coping mechanism, it may be that the use of pharmacological analgesia in itself affects the perception of time during labour. Coping with labour pain without pain relief may distort women's perceptions of time while the administration of pharmacological analgesia typically restores a more familiar relationship and a perception of time passing as normal. Non-pharmacological analgesia, such as SWI, may provide pain relief without disturbing women's sense of withdrawal, and the blurring of time.

5.5.2 Midwives accounts

The rapid onset of analgesia following the administration of SWI was also evident in the Midwives observations of women's responses:

> *Amazing. Quick effect like people* (pregnant women) *are coming in* (to birth suite) *and they are breathing away and they're huffing and puffing and it's all in the back and* (she) *is really anxious. And sterile water and she's like, 'I'll be off now'. […] It fixed everything. It fixed the back pain, and therefore it fixed the anxiety and the contraction pain.* (Alexandra, midwife eight years)

Anxiety may arise from a woman's sense of loss of control and ownership over labour which typically occurs on arrival at hospital (Carlsson, Ziegert, Sahlberg-Blom, & Nissen, 2011); this cyclical relationship of anxiety and pain has been noted for some time (Dick-Read, 1954). As illustrated in Alexandra's comment, relieving pain may address the accompanying anxiety and return a sense of individual control to women.

Other midwives also commented on the rapid onset of pain relief and women's positive responses:

> *When we see a women and you say to them, Oh after they've had the sterile water and the intense pain goes away and they say, "when is it supposed to work"? And you say "you wait for the next contraction" and then after that contraction they smile.* (Kirstie, midwife five years)

The rapid relief of pain generally associated with SWI is in contrast to delays of up to 30 minutes between the administration of pharmacological analgesics such as narcotics and

epidurals, and the onset of analgesia. The mostly rapid onset of pain relief following SWI provides a novel characteristic that may serve to encourage acceptance and wider use of the procedure, especially by clinicians.

Women's reactions to SWI made powerful impressions on midwives:

> *I had a beautiful case in birth suites the other night. This woman came in and she had been contracting for a few hours. [...] She was complaining bitterly about the back ache so were massaging and doing all this other stuff and I said, "how about sterile water injections?" [...] The pain score had been 10. Ten minutes later she said it was a five, which I thought was fantastic. And with that she got in the bath and went from 3 cm to fully* (dilated) *and having a baby in four hours. [...] She was rapt.* (Holly, midwife 25 years)

Arianne also reflects on how a woman's positive response to SWI was related to the contribution it made to her overall sense of control and achievement, which was unrelated to her actual birth outcome:

> *She had an obstructed labour. [...] She ended up with a caesarean section but she raved about the sterile water injection, how it helped her. But it doesn't matter the ways, it's just the woman feeling that they have achieved what they have set out to achieve. To be more in control during labour.* (Arianne midwife 25 years)

Sarah reiterates the importance of women retaining a sense of control over their labours:

> *She didn't want an epidural even though she was being induced. Had terrible back pain, had one lot* (of SWI), *three and a half hours later had another lot. She loved it. Instant relief.* (Sarah, midwife seven years)

These quotes illustrate the observation by Lowe (2000) that control is not solely related to the type of labour and birth women experience, but to more complex relationships such as women's perceptions of their involvement in decision making. The midwives observed that women may establish personal goals that are not related to the type of labour or birth they anticipate, or indeed experience, but which involve personal attainment from a sense of overall achievement. The choice of analgesia in labour, therefore, may not simply concern pain relief, but must also be congruent with, and supportive of, a woman's individual need for

and sense of control. As a non-pharmacological form of analgesia, SWI is unlikely to alter women's normal physical function or cognitive ability in the way that pharmacological methods may do; hence her sense of control is less likely to be affected.

Midwives also recounted examples of women in their care who had not experienced pain relief following SWI:

> *I've only had three occasions where it hasn't worked. The two that delivered very quickly, well maybe it was never going to work because it was all too far gone. And one girl who worked a little bit but not miraculous, she had an epidural half an hour later. I don't know why it didn't work for her.* (Sarah, midwife seven years)

Sarah observations that labour was *"all too far gone"* to benefit from SWI is supported by an early study that found that SWI was less effective in women approaching, or in, the second stage of labour (Lytzen, et al., 1989). Furthermore the results of the SWITCh trial supports the observations of other SWI trials that approximately 12% of women experience inadequate or no pain relief following SWI (Lytzen, et al., 1989; Martensson & Wallin, 1999).

Alexandra suggests that the all-encompassing nature of labour pain, which may make it difficult for women to discern between back pain and abdominal (front) pain and that this may influence the effect of SWI:

> *I've had one that didn't work, maybe one or two, but the one that I remember that didn't work, she wasn't perhaps, I think it was because the back pain was so bad. I think it did work on the back pain but once it allowed the front pain to be acknowledged, that came in with a vengeance.* (Alexandra, midwife eight years)

In the SWITCh trial, SWI was offered only to women requesting relief from back pain; however, once back pain is lessened, the woman's focus may shift to her abdominal (front) pain. As previously noted, the nature of labour pain is dynamic in that it typically increases in frequency and intensity as labour progresses and hence, it may also be difficult for labouring women to clearly distinguish between the characteristics of different types and locations of pain. Midwives typically base their assessment of women's pain on their verbal responses and non-verbal cues such as facial expressions and body movements. As verbal cues reduce and non-verbal expressions become more varied as the severity of pain increases, midwives may

experience considerable difficulties with making accurate assessments about women's labour pain (Baker, et al, 2001). Interventions, such as SWI, that are specific to types and physical locations of pain, may be less noticeable in the context of a woman's ongoing reactions to her overall experience of labour pain.

5.6 Reflections on using sterile water injections for back pain in labour

5.6.1 *"It worked and it made such a difference": Women's narratives*

Luci describes how SWI provided her with sufficient relief from her back pain in the early phase of labour, that it enabled her to return home and prepare herself and her family:

> *I came back home, got to spend you know a couple more hours with my kids, explained to the kids what was happening, yeah and then just able to mentally prepare myself a bit. OK, well it's happening today. Hubby had a chance to prepare himself, and yeah very, very happy I got it (SWI) done. [...] The difference it made in terms of how I felt, how I felt before I got to the assessment unit and then after the needle, being able to come home, being able to relax, [...] it was just amazing. I wouldn't have been able to do that if I was in the constant, the really severe pain I was getting. I would have gone into labour a lot more stressed and a lot more anxious and I don't think, you know, that would have benefited anyone really. But yeah because it worked and it made such a difference. (Luci, third baby)*

As previously discussed, back pain appears to be more strongly associated with latent phase labour; therefore, SWI may be less effective later in labour when pain is generally more intense and the distinction between types of pain may be more difficult to discern. Luci's experience illustrates the importance of effective analgesia in the latent phase of labour. It also confirms that SWI, unlike narcotic analgesia, does not necessitate inpatient admission, which is beneficial because there is evidence to suggest that women who are admitted to birth suites before labour is established are more likely to encounter interventions and have longer labours (McDermott, 2010; McNiven, Williams, Hodnett, Kaufman, & Hannah, 1998). Hence the current trend to encourage women in early labour to remain at home. However, this may be dependent on a number of clinical and social factors such as the availability of adequate and appropriate pain relief, a comfortable home environment, distance from hospital, and the availability of transport, and adequate support.

Siobhan, who has experienced two previous labours, also discussed the impact of relieving her back pain in early labour:

> *And it* (SWI) *did make things so much easier. It really, really did yeah. Especially in the beginning when you're like, Oh my god, this hurts, before you even get into the intense stuff. You know so, it does give you time as well to get your brain around it and to get yourself emotionally set for everything that's happening and going on and all of that kind of thing s as well. It lets you get in tune with everything. Yeah, it made it so much easier for myself.* (Siobhan, third baby)

Siobhan makes a distinction between the pain she encountered in the beginning her labour and the *"intense stuff"* she anticipates when labour becomes established. Women's individual sense of preparedness for the challenges of labour may involve a myriad of positive and negative facets drawn from their life experiences including that of pain and previous labours and births, brought together at a particular point in time (Carlsson, Hallberg, & Odberg Pettersson, 2009; Carlsson, Ziegert, Sahlberg-Blom, & Nissen, 2011). Back pain momentarily interrupts Siobhan's mental and emotional preparation for labour; relief of her pain allows her to continue. She went on to describe how a second SWI later in labour enabled her to deal with other pain:

> *I was absolutely fine with having the second lot. […] Just eliminating that* (back) *pain it made it a heck of a lot easier to deal with the other pains that were going on. You know, you get rid of one and you know you've sort of got enough room in your mind to sort of concentrate on the other pains that's happening, so it's not as overwhelming having, you know, one of them eliminated.* (Siobhan, third baby)

The elimination of her back pain enables Siobhan to broaden her mental focus to more fully experience, and respond, to her labour and birth:

> *It's all just a mind thing and I wanted to be really clear, you know, and go through it and all that kind of thing. […] So I mean I was fully able to see and to concentrate and understand what was going on, and I mean getting rid of that back pain, I could experience it* (labour and birth) *even more and appreciate what was happening you know, within myself and that kind of thing a lot more than if I hadn't been able to eliminate that back pain.* (Siobhan, third baby)

Though some women may use the challenge of labour pain to focus their mental and physical energies, others find that pain increases their sense of isolation and contributes to feelings of exhaustion and distress. Kerry describes how SWI relieved her back pain allowing her to regain new energy, recover her sanity and re-establish communication with those around her:

> *Oh I was so thankful. It just, it gave me that 45 minutes to regain some energy, because I was that exhausted, because they were coming every three minutes and sometimes less. Just from coping with the pain, I felt like I was going insane and then I could actually have a conversation because I wasn't in that much pain, yeah.* (Kerry, first baby)

As previously discussed, the type of analgesia women use also is likely to have an impact on how they experience labour and birth. Some multiparous women, including Odette, drew comparisons between using epidurals for pain relief in previous labours, and SWI in their current labour:

> *I had the sterile water injection and it stopped the back pain within a minute, or two minutes. [...] I was very much aware of when the contractions came and my body wanted to push and that sort of thing. I had, I felt like I had no choice, I needed to go with it sort of thing. [...] With the epidural, I just had, I had no clue. I was told when to push based on what the monitor showed on the screen. [...] Not having the epidural I felt more in control, so this is my control side coming out, more in control, more aware of what was going on, more a part of it. That's definitely a big positive. I was much more aware of what was going on. I could feel him getting lower and lower. [...] Feeling everything a bit more was definitely a better experience than being so numb to it, and being told push, like yep OK push , yep, yep, I'm getting a bit bored with this, but yep OK.* (Odette, third baby)

Research suggests that a woman's intention to labour without an epidural may be related to a number of factors such as parity, access to information and her degree of compliance with the decisions of care providers, versus her desire for active participation in decision making processes (Heinze & Sleigh, 2003; Le Ray, et al., 2008). The personal attitudes of attending clinicians and the norms of the institutional culture can also play a significant role in influencing women's choice of analgesia, including epidurals (Le Ray, et al., 2008). Odette's

account indicates that she received SWI towards the end of her labour. The period of transition between the first and second stages of labour has been described by women as the most painful (Wolf, 2002); and when back pain is a feature of the transition, the use of SWI may assist women to continue without an epidural. Odette also indicated that the use of SWI enabled her to exert control and experience her birth more fully compared to her previous labour with an epidural. The relationship between parity, SWI and pain relief is explored further in the Discussion chapter.

The telling and re-telling of her birth story has been described as an essential element of a woman's transition to motherhood (Davis-Floyd, 1992); it may also contribute to expectations about her next birth. Women contributing to this study were asked if they would use SWI again in a subsequent birth:

> *I would do it again in a heartbeat, I really would. Oh yeah, if I was going to have any more kids I would yeah,* (laughing). *Yeah, look hands down I would, yeah, definitely use it again. Absolutely.* (Luci, third baby)

Women who had repeat injections would also do likewise:

> *I definitely would. Definitely would and I would go for the third, fourth, however many that I need.* (Siobhan, third baby)

Women who experienced little pain relief contemplated using SWI again in preference to more conventional pharmacological analgesia:

> *I would still try it again for me. […] Yes definitely. I mean, what have you got to lose? […] Especially for people who don't want more traditional drugs, which is the category that I fall into.* (Margarite, first baby)

Although SWI failed to provide her with the analgesia effect she sought, in keeping with her desire to avoid *"traditional drugs"* Margarite views SWI as an option for a future labour.

Although birth stories allow for reflection on experience, they may also emphasise knowledge derived from that experience. Placing labour and birth narratives within a wider cultural context may enhance the relevance of the story, and the embedded knowledge, to the listener (Callister, 2004; Callister & Khalaf, 2009). With the growth of social media, birth stories have

become increasingly more accessible and indeed may figure prominently as an information source for pregnant women (Lagan, Sinclair, & George Kernohan, 2010). Hence, aspects of the labour experience, such as pain and analgesia use, may increasingly inform women's decisions (Raynes-Greenow, et al., 2007). With increasing access to birth stories, positive accounts of women using SWI are likely to inform other women, thus increasing demand for this intervention to become more widely available.

Women shared positive experiences of SWI with others, including relative strangers:

> *At my local supermarket, there are two ladies, one is four months pregnant and one is six months pregnant. And both of them I said: OK when you go in you have to try the sterile water. Water? What you're kidding? I'm like, no, it's an absolute brilliant wonder drug. It's absolutely amazing without it being a drug. I said you will not regret having it and it will make it so much easier for you definitely.* (Siobhan, third baby)

> *I'd recommend it. Actually I've got a girlfriend who's, she's due in March and she's starting to have a bit of pain already and I've already mentioned it to her, so yeah I would, I'd tell them. I think I've said it before it's a short term pain but definitely long term benefits and yeah just definitely worth it.* (Luci, third baby)

Siobhan and Luci recall themes previously discussed in this chapter, such as the notion of water as an injected analgesic *"without being a drug"*, and the concept of pain for gain. Other women's narratives included comments about the limitations of SWI, for example, that it only relieves back pain, and the intensity of the injection pain:

> *It's a bit tricky because it is for back pain only, so if it's, if it's an issue of back pain then definitely. […] It worked really quickly and very effectively. It eliminated my back pain and you can't ask for anything more. […] Bit more than bee sting at the beginning, but it's, that's nothing comparing, I would say that's nothing in comparison to the effectiveness and speed, that it provides relief for sort of thing. […] for me for that time period, it worked really, really effectively for back pain.* (Odette, third baby)

Through the telling and re-telling of birth stories women explore their own experiences, balancing positive and negative aspects to arrive at a personal perspective; story telling also allows others to draw vicariously from the account described (Savage, 2001).

Information from sources, such as birth stories, bears the credibility of a personal account and typically places less emphasis upon technical aspects, consequently making it easier to recall than more formal information. For these reasons it is likely to have greater appeal to listeners or readers in similar circumstances (Raynes-Greenow, et al., 2007). Recommending pain relieving options, such as SWI, may not be solely related to the analgesic effect but may also be related to other preferences such as labouring without the use of pharmacological analgesia (Hodnett, 2002; Savage, 2001). It is interesting to note that the majority of quotes in this section were from multiparous women. It may be that the novelty associated with the SWI procedure encouraged such women to make comparisons with other forms of analgesia they had used in previous labours and which may not have been as effective as anticipated.

5.6.2 *"It's had a massive impact": midwives' narratives*

As previously described, the use of SWI was a relatively new concept and practice for the majority of midwives participating in this study. As noted in the preceding section, the use of stories and anecdotes is a common way of sharing information and midwives also used storytelling to convey midwifery knowledge that may be outside the accepted canon of institutional teaching, or which may serve to link theory and clinical practice (Leamon, 2009; McHugh, 1999).

In the following section midwives discuss the generally positive impact of SWI on their clinical practice:

> *I think it's had a massive impact. Its huge because we actually can do something, do something that's not like, Oh we're going to rub you better, Oh get you in the shower. No, we have something that actually, chances are, will work 100%. Fantastic, massive impact.* (Sarah, midwife seven years)

> *Those of us that are nurses have the dilemma between the need to fix and the midwife position not to fix and to watch and wait. It's really nice as an RN* (registered nurse) *as well as a RM* (registered midwife) *to be able to fix. I really enjoy that. I'm not ashamed to say that. I enjoy that it's not for me to impose some painful journey on*

someone, unless she wants to do it that way. If she's seeking some relief and I am able to help, then I am rapt. (Alexandra, midwife eight years)

I think they see it that we are doing something for them as well, that's just not rub your back and have a hot shower and do your position, but they see us actually, Oh they are giving me something. Regardless if it's just water. (Karleen, midwife three years)

There is agreement, amongst the three midwives, that they experience positive reward in being able to actively engage in care that relieves a woman's labour pain. A clear distinction is made between activities such as massage, use of showers and change of position which the midwives view as passive and unlikely to affect substantial change in pain, and access to procedures such as SWI, viewed as being more likely to eliminate pain.

Alexandra distinguishes between her training as a nurse from that of a midwife, drawing comparisons between doing and not doing. Fahy (1998) argues that midwives *"doing to"* women, reflects a problem-based approach to labour, requiring protocol driven and techno-rational responses. Although reflecting the medical dominance so widespread in maternity care, this is at odds with the concept of midwives being in partnership with women (International Confederation of Midwives (ICM), 2011). The art of doing less, or seemingly nothing, may enhance the relationship between women and midwives by shifting the direction of power and trust towards the woman and her instinctive expertise in birth. However, this position would possibly be difficult to defend against the generally accepted and more reactive approach associated with modern, medicalised labour care (Fahy, 1998; Leap, 2010). Fleming (2010) cautions that although midwives may view themselves as separate from the medical paradigm, women may nonetheless view them as inseparable. The assumptions inherent in a doing less approach may also contradict women's preferences for interventions, including epidurals. In some respects then, the tensions between doing and not doing, which might represent either the active or passive position of the midwife, may be viewed in terms of what constitutes an intervention and how this is defined and understood, especially by midwives.

The following section, from midwives in one focus group, provides an example of interactive discussion on their ideas about what constituted an intervention, how this defined their views of midwifery practice and philosophy, and where they positioned SWI within these debates:

Are you hinting that it's (SWI) *an intervention? That its non midwife? [...]Is that what we are getting at? I think it's very midwife. It's as midwife as a bath because it's not a drug. It's invasive, but it's as invasive as we can get. It's immediate. It's effective.* (Alexandra, midwife eight years)

I don't feel like it's an intervention at all because it has no lasting effects on mother or baby. It's an intervention in terms of you actually breaking somebody's skin but it's an intervention in the same way that you can argue as putting someone in the bath is an intervention. [...] It's working in harmony with a woman's body and not taking away any of the other coping mechanisms. To me pethidine is an intervention although you are breaking the skin in more or less the same way, you are then taking away her natural coping mechanisms so that she can't get in the bath and suddenly she's not walking around so much, suddenly the baby is affected. An epidural clearly goes against how the body works but the sterile water is dot, dot, done and she can continue with all her previous coping mechanisms. So you've actually enabled her to use her natural coping mechanisms rather than taken them away. So to me that's not an intervention. It's an enabled woman. [...] I don't think it's about intervention as in penetrating skin, it's about intervention enabling or taking away the woman's coping mechanisms. (Sarah, midwife seven years)

Yeah, I think it's just that barrier of doing for the woman and doing something to the woman, you know, anything internal, doing VE's (vaginal examinations), *injections and of that sort of stuff. But I'm sure that there would be different schools of thought about the midwives role in administering something that involved giving an injection. But I think again you are absolutely right, if it's a drug free, effective, midwife initiated thing, and if it prevents all those other interventions and the cascade of interventions, then bring it on.* (Alexandra, midwife eight years)

Yeah, initially I was thinking that it was an intervention because we are doing something to the woman but when you consider what Sarah is saying, about its not

> *taking away, it's actually enabling her to actually do, follow her wishes, then I guess it's not. I have to rethink that,* (Karleen, midwife three years)

There is no precise definition in the midwifery/obstetric literature regarding what constitutes an intervention during labour. Initially Alexandra declares interventions to be *"non-midwife"*; that the term is synonymous with practices that are not instigated or approved of by midwives although, as previously discussed, midwifery practice encompasses a wide range of opinions on what constitutes an intervention. Sarah persuades Alexandra and Karleen towards her viewpoint by describing an intervention as an act that interferes with, reduces, or removes, a woman's coping mechanisms. This description may be drawn from a view of midwifery practice which supports birth as a normal physiological process, for which women have innate coping mechanisms, compared with obstetric views of birth as an imperfect process requiring pre-emptive support (Fahy & Parratt, 2006; Rooks, 1999). Furthermore, as the role of pregnant and labouring women has shifted from that of passive receivers of care to consumers seeking ever greater involvement in decision making, the term intervention has become associated with more technical or obstetric procedures that are generally viewed as unsupportive of normal birth (Benoit, Zadoroznyj, Hallgrimsdottir, Treloar, & Taylor, 2010). This compares with historical assumptions about birth as a process owned and managed by obstetricians, and that women should be *"unquestioningly submissive to the recommendations and demands of the orthodox obstetric profession"* (Dick-Read, 1954, p. 15).

Determining what constitutes an intervention may thus also reflect the flow of power and decision making between care providers and pregnant/labouring women. For example, some midwives may view themselves as guardians of normal birth; as gatekeepers protecting women from medical interference. Fahy & Parrat (2006, p. 47) discuss the concept of midwifery *"guardianship"* that fosters trust and mutual respect with the woman leading, as opposed to midwifery *"dominance"*, where midwives pursue their own agendas and impose them upon the women in their care. This would then suggest that the use of an intervention is not bound to specific professional groups but is more dependent on the quality of the relationship between the woman and her care providers. Therefore, an intervention may reflect something that is imposed upon the woman to achieve an outcome irrespective of any clinical indication, but rather used to pursue a particular philosophical stance held by the attending clinician.

Some midwives also discussed how using SWI affected their views of themselves and their practice:

> *I feel like after giving the injection, the women get some relief and that is something that I feel good for myself, and also the women are thankful to us and the interaction between us seems to be better. [...] Our interventions are appreciated or welcomed by the women.* (Carolyne, midwife five years)

> *And that you really are helping them. It's the same thing like when they are getting in the shower or bath and they go, 'it's so good'. That same sense of, that you are really doing something to help them.* (Kirstie, midwife five years).

Carolyn and Kristie acknowledge the positive effect of women's appreciation which is known to contribute to positive relationships (Berger, 2000) A number of qualitative studies have examined relationships between midwives and women with midwives being variously portrayed as friends (Pairman, 2010; Walsh, 1999), and as an *"anchored companion"* (Lundgren & Dahlberg, 2002, p. 155) suggesting a sense of equality and mutuality. Although there is now a considerable body of literature describing the nature of the midwife-woman relationship there is a dearth of research on the impact of these relationships on midwives views of themselves, and their sense of professional fulfilment. The role of the midwife involves observing women in pain, which may prompt feelings of distress and helplessness (Hunter, 2001), although perception of doing good through supporting women's goals and/or relieving pain may act as a buffer against work-related stress and burnout (Grant & Sonnentag, 2010). Participating in actions that are viewed by midwives as being important to their professional identity, and which contribute to building positive relationships with pregnant/labouring women, may assist in countering negative work-related effects, as well as enhancing their views of themselves as professionals.

Resistance from midwifery and other colleagues may impact upon the acceptability and uptake of new practices and procedures. A survey of SWI use amongst Australian midwives found that nearly a third who were currently using SWI reported encountering resistance from medical and midwifery colleagues (Lee, et al., 2012). Medical resistance was also reported in the USA (Martensson, et al., 2008a). During focus group discussions, midwives in this current study described difficult encounters with medical colleagues and their negative reactions to

SWI. Kirstie describes a woman's prerogative to use the analgesia of her choice and an obstetrician's views of what constitutes appropriate analgesia:

> *I remember one woman who had back pain, I consented her for the* (SWITCh) *trial,* (had) *given her the sterile water injection she said it was great. I rang the* (private practice) *obstetrician to say she'd come down from the ward* (and) *she'd had sterile water injections. 'What's that shit?' I said have you not heard about sterile water injection. […] Well I said she's got no more back pain and she's fine. I'm just calling to let you know that she's here and that she doesn't actually want anything. And they were very disgruntled with the decision that I had made. I think that's happened twice or I have discussed with the woman that she wanted the sterile water injections, rung the obstetrician and the obstetrician said, 'No just give them the epidural, don't muck around with that, just give them the epidural'.* (Kirstie, midwife five years)

In Australia, women may choose to access their maternity care through a private practice obstetrician or the public health system. Private practice obstetricians have much greater discretion in the provision of care for pregnant women as they are not bound by the same degree to the particular institutional policies and procedures. This may result in a greater variation and influence from the individual obstetrician's attitude, over the direction of care, especially in labour. Fahy and Parratt (2006) discuss the theory of birth territory and individuals discrete use of power, referred to as jurisdiction within this territory. Power may be integrative, where all persons within the birth territory share power to support the birthing woman. Conversely, power may be disintegrative, where one person exerts an ego-driven dominance over others (Fahy & Parratt, 2006). Collaboration between professionals requires mutual trust and respect for each other's skills and knowledge (Heatley & Kruske, 2011) and the use of language that conveys these sentiments (Reiger & Lane, 2009). Both of these factors appear absent in Kirstie's account of the discussion between herself and the obstetrician, who appears to exert disintegrative power, including the use of expletives, to disrupt the relationship between Kirstie and the labouring woman, and to devalue midwifery knowledge and expertise. Kirstie reflects on her experience:

> *It is frustrating because* (pause) *I think it's just such an amazing thing that we can do for women. That for someone who has never seen it* (SWI)*, who makes the decision*

> *and that biased assumption that it's stupid or not going to work.* (Kirstie, midwife five years)

Kirstie's sense of frustration may also reflect differences in approaches between obstetricians and midwives to research evidence, and their different perceptions of the legitimacy of that evidence. Reime et al (2004) have suggested that the technical nature of obstetric knowledge means that obstetricians are more likely to focus on risk-based outcomes, whereas midwives are more inclusive, using research that was socially derived, and which affords a more holistic view of women. Martensson et al. (2008a) noted that medical resistance to SWI may arise from the view that the concept is incompatible with existing ideas of effective analgesia in labour; that injecting water under the skin to produce an analgesic effect is untenable and any supporting evidence viewed as suspicious. It is interesting to note however, that most of the RCTs conducted to date that provide evidence for the use of SWI, have been conducted by obstetricians and anaesthetists and published in peer-reviewed, respected medical journals (Lee, et al., 2012). This supports the view that it is preconceived ideas and out-dated attitudes to SWI, rather than the quality of evidence, which influences resistance to use in maternity settings (Martensson, et al., 2008a).

Differences in attitudes towards SWI may leave midwives having to decide between supporting women's requests and obeying medical directives not to use the procedure. Sarah discusses her experience:

> *I have been told* (private practice obstetrician) *categorically not to give it to a woman on one occasion. She arrived from antenatal clinic, knowing about it and wanting it and we did give it to her but having been categorically told not to, it was a bit tricky.* (Sarah, midwife seven years)

Power relationships in birthing suites are known to be hierarchical, with midwives experiencing a greater sense of unease in balancing the directives of obstetricians with the requests and expectations of labouring women, and this may lead to ethical dilemmas (Blix-Lindström, Johansson, & Christensson, 2008). In the above quote, Sarah suggests that the obstetrician rejects her autonomous position and the woman's preferences, without consultation with either party, which is contrary to the basis of professional collaboration (Heatley & Kruske, 2011). To withhold pain relief, or an effective pain relieving procedure,

from a person making a direct request may also be viewed as unethical. However, organisational change is required to foster collaborative relationships and reduce conflicts that may impact on professional ethics (Heatley & Kruske, 2011; Reiger & Lane, 2009).

A few midwives reported receiving tacit support from medical colleagues for their use of SWI:

> *I've actually had some support publicly from amongst the anaesthetist saving them time. I thought they'd be very resistant but actually means they can carry on watching telly* (laughter) *while we take care of all this back pain.* (Sarah, midwife seven years)

Although presented humorously, Sarah makes the point that the provision of analgesia in labour is not the sole remit of any one profession. Indeed there are opportunities to incorporate the knowledge and skills of all practitioners involved in supporting labouring women. The recognition of the particular skills of different professional groups; however, is an essential feature of collaborative practice that is likely to result in a more positive experience for birthing women (Reiger & Lane, 2009).

5.7   Summary

This chapter presented data from interviews with women, and focus groups conducted with midwives. The data were presented thematically as five major themes, the first of which explored the causes of back pain in pregnancy, descriptions of back pain in labour from the perspectives of women and midwives and expectations about labour and birth. The second theme reported findings regarding the information on SWI provided to women, and their attitudes and motivations regarding its use. Midwives experiences of learning about, and using, SWI, often for the first time, are also discussed. The third theme explored the injection pain, information provided by midwives and how this was interpreted by women, and midwives' experiences of causing pain. Theme four discussed the analgesic effect of SWI from the perspectives of labouring women, and midwives observations of these effects. The final theme presented data on how SWI impacted on women's labours and birth experiences and the acceptability of SWI for use in their subsequent labours. It also explored the impact of SWI on midwifery practice and reactions from other midwives and medical colleagues. The following final Discussion chapter combines the key findings from both the qualitative and quantitative phases of the study

Chapter six: Discussion and conclusion

6.1   Overview

The previous chapter presented the thematic analysis of the qualitative data from women and midwives.

As the aim of a sequential explanatory mixed methods design is to integrate both the quantitative and qualitative data within the discussion, this chapter presents a synthesis of the findings from both phases of the research. Themes discussed include circumstances contributing to back pain in labour and the differences between the single and four injection techniques. The best and worst aspects of SWI are also explored including the impact on women's intentions to use SWI in future labours. The use of SWI in early labour and the influence of parity are also examined. Finally this chapter summarises the limitations of the study, presents implications for practice, and identifies areas for further research

6.2   Fetal position and lifestyle as factors associated with back pain in labour

As previously stated few studies have examined the contributing factors, underlying causes, or the characteristics of women experiencing back pain in labour. This is despite the fact that back pain occurs in about 30% of labouring women, and the association made, by clinicians, between back pain in labour and malposition of the fetus (Simkin, 2010). The results of both the quantitative and qualitative phases contribute to these areas of inquiry and support some of the conclusions of other research.

In early studies (Melzack & Schaffeberg, 1987), labouring women who experienced back pain concurrently with abdominal pain during contractions reported higher pain scores than those experiencing abdominal pain alone. By virtue of the inclusion criteria, all the women in the SWITCh trial had recorded VAS scores for their back pain of seven or greater, indicating they were experiencing severe pain; baseline data indicated that this generally occurred when the cervix was 3–5 cm dilated. This suggests a group of labouring women who are experiencing severe pain at a relatively early stage of their labour. The vivid descriptions of extreme

pressure, sensations of crushing and intense localised back pain, provided by the women who participated in the qualitative study, not only underpins this observation, but also highlights the physical symptoms observed by clinicians that could contribute to the common relationship made between back pain in labour and the fetus being in an OP position. Based on this observation, the clinical assumption is that the occiput of the fetal skull presses against the maternal spine and surrounding structures causing pressure and pain.

The presumed association between OP position and back pain featured prominently in the qualitative data, with evicence from Alexander to suggest intergenerational knowledge transfer: "*I think we were always trained that it was OP positions*". Simpkin (2010), cautions however that if clinicians automatically assume an association between back pain and OP position then they may not consider the possibility of OP position in labour in the absence of back pain, or other causes of back pain other than an OP position. This in turn may lead to assumptions about labour management that may not be appropriate.

An OP position is likely to be of particular concern to maternity care providers as it is strongly associated with obstructed labour, increased epidural use and/or caesarean section (Kjaergaard, et-al., 2008). Although epidural anaesthesia remains the most effective form of analgesia available to women in labour, there is an association between epidural use, persistent OP position and obstructed labour (Kjaergaard, et al., 2008; Lieberman, et al., 2005; Selin, et al., 2008). Obstructed labour is the most common indication for CS in labour (Gifford et al., 2000), to which epidurals, through their relationship with persistent OP position, may be a contributing factor (Lieberman, et al., 2005). In the SWITCh trial, obstructed labour was the main reason cited for CS, accounting for 61% of those performed. However the sample size in the SWITCh trial was insufficient to draw any conclusions regarding the effect of SWI on epidural and CS rates.

Midwives also considered lifestyle factors such as women's fitness levels and body weight as contributing to back pain in labour with Holly stating "*if you are not a healthy specimen, you are probably going to cop more back pain*". However in the SWITCh trial, prior to receiving the intervention, there was no difference in the VAS scores for back pain in women with a body mass index (BMI) of less or greater than 30 ($p=0.93$); the generally accepted definition of obese status (Lincare, 2007). However, the relationship between obesity and back pain has been suggested in a study conducted amongst Taiwanese women where those observed to

have a greater body weight and a history of back pain during pregnancy, were more likely to experience back pain in labour (Tzeng & Su, 2008). This is consistent with other studies reviewed by Leboeuf-Yde (2000) that examined general influences such as obesity on the occurrence of back pain in non-pregnant populations.

In summary, back pain is a significant factor in labour, affecting a substantial number of women, with possible implications for analgesic use, labour progress and management. The lack of research into possible contributing factors limits clinicians' ability to base their advice and management on evidence for the effectiveness of interventions.

6.3   Differences between the single and four injections

The results of the SWITCh trial indicate that while both techniques provided recordable reductions in back pain, the FI technique provided greater depth of analgesia at 30 minutes post-intervention than the single injection. Furthermore, within the context of the RCT design, although the SI failed the test of non-inferiority, the FI was not found to be statistically superior to SI, presenting the challenge of how best to interpret a statistically significant *and* non-significant outcome. As such, this could be understood as the SI being less effective than the FI, but by a relatively small clinical margin, which illustrates the difficulties in translating statistical outcomes, for example response to analgesia, into clinically relevant and meaningful information. Integrating the non-inferiority result with other quantitative descriptive and survey data from the study further assists with interpreting differences between the two techniques. Other outcomes, such as duration of analgesia, satisfaction, intention to use again and women's accounts of the best and worst aspects of each procedure, provide additional insights into the clinical differences between the techniques.

Deriving an average response to the analgesic effect of SWI is difficult as VAS data may be skewed towards the higher and lower ends of the scale prior to, and following, treatment. Hence, the recommendation by some authors to determine the number of participants that record at least a 50% reduction in pain as a means of presenting the data in a more clinically relevant format (Derry, et al., 2012; Moore, et al., 1997). In the SWITCh trial, the number of women reporting this level of reduction in pain was also significantly different at the 30 minute post-intervention measurement (SI n=68, 50.0% versus FI n=102, 73.3%). As with the difference between mean VAS scores, this remained statistically significant until 90 minutes

post-injection. Viewing the data from this dichotomous outcome as did, or did not, achieve an analgesic effect, demonstrates a greater clinical difference between the two techniques; again in favour of the FI. This difference was similarly reflected in the number of women who rated pain relief as the best aspect of their experience (SI n=53, 39.0% versus FI n=70, 54.3%). Similarly more women in the SI group commented on experiencing no analgesic effect than from the FI group (SI n=15, 11% versus FI n=10, 8%). The difference in analgesic failure between groups was more evident in the VAS data (<1cm change in VAS 30 minutes post injection) (SI n=27, 19.9% versus FI n=6, 4.3%). Once again a clearer clinical difference is evident in favour of the FI technique.

Further, using the results of the SWITCh trial to explore differences between the two techniques and the insights into SWI use provided by the qualitative data, enables the particular clinical applications of both techniques to be considered. As previously noted, SWI is generally offered only when back pain is rated on a VAS score as equal to, or greater than six; below this score the pain of the injections may overwhelm any benefit. However, as the injection pain of the SI was rated by women participating in the SWITCh trial as significantly less than those receiving the FI, this may indicate that the single injection would be suitable in situations where back pain was rated lower than a VAS of six. Also, the reduced level of effect and duration of the SI would be less noticeable in milder back pain. Similarly, if women wish to avoid the increased discomfort associated with four injections, and are aware that the quality and duration of the analgesia may be less, then the SI technique may be recommended. As the results of the SWITCh trial suggest that repeat injections were effective in re-establishing the analgesic effect, and there are no known side effects to repeated use, women may make multiple requests for repeat injections of SWI.

Maternity care is provided in a variety of settings within Australia and a cross-sectional study of SWI use amongst Australian midwives indicated that staffing levels were a possible issue limiting the use of SWI (Lee, et al., 2012). In some practice areas, particularly where only one care provider is available, the SI technique would be a suitable alternative to FI, making the procedure accessible to more women.

6.4   The best aspects of sterile water injections

The reduction in pain following either the FI or SI procedure was a major theme identified in the analysis of the qualitative data and dominated responses to the question regarding the best aspect of SWI in the postnatal questionnaire. This was also reflected in the quantitative data where there was a statistically significant difference between pre-injection and 30 minute post-injection VAS scores for both techniques. The synthesis of these data strongly supports the conclusion of the systematic reviews that SWI is effective in providing analgesia for back pain in labour (Fogarty, 2008; Hutton, 2009; Martensson & Wallin, 2008).

Women also commented on the speed with which analgesic benefit commenced following the SWI procedure, with the majority indicating relief was almost immediate or as Luci stated: *"pretty much instantaneous"*; a small number of women indicated relief occurred within 10 minutes. The difference in pre and post-injection VAS scores was also clinically significant at 10 minutes, while the analgesic effect of both techniques peaked at 30 minutes post-injection. The rapid onset of analgesia following SWI was listed as the "best aspect" of the experience almost equally by women in either the SI (n=36, 23.3%) or the FI (n=30, 26.5%) groups. Women who participated in a cohort study on SWI, and who responded to a follow-up survey (Peart, 2008), also made positive comments about the speed with which the analgesic effect was experienced. Moore (2009) notes that speed in the onset of pain relief is an important measure of the quality of an analgesic. Rapid onset was also observed by the participating midwives, one of whom (Alexandra) commented on the *"amazing quick effect"*, which may have encouraged them to suggest the procedure over other more traditional approaches to pain relief such as massage and water immersion. Indeed, there is some evidence to suggest that midwives experienced in using SWI, and who are knowledgeable about the benefits, are more likely to offer it prior to suggesting massage or water immersion (Lee, et al., 2012).

Moore (2009) defines an effective analgesic as one that combines efficacy with safety; therefore, an intervention must have few side effects and minimal interruption to normal activity. The lack of side effects for both mother and baby, were cited as the best aspect by only 10% of participants. Although this current study, and that by Peart et al. (2006), used similar questionnaires, there were marked differences in the numbers of women who commented on the non-pharmacological aspects of SWI. All participants (n=52) in the study by Peart et al responded that the lack of side effects was a significant consideration in their

choosing SWI. The disparity in responses between the two studies may be accounted for by differences in pregnancy gestation when information was provided to women. In the study by Peart et al. (2006) recruitment and consent was conducted in the antenatal period which may have provided greater opportunity for midwives and women to discuss and explore SWI and compare it with pharmacological analgesia. In the SWITCh trial, although written material was provided in the antenatal period, discussion regarding SWI generally occurred only when women requested analgesia for back pain in labour. Therefore, for women who participated in the SWITCh trial, the focus of the initial information and discussion may have centred on the analgesic benefits of SWI, rather than the absence of side effects, as this coincided with their requests for pain relief. Within the qualitative data, midwives accounts also focussed predominantly on the benefits of SWI in terms of pain relief and the lack of restriction on women's mobility, and this may reflect the focus of their discussions with women regarding SWI in labour.

The location (antenatal clinic versus birth suite) and timing of information provision, and the influence on women's perception of SWI, is further illustrated in the case study by Martensson (2010) which reported on the experience of a woman participating in an RCT comparing SWI to acupuncture (Martensson, et al., 2008b). The woman concerned had been provided with information and positive reinforcement, from her midwife, regarding acupuncture during the antenatal period, and had planned to use this method for analgesia during her labour. She had not received information on SWI; however, she had read about it on the Internet, was concerned about the frequent comments on the injection pain and decided against SWI as an option. While in labour the woman received information on both options and upon consenting to participate in the trial, was randomised to the SWI arm of the study. The woman received a number of repeat treatments (a total of 30 injections) with SWI during her labour and commented on her experience in highly positive terms. This illustrates how the information provided to women during their pregnancy, and the influence of the opinion of the care provider, may impact upon choice of analgesia.

In the SWITCh trial the quality of analgesia, speed of onset and the absence of side effects were all rated as the *"best aspects"* of both the SI and FI techniques. These findings are underpinned by the analgesic experience of women using SWI and the view of water as being a natural ingrediant; both reported as major themes within the qualitative data.

6.5   The worst aspects of sterile water injections

Responses to the postnatal questionnaire regarding the worst aspect of SWI were dominated by remarks about the pain associated with the injections. However, there was no difference in VAS scores of injection pain between women who were *"very satisfied"* or *"satisfied"* and those who were *"very dissatisfied"* or *"dissatisfied"*; and between women who would or would not use SWI, again or recommend to other women. The perceived effectiveness of SWI, from both the SI and FI groups, was significantly different in these groups. Women with greater differences in pre and post-injections scores were more likely to rate the experience of SWI positively and this is supported by the qualitative data. Women appeared to place the experience of the injection pain within the context of the overall pain relief they gained following the procedure. The theme of "*no pain, no gain*" was cited by a number of women, including Luci who commented on "*short term pain for a longer term relief"*. This suggests that women may accept pain from the injections providing there is an appreciable analgesic benefit. However, women are likely to feel dissatisfied when the procedure is perceived as ineffective at relieving their back pain.

For midwives, inflicting pain through administering the injections required them to consider the likely analgesic benefit. For example, Arianne noted that "*the benefits outweigh the little intense pain"* when she reflected on the prospect of causing labouring women further pain and others cited the notion of *"tough love"* to convey their thoughts about causing additional pain to women.

Reducing the pain associated with the injections may increase women's overall sense of satisfaction with SWI. As previously discussed, it had been theorised that subcutaneous injections would result in less injection pain than intradermal, however the two studies that compared intradermal with subcutaneous injections, produced conflicting results (Martensson, et al., 2000; Martensson & Wallin, 1999). Bahasadri et al (2006) discussed the issue of the injection pain and cited the trial by Martensson et al. (2000) as the basis for trialling a single injection technique. However, the study by Bahasadri (2006) did not include any data on women's perceptions of injection pain. The comparison of intradermal and subcutaneous techniques remains an area requiring further research to determine if altering tissue depth will reduce the injection pain.

Other methods such as combining SWI with local anaesthetic or the use of topical local anaesthetics in advance of SWI may prove useful in reducing the injection pain. One study (Gao, 2008) compared SWI to a similar volume of one per cent lidocaine for back pain in labour and reported no difference in post-injection pain scores between the two treatments. However, injections of lidocaine are also known to be painful and as no comparison of injection pain was reported conclusions cannot be confidently drawn from the study results. Another study diluted lignocaine with sterile water and found reduced levels of injection pain compared to undiluted lignocaine (Iwama, Ohmori, Kaneko, & Watanabe, 2001). Nevertheless, the combination of sterile water with pharmacological agents would also impact upon the non-pharmacological nature of SWI and may impose restrictions on use because of the need to involve doctors in prescribing the additional drugs such as local anaesthetic.

6.6   The timing of data collection and the impact on memories of pain

The data reported from the two research phases were gathered at three different time points using different methods of collection. The VAS scores were collected at the time that analgesia was requested for back pain and again following the SWI intervention; the postnatal survey was generally presented to women between one and seven days following birth, while the qualitative interviews, with women, were conducted up to three months following birth. Recall and interpretations of pain and pain relief may be different at each time point, which may be reflected in the data.

For example, memories of labour pain 48 hours following birth may not correlate with levels reported during labour. Although the pain of early labour may, at the time, be considered severe, in retrospect it may be rated lower when compared with the pain experienced later in labour. Hence, women may re-evaluate their perceptions of pain as the differing characteristics and intensity experienced in each phase of labour (early, transition and second stage) impacts on their memories (Lowe & Roberts, 1988).

The memory of acute pain may be related to the initial intensity of the pain being sufficiently severe to seek analgesia and then moderated by the effect of the analgesia provided (Waldenström & Schytt, 2009). Recall and interpretation of pain may also be affected by the process through which memories are recorded with some theoreticians describing a three stage process of encoding, storage and retrieval (Erskine, Morley, & Pearce, 1990). Clinical

procedures and other distractions, that are common during labour, can affect the storage and eventual retrieval of memories which could be repressed or present as vivid recollections (Hamann, 2009). Feelings and emotions associated with the personal experience of labour and birth may combine with pain recollections to construct memories of pain and painful events (Niven & Murphy-Black, 2000; Waldenström & Schytt, 2009). This process is evident in the qualitative data from this study where some participants, who did not report any analgesic effect, would still consider using SWI in a subsequent labour. This activity of memory recall could include a consideration of SWI as part of a collection of strategies that women would use to support their preference for avoiding more commonly used pharmacological analgesics; as Margarite stated: "*Especially for people who don't want more traditional drugs which is the category that I fall into*".

6.7 Use of sterile water injections in the latent phase of labour

The results of this study confirm that back pain is predominantly a feature of the transition from the latent to active phase of labour (median cervical dilatation 4 cm [IQR 3.0 / 5.0]) which is consistent with the results of other SWI studies (Ader, et al., 1990; Kushtagi & Bhanu, 2009; Labrecque, et al., 1999; Martensson & Wallin, 1999; Wiruchpongsanon, 2006). The latent stage of labour is not well defined in terms of a discrete beginning and end; there is often no distinct start to labour while the latent phase may last as long as 20 hours and still be considered within normal limits (Greulich & Tarrant, 2007). The transition from latent to active phase is determined by cervical dilatation (3-5 cm) and effacement (thinning) rather than by measures of chronological time (Zhang, Troendle, & Yancey, 2002). During the latent stage, softening and effacement (thinning) of the cervix occurs and the fetal head may flex, rotate and become further engaged in the maternal pelvis (Greulich & Tarrant, 2007). The resulting distension of the cervical, uterine and surrounding tissues can contribute to referred back pain (Bonica, 1979). The varied nature of the latent stage presents challenges to clinicians and women in terms of determining when labour has commenced and defining normal labour progress and/or the need for analgesic support. Difficulty in this area may prompt early and possibly inappropriate (i.e. prior to the commencement of active labour) admission to the birth suite (Greulich & Tarrant, 2007). Early admission to birth suite has been associated with increased intervention rates (Bailit, Dierker, Blanchard, & Mercer, 2005; Holmes, Oppenheimer, & Wen, 2001; McDermott, 2010).

Although back pain appears to be a common feature of early labour, only nine women (2.9%) recruited to the SWITCh trial were reported as having been either discharged home or to the antenatal ward following treatment with SWI. However, recruitment may have occurred more often in women who were already admitted to the birth suite in labour with severe back pain due to the requirement for women to be present for the two hour data collection period. Therefore, it is likely that women who were considered suitable for early discharge were not offered participation in the trial. The SWITCh trial was not designed to investigate the impact of SWI on rates and timing of birth suite admissions; however, the qualitative data from midwives and women provides insights into the benefits of SWI in latent labour management. The accounts provided by the midwives supports the view of Cheyne et al. (2006) that midwives take into account women's cues regarding pain and coping strategies when advising on early labour management. Providing effective analgesia for back pain in early labour may support women to return home to be supported by their families, as Luci indicated: *The difference it made in terms of how I felt, how I felt before I got to the assessment unit and then after the* (SWI) *needle, being able to come home, being able to relax. […] I would have gone into labour a lot more stressed and a lot more anxious.*

However, qualitative research examining women's and midwives' views of early birth suite admission versus home management presents some conflicting perspectives. For some women experiencing labour pain, the difference between the latent and active phases of labour may be indistinct and the recommendation to return home may be confusing and initiate feelings of uncertainty. Conversely, when responding to a request for analgesia involving options that would require admission, midwives may have difficulties in deciding on the best form of management that balances the needs of the individual woman against the evidence and clinical guidelines that support delaying admission birth suite (Cheyne, et al., 2006). Hence, clinicians may be perceived as emphasising the possible clinical benefit of delayed admission over the immediate needs of the individual woman (Cheyne et al., 2007; Nolan & Smith, 2010). The use of SWI in these instances assists in meeting midwives preferences for delayed admission and women's expectations of relief from pain, as unlike other forms of pharmacological analgesia, such as narcotics, SWI does not require admission to hospital following administration.

6.8 Using sterile water injections in subsequent labours

Women commented on their intention to use SWI in a subsequent labour, with Luci declaring that "*I would do it again in a heartbeat*". In this study, similar numbers of women from each group indicated they would use SWI again (SI n=91, 67.4%; FI n=89, 69.3%). These results are similar to those reported by Trolle et al. (1991) (69%), although less favourable than those reported by Lytzen et al. (1989) (80%) and Martensson and Wallin (1999) (79%). This difference may be influenced by the availability and use of other analgesics against which women may have made comparisons. For example, in Sweden in the 1980s approximately 16% of women in labour used epidurals (Gerdin & Cnattingius, 1990), while in the study by Lytzen et al (1989) , also conducted in Sweden, epidurals were used by only four % of participants. However, epidural use, during labour, in Queensland, in 2009, was 30% (Li, et al., 2011) and 44% for participants in the SWITCh trial. Hence, the greater use of analgesics such as epidurals by participants in the SWITCh trial may reflect an increased expectation for the desired effect of analgesics generally occurring now compared to the 1980s. Cultural differences in attitudes to pain relief in labour may also be a factor.

The results regarding intention to use SWI in a subsequent labour from this current and previously mentioned trials, compare favourably with results for the planned subsequent use of epidurals reported in another study (76%) and more favourably for planned subsequent use of pethidine (49%) (Henry & Nand, 2004). This indicates that, in terms of satisfaction with pain relief, if the injection pain itself was a significant deterrent to women despite a beneficial analgesic effect, it is likely that there would be greater disparity between the numbers of women rating the effect of SWI as effective, and those likely to use again.

Interestingly, the number of women who would recommend SWI to others (SI n=105, 77.8%; FI n=101, 79.5%) was greater than the number who responded they would use SWI again themselves (SI n=91, 67.4%; FI n=89, 69.3%). This suggests that for some women, even though they personally did not find the procedure acceptable, they perceived it suitable for other women.

6.9 Differences in parity

Nulliparous women were over-represented in the study sample (n=224, 73%) compared to multiparous women (n=81, 27%), and were more likely to use epidural analgesia (n=114,

51.0% versus n=11, 13.5%). More than twice as many multiparous women did not use any pharmacological analgesia (33%) compared to nulliparous women (13%). A number of studies have suggested that there is little clinical difference in the labour pain experienced by nulliparous and multiparous women; however, perceptions and previous experiences of pain may differ and affect analgesic use (Capogna, et al., 2010; Lowe, 1987). For example, epidural use is strongly associated with nulliparity (Le Ray, et al., 2008); fear of childbirth and a tendency towards greater compliance with, and dependency on, authoritative persons, including maternity care providers, is also associated with increased epidural use (Heinze & Sleigh, 2003). These factors are likely to be more common in primiparous women who may approach labour with higher degrees of apprehension. By contrast, women who express less fear of labour, display a higher degree of personal control and a desire for active participation in labour have lower rates of epidural use (Heinze & Sleigh, 2003). The analysis of data from the qualitative phase of this study suggests that multiparous women, with previous experiences of labour pain and pain relief, are more likely to have the sense of aforementioned control and; therefore, the confidence to undergo labour with recourse to less, or no, analgesia. Odette (third baby) comments: *Not having the epidural I felt more in control, so this is my control side coming out, more in control, more aware of what was going on, more a part of it.*

Multiparous women may also have sought a different labour experience through new forms of analgesia with fewer cognitive side effects that can detract from the birth experience, as Siobhan (third baby) stated: "*I wanted to be really clear you know and go through it and all that kind of thing*". In the SWITCh trial, there was no difference in parity with regard to the stage of labour at which back pain occurred with sufficient severity to require analgesia. However the qualitative data suggested that while nulliparous women in early labour may use analgesia such as SWI early, as they have no experience about how they will tolerate and react to the increasing intensity of labour, multiparous women may use SWI to relieve back pain and then utilise their experience of labour to cope with other labour pain. As Siobhan (third baby) commented: "*just eliminating that* (back) *pain it made it a heck of a lot easier to deal with the other pains that were going on*".

As expected, the quantitative data indicated that the labours of nulliparous women were lengthier than those of multiparous women. The unknown duration of labour for nulliparous

women may influence them to take a longer view of their analgesic needs and use analgesia such as SWI to provide them with period of respite to regain strength, as Kerry noted: "*it gave me that 45 minutes to regain some energy, because I was that exhausted*".

The combination of the quantitative and qualitative data supports the view that the experience of labour pain, including back pain, may be similar between nulliparous and multiparous women. However, the data also suggests that SWI use may support differing objectives depending on parity, such as a respite from pain for nulliparous women, or for multiparous women, providing a balance between using pain relief and the desire for greater control and participation in the experience of birth.

6.10   Limitations of the study

This research project has a number of limitations resulting from controllable and uncontrollable factors occurring over the course of the project. This section describes these limitations, the possible impact on the results and, where possible, strategies that were used to reduce the effect on the research.

The non-inferiority design of the study is not commonly used in clinical trials outside of pharmacology, and although appropriate for the purpose of this study, unfamiliarity with the approach may make the interpretation of the results difficult and limit the generality. Also, the design did not include a placebo component as both techniques had previously been demonstrated as superior to placebo controls (Wang, et al., 2006). There is considerable discussion in the literature regarding a no-placebo approach; however, it requires that two assumptions be made; firstly that the efficacy of both treatments is based on historical data not derived from the study population (Hung, 2003, 2007) and secondly, that the inferiority margin is clinically and statistically sound (Hou, 2009; Scott, 2009). Both the reliance on historical data to establish efficacy and the use of a fixed non-inferiority margin may increase the likelihood of a type one statistical error (Hung, 2003, 2007), where the hypothesis is erroneously rejected. The inclusion of a placebo may have strengthened the results of the SWITCh trial; however, the budget, sample size and timeline required for a three arm trial ruled out this option. As the test for superiority in this trial was found to be inconclusive the inclusion of a placebo group and/or a larger sample size may have provided a more conclusive outcome.

This study was conducted at two sites with staff who had different experiences of using SWI. At Site One, the four injection technique had been used by midwives for approximately 12 months prior to the commencement of the trial; therefore, many of the midwives administering the injections were experienced in using it. At Site Two, both a four and single injection technique were introduced, in conjunction with the trial, preceded by a comprehensive education program for midwives which explained the theoretical and practical aspects of the procedure. Although the procedure of SWI is relatively simple to perform, variations in technique that may impact on the effectiveness of the intervention, such as the tissue depth of the injection may be less evident in the four than the single injection technique. Therefore, day to day variations in technique that may have occurred with greater frequency at Site Two, due to the midwives inexperience with SWI, could also have contributed to the results in terms of overall reliability of each approach.

The midwives experienced with the four injection technique at Site One may have suggested a preference for that option when discussing SWI with labouring women, who then considered the single injection experimental and possibly less effective. However, at Site Two, where the two techniques were introduced simultaneously, midwives preferences for either technique were likely to be less apparent.

This research was conducted in two tertiary referral hospitals one of which included a birth centre. Although this scope of maternity service provision represents a number of medical and midwifery led models of care, in terms of generality, it is unknown if the same findings would have resulted if the studies had been conducted in other maternity care settings such as regional units or home birth situations.

A further limitation for this study is the sensitivity and design of the VAS, particularly when measuring differences between different types of pain that may occur concurrently, such as abdominal and back pain, and the SWI injection pain, as detailed in the Methods chapter. There may also be limitations in reducing a complex phenomenon such as pain, with physical, emotional and cultural aspects, to a single quantitative measurement (Wei, et al., 2010). The ceiling effect, where a woman may report pain at the high end of the scale, and then later report a significant increase in pain (Phumdoung, 2010) may also have impacted on both the VAS scores for back pain and those for the injection pain when one exceeded the other to a significant degree.

The aim of the qualitative phase was to gain a greater understanding of the use of SWI by women and midwives, and although a qualitative research design typically involves small cohorts, theoretically, the results of the qualitative phase may not apply generally to wider populations due to the smaller sample size. The number of women interviewed for the qualitative study was slightly fewer than anticipated due to extensive flooding of Brisbane and surrounding areas in January 2011, with the impact felt by the researcher and potential participants alike. Nonetheless, despite the smaller sample, data saturation was achieved in the themes identified as relevant to the research question.

Although these limitations may impact upon the degree to which the findings are generalisable they do not detract from the value and significance of the contribution of the research to the body of knowledge underpinning the use of SWI in labour.

6.11   Conclusions

This thesis has examined two related research questions:

i)   For women in labour with back pain, does a single, compared to four, sterile water injections result in clinically similar levels of pain relief?

ii) What are the experiences of women and midwives using sterile water injections to relieve back pain in labour?

The use of both a quantitative and qualitative phase within the sequential exploratory mixed methods design provides findings for both research questions from which a number of conclusions can be drawn.

The findings of the quantitative phase support the null hypothesis that there was a difference in the analgesic effect produced by the single injection compared to the four injection technique in favour of the four injection technique. The injection pain associated with the four injection technique was shown to be greater than that accompanying the single injection technique. The study also demonstrated that both techniques provided a recordable reduction in back pain and suggested that repeat injections were able to re-establish the analgesic effect. The findings of the qualitative phase provided insights into the experience of using SWI from the perspectives of women and midwives that support these quantitative outcomes.

One of the most significant findings of the qualitative phase concerned the impact of the injection pain on acceptability of SWI. In this study, women appeared to adopt a *"no pain no gain"* approach to the relationship between the injection pain and the analgesic effect experienced and that the procedure was considered sufficiently efficacious to be readily considered for use in subsequent labours. This suggests that the injection pain is not a significant factor in the acceptance of SWI, a conclusion which is supported by the findings related to satisfaction, intention to re-use and recommend to others, derived from the quantitative phase.

The findings of the qualitative phase also highlighted that the relationship between the fetal OP position and back pain was a dominant factor in the information provided by midwives to women as a possible cause of back pain in labour despite the lack of empirical evidence for this association.

6.12   Implications for clinical practice

As both techniques provided effective analgesia, each may be suitable in specific clinical situations. In scenarios where back pain is severe (VAS score greater than six) the four injection technique is likely provide more effective pain relief; whereas, the single injection, with a lower level of injection pain, may be more suitable for women with less severe back pain (VAS score less than six). However this theory is yet to be tested. Similarly, if women wish to avoid the increased discomfort associated with four injections, and are aware that the quality and duration of the analgesia may be less, then the single injection technique may be recommended with repeat injections re-establishing the analgesic effect. In some clinical locations such as regional units or homebirths, where only one care provider may be available, the single injection technique may be a suitable alternative to four injections which generally require two practitioners.

6.13   Implications for access to sterile water injections

The use of SWI in Australia may be restricted by a number of factors, including limited access to information about SWI for midwives and women, and some resistance to the use of SWI by both medical and midwifery care providers which impacted on availability and acceptance. Information about SWI as an effective non-pharmacological analgesic alternative for back pain in labour should be readily available to women and care providers. As access to

information on labour and birth is no longer restricted to print media, this information should be provided across the full information spectrum, including print and Internet/social media, to enable access by women and clinicians. Information on SWI should be included in education and training of all practitioners involved in maternity care to enable greater access for women to the procedure and consistent provision of information.

Finally, this research has indicated that much of the information and the explanations provided to women regarding back pain in labour is focused on assumptions about an OP fetal position, although other factors such as referred uterine pain and/or supine position in labour may be contributory. Information on back pain in labour should include other possible causative factors.

6.14 Significance

This thesis extends the small, but growing, body of evidence exploring the best techique for delivering SWI to women in labour with back pain. The research has the potential to make a significant contribution to maternity care in Australia and internationally. Maternity care is offered in a diverse range of settings with midwives working in models of care offering different services and options in terms of pain management. For many women options such as narcotics and epidurals may not be acceptable due to personal preference and/or experience, perceived side effects and/or cultural considerations, or indeed they may be unavailable. Making SWI available with a best practice framework and offering an evidenced-based technique that provides an effective alternative to the relief of back pain in labour, which is free of side effects, will assist in addressing consumer demand for low intervention analgesia strategies. The procedure is relatively simple and not technology dependent; therefore, it is ideal as an analgesic strategy for any maternity care setting or model of care.

This mixed methods research presents findings from the first qualitative study into the use of SWI by women and midwives and provides further insights into the expereince of back pain in labour, the analgesia provided by SWI and the complex relationship between the injection pain and the acceptability of the procedure. The findings from the qualitative data have implications for how and when information should be presented to women regarding back pain in labour, the administration of SWI and the associated injection pain. Improving

knowledge about SWI amongst women, and promoting informed decision making, could advance the use of SWI as a legitimate and effective analgesic strategy.

6.15   Areas for further research

6.15.1 Further questions about sterile water injection techniques

In some respects, this research poses as many questions as it set out to answer. For example, it is not known if the use of two injections will result in a degree of analgesia that is similar to either the four or single injection approach tested here. Furthermore, research into variations of SWI techniques are needed with regard to the optimal tissue depth and volume of injected sterile water required to obtain the greatest analgesia with the least discomfort. Strategies for reducing the degree of injection pain such as the addition, or topical use, of local anaesthetic, and the use of other water-based solutions, such as dextrose, are also areas for investigation. Such research should be designed and report findings using the criteria outlined by the Cochrane Review into SWI (Derry, et al., 2012).

6.15.2 The occurrence and impact of back pain in labour

Larger cohort studies are required to determine the actual incidence of back pain in labour and to ascertain if women who experience back pain in labour use more analgesia, particularly epidurals, and have higher rates of CS than women who do not have back pain. Studies are also needed to identify possible causes and factors that contribute to back pain in labour, and whether there is an association between fetal position and back pain. The possible contribution of lifestyle factors and obesity to back pain in labour also requires further investigation from both a quantitative and qualitative perspective. Such research would assist in determining whether back pain in labour was a normal occurrence or indicative of abnormalities.

6.15.3 The impact of sterile water injections on maternity care provision and birth outcomes

Future research into SWI should be undertaken to examine the use of SWI in maternity care settings other than metropolitan hospital based services, including regional centres and domestic environments.

Further qualitative studies of women in labour with back pain would also afford very useful insights into the experience and provide a greater depth of understanding of this phenomenon.

This research touched on aspects such as the effect of SWI on birth outcomes. The impact of SWI on birth outcomes such as CS has been suggested in the work of Hutton et al. (2009) and this may represent an important feature of SWI use in labour. Therefore future trials should be powered to include caesarean section as a clinically important primary end point.

6.16 Summary

This chapter has discussed the overall synthesis of the quantitative and qualitative phases of this mixed methods research. The limitations of the research have been discussed in relation to the research design and generalisation of the findings. The conclusions of the research have been presented along with recommendations for clinical practice, information provision, education and future research.

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Appendix 1: Summary of studies of SWI

Author, year, title, country	Study design and sample	Level of evidence	Results: Intervention group(s)	Results: Control group (or other intervention)	Outcome
FOUR INJECTION TECHNIQUE					
Bengtsson et al. 1981 Pain due to urolithiasis treated by intracutaneous injection of sterile water. A clinically controlled double-blind investigation Denmark	Randomised controlled trial Participants (male and female) with radiological confirmation of urolithiasis and associated pain *Intervention:* Four injections of 0.1 ml sterile water (n=18) *Control:* Four injections of 0.1 ml normal saline (n=14).	II	88% (n=16) reported a positive analgesic effect	36% (n=5) reported a positive analgesic effect	Median duration of analgesia was significantly longer (97 mins.) in the intervention group compared with control (25 mins.) (p<0.05)
Lytzen et al. 1989 Relief of low back pain in labour by using intracutaneous nerve stimulation (INS) with sterile water papules. Sweden	Prospective cohort study No control group Women in first stage labour with back pain (n=83) *Intervention:* Four intradermal injections of 0.1ml sterile water	IV	Mean pre-intervention VAS score: 6.05 cm Mean VAS at one hour post intervention 2.92 cm	NR	Significant reduction in VAS score for back pain following intervention (p<0.001).

Appendix 1: Summary of studies of SWI continued

Ader et al. 1990 Parturition pain treated by intracutaneous injections of sterile water Sweden	Randomised controlled trial Women in first stage labour with back pain. *Intervention:* Four intradermal injections of 0.1 ml sterile water. (n=24) *Placebo:* Four injections intradermal of 0.1 ml normal saline. (n=21)	II	Mean reduction from baseline VAS (mm): 10 mins 4.2 45 mins 3.5 90 mins 2.9	Mean reduction from baseline VAS: 10 mins 1.9 45 mins 1.7 90 mins 0.8	Mean reduction from baseline VAS was significantly greater in the intervention group compared to control at 10, 60 and 90 minutes (p=<0.5)
Trolle et al. 1991 The effect of sterile water blocks on low back labour pain Denmark	Randomised controlled trial Women in labour with severe back pain. *Intervention:* Four intradermal injections of 0.1 ml sterile water. (n=141) Placebo: Four injections intradermal of 0.1 ml normal saline. (n=131)	II	89.4% (n=126) reported a positive analgesic effect	45% (n=59) reported a positive analgesic effect	Mean reduction from baseline VAS was significantly greater in the intervention group compared to control at 60 minutes (p=<0.001)

Appendix 1: Summary of studies of SWI continued

Dahl and Aarnes 1991 Sterile water papulae for analgesia during labor Norway	Non-randomised controlled trial Women in labour at term with back or suprapubic pain *Intervention:* 2 or 4 injections of "small" amounts of sterile water surrounding the area (lumbar and/or suprapubic) indicated as painful by the participant (n=101) *Control:* "Dry needling" (insertion of needle without injection) with 2 or 4 needles into the area (lumbar and/or suprapubic) indicated as painful by the participant (n=50)	III-2	57.6% (n=58) reported great than 50% reduction in pain. Mean duration of analgesia was 79 min (±15)	18% (n=9) reported great than 50% reduction in pain. Mean duration of analgesia was 19 min (±15)	More women in the intervention group compared to control, reported an at least 50% reduction in pain following the intervention (p<0.001)
Peart et al. 2006 Use of sterile water injections to relieve back pain in labour Australia	Prospective cohort. Women in labour at term with VAS for back pain ≥ 7 *Intervention:* Four intradermal injections of 0.1 - 0.5ml sterile water. (n=32)	IV	Mean difference between pre and post injection VAS (cm) 5 min 6.13 30 min 5.66 60 min 4.76 90 min 4.51	NR	Mean reduction from baseline VAS was significant at all time intervals measured (p<0.001)

Appendix 1: Summary of studies of SWI continued					
Wiruchpongsanon 2006 Relief of low back labor pain by using intracutaneous injections of sterile water: a randomized clinical trial Thailand	Randomised controlled trial Women in labour at term with severe back pain. Intervention: Four intradermal injections of 0.1 ml sterile water. (n=25) Placebo: Four injections intradermal of 0.1 ml normal saline. (n=25)	II	Mean difference between pre and post injection VAS (mm) 30 min 55.1 60 min 69.2 120 min 65.2	Mean difference between pre and post injection VAS (mm) 30 min 18.6 60 min 16.1 120 min 16.8	Mean reduction from baseline VAS was significant at all time intervals measured (p<0.001)
Martinez Galiano 2009 Analgesic effectiveness of intradermal injections of sterile water into Michaelis' rhomboid during the first stages of labour Spain	Non-randomised interventional. Women in labour at term with back pain. *Intervetion:* Four intradermal injections of 0.05 - 0.1ml sterile water. (n=32)	IV	Mean VAS pre intervention: 8.48 cm. Mean VAS 10 minutes post intervention: 2.48 cm	NR	SWI was perceived as highly effective in relieving back pain in labour

Appendix 1: Summary of studies of SWI continued

| Saxena et al.

2009

Intracutaneous Injections of Sterile Water over the Sacrum for Labour Analgesia

India | Randomised controlled trial

Women in labour at term with severe back pain.

Intervention:
Four intradermal injections of 0.5 ml sterile water.
(n=50)

Placebo:
Four injections intradermal of 0.5 ml normal saline. (n=50) | II | Mean VAS scores (mm)
0 min   75.3
10 min   34.2
45 min   33.2
90 min   49.3 | Mean VAS scores (mm)
0 min   74.7
10 min   73.4
45 min   77.4
90 min   83.7 | Mean reduction from baseline VAS was significant at all time intervals measured ($p<0.001$) |

SINGLE INJECTION TECHNIQUE

| Ahmadnia & Younesi

2004

Treatment of renal colic using intracutaneous injection of sterile water

Iran | Randomised controlled trial

Participants with radiological and/or clinical confirmation of renal colic and associated pain.

Intervention:
Single intradermal injection of 0.5 ml sterile water given at the most painful point indicated by the participant (n=50). | II | Mean VAS pre intervention (cm): 9.86

Mean VAS post intervention (cm)
30 min   0.76
90 min   1.02 | Mean VAS pre intervention (cm): 9.96

Mean VAS post intervention (cm)
30 min   5.94
90 min   6.70 | Mean VAS was significantly different between groups in favour of SWI ($p=<0.001$) |

	Control: Single intradernal injection of 0.5 ml normal saline given at the most painful point indicated by the participant (n=50)				

Appendix 1: Summary of studies of SWI continued

| Bahasadri et al.

2006

Subcutaneous sterile water injection for labour pain: a randomised controlled trial

Iran | Randomised controlled trial

Women in first stage labour at term with back pain.

Intervention:
Single subcutaneous injection of 0.5 ml sterile water given at the most painful point indicated by the participant (n=50).

Control:
Single subcutaneous injection of 0.5 ml normal saline given at the most painful point indicated by the participant (n=50) | II | Median pain score (faces rating scale 0-5)
Pre intervention: 4
Post intervention:
10 min   2
45 min   2 | Median pain score (faces rating scale)
Pre intervention: 4
Post intervention:
10 min   4
45 min   4 | Median pain score was significantly lower in the intervention group compared with control (p<0.01) |
| Kushtagi & Bhanu

2009

Effectiveness of subcutaneous injection of sterile water to the lower back for pain relief in labour | Randomised controlled trial

Women in active labour at term with back pain.

Intervention:
Single subcutaneous injection of 0.5 ml sterile water given at the centre of Michaelis' rhomboid (n=50). | II | Median VAS scores (cm)
Pre intervention: 8
Post intervention:
10 min   5
45 min   4 | Median VAS scores (cm)
Pre intervention: 8
Post intervention:
10 min   7
45 min   7 | Pain relief was significantly greater in the intervention group compared with control. (p value not provided) |

India

Control:
Single subcutaneous injection of 0.5 ml normal saline given at the centre of Michaelis' rhomboid (n=50).

Appendix 1: Summary of studies of SWI continued

SUBUTANEOUS VS INTRADERMAL TECHNIQUE

| Martensson & Wallin

1999

Labour pain treated with cutaneous injections of sterile water: a randomised controlled trial

Sweden | Randomised controlled trial

Women in labour at term with severe back pain.

Intervention:

Four intradermal injections of 0.1 ml sterile water (group 1) (n=33).

Four subcutaneous injections of 0.5 ml sterile water (group 2) (n=33).

Control:
Four subcutaneous injections of 0.1 ml normal saline (group 3) (n=33). | II | Median difference in pre and post intervention VAS (cm)

Group 1
10 min   5.0
45 min   4.9
90 min   1.0

Group 2
10 min   4.5
45 min   4.0
90 min   2.1 | Median difference in pre and post intervention VAS (cm)

Group 3
10 min   1.7
45 min   1.0
90 min   0.0 | Difference in VAS post intervention was not significant for the 2 treatment groups [OR (95% CI) 0.756 (0.268, 2.137]

Difference in VAS post intervention was significant between treatment and placebo groups [OR (95% CI) 4.250 (1.372, 13.162)] |
| Martensson et al.

2000

Subcutaneous versus intracutaneous injections of | Randomised controlled trial with crossover design

Healthy female non-pregnant volunteers aged 18 - 45 | II | VAS of injection pain (mm): 41.3 | VAS of injection pain (mm): 60.8 | Subcutaneous injections were significantly less painful than intracutaneous (intradermal) (p<0.001) |

| sterile water for labour analgesia: a comparison of perceived pain during administration

Sweden | *Intervention:*
Four subcutaneous injections of 0.5 ml sterile water (n=50).

Control:
Four intradermal injections of 0.1 ml sterile water (n=50). | | | | |

Appendix 1: Summary of studies of SWI continued

SWI COMPARED TO OTHER ANALGESICS
(non-pharmacological and pharmacological)

| Ranta et al.

1994

Parturients' assessment of water blocks, pethidine, nitrous oxide, paracervical and epidural blocks in labour

Finland | Prospective Cohort
Women in labour at term

Interventions:
SWI (four injections of 0.1 ml) (n=69)

Nitrous Oxide (NO) (50%) (n=210)

Pethidine (P) (1mg/kg) (n=50)

Paracervical block (PCB) (Bupivicaine 0.25%, 5ml) (n=128)

Epidural block (EDA) (Bupivicaine 0.25%, 5-7ml initial dose then infusion at 5ml/hr) (n=82) | IV | Pain scores (0-10 cm) in first stage labour following treatment
SWI: 7
NO   8
P   8
PCB 6
EDA 2 | NR | Only EDA provided a significant reduction in pain (p<0.01). Participants rated adequacy of analgesia following SWI higher than nitrous oxide or pethidine. |

Appendix 1: Summary of studies of SWI continued

		II			
Labrecque et al. 1999 A randomized controlled trial of nonpharmacologic approaches for relief of low back pain during labour Canada	Randomised controlled trial Women in labour at term with back pain. *Interventions:* Four intradermal injections of 0.1 ml sterile water (group 1) (n=11). Transcutaneous electrical nerve stimulation (TENS) (group 2) (n= 12) *Control:* Standard care (back massage, water immersion, liberal mobilisation) (group 3) (n=12)	II	Mean pain intensity (mm) during intervention period (0-180 min) Group 1: 32 Group 2: 66	Mean pain intensity (mm) during intervention period (0-180 min) Group 3: 79	Mean pain intensity scores were significantly lower in the SWI group compared to either TENS or standard care (p=0.001)
Martensson et al. 2008 Acupuncture versus subcutaneous injections of sterile water as treatment for labour pain	Randomised controlled trial. Women in labour at term *Interventions:* Acupuncture needles inserted at points used in clinical practice at research site (n=62)	II	Acupuncture: mean VAS (mm) during study period (30-180min) 75.6	SWI: mean VAS (mm) during study period (30-180min 57.0	Mean VAS during the study period was significantly lower in the SWI group compared to acupuncture (p<0.001)

Sweden	SWI: Four subcutaneous injections of 0.5 ml sterile water (n=66).				

Appendix 1: Summary of studies of SWI continued

| Sigirci et al

2005

Comparison of Dicolfenac Sodium and intracutane sterile water injections in renal colic: A randomised controlled trial.

Turkey | Randomised controlled trial

Patients with diagnosis of renal colic.

Interventions:
Intramuscular injection of 75mg Diclofenac Sodium (group 1) (n=39)

Four intradermal injections of 0.2 ml sterile water (group 2) (n=40).

Control:
Four intradermal injections of 0.2 ml normal saline (group 3) (n=40). | II | VAS scores (cm) post intervention

Group 1:
1 min   8.8
5 min   8.3
15 min   6.0
30 min   3.0
60 min   1.1
120 min 0.7
360 min 1.2

Group 2:
1 min   5.7
5 min   2.1
15 min   2.1
30 min   1.1
60 min   0.5
120 min 0.6
360 min 0.6 | VAS scores (cm) post intervention

Group 3:
1 min   4.5
5 min   5.1
15 min 6.2
30 min 6.9 | SWI provided significantly greater analgesia compared to either Diclofenac Sodium or normal saline (p<0.5) |

Appendix 1: Summary of studies of SWI continued

SWI FOR OTHER PAIN SYNDROMES

Byrn et al 1991 Treatment of neck and shoulder pain in whip-lash syndrome patients with intracutaneous sterile water injections. Sweden	Prospective cohort Patients with clinical symptoms of whiplash syndrome *Intervention:* Intradermal injection of sterile water (0.2 ml) given at located trigger points (n=10)	IV	Post intervention VAS scores (cm) n=8 0 n=2 2	NR	SWI provided analgesia and improved mobility.
Byrn et al. 1993 Subcutaneous sterile water injections for chronic neck	Randomised controlled trial Patients with clinical symptoms of whiplash syndrome *Intervention*:	II	Reduction in VAS (cm) from enrolment to 3 months: 8.1 to 3.8	Reduction in VAS (cm) from enrolment to 3 months: 8.3 to 7.5	SWI provided a greater reduction in pain at 3 months compared to normal saline (p<0.001)

and shoulder pain following whiplash injuries Sweden	Subcutaneous injection of sterile water (0.2 – 0.5 ml) given at located trigger points. Repeated up to 3 times over 2 months (n=20). *Control:* Subcutaneous injection of normal saline (0.2 – 0.5 ml) given at located trigger points. Repeated up to 3 times over 2 months (n=20).				

Appendix 1: Summary of studies of SWI continued					
Wreje & Brorsson 1995 A multicentre randomized controlled trial of injections of sterile water and saline for chronic myofacial pain syndromes Sweden	Randomised controlled trial. Patients seeking outpatient health care for non-malignant pain localised to one or both upper body quadrants for at least 3 months. *Intervention:* Injections of sterile water (approx. 0.5ml) subcutaneously and intradermally to identified trigger points. *Control:* Injections of normal saline (approx. 0.5ml) subcutaneously and intradermally to identified trigger points	II	Mean reduction VAS (cm): 10 min 2.4 14 days 1.6	Mean reduction VAS (cm): 10 min 2.5 14 days 1.6	SWI provided no clinical benefit over normal saline in terms of analgesia.

NHMR C Levels of Evidence : (I) a systematic re view of Level II studies **(II)** a randomised controlled trial **(III)** a pseud -randomised controlled trial **(III-2**) a prospective stud y with concurrent control/ s**(III-3)** a comparative study without concurrent control/s **(IV)** case series. NR: not reported

Appendix 2: Summary of studies reporting effectiveness and/or intention to use SWI in future labours

Author, year, title, country	Study design and sample	Effective analgesia			Use in next labour		
		Effective	Partially effective	Not effective	Yes	No	Undecided
Lytzen et al. 1989 Relief of low back pain in labor by using intracutaneous nerve stimulation (INS) with sterile water papules. Sweden	Prospective cohort study women in first stage labour with back pain (n=83) *Intervention:* Four intradermal injections of 0.1ml sterile water	1st stage: 78% n=65 2nd stage: 53% n=45	1st stage: 9% n=8 2nd stage: 33% n=28	1st stage: 12% n=10 2nd stage: 14% n=12	80% n=67	13% n=11	7% n=5
Trolle et al 1991 The effect of sterile water blocks on low back labour pain Denmark	Randomised controlled trial Women in labour with severe back pain. *SWI:* Four injections of 0.1 ml sterile water. (n=141) *Placebo:* Four injections of 0.1 ml normal saline. (n=131)	NR	NR	NR	SWI: 69% n=96 Placebo 50% n=66	SWI: 12% n=18 Placebo 26% n=35	SWI: 19% n=27 Placebo 23% n=30

Appendix 2: Summary of studies reporting effectiveness and/or intention to use SWI in future labours continued

Martensson and Wallin 1999 Labour pain treated with cutaneous injections of sterile water: a randomised controlled trial Sweden	Randomised controlled trial Women in first stage labour with severe back pain *Interventions:* Four intradermal injections of 0.1 ml sterile water (n=33) (Group 1) Four subcutaneous injections of 0.5 ml sterile water (n=33) (Group 2) *Control* Four injections of 0.1ml normal saline subcutaneously (n=33) (Group 3)	SWI groups (1&2): 73% n=45 Placebo group: 27% n=9	SWI groups (1&2): 16% n=10 Placebo group: 27% n=9	SWI groups (1&2): 11% n=7 Placebo group: 45% n=15	SWI groups (1&2): 79% n=49 Placebo group: 58% n=18	SWI groups (1&2): 14% n=9 Placebo group: 42% n=13	NR NR
Labreque et al. 1999 A randomized controlled trial of non-pharmacologic approaches for relief of low back pain during labour. Canada	Randomised controlled trial Women in labour at term with back pain. *Interventions:* Four intradermal injections of 0.1 ml sterile water (group 1) (n=11). Transcutaneous electrical nerve stimulation (TENS) (group 2) (n= 12) *Control:* Standard care (massage, water immersion, mobilisation) (group 3) (n=12)	NR	NR	NR	Group 1 90% n=11 Group 2 90% n=11 Group 3 40% n=4	Group 1 10% n=1 Group 2 10% n=1 Group 3 60% n=6	NR

NR: not reported

Appendix 3: Four injection technique clinical protocol

The SWITCh Trial:
(Sterile Water Injection Techniques Comparison Trial)

Protocol for:
Four Injection SWI Technique

Selection Criteria for SWI
Inclusion
Women at term (between 37 and 42 weeks)
>   Nulliparous or multiparous
>   Singleton pregnancy
Cephalic presentation
>   First stage labour (spontaneous or induced)
>   No previous analgesia
>   Back pain assessed by VAS as equal to or greater than **7**

Exclusion
>   Gestation less than 37 weeks
>   Multiple gestation
>   Malpresentation (Breech Transverse etc.)
>   Second stage labour
>   Pharmacological analgesia prior to SWI
>   Back pain assessed by VAS as less than 7
>   Any complications of pregnancy or labour (bleeding, diabetes hypertension)

Consent
Please ensure that consent form has been completed, Team Leader to complete if initial consent is being sought in Birth Suite. If consent is already signed, ask woman to verbally reaffirm consent and document in progress notes.

Preparation
Explanation
- Procedure
- Woman aware that she will experience an initial "wasp-like" stinging sensation for 20 – 30 secs
- Show woman the VAS scoring tool on the Data Collection Form to determine pain score before procedure

Equipment
- 1 ml syringes
- 25g needles (orange)
- Ampoule of Sterile Water
- Gloves
- Alcohol swabs

- Sharps container

  Position
- Position woman sitting on a stool or edge of a bed and leaning forward (similar to position for epidural)
- The Midwife should be able to comfortably reach the woman's back without bending or leaning.
- Have support person hold the women's hands to prevent any sudden movents in response to stinging sensation.
  Procedure
  Identify anatomical landmarks
- 4 locations on the lower back
o Two over each posterior superior iliac spine (PSIS)
o And two 3cm below and 1cm medial to the PSIS
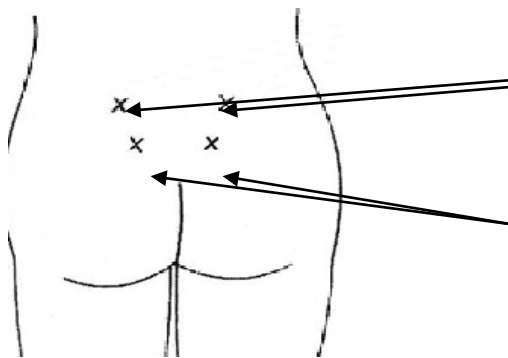
First injection point; Posterior superior iliac spines (PSIS)

Second injection points; 3 cm below and 1 cm medial to the PSIS

Mark injections sites with a pen if needed

- Cleanse injection sites

- Inject **0.1ml** water just below the skin (intradermal) at approx 15 degree angle (injection should raise a visible "bleb" under the skin)

- Use 2 midwives to inject at the first and second injection points simultaneously during a contraction.

- Cover injection site with a 10cm x 10 cm Fixamul® or similar dressing.

- Do not rub or massage injection sites as this may reduce effect.

  Documentation
- Pre injection VAS pain score
- Post injection VAS pain score at 10 mins
- VAS pain score associated with procedure
- VAS pain score for back pain at 30, 60, 90 and 120 mins (if no other analgesia used)
- The reason if the sequence of VAS scores is not completed (birth, epidural, narcotics etc).
- Pre and post VAS scores for repeat injections

Appendix 4: Single injection technique clinical protocol

The SWITCh Trial:
(Sterile Water Injection Techniques Comparison Trial)

Protocol for:
Single Injection SWI Technique

Selection Criteria for SWI
Inclusion
Women at term (between 37 and 42 weeks)
 Nulliparous or multiparous
 Singleton pregnancy
Cephalic presentation
 First stage labour (spontaneous or induced)
 No previous analgesia
 Back pain assessed by VAS as equal to or greater than **7**

Exclusion
 Gestation less than 37 weeks

 Multiple gestation
 Malpresentation (Breech Transverse etc.)
 Second stage labour
 Pharmacological analgesia prior to SWI
 Back pain assessed by VAS as less than 7
 Any complications of pregnancy or labour (bleeding, diabetes hypertension)

Consent
Please ensure that consent form has been completed, Team Leader to complete if initial consent is being sought in Birth Suite. If consent is already signed, ask woman to verbally reaffirm consent and document in progress notes..

Preparation
Explanation
- Procedure
- Woman aware that she will experience an initial "wasp-like" stinging sensation for 20 – 30 secs
- Show woman the VAS scoring tool on the Data Collection Form to determine pain score before procedure

Equipment
- 1 ml syringes
- 25g needles (orange)
- Ampoule of Sterile Water
- Gloves
- Alcohol swabs
- Sharps container

Position

- Position woman sitting on a stool or edge of a bed and leaning forward (similar to position for epidural)
- The Midwife should be able to comfortably reach the woman's back without bending or leaning.
- Have support person hold the women's hands to prevent any sudden movents in response to stinging sensation.

Procedure

The injection site will be the area that the woman perceives is the most painful or most central point of back pain
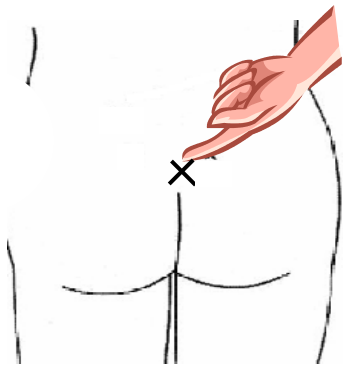
Ask woman to indicate or point to the

most painful point or central point of

back pain

Mark injection site with a pen if

needed

- Cleanse injection site

- Inject **0.1ml** water just below the skin (intradermal) at approx 15 degree angle (injection should raise a visible "bleb" under the skin)

- Inject during a contraction.

- Cover injection site with a 10cm x 10 cm gauze square / opsite dressing..

- Do not rub or massage injection sites as this may reduce effect.

Documentation

- Pre injection VAS pain score
- Post injection VAS pain score at 10 mins
- VAS pain score associated with procedure
- VAS pain score for back pain at 30, 60, 90 and 120 mins (if no other analgesia used)
- The reason if the sequence of VAS scores is not completed (birth, epidural, etc. for epidural , vaginal exam if known).
  Pre and post VAS scores for repeat injections

Appendix 5: SWITCh Trial Participant Information

The SWITCh Trial – (Sterile **W**ater **I**njections **T**echniques **C**omparison **T**rial)

A randomised, controlled trial of a single versus four intradermal sterile water injection technique for relief of continuous lower back pain during labour.

Information for participants

Student Researcher: Nigel Lee RM BHlthSc (Mid) MMid Ph 0427231390 nigel.lee@mater.org.au
Principal Supervisor: Prof. Sue Kildea RM, BHSc Hons, PhD sue.kildea@mater.org.au
Co investigators: Vanessa Wright RM vanessa.wright@mater.org.au
Peter Coxeter BHlthSc (Acu) MPH peter.coxeter@mater.org.au
Dr.MichaelBeckman MBBSFRANZCOG michael.beckman@mater.org.au
Adj. Prof Joan Webster RN BA   Joan_Webster@health.qld.gov.au
Patricia Smith RN RM MN GradCertMgt Tric_Smith@health.qld.gov.au

Thank you for taking the time to read this information sheet.

We would like to invite you to participate in a research study to examine if a single sterile water injection (SWI) technique offers the same pain relief as the routinely used four injection method for continuous lower back pain during labour. The Mater Human Research Ethics Committee, the Australian Catholic University Human Research Ethics Committee and the Royal Brisbane & Women's Hospital Human Research Ethics Committee have approved the study, and it is being conducted at Mater Mothers' Hospital, Mater Health Services, Brisbane and the Royal Brisbane & Women's Hospital. The study is being undertaken by the student researcher towards a Masters of Philosophy research degree. The purpose of this information sheet is to clearly explain the study and help you decide if you would like to participate. Please take your time to read this information before consenting to participate. You may also wish to discuss the study with family, friends or another health care provider. The study investigators can be contacted on the numbers provided at the end of this information sheet to answer any additional questions you may have.

What are sterile water injections?
About one third of women will experience back pain during their labour. The pain may often persist during the normal resting phase of labour contractions (often referred to as "back labour"). SWI is a procedure that is used to provide relief from back pain during labour. The procedure involves injections of very small amounts of sterile water (0.1ml) under the skin at four points surrounding the lower back. The injections cause a stinging sensation, like a wasp sting, that lasts for about 30 seconds and then goes away completely. To distract from the sting the injections are done during a contraction. As the stinging fades the back pain eases, the pain relief may last for up to two hours. The injections can be repeated if needed.
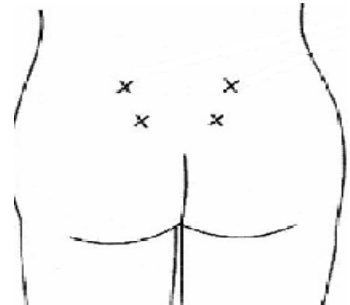
SWI has been shown to provide good pain relief from back pain for most women (85%). SWI have no known side effects and will not affect your baby. SWI can be used alongside any other form of natural or medical pain relief.

What is the study about and why is it being conducted?

The most common SWI technique used worldwide is the four injection technique (as shown in the diagram). Recently, a technique using just one injection of sterile water has been tried that appears to provide similar levels of pain relief. The single injection is given at the most painful point on the back. The aim of the study is to see if the single injection technique is as effective as the standard four injection technique in relieving continuing lower back pain during birth. This study is a randomised controlled trial, which is recognised as the best way to compare alternate forms of treatments. This is because the two groups are chosen by chance, like the toss of a coin, and ensures that all participants are similar in all ways except the treatment being compared.

Who can participate in the trial?

All normally healthy pregnant women at term (37 to 42 weeks), who expect to have a normal birth, and who experience significant back pain during their labour may participate in the trial.

What will happen if I agree to participate in the trial?

If you experience significant back pain during your labour, and are eligible to participate, a midwife will explain the trial to you in detail and answer any questions you may have. If you agree to participate, you will then be asked to sign a form indicating that you consent to take part in the trial.

You will then be randomly allocated to receive either of the two techniques, meaning you have an equal chance of receiving the single injection or four injection SWI technique. Your midwife will have no influence over which technique is used. The procedure you have been allocated to, will be done by two midwives while the midwife caring for you is not in the room. Your midwife will remain unaware of the technique used. To help ensure this we ask that you do not discuss which technique was used with your midwife or anyone else associated with the trial to prevent any bias. Your midwife will ask you to rate your pain on a scale of one to 10 before the SWI are performed, and again at 10 and 30 minute intervals after the procedure. We will also ask you to rate any discomfort you felt from the procedure itself. The day after your baby is born we will visit or contact you to ask a small number of questions about how satisfied you were with SWI. The study will also gather data from your health record such as how long your labour was and what type of birth you had.

Can I use other forms of pain relief as well?

Using SWI and participating in the study does not mean that you will not be able to use any other form of pain relief. All other forms of natural and medical pain relief are available to you whenever you choose.

Risks

Apart from the brief stinging sensation during the procedure, there have been no adverse events reported in previous studies using SWI.

Benefits

The study is not intended to directly benefit participants and if you agree to take part you will not benefit directly from the trial. However, you will assist in determining which SWI technique is the most effective in providing pain relief for women with back pain in labour.

What alternatives to being in this study are available?

Taking part in this study is voluntary

Participation in the study is voluntary and you are not obliged to participate if you do not wish to. If you do, you can withdraw at anytime. Before you make any decision regarding your participation you are encouraged to talk further with a member of the research team (study investigators or research midwife) for additional information or clarification. You should only sign the consent form after you have been fully informed. We will also ask you to verbally confirm your consent during delivery at the Birthing Suites and this will be documented in your health record. You may choose to withdraw from the trial at any time.

Whatever your decision at any time, you can be assured that it will not affect the care that you receive from either your midwife, doctor or any other medical staff at Mater Mothers' Hospitals.

Confidentiality

All aspects of the study, including all information and results, will be strictly confidential. Patients will be assigned a study number and only the study

investigators will have access to participant's medical information. Any of your information which is stored on a Mater computer will be accessed only by study staff with access to the files (they are protected by password). The research team may only link your allocated study number to your identity if there is a risk of harm to you or others. Research documentation will be stored for 15 years in a locked filing cabinet. No identifying information will be used during statistical analysis. Any presentations or publications emerging from this study will not contain any identifying information. You will not incur any additional costs as a result of participation in the study.

Will I be informed about the results when the research project is finished?

It is anticipated that the trial will run for 12 months. You will be able to request information about the overall progress of the project once it has concluded.

Who may I contact for further information or concerns?

This study has been approved by Mater Health Services Human Research Ethics Committee. You are free to discuss your participation in this study with the midwife researcher or principal investigator Mr Nigel Lee on 0427231390. Should you have any complaints about the conduct of the research, or wish to raise any concerns you may have, please contact Mater's Research Ethics Coordinator on 07 3163 1585, the Coordinator or Chairperson, Human Research Ethics Committee, Royal Brisbane & Women's Hospital, Herston, Qld, 4029 telephone (07) 3636 5490. or write to the Chair of the Australian Catholic University Human Research Ethics Committee care of the Research Services Office. The address is given below

QLD: Chair, HREC
C/- Research Services
Australian Catholic University
Brisbane Campus
PO Box 456
Virginia Qld 4014
Tel: 07 3623 7429
Fax: 07 3623 7328
.

Please visit the SWITCh website for more information on sterile water injections and the SWITCh Trial at
http://maternity.mater.org.au/switch

Appendix 6: SWITCh Trial consent form

The SWITCh Trial:
(Sterile Water Injection Techniques Comparison Trial)

Consent Form

A Randomised, Controlled Trial of a Single Versus a Four Intradermal Sterile Water Injection Technique for Relief of Continuous Lower Back Pain During Labour.

This research projected is being conducted by the Mater Mothers' Hospital, the Australian Catholic University and the Royal Brisbane and Women's Hospital has been approved by the relevant Human Research Ethics Committees.

Student researcher:	Nigel Lee	RM BHlthSc (Mid) MMid	Ph 0427231390
Principal Supervisor:	Professor Sue Kildea	RM, BHSc Hons, PhD	Ph 3163 8097
Co-researcher:	Vanessa Wright	RM	Ph 3163 1916
Co-researcher:	Peter Coxeter	BHlthSc (Acu) MPH	Ph 3163 8097
Co-researcher:	Dr Michael Beckmann	MBBS FRANZCOG	Ph 3163 8097
Co-researcher:	Adj Prof. Joan Webster	RN BA	Ph 3636 8111
Co-researcher	Patricia Smith	RN RM MN GradCertMgt	Ph 36368330

Thankyou for considering participation in our project.

Please indicate with a ✓ that you agree with the following statements and sign the consent agreement below.

I ……………………………………… (participants name) have:

☐   Read and understood the information sheet;

☐   Had any questions or queries answered to my satisfaction;

☐   Been informed of the possible risks or side effects of procedures being conducted;

☐   Understood that the project is for the purpose of research

☐   Understood that the project will involve randomisation of participants;

☐   Been informed that the confidentiality of the information will be maintained and safeguarded;

☐   Given permission for access to my medical records, for the purpose of this research;

☐   Given permission for medical practitioners, other health professionals, hospitals or laboratories outside this hospital, to release information concerning my disease and treatment which is needed for this trial and understand that such information will remain confidential;

☐   Been assured that I am free to withdraw at any time without comment or penalty; and

☐   Agreed to participate in the project.

Signatures
Participant : ....Witness...
Date …………………………………………………….Date ……………………………………
Investigator (if applicable) …………………………………Date………………………………..
(**NB** A copy of the signed statement needs to be given to the participant(s)**)**

Appendix 7: SWITCH Trial Health Professionals Information

The SWITCh Trial – (Sterile **W**ater **I**njections **T**echniques **C**omparison **T**rial)

A randomised, controlled trial of a single versus four intradermal sterile water injection technique for relief of continuous lower back pain during labour.

Student Researcher: Nigel Lee RM BHlthSc (Mid) MMid Ph 0427231390 nigel.lee@mater.org.au
Principal Supervisor: Prof. Sue Kildea RM, BHSc Hons, PhD sue.kildea@mater.org.au
Co investigators: Vanessa Wright RM vanessa.wright@mater.org.au
                        Peter Coxeter BHlthSc (Acu) MPH peter.coxeter@mater.org.au
                        Dr.MichaelBeckman MBBSFRANZCOG michael.beckman@mater.org.au
                        Adj. Prof Joan Webster RN BA   Joan_Webster@health.qld.gov.au
                        Patricia Smith RN RM MN GradCertMgt Tric_Smith@health.qld.gov.au

Health professional information sheet

As a midwife or medical officer involved in the care of women in labour we would like you to be familiar with the SWITCh trial and its aims, including the recruitment, consent, randomisation and data collection process.

The trial is being conducted by the Mater Mothers' Research Centre at the Mater Mothers' Hospital and the Royal Brisbane and Women's Hospital

This information sheet aims to provide you with some important information regarding the SWITCh trial. Further details can be obtained from the clinical investigators via the above contact details.

Background

Almost one in three women suffers continuous lower back pain during labour and birth[1]. Sterile water injections (SWI) of the lower back have been used in midwifery practice to provide pain relief to women experiencing lower back pain during labour. The most frequently used SWI technique consists of four intradermal injections of sterile water into the skin surrounding the Michaelis' rhomboid over the sacral area. High quality evidence from systematic reviews supports the four injection SWI technique as an effective intervention for the management of continuous back pain during labour[2,3]. However,

the authors also highlighted one trial[4] that reported a comparable reduction in pain scores following administration of a singular SWI technique at the most painful point. This trial, however, was not adequately designed to compare SWI techniques. A single injection SWI technique would offer clinical improvements including less discomfort and greater acceptance of the procedure by women during labour. Use of a single injection technique would also reduce the number of staff and time required to administer the procedure with relative cost benefits.

Aim of the study

The aim of this study is to determine whether a single intradermal SWI technique provides similar pain relief for women with lower back pain in labour compared to the four injection intradermal technique.

Primary outcome: Relief of pain measured by VAS at 30 minutes post-intervention.

Secondary outcomes:

a) Pain relief measured by VAS 10, 60, 90 and 120 minutes post-intervention.

b) Level of administration discomfort associated with SWI procedure (measured by VAS at 10 minutes post SWI).

c) Likelihood to use again with subsequent labour.

d) Patient satisfaction with analgesic effect.

Entry criteria

- Women at term (between 37 and 42 weeks)

- nulliparous or multiparous
- singleton pregnancy
- cephalic presentation
- first stage labour (spontaneous or induced)
- no previous analgesia
- back pain assessed by VAS as equal to or greater than seven to qualify.

Exclusion criteria

gestation less than 37 weeks

- multiple gestation
- malpresentation (breech transverse etc.)
- second stage labour
- pharmacological analgesia prior to SWI
- back pain assessed by VAS as less than seven
- any complications of pregnancy or labour (bleeding, diabetes, hypertension).

Sample size

A sample size of 319 will be required to achieve 90% power to detect that the single injection technique is "no worse" than the four injection technique.

Recruitment and consent

A number of strategies will be used to ensure that the majority of women presenting in labour will have been provided with information regarding the trial. The majority of women will be consented to the trial in the Birth Suites and Birth Centre .

Consent should be attended to by either the researchers based within the birth suites, the clinical facilitators or the midwifery team leader. Consent forms and patient information sheets will be kept in the "SWI trial" folder in the Birth Suites and Birth Centre.

Treatment allocation

Consenting women will be randomised using prepared sealed envelopes containing:

a) treatment allocation form

b) intrapartum data collection sheet

c) postnatal data collection sheet.

Following consent, the woman is randomised to either SWI technique. The procedure should be performed by two midwives whilst the midwife caring for the woman is absent from the room. It is important that the woman's midwife is not aware of which technique has been used to prevent any bias during recording the VAS pain scores.

Women may have any other form of analgesia they request following the SWI procedure and may withdraw from the trial at any time.

Participating in the trial

The SWITCh trial has the potential to make a significant contribution to the evidence surrounding the use of sterile water injections and we would encourage all staff to participate in recruitment and data collection for the trial.

References

1. Melzack R & Schaffeberg D. (1987) Low-back pain during labour. *American Journal of Obstetrics and Gynecology*. 156: 901-5.

2. Martensson L & Wallin G. (2008) Sterile water injections as treatment for low-back pain during labour: A review. *Australian and New Zealand Journal of Obstetrics and Gynaecology*. 48: 369–374.

3. Fogarty V. (2008) Intradermal sterile water injections for the relief of low back pain in labour: A systematic review of the literature. Women and Birth. 21: 157-163.

4. Bahasadri S, Ahmadi-Abhari S, Dehghani-Nik M & Habibi, G. (2006) Subcutaneous sterile water injection for labour pain: A randomised controlled trial. *Australian & New Zealand Journal of Obstetrics and Gynaecology* 46(2): 102-1

Appendix 8: SWITCh Trial Intrapartum data collection form

The SWITCh Trial:
Sterile Water Injection Techniques Comparison Trial

Intrapartum Data Collection Tool   Midwife to complete

Date........................

Patient Identification sticker
Name:
UN Number:

Please ensure that all data is completed

Parity   G.......   P........

Gestation   ....weeks   ....days

Onset of Labour
Spontaneous ☐   Induced ☐

Most Recent Vaginal Exam (if known)

Time.......   Dilatation...........cms

Effacement........cms   Descent.......

Visual Analogue Scale
Please get the woman to view the scale and indicate on it the scores for the following measurements
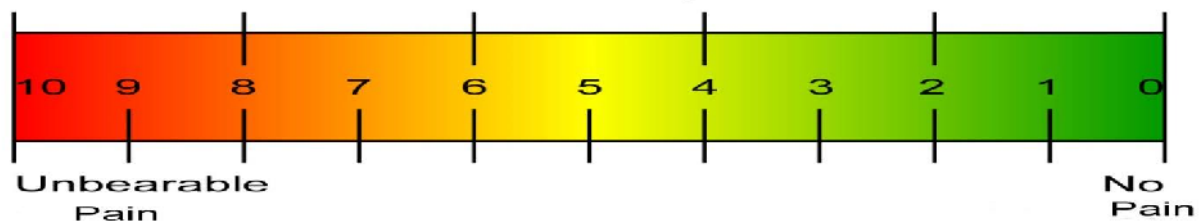
VAS of Back pain prior to injection   Time.........   VAS score.......

Injection given at   Time.........

VAS of pain from injections   **Time..........**   **VAS score.......**

VAS of back pain at 10 Mins   Time..........   VAS score.......

VAS of back pain at 30 Mins   **Time..........**   **VAS score.......**

VAS of back pain at 60 Mins   Time..........   VAS score.......

VAS of back pain at 90 Mins   Time..........   VAS score.......

VAS of back pain at 120 Mins   Time..........   VAS score.......

☐

Began using   N2O / O2 continuously at (time) ……...

and / or .☐...Pethidine at (time)……...   (please complete scores following either)

Reason if VAS not completed (epidural, LSCS, birth etc)

Time…………………………Reason……………………………………………………………………
………

Research Assistant to complete from medical records

Time of epidural insertion: …………..

If epidural used: last known vaginal exam

Time.......   Dilatation...........cm

Effacement........cm   Descent.......

Repeat SWI

Received repeat SWI ☐   Time........

Pre VAS score   ......

Post VAS score   ....

Appendix 9: SWITCh Trial Postnatal Data Collection Form

The SWITCh Trial:
Sterile Water Injection Techniques Comparison Trial

Postnatal Data Collection Tool

To be completed by the Participant

Patient Identification sticker

Name:

UN Number:

The following questions are about your experience of using Sterile Water injections (SWI) for relief of back pain during your labour.

1) What was the best aspect (what you liked most) about using SWI?

....

....

2) What was the worst aspect (what you liked least) about using SWI?

....

....

3) How satisfied were you with the pain relief provided by SWI?

☐ very satisfied

☐ satisfied

☐ undecided

☐ dissatisfied

☐ very dissatisfied

4) Would you use SWI for relief of back pain in labour again ☐ Yes ☐ No

5) Would you recommend SWI to other women ☐ Yes ☐ No

Please complete the questions over the page

We would like to know how you found out about the SWITCh Trial

Where did you first find out about the trial?

☐ Antenatal classes (public or private)

☐ Antenatal clinic

☐ Private Obstetric Practice

☐ Pregnancy Assessment and Observation Unit

☐ Birth Suite

☐ Website

☐ Other (please tell us where / how) ....

....

Did you visit the website? ☐ Yes ☐ No

If yes, did you find it helpful?

☐ very helpful

☐ helpful

☐ undecided

☐ not helpful

☐ not at all helpful

Appendix 10: SWITCh2 Study Participant Information (women)

The SWITCh2 Study

The Experience of Women and Midwives Using Sterile Water Injections in Labour

Mater Health Services

Information for participants: Women

Student Researcher:	Nigel Lee RM BHlthSc (Mid) MMid	Phone 0427231390 nigel.lee@mater.org.au
Principal Supervisor:	Prof. Sue Kildea RM, BHSc Hons, PhD	Phone 3163 6388 sue.kildea@mater.org.au
Co-Investigators:	Dr Helen Stapleton RM, MSc, PhD	helen.stapleton@acu.edu.au
	Patricia Smith RN RM MN GradCertMgt	Tric_Smith@health.qld.gov.au

Thank you for taking the time to read this information sheet.

We would like to invite you to participate in a research study to explore the experience of using sterile water injections for back pain in labour. The Mater Human Research Ethics Committee, the Royal Brisbane and Women's Hospital Human Research Ethics Committee and the Australian Catholic University Human Research Ethics Committee have approved the study, and it is being conducted at the Mater Mothers' Hospital, Brisbane and the Royal Brisbane and Women's Hospital. The study is being undertaken by the student researcher towards a Doctor of Philosophy research degree. The purpose of this information sheet is to clearly explain the study and help you decide if you would like to participate. The student researcher or the principal supervisor can be contacted on the number provided above to answer any additional questions you may have.

Before you decide whether to take part in the study it is important that you understand what the research is for and what you will be asked to do. Please take time to read the following information and discuss it with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep. You will also be asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving a reason.

The standard of care you receive will not change whether or not you decide to participate in this study. You are welcome to phone the student researcher or principle supervisor if you would like any further information.

What is the study about and why is it being conducted

The purpose of the research study is to explore the experience of women in labour using sterile water injections (SWI). I would like to ask questions about what it was like for you, your thoughts, your feelings as well as situations, events and people connected with your experience.

It is hoped that any information gained from this research will be used to make recommendations for best practice and will offer insights into the experiences using SWI. The results of the study may also lead onto further research into the use of SWI.

Why have I been invited to participate?

You have been invited because you received SWI for back pain during your labour, and also agreed to participate in the SWITCh Trial (Sterile Water Injections Techniques Comparison Trial).

What will happen if I agree to participate?

If you are considering participating in the study, either speak to the research assistant who provided you with this information sheet or contact the student researcher on the phone number or email address given above. The student researcher will then contact you to answer any questions you may have and arrange to provide you with a consent form. The study will involve up to 10 participants, who will all be interviewed separately. The interview will take approximately one hour. If you choose to take part I will organise a location for the interview convenient to you. The study will also gather data from your health record such as how long your labour was and what type of birth you had.

You will not incur any additional costs as a result of participation in the study.

Are there any risks?

Whilst it is not anticipated that there will be any risks associated with participating in the study, talking about your labour and birth experience may be upsetting for you. You are free to stop the interview at any time if you do not wish it to continue. If the interview upsets you and you feel you would like some additional help after the interview I will be able to advise you who to contact, for example GP, Patient Advocate, or Counsellor.

Are there any benefits?

If you agree to take part you will not benefit directly from the study. However you will assist in expanding our knowledge and understanding of the use of SWI.

What alternatives to being in this study are available?

Taking part in this study is voluntary

Participation in the study is voluntary and you are not obliged to participate if you do not wish to. If you do, you can withdraw at anytime. Before you make any decision regarding your participation you are encouraged to talk further with either the student research or the principal supervisor, for additional

information or clarification. You should only sign the consent form after you have been fully informed. You may choose to withdraw from the study at any time.

You are free to withhold any information you prefer not to discuss and can decline to answer any questions we ask. Whatever your decision at any time, you can be assured that it will not affect the care that you receive from either your midwife, doctor or any other medical staff at Mater Mothers' Hospitals

Confidentiality

The interview will be recorded on a digital audio recorder and transcribed onto a computer. The audio files and transcript files will be stored electronically with password protection, accessible only to the student researcher and the principal supervisor. Your response will be treated with full confidentiality and anyone who takes part in the research will be identified only by code numbers or pseudonyms. The interviews will be analysed by the researchers. At the end of the research researcher will complete a thesis and the results may be published in peer reviewed journals and conference presentations. No research participant will be identifiable from any publications. Your participation in the study will not be made known to other persons outside the study.

Will I be informed about the results when the research project is finished?

It is anticipated that the study will run for 12 months. You will be able to request information about the overall progress of the project once it has concluded by contacting the student researcher.

Who may I contact for further information or concerns?

This study has been approved by Mater Health Services Human Research Ethics Committee. You are free to discuss your participation in this study with the midwife researcher or student researcher, Mr Nigel Lee on 0427231390. Should you have any complaints about the conduct of the research, or wish to raise any concerns you may have, please contact Mater's Research Ethics Coordinator on 07 3163 1585, the Coordinator or Chairperson, Human Research Ethics Committee, Royal Brisbane & Women's Hospital, Herston, Qld, 4029 telephone (07) 3636 5490 or write to;

QLD: Chair, HREC
C/- Research Services
Australian Catholic University
Brisbane Campus
PO Box 456
Virginia Qld 4014
Tel: 07 3623 7429
Fax: 07 3623 7328
.

Appendix 11: SWITCh2 Study Consent Form (women)

The SWITCh 2 Study:
The Experience of Women Using Sterile Water Injections in Labour
Consent Form: Women

We would like to invite you to participate in a research study to explore the experience of using sterile water injections for back pain in labour. The Mater Human Research Ethics Committee, the Royal Brisbane and Women's Hospital Human Research Ethics Committee and the Australian Catholic University Human Research Ethics Committee have approved the study, and it is being conducted at the Mater Mothers' Hospital, Brisbane and the Royal Brisbane and Women's Hospital. The study is being undertaken by the student researcher towards a Doctor of Philosophy research degree

Student researcher:	Nigel Lee	RM BHlthSc (Mid) MMid	Ph 0427231390
Principal Supervisor:	Professor Sue Kildea	RM, BHSc Hons, PhD	Ph 3163 8097
Co-Investigators:	Dr Helen Stapleton	RM, MSc, PhD	Ph 3163 6081
	Patricia Smith	RN RM MN GradCertMgt	Ph 36368330

Thankyou for considering participation in our project.

Please indicate with a ✓ that you agree with the following statements and then sign the consent agreement below.

I ……………………………………………… (participants name) have:

☐ Read and understood the information sheet;

☐ Had any questions or queries answered to my satisfaction;

☐ Been informed of the possible risks of participating in the study;

☐ Understood that the project is for the purpose of research ;

☐ Understood that the project will involve participation in interviews that will be recorded;

☐ Understood that the interview will last between 60 and 90 minutes;

☐ Been informed that the confidentiality of the information will be maintained and safeguarded;

☐ Given permission for access to my medical records, for the purpose of this research;

☐ Given permission for medical practitioners, other health professionals, hospitals or laboratories outside this hospital, to release information concerning my condition and treatment which is needed for this study and understand that such information will remain confidential;

☐ Been assured that I am free to withdraw at any time without comment or penalty; and

☐ Agreed to participate in the project.
Signatures

Participant   :
....Witness...

Date ……………………………………………Date …………………………………

Investigator (if applicable) ……………….....…….Date……………………………………..

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Appendix 12: SWITCH2 Study - Recruitment Email for Midwives

Dear #midwife's name#

We would like to invite you to participate in a research study to explore the experience of using sterile water injections for back pain in labour. The Mater Human Research Ethics Committee, the Royal Brisbane and Women's Hospital Human Research Ethics Committee and the Australian Catholic University Human Research Ethics Committee have approved the study, and it is being conducted at the Mater Mothers' Hospital, Brisbane and the Royal Brisbane and Women's Hospital. The study is being undertaken by the student researcher towards a Doctor of Philosophy research degree. The purpose of this information sheet is to clearly explain the study and help you decide if you would like to participate. The student researcher or the principal supervisor can be contacted on the number provided above to answer any additional questions you may have.

Before you decide whether to take part in the study it is important that you understand what the research is for and what you will be asked to do. Please take time to read the attached information and discuss it with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep. You will also be asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving a reason.

Your role, position within the Birth Suite and your relationship with other colleagues will not change whether or not you decide to participate in this study.

Kind regards

Nigel Lee

Appendix 13: SWITCh2 Study Participant Information (midwives)

The SWITCh2 Study

The Experience of Women and Midwives Using Sterile Water Injections in Labour

Information for participants: Midwives

Student Researcher:	Nigel Lee	Phone 0427231390
	RM BHlthSc (Mid) MMid	nigel.lee@mater.org.au
Principal Supervisor:	Prof. Sue Kildea	Phone 3163 6388
	RM, BHSc Hons, PhD	sue.kildea@mater.org.au
Co-Investigators:	Dr Helen Stapleton	
	RM, MSc, PhD	helen.stapleton@acu.edu.au
	Patricia Smith RN RM MN GradCertMgt	Tric_Smith@health.qld.gov.au

Thank you for taking the time to read this information sheet.

We would like to invite you to participate in a research study to explore the experience of using sterile water injections for back pain in labour. The Mater Human Research Ethics Committee, the Royal Brisbane and Women's Hospital Human Research Ethics Committee and the Australian Catholic University Human Research Ethics Committee have approved the study, and it is being conducted at the Mater Mothers' Hospital, Brisbane and the Royal Brisbane and Women's Hospital. The study is being undertaken by the student researcher towards a Doctor of Philosophy research degree. The purpose of this information sheet is to clearly explain the study and help you decide if you would like to participate. The student researcher or the principal supervisor can be contacted on the number provided above to answer any additional questions you may have.

Before you decide whether to take part in the study it is important that you understand what the research is for and what you will be asked to do. Please take time to read the following information and discuss it with others if you wish. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep. You will also be asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving a reason.

Your role, position within the Birth Suite and your relationship with other colleagues will not change whether or not you decide to participate in this study.

What is the study about and why is it being conducted

The purpose of the research study is to explore the experience of midwives administering sterile water injections (SWI) to women in labour. I would like to ask questions about how well prepared you felt, any difficulties you encountered and how women responded to the injections.

It is hoped that any information gained from this research will be used to make recommendations for best practice and will offer insights into the experiences using SWI. The results of the study may also lead onto further research into the use of SWI.

Am I eligible to participate?

You are eligible to participate if you are a midwife working on the birth suite and use SWI within your clinical practice.

What will happen if I agree to participate?

If you are considering participating in the study, contact the student researcher on the phone number or email address given above. The student researcher will then contact you to answer any questions you may have and arrange to provide you with a consent form. The study will involve up to 10 midwives, who will be interviewed in groups. The interview will take approximately one hour and take place at a mutually convenient location. Prior to the interview, you will also be asked to complete a brief questionnaire regarding you education, training and clinical experience as a midwife.

You will not incur any additional costs as a result of participation in the study.

Are there any risks?

Whilst it is not anticipated that there will be any risks associated with participating in the study, talking about your clinical practice may at times be difficult for you. You are free to stop the interview at any time if you do not wish it to continue. If you feel you would like some additional help after the interview I will be able to advise you who to contact, for example Staff Advocate, Professional Representative or Counsellor. In the unlikely event the interview reveal knowledge of an incident that may have implications for practice and safety, the researcher is obliged to seek advice from the principal supervisor and the issue may be referred to the appropriate Midwifery Manager and / or Practice Development Midwife for review.

Are there any benefits?

If you agree to take part, it is not anticipated that you will benefit directly from the study. However you will assist in expanding knowledge and understanding of the use of SWI.

What alternatives to being in this study are available?

Taking part in this study is voluntary

Participation in the study is voluntary and you are not obliged to participate if you do not wish to. If you do, you can withdraw at anytime. Before you make any decision regarding your participation you are encouraged to talk further with either the student researcher or the principal supervisor, for additional information or clarification. You should only sign the consent form after you have been fully informed. You are free to withhold any information you prefer not to discuss and can decline to answer any questions asked.

Whatever your decision, you can be assured that it will not affect your position within your department, your relationship with co-workers or the terms of your employment.

Confidentiality

The interview will be recorded on a digital audio recorder and transcribed onto a computer. The audio files and transcript files will be stored electronically with password protection, accessible only to the student researcher and the principal supervisor. Your response will be treated with full confidentiality and anyone who takes part in the research will be identified only by code numbers or pseudonyms. The interviews will be analysed by the researchers. At the end of the research researcher will complete a thesis and the results may be published in peer reviewed journals and conference presentations. No research participant will be identifiable from any publications. Your participation in the study will not be made known to other persons outside the study.

Will I be informed about the results when the research project is finished?

It is anticipated that the study will run for 12 months. You will be able to request information about the overall progress of the project once it has concluded by contacting the student researcher.

Who may I contact for further information or concerns?

This study has been approved by the Mater Health Services, Royal Brisbane and Women's Hospital and Australian Catholic University Human Research Ethics Committees. You are free to discuss your participation in this study with the midwife researcher or student researcher, Mr Nigel Lee on 0427231390. Should you have any complaints about the conduct of the research, or wish to raise any concerns you may have, please contact Mater's Research Ethics Coordinator on 07 3163 1585, the Coordinator or Chairperson, Human Research Ethics Committee, Royal Brisbane & Women's Hospital, Herston, Qld, 4029 telephone (07) 3636 5490 or write to;

QLD: Chair, HREC
C/- Research Services
Australian Catholic University
Brisbane Campus
PO Box 456
Virginia Qld 4014
Tel: 07 3623 7429
Fax: 07 3623 7328
.

Please visit the SWITCh website for more information on sterile water injections and the SWITCh Trial at
http://maternity.mater.org.au/switch

Appendix 14: SWITCh2 Study Consent Form (midwives)

The SWITCh 2 Study:
The Experience of Women Using Sterile Water Injections in Labour

Consent Form: Midwives

We would like to invite you to participate in a research study to explore the experience of providing sterile water injections for back pain in labour. The Mater Human Research Ethics Committee, the Royal Brisbane and Women's Hospital Human Research Ethics Committee and the Australian Catholic University Human Research Ethics Committee have approved the study, and it is being conducted at the Mater Mothers' Hospital, Brisbane and the Royal Brisbane and Women's Hospital. The study is being undertaken by the student researcher towards a Doctor of Philosophy research degree

Student researcher:	Nigel Lee	RM BHlthSc (Mid) MMid	Ph 0427231390
Principal Supervisor:	Professor Sue Kildea	RM, BHSc Hons, PhD	Ph 3163 8097
Co-Investigators:	Dr Helen Stapleton	RM, MSc, PhD	Ph 3163 6081
	Patricia Smith	RN RM MN GradCertMgt	Ph 36368330

Thankyou for considering participation in our project.

Please indicate with a ✓ that you agree with the following statements and then sign the consent agreement below.

I ………………………………………… (participants name) have:

☐ Read and understood the information sheet;

☐ Had any questions or queries answered to my satisfaction;

☐ Been informed of the possible risks of participating in the study;

☐ Understood that the project is for the purpose of research

☐ Understood that the project will involve participation in interviews that will be recorded;

☐ Understood that the interview will last between 60 and 90 minutes;

☐ Been informed that the confidentiality of the information will be maintained and safeguarded;

☐ Been assured that I am free to withdraw at any time without comment or penalty; and

☐ Agreed to participate in the project.

Signatures

Participant   :
....Witness.. ....

Date ………………………………………… Date …………………………………

Investigator (if applicable) ………………………Date………………………………………..

Appendix 15: Interview guide for women participants

Pre interview

o Research topic / aim

o Significance

o Info sheet

o Consent / confidentiality/ anonymity

o Set up mic / demonstrate

o Taking breaks / Stopping interview

o Declining to answer

o Emotions

o Off record remarks

o Note taking

Context of pain

o Thoughts and experiences of pain (prior to labour)

▪ History of back pain Menses Migraines   (chronic pain)

▪ Analgesia / pain coping strategies

Preparation of birth

o Information about birth

▪ At what point during your preg did you start thinking about prep for birth

▪ How: classes internet   magazines

▪ Who: mum/sister/friend   /workcolleague /m/w dr

▪ What influence on did ANC provider have on birth prep

Expectation about labour & birth

▪ Thoughts about labour

• Excited,   anxious,   didn't want to know

▪ Planned supports / who

▪ Did you write / prepare a birth plan

Labour

- How labour started and what happened

- What you thought about being in "labour" Actuality vs expectation

- Coping with labour

- Things that made it easier / feel better / confident

- Support persons

- Things that made it harder (routines, EFM, VE, environment, waiting,)

Back pain in labour

- When did it start

• Intensity (stronger than contractions)

• Periodic, constant

• <u>Can you describe it (burning, ache, sting, stab)</u>

• Where

• How did you feel – change analgesia / coping strategies

- Anything that contributed to your backpain

- Position / baby's position / movement restrictions/

SWI use

- Did you hear about SWI during pregnancy

- When did you first consider SWI

o Who's idea

o How did you feel about using SWI

- Anxious, curious, relieved, uncertain

o How did the mw discuss it with you

- Attitudes of support persons to SWI

o Experience of receiving the injection(s)

- Waiting for contraction and injections

- Would it have been easier given imbetween contractions

- How long did the injection discomfort last

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- Did the stinging exceed expectations

- Experience of the effect

- Relieved / unrelieved

- Compare with expectations (if any)

- Pain of injections vs effect

- Effect on labour / pain / coping / attitude

- Duration

- Consider repeat SWI   why   why not

- (if repeat SWI) as above

- Overall how did you feel about using SWI for you backpain

- Consider using swi in next labour   why   why not

- Consider recommending to others   why   why not

- thoughts about being involved in research

    Finish

- Do you have any questions of comments on what we have discussed?

- Were there any other things you thought I might be asking you about?

- Thank for time and contribution

- Contact for clarification

    Notification of final report

Appendix 16: Interview guide for midwives focus groups

Focus Group Ground Rules

Information, discussions etc should remain confidential and not discussed outside of the group

Although the object of the group is to discuss and challenge and explore the topic, not just agree, respect each others opinions.

Please speak one at a time.

2. Please speak in a voice at least as loud as mine.

3. Avoid side conversations with your neighbours.

4. I need to hear from everyone during the course of the session but you don't have to answer every question.

6. There are no wrong answers-you cannot fail during this session.

7. Say what's true for you, and have the courage of your convictions.

8. Don't let the group sway you, and don't sell out to group opinion or to a strong talker. It is OK, however, to change your mind during the course of the session because of something you hear or see.

Interview Guide

Supporting women in labour

o   thoughts and ideas about what it is to be the midwife supporting women in labour

o

- Non pharmacological analgesic strategies

o what strategies etc would you use to help women cope with pain in labour

o for women specifically wanting to have a normal birth (drug free)

- Back pain in labour

o what causes back pain in labour

o does back pain change your approach to care

o does back pain change the way women approach (cope) labour

SWI use

Learning the technique

- When did you first hear about SWI

- What did you think about SWI

- Learning experience,(formal, informal, effective, confidence)

Applying SWI

- First time you used it (expectations, feelings etc.)

- An example of when it worked well

- An example of when it did not work well, (coping with analgesic failure)

- How do women respond to the injections

Injection pain

- Inflicting pain on women (pain vs effect)

- Influences and considerations in offering women SWI

Changing practice

Has using SWI changed the way you practice (back pain)

- Likelihood to recommend the practice to other midwives and women, why or why not

Appendix 17: SWITCh2 Study Questionnaire for participating midwives

The SWITCh2 Study

The Experience of Midwives Using Sterile Water Injections in Labour

Mater Health Services

Questionnaire

Student Researcher:	Nigel Lee RM BHlthSc (Mid) MMid	Phone 0427231390 nigel.lee@mater.org.au
Principal Supervisor:	Prof. Sue Kildea RM, BHSc Hons, PhD	sue.kildea@mater.org.au
Co-Investigator:	Dr Helen Stapleton RM, MSc, PhD	helen.stapleton@acu.edu.au
	Patricia Smith RN RM MN GradCertMgt	Tric_Smith@health.qld.gov.au

Study ID ………

Please answer the following questions

Original year of midwifery registration ……………………..

Mode of midwifery study (hospital or tertiary) ……………………..

Years of birth suite experience ……………………..

Duration of experience using SWI ……………………..

Have you administered both the single

and four injection technique. Yes / No

Appendix 18: Human Research Ethics Committee approvals

The SWITCh trial:

HREC	Reference No:	Date of approval
Mater Health Services	1422M	24/11/2009
Australian Catholic University	Q2009 48	12/11/2009
Royal Brisbane and Women's Hospital	HREC/10/QRBW/155	21/04/2010

The experience of women and midwives using sterile water injections in labour

HREC	Reference No:	Date of approval
Mater Health Services	1595M	30/09/2010
Australian Catholic University	Q2010 51	15/10/2010
Royal Brisbane and Women's Hospital	HREC/10/QRBW/406	12/10/2010

MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

24th November 2009

Mr Nigel Lee
Birth Suites
Mater Mothers' Hospital

Dear Mr Lee

Re: A Randomised, Controlled Trial of a Single Versus a Four Intradermal Sterile Water Injection Technique for Relief of Continuous Lower Back Pain During Labour. *Ref №. 1422M*

I write to advise that the Mater Health Services Human Research Ethics Committee has granted ethical approval for the proposed amendments for the above study.

Documents reviewed and approved include:

- *Letter dated 11th November 2009 outlining request for approval of supplementary recruitment material*
- *Outline of Website Content*
- *Sterile Water Injections Information Pamphlet*
- *Web Video Script*
- *CD-ROM containing video*

Please accept our best wishes for the remainder of the study and should you have any queries, please do not hesitate to contact the Research Ethics Secretariat on 3163 1585. *In all future correspondence with the Committee please quote the Mater reference number.*

Yours sincerely

Dr Helen Liley
Chairperson
Mater Health Services Human Research Ethics Committee

Human Research Ethics Committee

Committee Approval Form

Principal Investigator/Supervisor: Professor Sue Kildea   Brisbane Campus

Co-Investigators:

Student Researcher: Mr Nigel Lee   Brisbane Campus

Ethics approval has been granted for the following project:
A Randomised, Controlled Trial of a Single Versus a Four Intradermal Sterile Water Injection Technique for Relief of Continuous Lower Back Pain During Labour. (The SWITCh Trial: Sterile Water Injections Techniques Comparison Trial)

for the period: 1 January 2010 to 31 May 2011

Human Research Ethics Committee (HREC) Register Number: Q2009 48

The following <u>standard</u> conditions as stipulated in the *National Statement on Ethical Conduct in Research Involving Humans* **(2007) apply:**

    (i)   that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
- security of records
- compliance with approved consent procedures and documentation
- compliance with special conditions, and

    (ii)   that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:
- proposed changes to the protocol
- unforeseen circumstances or events
- adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than low risk. There will also be random audits of a sample of projects considered to be of negligible risk and low risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a *Final Report Form* and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an *Annual Progress Report Form* and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.

Signed: *K. Pashley.*   Date: 12 November 2009
         (Research Services Officer, McAuley Campus)

Queensland Government

Office of the Human Research Ethics Committees

Queensland Health

Mr Nigel Lee
Mater Mothers' Research Centre
Level 2, Quarters Building
Mater Health Services
South Brisbane   Q   4101

Dear Mr Lee,

Re: Ref Nº: HREC/10/QRBW/155: A Randomised, Controlled Trial of a Single Versus a Four Intradermal Sterile Water Injection Technique for Relief of Continuous Lower Back Pain During Labour

A sub-Committee of the Royal Brisbane & Women's Hospital (RBWH) Human Research Ethics Committee (HREC) reviewed the above protocol on 09 April, 2010 & 19 April, 2010. This protocol was previously reviewed and approved by the Mater Mothers' Hospital Human Research Ethics Committee on 29 October, 2009 and that approval has now been endorsed by the RBWH HREC on 19 April, 2010.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition with specialty and affiliation with the Hospital *(Attachment 1)*.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the District CEO or Delegate of that site has been obtained.

A copy of this approval will also be sent to the District Research Governance Office (RGO). Please ensure you submit a completed Site Specific Assessment (SSA) Form to the RGO for authorisation from the CEO or Delegate to conduct this research at the Royal Brisbane & Women's Hospital Metro North District.

HREC approval is valid for three (3) years from the date of this letter. The documents reviewed and approved include:

Document	Version	Date
Covering Letter		29 March 2010
Application: NEAF		23 March 2010
Site Specific Assessment (SSA) Form *(noted)*	2.0 (2009)	23 March 2010
SWITCh Trial Protocol	Version 3 Final	18 March 2010
SWITCH Trial Four Injection Protocol		16 March 2010
Research Funding Schedule *(reviewed in accordance with Section 3.3.18 of the National Statement)*		
Curriculum Vitae of Nigel Lee		23 March 2010
Responses to Mater Health Services Scientific Sub-Committee questions		13 October 2009
SWITCH Trial Website	2	30 March 2010
Participant Consent Form	3	16 March 2010
Participant Information Sheet	6	16 March 2010
Data Collection Forms and Participant Questionnaire	2	06 April 2010
Letter of Support from Women's and Newborn Services and Unit Managers		09 February 2010
Approval from Mater Health Services Human Research Ethics committee		29 October 2009
Amendment approval from Mater Health Services Human Research Ethics Committee		18 March 2010
Committee Approval Form from Australian Catholic University Human Research Ethics Committee		12 November 2009
Amendment approval from Australian Catholic University Human Research Ethics Committee		25 February 2010
Data Collection Information Form	2	06 April 2010
Intrapartum Data Collection Form	2	06 April 2010
Postnatal Data Collection Form	2	06 April 2010
Partogram Data Collection Form	2	06 April 2010
Response to Request for Further Information		19 April 2010
Responses to Discrepancies in Documents (Rationale for Changes)		
Health Professional Information Sheet	3	17 April 2010

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:

- Unforeseen events that might affect continued ethical acceptability of the project. Serious Adverse Events must be notified to the Committee as soon as possible. In addition, the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

2. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC Coordinator. These should include a covering letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

3. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office.

4. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office (by-passing the HREC).

5. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a covering letter from the Principal Investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC Coordinator as per standard HREC SOP. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf

6. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

7. The HREC will be notified, giving reasons, on any sponsor reports or other information which might affect the ongoing ethical acceptability in line with the requirements of the ICH GCP guidelines as annotated by the TGA: http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf

8. The Principal Investigator will provide an Annual Report to the HREC and at completion of the study in the specified format.

9. The District Administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on Hospital premises or claiming any association with the Hospital, or which the Committee has approved if conducted outside Royal Brisbane & Women's Hospital Metro North Health Service District.

Should you have any queries about the HREC's consideration of your project please contact the HREC Coordinator on 07 3636 5490. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Once authorisation to conduct the research has been granted, please complete the Commencement Form *(Attachment II)* and return to the office of the Human Research Ethics Committee.

The HREC wishes you every success in your research.

Yours sincerely,

Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North **DISTRICT**
21.04.2010

MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

30 September 2010

Mr Nigel Lee
Researcher – SWITCh Trial
Mater Medical Research Institute
Mater Health Services
Room 65, Level 3 Quarters Building

Dear Mr Lee

Re: Protocol *Ref No. 1595M – SWITCh2 study: The experience of women and midwives using sterile water injections in labour*

I write to advise that the Mater Health Services Human Research Ethics Committee considers the above study to meet the requirements of the *National Statement on Ethical Conduct in Human Research* (2007) and has granted ethical approval for your research proposal. Please accept our very best wishes for the success of this study. *In all future correspondence with the Committee please quote the Mater reference number.*

Documents reviewed and approved include:

- Mater Ethics Application form cover sheet
- NEAF
- Research Protocol
- Staff Information Sheet
- Participant Information Sheet: Women
- Participant Information Sheet: Midwives
- Consent form for Women
- Consent form for Midwives
- Text of recruitment email for Midwives
- Email correspondence dated 13 September 2010 in response to SSC comments
- Email correspondence dated 29 September 2010 in response to HREC comments

This approval is valid until **30 September 2013**. Please note the following conditions of approval.

- Any departure from the protocol detailed in your proposal must be reported immediately to the Committee.
- When you propose a change to an approved protocol, which you consider to be minor, you are required to submit a written request for approval to the Chairperson, through the Secretary. Such requests will be considered on a case by case basis and interim approval may be granted subject to ratification at the next meeting of the Committee.
- Where substantial changes to any approved protocol are proposed, you are required to submit a full, new proposal for consideration by the Human Research Ethics Committee.

F0621
11/07

- You are required to advise the Research Ethics Coordinator immediately of any complaints made, or expressions of concern raised, in relation to the study, or if any serious or unexpected adverse events occur.
- Under the *NHMRC National Statement on Ethical Conduct in Research Involving Humans*, research ethics committees are responsible for monitoring approved research to ensure continued compliance with ethical standards, and to determine the method of monitoring appropriate to each project. You are required to provide written reports on the progress of the approved project annually, the first report being due on **30 September 2011** and finally on completion of the project. *(The Progress Report is located at http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx or can be accessed through the Mater Intranet, Applications, Research Register then under the project name or alternately can be emailed to you).* Please inform the Committee of publications, presentations at Conferences, education and quality improvement outcomes from this study. The Committee may also choose to conduct an interim audit of your research.
- Please be aware that all study procedures including follow up of participants and data analysis should be completed within the approval time frame or an extension should be requested.

Please contact the Executive Director in the participating hospital/hospitals prior to commencing of the study. To access medical records, for the purpose of this study, please provide a copy of this approval letter to the Corporate Health Information Manager. I would also be grateful if you could confirm the date of commencement. (All correspondence should be directed to the Mater Research Ethics Coordinator.)

Yours sincerely

Dr Helen Liley
Chairperson
Mater Health Services Human Research Ethics Committee

ACU

AUSTRALIAN CATHOLIC UNIVERSITY

Human Research Ethics Committee

Committee Approval Form

Principal Investigator/Supervisor: Professor Sue Kildea   Brisbane Campus

Co-Investigators:

Student Researcher: Mr Nigel Lee   Brisbane Campus

Ethics approval has been granted for the following project:
The experience of women and midwives using sterile water injections in labour

for the period: 15 October 2010 to 30 SEptember 2013

Human Research Ethics Committee (HREC) Register Number: Q2010 51

The following <u>standard</u> conditions as stipulated in the *National Statement on Ethical Conduct in Research Involving Humans* (2007) apply:

(i)   that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
- security of records
- compliance with approved consent procedures and documentation
- compliance with special conditions, and

(ii)   that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:
- proposed changes to the protocol
- unforeseen circumstances or events
- adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than low risk. There will also be random audits of a sample of projects considered to be of negligible risk and low risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a *Final Report Form* and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an *Annual Progress Report Form* and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.

Signed: *K. Pashley.*   .....   Date: 15.10.2010
             (Research Services Officer, McAuley Campus)

Office of the Human Research Ethics Committees

Queensland Health

Mr Nigel Lee
Birth Suite
Mater Mothers' Hospital
Raymond Terrace
South Brisbane   Q   4101

Dear Mr Lee,

Re: **Ref Nº: HREC/10/QRBW/406: The experience of women and midwives using sterile water injections in labour**

A sub-Committee of the Royal Brisbane & Women's Hospital (RBWH) Human Research Ethics Committee (HREC) reviewed the above protocol on 07/10/2010 and 11/10/2010. This protocol was previously reviewed and approved by the Mater Health Services Human Research Ethics Committee on 30 September, 2010 and that approval has now been endorsed by the RBWH HREC on 11 October, 2010.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition with specialty and affiliation with the Hospital *(Attachment 1)*.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the District CEO or Delegate of that site has been obtained.

A copy of this approval will also be sent to the District Research Governance Office (RGO). Please ensure you submit a completed Site Specific Assessment (SSA) Form to the RGO for authorisation from the CEO or Delegate to conduct this research at the Royal Brisbane & Women's Hospital Metro North District.

HREC approval is valid for three (3) years from the date of this letter. The documents reviewed and approved include:

Document	Version	Date
Cover Letter		05 October 2010
Application: NEAF	2.0 (2008)	05 October 2010
SWITCh2 Protocol	4	03 August 2010
SWITCh Trial Data Form: Midwives	1	03 August 2010
SWITCh Trial Recruitment Email for Midwives	1	03 August 2010
Responses to Mater HREC/SSC Review		
Letter of Approval from Mater Health Services HREC		30 September 2010
Response to Request for Further Information		11 October 2010
SWITCh Trial Information Sheet for Participants: Women	3	07 October 2010
SWITCh Trial Consent Form: Women	3	07 October 2010
SWITCh Trial Information Sheet for Participants: Midwives	3	07 October 2010
SWITCh Trial Consent Form: Midwives	3	07 October 2010

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
   - Unforeseen events that might affect continued ethical acceptability of the project. Serious Adverse Events must be notified to the Committee as soon as possible. In addition, the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of event.

2. Amendments which do not affect either the ethical acceptability or site acceptability of the project (e.g. typographical errors) should be submitted in hard copy to the HREC Coordinator. These should include a covering letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.

3. Proposed amendments to the research project which may affect both the ethical acceptability and site suitability of the project must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office.

4. Amendments to the research project which only affect the ongoing site acceptability of the project are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office (by-passing the HREC).
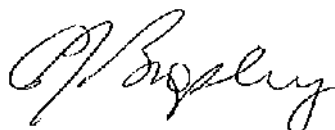
5. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. <u>Major amendments</u> should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a covering letter from the Principal Investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC Coordinator as per standard HREC SOP. Further advice on submitting amendments is available from http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf

6. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.

7. The HREC will be notified, giving reasons, on any sponsor reports or other information which might affect the ongoing ethical acceptability in line with the requirements of the ICH GCP guidelines as annotated by the TGA: http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf

8. The Principal Investigator will provide an Annual Report to the HREC and at completion of the study in the specified format.

9. The District Administration and the Human Research Ethics Committee may inquire into the conduct of any research or purported research, whether approved or not and regardless of the source of funding, being conducted on Hospital premises or claiming any association with the Hospital, or which the Committee has approved if conducted outside Royal Brisbane & Women's Hospital Metro North Health Service District.

Should you have any queries about the HREC's consideration of your project please contact the HREC Coordinator on 07 3636 5490. The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Once authorisation to conduct the research has been granted, please complete the Commencement Form *(Attachment II)* and return to the office of the Human Research Ethics Committee.

The HREC wishes you every success in your research.

Yours sincerely,

Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North **DISTRICT**
12.10.2010

Appendix 19: Publication one: Study protocol

BMC
Pregnancy & Childbirth

STUDY PROTOCOL

Open Access

A randomised non-inferiority controlled trial of a single versus a four intradermal sterile water injection technique for relief of continuous lower back pain during labour

Nigel Lee[1,4*], Peter Coxeter[2], Michael Beckmann[1], Joan Webster[3], Vanessa Wright[1], Tric Smith[3] and Sue Kildea[1,4]

Abstract

Background: Almost one third of women suffer continuous lower back pain during labour. Evidence from three systematic reviews demonstrates that sterile water injections (SWI) provide statistically and clinically significant pain relief in women experiencing continuous lower back pain during labour. The most effective technique to administer SWI is yet to be determined. Therefore, the aim of this study is to determine if the single injection SWI technique is no less effective than the routinely used four injection SWI method in reducing continuous lower back pain during labour.

Methods/design: The trial protocol was developed in consultation with an interdisciplinary team of clinical researchers. We aim to recruit 319 women presenting at term, seeking analgesia for continuous severe lower back pain during labour. Participants will be recruited from two major maternity hospitals in Australia. Randomised participants are allocated to receive a four or single intradermal needle SWI technique. The primary outcome is the change in self-reported pain measured by visual analogue scale at baseline and thirty minutes post intervention. Secondary outcomes include VAS change scores at 10, 60, 90 and 120 min, analgesia use, mode of birth and maternal satisfaction.

Statistical analysis: Sample size was calculated to achieve 90% power at an alpha of 0.025 to detect a non-inferiority margin of ≤ 1 cm on the VAS, using a one-sided, two-sample t-test. Baseline demographic and clinical characteristics will be analysed for comparability between groups. Differences in primary (VAS pain score) and secondary outcomes between groups will be analysed by intention to treat and per protocol analysis using Student's t-test and ANOVA.

Conclusion: This study will determine if a single intradermal SWI technique is no less effective than the routinely used four injection technique for lower back pain during labour. The findings will allow midwives to offer women requesting SWI during labour an evidence-based alternative technique more easily administered by staff and accepted by labouring women.

Trial Registration: ACTRN12609000964213

Background

Almost one in three (30%) women in labour suffer from continuous lower back pain [1]. This pain is often associated with varying degrees of fetal malposition, particularly occipito-posterior position, which may apply pressure on pain-sensitive structures within the pelvis

[2]. Characteristically, the pain persists throughout the normal painless resting intervals between contractions and is associated with greater analgesic requirement [2].

Administration of Sterile Water Injections (SWI) into the lower back is used in midwifery to provide pain relief to women experiencing lower back pain during labour. The sterile water causes osmotic and mechanical irritation resulting in a brief (15-30 second) and significant stinging sensation. The onset of pain relief follows

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almost immediately and may last for up to two hours. The procedure can be repeated a number of times [3]. The therapeutic effect has been explained by gate control theory [4] whereby the painful stinging stimulates competing nerve fibres, creating a block to the slower visceral signals from uterine contractions and back pain. The most frequently used SWI technique consists of four intradermal injections into the skin surrounding the Michaelis rhomboid over the sacral area.

Systematic reviews [3,5] and meta-analysis [6] have reported a significant reduction in self-reported pain measures in groups receiving SWI compared with controls. Authors concluded that SWI are an effective therapeutic intervention for the management of continuous back pain during labour. However, the included randomised controlled trials (RCT) were heterogeneous and incorporated different SWI techniques (single and four-injection SWI methods), methods of administration (intradermal or subcutaneous), and comparison groups (normal saline, transcutaneous electronic nerve stimulation and "standard care" defined as massage, counter pressure and water immersion). Authors of the systematic reviews [3,5] highlight that the analgesic efficacy obtained following administration of a single SWI at the most painful point [7] appear comparable to that obtained using the four injection SWI technique. The analgesic benefit of the single SWI method is further supported by results of a more recent randomised controlled trial (RCT) [8] which compared a single SWI to a placebo. The comparable analgesic benefit observed for both techniques has led authors to conclude there is need for further research [3,5]. There have been no trials conducted to date comparing the two SWI techniques.

There may be important clinical benefits in demonstrating the comparable analgesic efficacy of a single versus four needle SWI technique. The relative reduction in discomfort associated with the single injection procedure may increase the woman's satisfaction and acceptability with SWI treatment during labour, and willingness to use the procedure again in the future. In addition, improved resource allocation can be expected as only one midwife is required to administer a single SWI compared with the current recommendation for two midwives to administer the four injection technique. Therefore, the aim of this study is to compare a single intradermal SWI technique with the standard four injection intradermal technique in the degree and duration of analgesic benefit.

Methods/design
A randomised, controlled, non-inferiority design was considered most appropriate method to answer our stated aim. Where two treatments, have both previously been shown to be superior to a placebo, and/or in cases where the use of a placebo may be unethical or impractical, a non inferiority design can be used to determine if one treatment is "no worse" than the other[9,10]. Usually, as in this study, the interventions include a new treatment and an active comparator, or a treatment currently in use. In relation to this trial, the single injection is the new treatment and the four injection technique is the active comparator. The null hypothesis is not proven if the measured effects of the two treatments lie within a specified non-inferiority margin [11].

Hypothesis
The null hypothesis is conventionally stated in an RCT which assumes that there is no difference between the intervention group and controls. The null hypothesis places the onus on the intervention to be proven [12]. The null hypothesis is accepted if it cannot be refuted at the *a priori* defined level of significance. However, a non-inferiority design is attempting to show that two active treatments are similar in effect [13]. Therefore, the null hypothesis cannot be rejected if the measured treatment effects lie within a pre-specified non-inferiority margin [11]. Within non-inferiority design the sample size must be robust enough to test the quantitative or clinically relevant margin or definition of non-inferiority [13]. This margin is informed by considerations of clinically relevance, with any treatment differences falling outside this range indicating that any dissimilarity between treatments is unacceptably large [9].

The predefined non-inferiority margin for the present study was defined by the minimal clinically (i.e. not statistically) significant difference in the Visual Analogue Scale (VAS) to measure self-reported pain. Therefore, the null hypothesis (H_0) would be "treatment is inferior", the alternative hypothesis (H_A) "treatment is non-inferior":

> H_0: Difference between the four injection intradermal SWI and single injection intradermal SWI is ≥ 1 cm on the 10 cm VAS
>
> H_A: Difference between the four injection intradermal SWI and single injection intradermal SWI is < 1 cm on the 10 cm VAS

Study site and population
The study population will be recruited from the Birth Suites of two major maternity hospitals. Women eligible for the study are those that request analgesia for continuous severe lower back pain during labour (≥ 7 on the VAS) and provide informed consent. The categorisation of severe back pain as ≥ 7 on the VAS has been previously validated [14] and consistent with defined

inclusion criteria in previous SWI studies [14-17]. Women with a baseline VAS score of <7 were more likely to find administration of the procedure unacceptable [16].

The eligibility criteria are pre-specified as:

Inclusion criteria
Participants eligible for the study will be defined as:

> Women at term (between 37 and 42 weeks)
> Nulliparous or multiparous
> Singleton pregnancy
> Cephalic presentation
> First stage labour (spontaneous or induced)
> No previous analgesia pharmacological analgesia (nitrous oxide inhalation, narcotics)
> Back pain assessed by VAS as ≥7
> Ability to give informed consent. This may exclude women of non-English speaking backgrounds, where an interpreter is unavailable, and those women whose consent is required to be provided by a parent or guardian.

Exclusion criteria
> Gestation <37 weeks
> Multiple pregnancy
> Malpresentation (Breech Transverse etc.)
> Second stage labour
> Pharmacological analgesia prior to SWI
> Back pain assessed by VAS <7
> Women whose labour would be considered high risk.

Interventions
Control group
Participants randomised to the control group will be given SWI using the standard four injection intradermal technique into the skin surrounding the Michaelis rhomboid over the sacral area. Anatomically, the injections will be administered: two over each posterior superior iliac spine (PSIS) and two three cm below and one cm medial to the PSIS (Figure 1). Minor discrepancies or changes to the anatomical position or alignment of the four injections have not been shown to impact on any analgesic effect [18].
Intervention group
Participants randomised to the intervention group will be given SWI using the single injection intradermal technique.

The anatomical site for the single injection will be over the single most painful point as indicated by the woman (Figure 2).
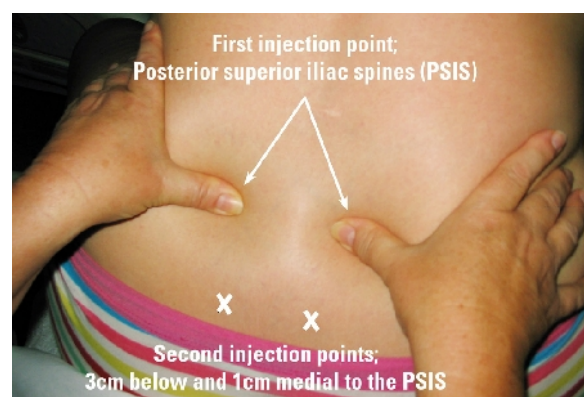
Figure 1 The four injection technique.

Primary outcome
Decrease in pain measured by VAS at 30 minutes post-intervention.
Secondary outcomes
Secondary outcomes will include:

> a) Pain score measured by VAS 10, 60, 90 and 120 mins post-intervention
> b) Level of administration discomfort associated with SWI procedure (measured by VAS at 10 minutes post SWI)
> c) Subsequent analgesia use (pharmacological and non-pharmacological)
> d) Mode of birth
> e) Likelihood to use again with subsequent labour
> f) Patient satisfaction with analgesic effect

Sample size
A sample size of 133 in each group will be required to achieve 90% power to detect non-inferiority using a one-sided, two-sample t-test. The significance (alpha) of the test is 0.025. The non-inferiority margin is ≤ 1 cm on the VAS and the true difference between the means

Figure 2 The single injection technique. Woman indicates the most painful point or central to the most painful area.

is assumed to be zero (cms). A standard deviation (SD) of ± 2.5 on the VAS was conservatively estimated from results reported in a recent meta-analysis [6] of SWI studies. As consent and randomisation will occur in the birth suite, attrition is expected to be minimal. However, we have estimated a 20% attrition to account for cases of precipitate birth prior to the assessment of the primary outcome, or other unforseen reasons for withdrawal such as emergency caesarean section. Thus a total of 319 participants will be required.

Recruitment of participants

Trial participation is invited through public antenatal clinics, antenatal education classes and on the Birth Suites at both recruiting hospitals. Although both sites use a number of models of care in the provision of maternity services, all women return to the public antenatal clinic at a particular gestation; 36 weeks and 30 weeks at the Site One and Site Two, respectively. At this time women will be provided with information regarding the trial. The recruitment strategy aims to provide information regarding the trial prior to presentation to the Birth Suite in labour.

Consent

The recruitment strategies are designed to ensure that women receive information regarding SWI as an intervention for back pain and information on the trial, at or before 36 weeks gestation (i.e. prior to inclusion criteria of 37-42 weeks gestation). The majority of women will consent to the trial on presentation to the Birth Suite in labour at both sites. Clinical midwives and/or clinical facilitators from both sites will be available to receive informed consent. A trial investigator will be available via mobile phone to provide support for midwives undertaking consent and enrolment procedures, and to promote continuity of procedures and trial fidelity across the two sites. Women who have been provided with a participant information sheet and indicate an interest in joining the trial will be able to contact the research midwife or investigators for further information or clarification before consent. A video demonstrating the four injection technique is available for women to access at the trial website. http://maternity.mater.org.au/switch. A form will be placed with the woman's chart to highlight that the woman has consented to participate in the study if eligibility criteria is met. Verbal consent will be re-affirmed immediately prior to randomisation and documented within in the woman's clinical chart. Women are able to withdraw consent at any time (i.e. before, during or after the procedure and/or before completing follow-up questionnaire) without affecting their usual clinical care or request alternative and available means of analgesia.

Randomisation

The randomisation schedule for Site One will be prepared by a statistician using a computer-generated list of random numbers. Blinding of allocation to the study intervention will be undertaken using opaque sealed envelopes prepared by Site One administrative staff. A separate randomisation sequence was generated for Site Two in permuted blocks of four to ensure an equal number of participants across both arms of the trial where smaller recruitment numbers are expected. Blinded allocation at this site will be undertaken using similarly prepared opaque sealed envelopes (Figure 3).

Blinding

At both sites, the envelopes will be kept in a locked cupboard on the birth suite and available for randomisation 24 hours/day. The key will be held by the Midwifery Team Leader who will obtain and open one envelope, then with the assistance of another midwife will administer the SWI using the technique detailed within the envelope. The two midwives will be present during the procedure regardless of the SWI technique being administered, to assist with blinding of the procedure to the midwife providing care and collecting data. The injection site(s) will be covered with a hypoallergenic opaque dressing to prevent visualisation of the number of injections used. The participants will be aware not to discuss the type of intervention they were allocated to with their midwife. The midwife caring for the woman will then return to collect the intervention data.

Data collection

Upon randomisation the attending Midwife will document the following data:

- UR number
- Gravity and Parity
- Gestation
- Spontaneous or induced labour
- Findings of last vaginal exam and time
- VAS score and time
- Time of administration

Following administration of SWI the following data will be recorded:

- VAS related to analgesia effect at 10 mins
- VAS related to discomfort felt during the procedure (at 10 mins)

Figure 3 Randomisation and participant flow.
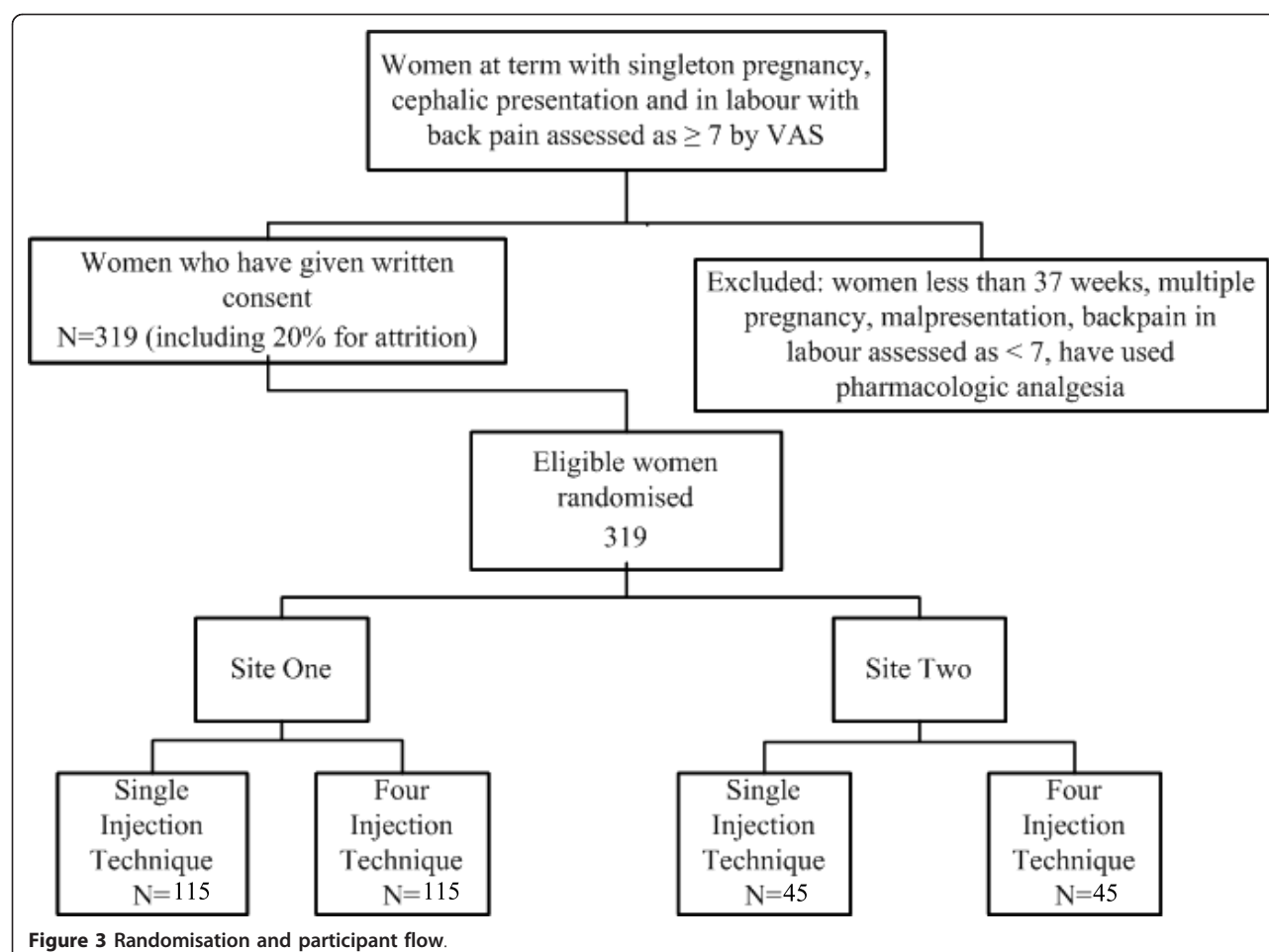
• VAS related to analgesic effect at 30 minute intervals up to 2 hours post procedure

At Site One the following data will be extracted from the obstetric database by the research midwife following birth:

• Age
• Booking weight & BMI
• Mode of birth
• Time of birth
• Any other analgesia used (pharmacological and non pharmacological)
• Model of care
• Educational level

The obstetric databases at Site One and Site Two vary slightly in the data items collected. As separate data collection forms have been generated for the randomisation process for Site Two, the data collection forms have been amended to account for any differences in information captured by the database.

The following self-reported data will be sought from the woman within 48 hours following birth:

• Perceived satisfaction with SWI administration
• Perceived satisfaction with SWI analgesic benefit
• Likelihood to use again with subsequent labour
• Likelihood to recommend to SWI to others

Data will be collected by the Midwife caring for the labouring woman then returned to a securely locked cupboard. Completed data forms will be de-identified and entered into a password protected electronic database. Identified data collection forms will be kept in locked storage for 15 years. Data collection forms at the second site will be stored in a locked cupboard and collected on a fortnightly basis. Data will be entered into a Microsoft Excel spreadsheet and transmitted as a password protected file

Data collection tools

The intrapartum data collection tool has been adapted from an existing document that was used as an audit

tool during the introduction of SWI at Site One. For self reported postnatal data, the data collection tool previously published and used in the Australian study by Peart et al. [16] has been made available for use. This tool has been tested for face readability, language and face validity. The instrument will be administered by a researcher blinded to the particular technique used.

Statistical analysis

Demographic and other baseline characteristics will be analysed for comparability between groups to assess the adequacy of randomisation. Differences in VAS pain score between the two groups will be analysed using Student's t-test and analysis of variance (non-parametric tests used if data is highly clustered toward extremes). Data analysis for the primary outcome will determine if the treatment effect lies within the a priori defined non-inferiority margin (± 1 cm) and the null effect (0 cm) at a one-sided alpha of 0.025. The pre-specified non-inferiority margin was based on a one cm (95% CI 0.6-1.4 cm) minimally clinically significant difference reported for VAS in severe pain [14]. The Mann-Whitney U test will be utilised for non-parametric data and chi-squared test for categorical variables. Women who give birth or elect for narcotic and/or regional analgesia after the collection of the primary measure (VAS score 30 minutes post injection) but before the completion of the secondary outcomes (VAS up to 120 mins) will be included in the trial. Women giving birth or electing for narcotic and/or regional anaesthesia prior to the collection of the primary outcome measure will be included in the Intention to Treat (ITT) analysis. The conservative nature of ITT may obscure differences between treatments groups therefore increasing the chance of falsely declaring equivalence [19]. To address this, some authors have recommended that Per Protocol (PP) analysis also be conducted alongside ITT to provide a more robust conclusion if both methods support the non-inferiority [9,20]. Other authors [21] argue that the benefits of ITT analysis continue to outweigh the PP approach. As it is unlikely that participants in this trial will cross from one intervention to another, the ITT approach will be used unless the dropout out rate exceeds the estimated margin allowed of 20%. Should the dropout rate exceed 20% then a PP analysis will also be conducted. Figure 4 outlines possible scenarios for the outcome of the data analysis based on the pre-defined noninferiority margin, indicated as the shaded area. Error bars indicate 90% confidence intervals (CI). If the CI is completely to the left of zero, the treatment is inferior (scenario A). Scenarios C,D and E indicate noninferiority as the CI lies within the specified margin (shaded area). Scenario F would indicate superiority. An inconclusive result (scenario B) is unlikely as the sample size is sufficiently powered to provide a result [22].

In the event that women experience no relief from the single injection and request the four injection technique, these women will remain within the study, and the data will be analysed according to ITT and per protocol principles.

Women requesting a repeat injection will receive the standard four injection technique. A pre-injection VAS score will be sought prior to administration and post injection VAS score will be collected at 30 minutes. These will be reported separately.

Confidentiality and data security

The data is de-identified, coded and entered onto a password protected database.

Data safety monitoring board

A Data Safety Monitoring Board has not been established for this trial. As there have been no adverse events reported in any previous trial on the topic, the trial was considered to be low risk. However, a senior obstetrician at both sites has agreed to act as a clinical monitor to investigate any adverse events that may be associated with the trial. This process has been approved by the Human Research Ethics Committee at each site.

Project management

Project management will be overseen by the research team that consists of midwifery and obstetric clinicians, midwifery academics and researchers from both sites. The research team will meet regularly during the projects development phase and regular contact and progress reports maintained via email during the recruitment phase of the trial.

Ethical issues

Human Research Ethics Committee (HREC) Approval
  Mater Health Services HREC   No:1422M
  Australian Catholic University HREC   No:Q2009 48
  Royal Brisbane and Women's Hospital HREC   No:
HREC/10/QRBW/155

Women of Non-English Speaking Backgrounds (NESB) and minors

At both sites, an onsite interpreter service is available during "office hours" for the most common language groups of Vietnamese and Mandarin/Cantonese with contract interpreters for eighteen other languages available. At other times the Birth Suite accesses a telephone interpreter service. For NESB women considering SWI as an intervention for back pain, the interpreter service accessed at the time will be utilised to provide information and gain consent for inclusion in the trial. To supplement this, copies of the Participant Information Sheet and consent form will be available in Vietnamese
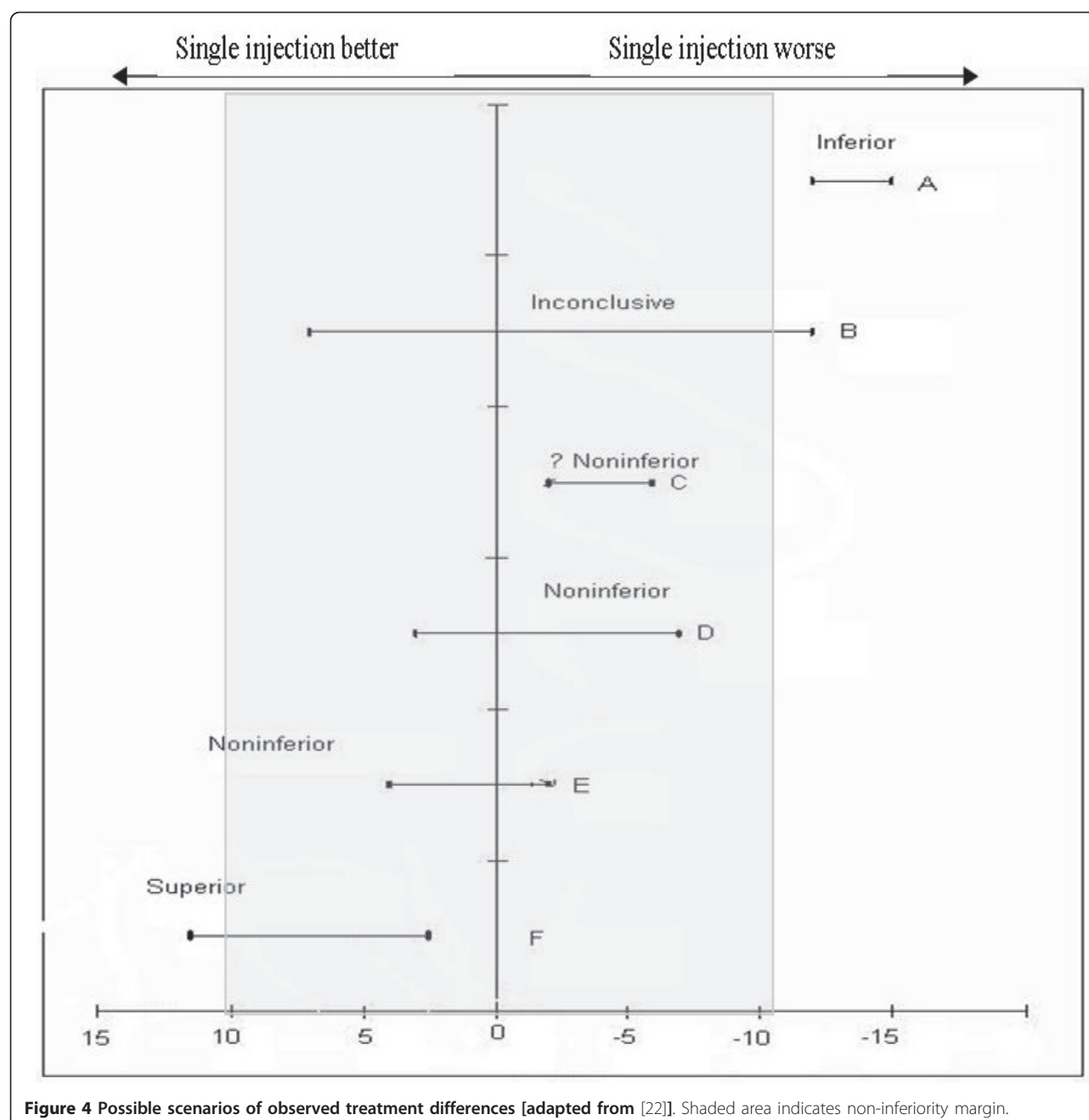
Figure 4 Possible scenarios of observed treatment differences [adapted from [22]**]**. Shaded area indicates non-inferiority margin.

and Mandarin/Cantonese. In the event that a suitable interpreter cannot be found, inclusion in the trial will not be offered. Postnatal data will be collected using this method as interpreters are required when providing routine postnatal information.

Potential risks

The four injection SWI technique is routinely used in the birth suites at Site One. Therefore, no additional risks from study participation would be expected. Moreover, no allergic or systemic reactions to the procedure have been reported in the literature other than the brief

stinging sensation immediately following administration [5].

Discussion

This study employs a randomised controlled non-inferiority design determining if the single SWI technique is non-inferior to the four SWI technique more commonly used in clinical practice. This research gap was identified in the literature.

The project has the potential to make a significant contribution to maternity and midwifery research and

patient care. Nationally and internationally, maternity care is offered in a diverse range of settings and models of care, offering different services and options in terms of pain management. Many women may not have access to narcotics and epidural analgesia, or these forms of analegisia may be unacceptable due to actual or perceived side effects or cultural considerations. The implementation of a best practice, evidenced based SWI technique for the relief of back pain in labour will provide an alternative analgesic option that addresses consumer demand for low intervention strategies. The procedure is not technology dependent, relatively simple, and may be an effective and feasible analgesic strategy suitable for any maternity care setting or model. Therefore, this trial will make a significant contribution to the evidence supporting the most effective administration of SWI. Important clinical (e.g. increased women's satisfaction/acceptability of SWI administration) and cost benefits (e.g. reduced staff/time required for administration) might be expected if the analgesic efficacy of the single needle technique can be shown to be no less effective than the four injection method.

Associate investigators
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Authors' contributions
NL originally conceived the study and has overall responsibility for the trial; NL and PC designed the study and drafted the initial study protocol; SK, MB and JW reviewed the study protocol; NL wrote the grant applications which were reviewed by PC and SK: NL developed the data collection tools and processors; VW and PS co-ordinate recruitment; NL with the assistance of PC, JW and SK will undertake the data analysis; NL, PC, SK, JW and MB drafted the trial protocol manuscript. All authors read and approved the final manuscript.

Project team

Principal investigator

Nigel Lee (Australian Catholic University/Mater Health Services)

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Appendix 20: Publication two: SWITCh trial results

Comparison of a single vs. a four intradermal sterile water injection for relief of lower back pain for women in labour: A randomised controlled trial

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ABSTRACT

Objective: sterile water injections are a simple, safe, effective, non-pharmacological technique for relieving back pain in labour, however the number of injections required to achieve optimal analgesia is unknown. The objective of this trial was to evaluate the degree and duration of analgesia provided by a single injection of sterile water, compared to four injections.
Design: randomised controlled non-inferiority trial.
Participants and setting: three hundred and five women in labour at term, requesting analgesia for back pain were recruited from two metropolitan hospitals in Brisbane, Australia.
Intervention: participants were randomly assigned to receive either one ($n=147$) or four ($n=158$) sterile water injections.
Outcome measures: difference in self-reported pain measured using a visual analogue scale (VAS) between baseline and 30 mins post-intervention. The clinically acceptable margin of difference was defined as ≤ 1 cm on the VAS between the single injection compared to four injection technique. Secondary outcomes include VAS score on injection and 10, 60, 90 and 120 mins post-intervention, analgesia use, mode of birth and maternal satisfaction.
Findings: the mean difference in the pre and post (30 mins) injection scores between two groups was -1.48 cm (95% CI -2.10, -0.86) in favour of the FI technique, however the injection pain associated with the FI was significantly greater than that of the SI technique ($p < 0.001$). There were no significant differences between the two groups in terms of other analgesic use, mode of birth or maternal satisfaction.
Conclusion: the four injection technique was associated with increased level of analgesia at 30 mins post-intervention compared to the single injection, but also a greater degree of injection pain.

Introduction

Almost one in three women in labour suffer from severe lower back pain (Melzack and Schafeberg, 1987; Tzeng and Su, 2008). Clinicians often associate back pain with varying degrees of fetal malposition, particularly an occipito-posterior (OP) position (Simkin, 2010), as this is thought to cause pressure on pain-sensitive structures within the pelvis. Back pain in labour may also be referred pain (Ader et al., 1991). Characteristically, the pain persists throughout the normally painless resting intervals between contractions (Tzeng and Su, 2008). It may be associated with greater use of pharmacological analgesia, including epidural anaesthesia (Hutton et al., 2009) which is associated with a cascade of interventions and iatrogenic sequelae such as increased augmentation of labour, instrumental birth and urinary retention (Lieberman and O'Donoghue, 2002; Weiniger, 2006). Sterile water injections (SWI) administered into the lower back have been demonstrated to provide a suitable analgesic alternative with none of the aforementioned negative outcomes, hence their suitability for women wishing to avoid regional anaesthesia, or in localities where this service is not available (Hutton et al., 2009). The procedure is inexpensive, low technology, safe, and suitable for

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most maternity care settings (Hutton et al., 2009). The injection of sterile water causes somatic and mechanical irritation resulting in a brief (15–30 s), but significant, stinging sensation. Pain relief follows almost immediately and may last for up to 2 hrs; the procedure can be repeated a number of times (Martensson and Wallin, 2008). The physiology of the effect is thought to be related to the stimulation of ascending (gate control theory) (Melzack and Wall, 1965) and descending (diffuse noxious inhibitory controls; DNIC) (Le Bars et al., 1979) pain modulation systems. The most frequently used SWI technique consists of four intradermal injections into the skin surrounding the Michaelis rhomboid over the sacral area (Reynolds, 2000). Two clinicians, working in tandem, administer the injections concurrently.

All the blinded RCTs that have previously compared the four injection (FI) technique using sterile water against normal saline placebo controls demonstrated a statistically significant reduction in pain in favour of SWI (Ader et al., 1990; Trolle et al., 1991; Martensson and Wallin, 1999; Wiruchpongsanon, 2006; Saxena et al., 2009). However Derry et al. (2012) highlighted the need for SWI trials to report findings in a clinically relevant format. The intensity of the injection pain associated with the FI technique, may impact on the acceptability of the procedure to women (Fogarty, 2008; Martensson and Wallin, 2008). Hypothesising that one injection would result in less pain, two studies tested a single injection (SI) technique compared to a placebo and also reported a significant reduction in pain (Bahasadri et al., 2006; Kushtagi and Bhanu, 2009). Prior to our study no SI trial had been designed to compare the analgesic outcomes with the FI technique and hence it was not known if the two techniques provided similar levels of analgesia (Fogarty, 2008; Martensson and Wallin, 2008). The aim of this study was therefore to compare a single intradermal SWI with the four injection technique in both the degree and duration of analgesic effect. The results have significant implications for midwifery practice, and for women seeking alternatives to pharmacological interventions for the relief of back pain in labour.

Design and methods

A randomised, controlled, non-inferiority (NI) study was considered the most appropriate research design. Non-inferiority studies are particularly well suited to comparing an existing treatment with a new variation, and are becoming increasingly common in practice-based RCTs (Scott, 2009).

The study was conducted in two tertiary maternity hospitals in the same Australian city; ethics approval was granted at both sites. Women aged 18 years or over, with a term (37–42 weeks), singleton, cephalic pregnancy, in first stage labour with back pain assessed on a visual analogue scale (VAS) as a score of seven centimetres (cm) or more, and no concomitant serious medical condition, were eligible for inclusion. Previous trials have defined the degree of back pain required for inclusion as 'severe' (Ader et al., 1991; Trolle et al., 1991; Martensson and Wallin, 1999; Bahasadri et al., 2006), this equates to a VAS of ≥ 7 cm (Collins et al., 1997). Consistent with previous trials testing both four and single injection techniques, women who had used pharmacological analgesia prior to randomisation were excluded. Information regarding the trial was provided to women during routine antenatal visits. Consent was obtained in labour, from those who met the inclusion criteria, by a midwife who was not the primary care provider. Following consent, women were randomly allocated to receive SWI using either the single or four injection techniques. Separate randomisation schedules were prepared in advance for both sites using a computer-generated list of random numbers with allocations contained in opaque sealed envelopes. As blinding of participants was not possible, two midwives, who were not directly involved in caring for the woman, performed the

SWI as according to the instructions contained in treatment allocation envelope. The woman's primary midwife, who collected the outcome data, was not present during the procedure and the woman was asked not to discuss the number of injections received. To prevent visualisation, the sites for both the single and for injections were covered with an identical opaque waterproof dressing.

Both techniques involved intradermal injections of 0.1 ml of sterile water; a 1 ml syringe and a 23 gauge (g) needle were used for this purpose. Where randomisation indicated four injections, these were administered into four discrete points surrounding the Michaelis rhomboid over the sacral area: two over each posterior superior iliac spine (PSIS), and two, 2–3 cm below, and 1 cm medial to the PSIS (Lee et al., 2011). This technique is described in previous trials and considered a standard approach (Lytzen et al., 1989; Labrecque et al., 1999; Martensson and Wallin, 1999). Minor discrepancies, including changes to the anatomical position or alignment of the four injections, have not been shown to impact on analgesic effect (Duff, 2008). The single injection was given as recommended (Bahasadri et al., 2006), at the point on the back indicated by the woman as the most painful, or central to the most painful area (Lee et al., 2011). Two midwives performed the FI technique to reduce the time taken to complete the procedure and to enable blinding of the techniques; two midwives were also present for the SI technique. In this trial we used an intradermal, rather than a subcutaneous, method of administration as this is the most common technique used in practice (Fogarty, 2008; Martensson and Wallin, 2008). No differences in analgesic effect between the two methods have been previously reported (Martensson and Wallin, 1999). Using a VAS, women were asked to rate their back pain immediately prior to receiving the intervention, and following the intervention at 10, 30, 60, 90 and 120 mins. Women were also asked to score the injection pain felt during the procedure. On their first postnatal day women were asked to complete a questionnaire regarding their level of satisfaction with the intervention, the best and worst aspects, if they would use the SWI again, or recommend it to other women.

Recruitment

Recruitment occurred between January 2010 and February 2011; 352 women were eligible for inclusion over the study period. Of these, 44 declined participation and a further three were unable to participate for other reasons (Fig. 1). Thirty-two women who declined participation received SWI outside of the trial. A total of 305 women were thus randomised, 215 at Site One and 90 at Site Two.

Statistical methods

The primary outcome for this study was the difference between the groups in pre- and post-injection VAS scores measured at 30 mins. The non-inferiority margin of 1 cm was established, as this represents the minimum change in VAS required to indicate a significant difference in reported pain (Kelly, 2001). Visual analogue scale outcomes have also been reported as dichotomous outcomes for pain relief of at least 50% or 30% difference between pre- and post-injection self-reported pain scores at 10, 30, 60, 90 and 120 mins as this is the recommended format for clinically relevant outcomes detailed in the recent Cochrane review (Derry et al., 2012). Other secondary outcomes include analgesic use other than SWI, mode of birth, satisfaction with SWI, likelihood to use it again, and likelihood to recommend it to other women.

A sample size of 133 in each group was required to achieve 90% power to detect non-inferiority using a single sided 97.5%
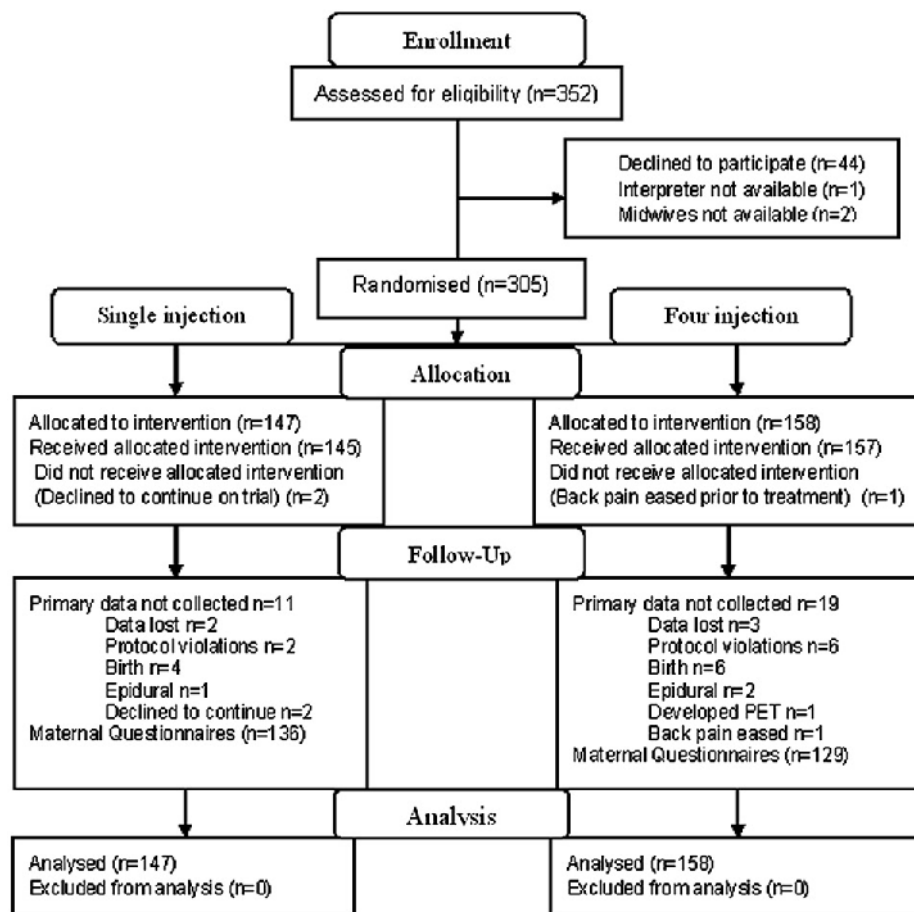
Fig. 1. Participant flow and allocation.

confidence interval (CI). An allowance of 20% was made for attrition, thus a total of 319 participants were required.

Data were analysed using SPSS for Windows, (Rel. 17.0.1. 2008. Chicago: SPSS Inc.). As not all participants returned data for all outcomes, VAS scores were analysed on an available case basis. A per protocol (PP) analysis was also conducted to validate the primary outcome results (Wang et al., 2006; Scott, 2009). Interpretation of NI was based upon the lower end of a two sided 95% CI (equivalent to a single sided 97.5% CI) (Piaggio et al., 2006; Lesaffre, 2008). Non-inferiority is demonstrated if the lower confidence interval bound does not contain any values that are outside the non-inferiority margin (Miller et al., 2006). Data for secondary outcomes were analysed on an intention to treat basis (ITT). Demographic and other baseline characteristics are also reported to assess comparability between groups, however formal statistical testing was not carried out to assess differences. Continuous outcomes were initially analysed using exploratory data analysis to determine if they were normally distributed. An independent t-test was used for variables found to be normally distributed to compare the SI and FI groups, and non-parametric data were analysed using a Mann–Whitney U test. Categorical variables were analysed using χ^2 test or Fisher's exact test when numbers were small. Mean differences and 95% CIs are given for VAS data means and standard deviations (SDs) are used to describe other normally distributed continuous variables. Medians and interquartile ranges (IQR; 25th and 75th centile) are provided for non-parametric data. Relative risk (RR) and associated 95% CIs were calculated to compare analgesia

and birth outcomes between the study groups. The level of statistical significance was set at 0.05.

Results

Baseline characteristics were similar between treatment groups (Table 1), with some differences noted. For example, 24 women (16.4%) in the SI group received their antenatal and intrapartum care through a private obstetrician compared to 12 (7.6%) in the FI group. However, as this imbalance occurred by chance, and insurance status is unlikely to impact on the perception of pain and therefore the primary outcome, no adjustments in the analysis were considered necessary.

Data for the primary outcome were not collected from 30 participants (SI $n=11$; FI $n=19$). Reasons included lost data (SI $n=2$; FI $n=3$), protocol violations such as prior use of pharmacological analgesia (SI $n=1$; FI $n=6$), preterm labour (SI $n=1$), pre VAS score less than seven (FI $n=1$), and pre eclampsia (FI $n=1$). Two participants declined to continue in the trial (SI $n=2$) and for one, her back pain eased prior to injection (FI $n=1$). Ten women gave birth (SI $n=4$; FI $n=6$) and three women received epidurals (SI $n=1$; FI $n=3$) prior to the 30 mins VAS score. Primary outcome data were thus collected from 275 participants (SI $n=136$, FI $n=139$). Not all women completed all VAS scores. The main reasons for incomplete data in both groups were insertion of epidural (SI $n=22$; FI $n=17$) and birth (SI $n=31$; FI $n=28$). Scores were also ceased on women as they entered the second stage of

labour (SI $n=3$; FI $n=6$), when they received pharmacological analgesia (SI $n=2$; FI $n=4$), when they received repeat SWI (SI $n=2$; FI $n=2$), were transferred off the birth suite in early labour (SI $n=4$; FI $n=6$), and for 17 women, reasons for ceasing to collect scores were not recorded (SI $n=8$; FI $n=9$). Ninety per cent of the sample provided primary outcome data and the estimated sample size was achieved. Forty-nine per cent of participants completed all the VAS data.

Primary outcome

The mean difference in the pre- and post (30 mins)-injection scores between the SI and FI groups was -1.48 cm (95% CI -2.10, -0.86, $p < 0.001$) in favour of the FI technique, indicating that, on average the FI provided a greater reduction in pain than the SI technique. The PP analysis demonstrated a difference of 1.51 cm (95% CI -2.13, -0.89, $p < 0.001$). Both CI lower bounds are outside the clinically significant non-inferiority margin of 1 cm (Fig. 2), and therefore the SI technique cannot be considered as non-inferior, or clinically as good, as the FI technique. Fig. 2 illustrates the CI in relation to the line of non-inferiority for the primary outcome. To facilitate comparison, results for VAS scores at other time intervals are also presented in relation to the NI line, although this data was not formally tested for non-inferiority.

Table 1
Baseline characteristics of women enrolled in the trial.

	Single injection n=147	Four injection n=158
*Age	28.8 ± 5.0	27.6 ± 4.9
#BMI	23.4 (20.9 26.7)	23.2 (20.7 26.1)
Tertiary education	94 (64.4)	88 (56.1)
Public insurance	122 (83.6)	146 (92.4)
Nulliparous	106 (72.6)	117 (74.1)
#Gestation	39.6 (39.0 40.0)	39.5 (39.0 40.0)
Spontaneous onset of labour	117 (80.1)	136 (86.1)
#Cervical dilatation	4.0 cm (3.0 5.0)	4.0 cm (3.0 5.0)

Values are number (%) unless otherwise stated.
  * Mean ($\pm$ SD).
  # Median (IQR).

Other VAS outcomes

The median baseline VAS for back pain prior to injection was 8.0 (IQR: 7.0/9.0). Women in the SI group ($n=142$) rated the injection pain (median [IQR] 8.0 [7.0/9.0]) lower than women in the FI group ($n=152$) (median [IQR] 9.0 [8.0/10.0]) ($p < 0.001$). The difference in the number of women experiencing 50% or more, or a 30% or more reduction in pain following injection was statistically significant up to 60 mins post-intervention. After 60 mins, more women in the FI group continued to report a reduction in pain compared to the SI group, although the difference was not statistically significant (Table 2).

Analgesia and birth outcomes

There were no differences in the use of pharmacological analgesia subsequent to the administration of either technique. The relative risk (RR) for the final choice of pharmacological analgesia compared to no analgesic use is provided in Table 3.

There were no differences observed in mode of birth. The rates of normal vaginal birth (NVB) were 65.3% ($n=96$ SI) and 62.0% ($n=98$ FI). The RR for instrumental (ventouse or forceps) and caesarean section (CS) compared to NVB is provided in Table 4.

Obstructed labour was the most frequently cited indication for CS, accounting for 30 (60.0%) of such births. A further 16 (32.0%) CS were performed for non-reassuring fetal status. One woman in the SI group and two women in the FI group underwent a CS for an unexpected breech presentation in labour.

Repeat injections

Pre and 30 mins post-injection VAS scores were collected on 19 women who requested repeat injections; the FI technique was used in all cases. The median (IQR) pre-injection VAS score was 8.00 cm (6.75/10.00). The mean difference between pre-injection and thirty minutes post injection was 4.89 cm (SD 2.73). Although this cohort is small, the difference was statistically significant ($p < 0.001$). Thirteen women (68%) reported a reduction in pain of 50% or more and 16 women (84%) reported a reduction in pain of 30% or more. This suggests that repeat injections can re-establish the analgesic effect.
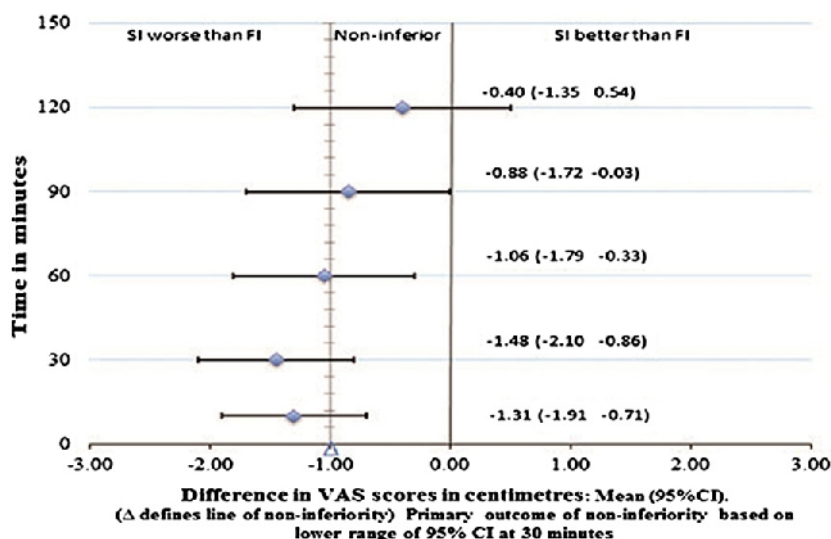
Fig. 2. Observed treatment difference for primary (30 mins) and secondary outcomes of single vs. four injection at different time intervals.

Table 2
Number of participants with difference in pre- and post-injection VAS scores of equal to or greater than 50% and 30%.

Time since injection (mins)	Single injection			Four injection			p value for ≥ 50%	p value for ≥ 30%
	n	≥ 50%	≥ 30%	n	≥ 50%	≥ 30%		
10	138	75 (54.3)	96 (69.5)	147	107 (72.8)	128 (87.0)	0.001	< 0.001
30	136	68 (50.0)	93 (68.3)	139	102 (73.3)	117 (84.1)	< 0.001	0.002
60	108	48 (44.4)	69 (63.9)	125	75 (60.0)	95 (87.9)	0.017	0.043
90	82	31 (37.8)	43 (52.4)	100	49 (49.0)	64 (64.0)	0.130	0.114
120	70	27 (38.5)	35 (50.0)	83	36 (43.3)	45 (54.2)	0.547	0.602

Values are number (%).

Table 3
Comparison of pharmacological use between groups and relative risk (RR).

Type of pharmacological analgesia	Single injection, n=148	Four injection, n=157	RR (95% CI) reference group='No analgesia used'
No analgesia used	26 (17.5)	33 (21.0)	1.00
Nitrous oxide inhalation	47 (31.7)	37 (23.5)	1.27 (0.90-1.79)
IM/IV narcotics	13 (8.8)	17 (10.1)	0.92 (0.54-1.58)
Epidural	62 (41.8)	70 (44.9)	1.06 (0.75-1.49)

Values are number (%).

Table 4
Comparison of mode of birth between groups and relative risk (RR)..

Mode of birth	Single injection, n=147	Four injection, n=158	RR (95% CI) reference group=normal vaginal Birth
Normal vaginal birth	96 (65.3)	98 (62)	1.00
Ventouse	21 (14.3)	26 (16.5)	0.91 (0.68–1.22)
Forceps	7 (4.8)	7 (4.4)	1.10 (0.56–1.74)
Caesarean section	23 (15.6)	27 (17.1)	0.93 (0.70–1.25)

Values are number (%).

Responses to the postnatal questionnaire

Two hundred and sixty-two women (85.0%) completed a questionnaire administered on the first postnatal day; distribution of respondents was similar between groups: SI (133; 90.0%) and FI groups (129; 82.0%). There was no difference in the number of women who reported being 'very satisfied' or 'satisfied' with either technique (SI 88, 66.2%; FI 97, 75.2%, $p=0.142$). Thirty-six women in the SI group (12.4%) compared with twenty-six women in the FI group (6.6%) responded that they were 'dissatisfied' or 'very dissatisfied'. There were no differences in the proportion of women who stated that they would choose SWI again (SI 91, 66.9%; FI 89, 70.54%, $p=0.618$) or recommend it to other women (SI 105, 81.4%, FI 101, 75.9%, $p=0.353$). Women were asked to comment on the best ('what you liked most') and worst ('what you liked least') aspects of using SWI. The degree of analgesia, the speed of onset of pain relief, and the non-pharmacological nature of the intervention were rated as the most positive aspects. The pain associated with injections was most frequently cited as the worst aspect, particularly when the analgesic affect was perceived as ineffective or insufficient. There was no difference in the median [IQR] VAS score for injection pain in treatment groups

between women who were very satisfied/satisfied and those women who were very dissatisfied/dissatisfied (SI 8.0 [7.0/9.0], $p=0.979$; FI 9.0 [8.0/10.0], $p=0.086$), would or would not use SWI again (SI 8.0 [7.0/9.0], $p=0.317$; FI 8.0 [9.0/10.0], $p=0.140$) and would or would not recommend to other women (SI 8.0 [7.0/9.0], $p=0.836$; FI 8.0 [9.0/10.0], $p=0.129$). However the mean difference in VAS scores at 30 mins was significantly different in women reporting very satisfied/satisfied and those very dissatisfied/dissatisfied (SI 2.67, 95% CI 1.66–3.69, $p < 0.001$; FI 2.32, 95% CI 1.30–3.36, $p < 0.001$). Similarly, the mean difference in VAS scores was also significantly different in women who would, or would not, use SWI again (SI 1.37, 95% CI 0.44–2.29, $p=0.004$; FI 2.00, 95% CI 1.05–2.93, $p < 0.001$) and women who would, or would not, recommend SWI to other women (SI 1.76, 95% CI 0.67–2.85, $p=0.002$; FI 1.62, 95% CI 0.57–2.68, $p=0.003$).

Discussion

To our knowledge this is the first trial to compare the single and four SWI techniques. Our study makes a significant contribution to the small, but growing, body of evidence exploring the most effective technique for administering SWI. The results indicate that four injections administered concurrently provided a greater depth of analgesia than a single injection. The four injection technique achieved a 70% reduction in back pain. This is similar to reductions in pain levels (64–70%), between 30 and 45 mins post-injection, observed by other studies that compared the FI technique to a normal saline placebo (Trolle et al., 1991; Martensson and Wallin, 1999; Wiruchpongsanon, 2006; Saxena et al., 2009). When the SI technique was used, pain levels were reduced by 51%, which is almost identical to findings of previous SI trials (Bahasadri et al., 2006; Kushtagi and Bhanu, 2009). The FI technique generally requires two midwives for administration purposes (Duff, 2008), which may prove difficult to accommodate in some practice settings, including out of hospital locations. Although the SI technique may be offered as a viable alternative in these settings, our findings suggest that the depth of analgesia may be lower and of a shorter duration. These differences may be of greater relevance for nulliparous women with back pain in early labour than for multiparous women with back pain in more advanced stages of labour who might reasonably be expected to require less analgesia. Our findings demonstrate that repeat injections are effective and will successfully re-establish analgesic effect.

As previously reported, the pain associated with administration negatively impacted on women's experiences of SWI (Fogarty, 2008; Martensson and Wallin, 2008). Similarly in this study, women's responses to questions regarding the worst aspect of SWI were dominated by remarks concerning the pain associated with the injection(s). Bahasadri et al. (2006) theorised that a single SWI would result in less injection pain therefore

increasing acceptability. Unsurprisingly, women in our study rated the FI technique as more painful than the SI, although there were no differences in VAS scores of injection pain between those who expressed satisfaction or dissatisfaction, who would or would not use SWI again, or recommend it to other women. Women with a greater difference in pre- and post-injections scores were more likely to rate the experience positively, regardless of the perceived administration pain. Previous research (Lytzen et al., 1989; Martensson and Wallin, 1999) has demonstrated a similar relationship exists between women who found SWI effective or ineffective, and those who would, or would not, use the procedure again. If the injection pain itself was a significant negative factor in the experience of SWI it is likely that there would be greater disparity between the numbers of women rating the effect of SWI as effective and those likely to use it again. This suggests that women will accept the pain associated with injection(s) providing there is analgesic benefit and conversely, injection pain is likely to influence ratings of dissatisfaction when the procedure is perceived as ineffective. Also, a limiting factor for this study is the sensitivity and design of the VAS for measuring differences between different types of pain that may occur concurrently, such as abdominal and back pain, and the injection pain associated with SWI. If a woman rates her labour pain towards the 'worst pain imaginable' and then experiences a significantly greater pain, there is not the scope within the instrument to rate the pain beyond this fixed endpoint (Bergh et al., 2009). Additionally, the interpretation of the maximum description of pain, 'worst pain imaginable', may change as the intensity of labour progresses (Wei et al., 2010). Therefore the experience of the injection pain may be greater in the early stage of labour when other concurrent pain may be less severe.

An interesting outcome of this study is that the level of analgesia provided by SWI is related, at least in some degree, to the scale of the discomfort associated with the injections. Previous studies have suggested that the physiology behind SWI involves stimulation of ascending and descending pain modulation systems (Ader et al., 1991; Trolle et al., 1991; Martensson and Wallin, 1999). Therefore the greater degree of injection pain stimulates an increased pain modulating response, providing greater depth and duration of analgesia. However this effect did not appear to be proportionate, in that the FI did not provide four times the analgesic effect.

The OP position of the fetus has been cited as a common contributing factor for back pain in labour although there appears to be insufficient evidence to support or refute this claim (Simkin, 2010). The OP position is known to be a contributing factor in obstructed labour which increases the risk of interventions such as epidural anaesthesia and CS (Kjaergaard et al., 2008). In this study, obstructed labour was the main indication for both instrumental birth and CS in both groups; no significant differences were observed between the two groups for rates of CS. Fetal position prior to receiving SWI was not recorded in this study, however one study reported that 40% of participating women had a fetus in the OP position (Labrecque et al., 1999), although how fetal position was determined is not described. Trolle et al. (1991) also reported a higher incidence of CS in their control group, where OP position was cited as common indication (42%). The meta-analysis by Hutton et al. (2009) reported a 49% difference in CS rates in women receiving SWI compared to control groups in eight SWI studies involving 828 women, concluding that a large RCT is required to investigate the effect of SWI on birth outcomes such as CS. It is currently not known if the rates of epidural analgesia and CS are likely to be higher in women who report back pain in labour. Our study was not sufficiently powered to determine effects of SWI on birth outcomes, specifically caesarean section, and pharmacological analgesic use. Future trials should be powered to include CS as the most clinically important primary end point.

Clinical implications

This study has demonstrated that SWI is effective in relieving back pain, with the FI technique being clinically more effective than the SI in providing significantly better analgesia at 30 mins post-injection. Repeat injections are effective in re-establishing analgesia. In some practice areas, particularly where only one care provider is available, the SI technique is a suitable alternative to FI. Similarly, if women wish to avoid the increased discomfort associated with four injections, and are aware that the quality and duration of the analgesia may be less, then the SI technique may be recommended. The technique is acceptable to women, although the pain associated with injection(s) appears to reduce satisfaction scores when the analgesic effect is perceived as inadequate. Further research into variations in SWI techniques are needed, for example regarding the optimal tissue depth for injection, and the volume of sterile water injected to obtain the greatest analgesic benefit, with the least associated discomfort.

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