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Measuring the quantity and quality of midwifery support of women during labour and childbirth:

The development and testing of the 'Supportive Midwifery in Labour Instrument'

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ABSTRACT

The thesis describes the development and testing of a new computer based systematic observation instrument designed to facilitate the recording and measurement of the quantity and quality of midwifery intrapartum support. The content of the systematic observation instrument, the 'SMILI' (Supportive Midwifery in Labour Instrument), was based on a comprehensive review of the literature. The instrument was found to be valid and reliable in a series of studies. The feasibility and usability of the SMILI was extensively tested in the clinical setting in four maternity units in Scotland, UK. One hundred and five hours of direct observation of forty nine labour episodes were undertaken by four trained midwife observers.

The clinical study demonstrated that the study and the instrument were feasible, usable and successful in measuring the quantity and quality of midwifery intrapartum support. The data collected has provided significant new information about the support given by midwives in the National Health Service of Scotland, UK. Continuous one to one support was the norm, with 92% of the observed midwives in the room for more than 80% of the observation period. Emotional support, including rapport building, encouragement and praise, was the most frequently recorded category of support.

Key Words:

Support; Labour; Systematic Direct Observation; Midwife; Quality; Quantity; Observation instrument;

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PERSONAL STATEMENT

As a clinical midwife submitting a proposal to undertake a doctoral study, my central aim was to undertake research that would provide new evidence to improve the impact of my and my colleagues' practice in the labour room. Working as a consultant midwife with a particular remit for promoting normal birth, I had become aware of the considerable variation between the behaviours of my colleagues and their approaches to providing support to women during labour. In the unit in which I was working we were privileged to have enough staff to provide one to one care to all women in active labour, yet some midwives seemed to feel unsure about what to do to support women in coping with labour and spent a considerable amount of time out of the labour room undertaking other tasks. Some of the midwives appeared to consider their role and effect as relatively unimportant. One colleague commented 'I don't think they really want me in there, they're either going to do it or they're not'. I encountered the view from several midwives who felt that labour and childbirth is a physiological process that would either proceed smoothly or not with little influence from the midwife. The midwife's role was seen as identifying when things were not proceeding smoothly and instigating the appropriate interventions. Other colleagues had a quite different approach and would stay continuously with the woman providing encouragement, praise and physical support such as massage. As the consultant midwife on the maternity unit, part of my role was to promote the adoption of evidence based practice, however evidence on the content of care in a labour room that would have the best impact on promoting the most normal birth possible for the woman appeared to be very scarce. When the opportunity arose to undertake a PhD sponsored fully by the Royal College of Midwives with the overall goal of contributing to our knowledge of how best to promote normal birth, I was clear where my focus would lie. While it was very apparent that large scale factors such as staffing levels, system configuration, demographics and government policy had an impact on our ability to assist women to have the most normal birth possible, I was keen to ensure that the 'small scale factor' of what went on in the labour room between the midwife and

the woman she cared for was based on robust evidence. I submitted my proposal, it was accepted and my study of midwifery support in labour began.

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Glossary of Terms

Term used in thesis	Definition (author's own)
Induction of labour	Medical process undertaken to instigate labour. A number of methods may be used including chemical (prostaglandins or syntocinon) or surgical (amniotomy).
Augmentation of labour	Medical process undertaken to speed up the progress of labour. A number of methods may be used, as for induction.
Labour dystocia	Difficult or abnormally slow labour.
Electronic Fetal Monitoring or Cardiotocography (CTG)	The monitoring of the fetal heart beat and uterine contractions electronically during pregnancy and labour. This generally requires the use of two external transducers attached to the maternal abdomen.
Fetal hypoxia	Where the fetus is deprived of an adequate supply of oxygen in the uterus.
Amniotomy/ ARM or Artificial rupture of the membranes	Surgical rupture of the amniotic sac to induce or augment labour.
Prostaglandin gel	Synthetic form of naturally occurring hormone with oxytocic properties, inserted into the vagina to assist in the induction of labour.
Intravenous syntocinon	Synthetic form of the hormone oxytocin which stimulates contraction of the uterus in order to induce or augment labour.
Epidural analgesia	Form of local anaesthesia used in labour. Local anaesthetic is injected into the epidural space in order to temporarily block the spinal nerves.
Ventouse birth	A form of operative vaginal delivery where a vacuum extraction cap is applied to the fetal scalp in order to expedite delivery.
Forceps delivery	A form of operative vaginal delivery where two metal blades are applied to the fetal head to assist delivery.
Episiotomy	A surgical incision made to the perineal body during advanced second stage of labour to enlarge the vaginal orifice in order to expedite delivery of the fetus.
Perineal trauma	Damage to the perineal body during birth.
Perineum/Perineal body	The fibromuscular pyramid between the lower third of the vagina anteriorly, the anal canal posteriorly and the ischial tuberosities laterally.
Fetal Scalp Electrode	Invasive method of continuous electronic fetal monitoring through the attachment of a monitor to the fetal scalp during labour.

CHAPTER ONE - INTRODUCTION

The funding body for the PhD studentship which enabled this study to be undertaken is the professional body for midwives in the UK, the Royal College of Midwives (RCM). The goal of the studentship set by the RCM was the generation of new knowledge to assist in the promotion of normal birth and the reduction in unnecessary medical interventions in childbirth. The ultimate aim of the research detailed in the thesis that follows is to make an original contribution to knowledge of the professional support provided to women during labour and childbirth, in order to improve the quality of clinical care and women's experiences.

This aim is achieved through the identification of the current knowledge of intrapartum support, the gaps in that knowledge and the development of a research method specifically designed to address those gaps. The series of interlinked studies detailed in the thesis that follows describe the development and clinical testing of a novel computer based data collection instrument designed to record and measure the quantity and quality of intrapartum midwifery support in order to inform clinical practice:

'*It is only with careful and systematic inquiry about the nature of midwifery care that the profession can clearly define and explicate a model of excellence that can be upheld as a standard for all women'* (p4 Kennedy 2000).

The introductory chapter which follows sets the scene for these studies through broadly outlining the current global context of childbirth, highlighting the particular issues of high intervention levels in childbirth in developed countries and defining 'normal childbirth'.

1.1 BACKGROUND

Childbirth has short, medium and long-term implications for the well-being of babies, women, their families and society (Clement 1998, Brown and Lumley 1998b, Creedy et al 2000, Bick 2003 and 2009a, Betran et al 2007, CEMACH 2007, Villar et al 2007, Bager and Wohlfahrt 2008, Hansen et al 2008). The type of care provided to women during pregnancy and childbirth has significant consequences for maternal and neonatal mortality and morbidity and women's psychological and emotional well-being in early motherhood (Oakley 1980 and 1993, O'Hara 1986, Morris-Thompson 1992, Bick and MacArthur 1994 and 1995, Green et al 1998, Clement et al 1999, Bick 2003 and 2009, Schytt and Waldenstrom 2007, Villar et al 2007, Bager and Wohlfahrt 2008, Hansen et al 2008, Knight et al 2008, Leeds and Hargreaves 2008, Leung and Leung 2008, Liston 2008, Pallasmaa et al 2008).

While this study focuses on the care of women during childbirth in the developed world, it is helpful to place this care in its broader international context. Worldwide, there are clear differences between the problems faced by childbearing women in developing countries and those of women in developed countries. In developing countries, childbirth remains a major cause of mortality and morbidity, with as many as one in eight women dying as a result of pregnancy related complications (www.who.int/reproductivehealth accessed 24.10.11). In 2008, an estimated 358,000 women died while pregnant or giving birth, 99% of these maternal deaths were in developing countries (Hogan et al 2010). Each year up to eight million women suffer serious illnesses and lifelong disabilities as result of pregnancy related complications (UNFPA 2011). The 58 countries with the highest rates of maternal, fetal and newborn mortality account for 91% of the world's maternal deaths, but have less than 17% of the world's skilled birth attendants. Only one third of women in many developing countries have access to skilled birth attendants (UNFPA 2011).

In developed countries, childbirth has changed dramatically over the last century. Public health improvements, pharmacological and surgical developments and the universal provision of

professionalised healthcare led to dramatic falls in mortality rates of mothers and babies (Loudon 1992). Significant problems exist, however. The rates of medical interventions in the childbirth process including the number of births by caesarean section have risen very dramatically over the last 40-50 years. These increases cause concern to many as these very high levels of intervention have increasingly been demonstrated to bring risks as well as the benefits for which they were developed.

Medical interventions such as induction of labour, augmentation of labour, epidural analgesia, episiotomy and electronic fetal monitoring were originally developed to identify and respond to serious problems and prevent morbidity and mortality. In many developed countries, these interventions became part of routinised care and have often been employed where no pathology is identified (Williams et al 1998a, Mead et al 2000, Downe et al 2001, Albers 2007). Such routinised use does not improve key outcomes such as neonatal and maternal morbidity and mortality and is linked to an increased chance of further medical interventions, known as the 'cascade of intervention', creating an iatrogenic effect (Eason et al 2000, Roberts et al 2000, Tracy and Tracy 2003, Althabe et al 2004, Howell 2005, Devane et al 2005, Alfrivic et al 2006, Albers 2007). Over the last thirty years, the rates of lower segment caesarean section (surgical delivery of a baby rather than vaginal birth) have risen dramatically, from 5% of births in developed countries in the 1970s, to more than 50% in some regions (Villar et al 2007). The World Health Organisation (WHO) recommends an average caesarean section rate of 15% of all births for optimal outcomes (WHO, 1985). In the UK, the average national annual caesarean section rate rose from 12% in 1990 to 24.8% in 2009/10 (Information Services Division 2011, Information Centre NHS England 2011). This rise has not been correlated with a reduction in perinatal mortality and morbidity (Barros 2005, Costello and Osrin 2005, CMACE 2010). In the USA, which has an average caesarean section rate of 31%, maternal mortality rates have risen from 6.6 per 100,000 in 1987 to 13.3 per 100,000 in 2006 (Amnesty International 2010). A growing body of research identifies significant risks to mothers and babies of caesarean birth. These include increased rates of serious maternal and neonatal morbidity and hospitalisation

and of longer term childhood problems associated with food allergies, asthma and type one diabetes (Villar and Valladares 2006, Bager and Wohlfahrt 2008, Hansen et al 2008, Knight et al 2008, Leung and Leung 2008, Liston 2008, Pallasmaa et al 2008). In the triennial UK enquiry into maternal deaths, elective caesarean section (non-emergency operative delivery carried out before labour commences) was found to represent a 2.84 greater risk of maternal death than a vaginal birth (CEMACH 2007), leading the authors to conclude 'the operation is not as risk free as many have thought' (CEMACH 2007). A retrospective register based study for 110,717 singleton births in Finland between 1997 and 2002 found the rate of severe maternal morbidity was 5.2 per 1000 for vaginal birth, 12.1 for elective caesarean and 27.2 for intrapartum caesarean, leading the authors to conclude 'caesarean delivery, even an elective one, carries a significantly higher risk of life-threatening maternal complications than vaginal delivery' (Pallasmaa et al 2008).

A WHO study examining data from 126 countries found that in developed countries with overall low mortality, there was a direct association between higher rates of caesarean and mortality: 'Caesarean section rates above 15% are predominantly correlated with higher maternal mortality. A similar pattern is found for infant and neonatal mortality' (p111 Betran et al 2007). The increased rate of medical interventions and caesarean section have significant financial as well as health costs: it is estimated that a caesarean birth costs approximately three times as much as an uncomplicated vaginal delivery (Henderson et al 2001, Petrou and Glazener 2002, Tracy and Tracy 2003). These financial costs were highlighted by a comprehensive retrospective study examining neonatal health in Brazil, which concluded that: 'the increased medicalisation of pregnancy and childbirth led to changes that are at best wasteful, if not downright iatrogenic' (p851 Barros 2005).

The dominant medicalised maternity care system in developed countries has other consequences for women and their families. The majority of women in the UK express the preference to give birth with as little medical intervention as necessary (RCOG 2001, Green et al 2003, Turner 2008). A systematic review of studies suggests that only a small minority of

women worldwide would prefer a caesarean birth to a vaginal birth (Mazzoni 2011). Studies have identified negative psychological consequences for some women of medical interventions in labour (Oakley 1980, O'Hara 1986, Green and Coupland 1990, Clement et al 1999). Research identifies clear links between the number of medical interventions during childbirth and women's perceptions of inadequate care during labour, and the development of acute post-traumatic symptoms in around 6% of women postnatally (Creedy et al 2000). There is evidence that women have life-long memories of their children's births (Simkin 1991, Beech and Phipps 2004), poor experiences can undermine the development of a positive mother-baby attachment (Morris-Thompson 1992, Oakley 1993, Schytt and Waldenstrom 2007, Davies et al 2008, Leeds and Hargreaves 2008) and can influence women's decisions about future childbearing negatively (Ryding 1993). Women's views and memories of their child's birth are increasingly recognised as important outcomes of childbirth in their own right alongside physical well-being (Lavender and Walkinshaw 1998, Lavender et al 1999 and 2006, NCT 2002, Beech and Phipps 2004).

In response to this growing body of evidence, the reduction of unnecessary medical interventions in pregnancy, labour and childbirth and a concomitant rise in normal birth is a priority identified by many governments, including the UK's, along with international and national professional and lay organisations (Beech and Phipps 2004, RCM 2004, ICM 2005, DoH 2007, MCWP 2007, NICE 2007, NHS QIS 2009).

1.3 DEFINITION OF NORMAL BIRTH AND INTERVENTIONS IN CHILDBIRTH

The overall goal of this study, defined by the funding body the Royal College of Midwives UK, was the generation of new knowledge to assist in the promotion of normal birth and the reduction in unnecessary medical interventions in childbirth. It is perhaps helpful at this point to define both of these central concepts. What is a 'normal birth' and what are 'unnecessary medical interventions'?

It is possible to answer the question 'what is normal birth?' in a number of ways. Childbirth is a physical event with one clear and specific outcome: the arrival of a newborn (or newborns). Childbirth has been a central part of the human experience throughout history and across all different societies and cultures. Different levels of response to the question 'what is normal birth?' are required and are relevant for different purposes. Broad definitions of normal birth have been developed by all the national and international bodies with an interest in maternal and child health. The World Health Organisation definition of normal birth is:

'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 both mother and infant are in good condition' (p4 WHO, 1996).

The International Congress of Midwives' definition of normal birth is:

'A unique dynamic process in which fetal and maternal physiologies and psychosocial contexts interact (with the goal of mother and baby being well). Normal birth is where the woman commences, continues and completes labour with the infant being born spontaneously at term with cephalic presentation, without any surgical, medical or pharmaceutical intervention but with the possibility of referral when needed' (p1 ICM, 2008).

Such definitions set the general parameters for the definition of a birth as 'normal' but do not seek to provide more detailed differentiation between normal and abnormal labour and birth. It is at the more detailed level and the translation of definitions of normality into clinical practice that controversies and differences arise. One area of controversy is the definition of 'low risk' as alluded to in the WHO definition. Clinical practice in maternity care systems in many developed countries has become defined by a medical model that views labour and childbirth as 'normal only in retrospect' (Wagner 1994, Gould 2000), labour and childbirth are considered to be inherently 'high risk' (Hull et al 1986, O'Driscoll and Meagher 1986). This view has led to the development of practices to manage these risks such as augmentation to hasten labour progress if cervical dilatation proceeds at a rate slower than 1cm an hour to prevent labour

dystocia (Hull et al 1986, Dunnihoo 1990), routine continuous electronic fetal monitoring to identify fetal hypoxia and prevent injury to the fetus (Williams et al 1998a) and routine episiotomy to prevent severe perineal trauma (Albers et al 1999, Eason et al 2000). Robust evidence has emerged that such practices, when carried out routinely, can create more morbidity than they prevent: high quality research evidence indicates that the rate of normal progress in a first labour may be as slow as 0.5cm an hour rather than 1cm (Menticoglou et al 1995), that continuous electronic fetal monitoring for women without significant risk factors increases the rates of operative delivery without reducing the rates of fetal hypoxia and neonatal morbidity and mortality (Devane et al 2005, Alfrivic et al 2006) and that routine episiotomy rather than selective episiotomy leads to more severe perineal trauma without reducing risks to the neonate (Albers et al 1999, Eason et al 2000, Carroli and Belizan 2004). If practitioners are advised, for example, that a labour progressing at a rate slower than 1cm an hour has become higher risk and requires intervention or that all women admitted in labour should have electronic fetal monitoring, then 'unnecessary medical interventions' are likely to be instigated.

Translation of research findings into practice is not universal and can be very slow as it may require attitudinal as well as behavioural change on the part of maternity care professionals. The use of medical interventions in childbirth has become so common and is so variable between different settings, it appears clear that medical interventions are not only used in response to pathology. A study of five maternity units in the UK to identify the rates of medical intervention in 'spontaneous vaginal deliveries', found that 62.3% of women recorded as having a 'spontaneous vaginal delivery' had had a medical intervention such as amniotomy, epidural, episiotomy or intravenous oxytocin, leading the authors to conclude:

'Within the maternity services abnormality is becoming more often defined as a deviation from the average, rather than as a pathological entity in its own right. This leads to more women becoming defined into 'at risk' groups. There is some evidence that such a categorisation may benefit a few, but risk increased intervention with consequent morbidity for the many' (p602 Downe et al 2001).

Definitions of 'normal birth' are often worded in terms of the presence or absence of interventions. A UK lay organisation, AIMS (Association for the Improvement in Maternity Services) has proposed three potential categories for defining births:

1. *Operative or instrumental delivery (caesarean section, forceps or ventouse)*
2. *Obstetric delivery (that is a vaginal birth preceded by a variety of interventions such as artificial rupture of membranes (ARM), prostaglandin gel, induction of labour, syntocinon augmentation, epidural and episiotomy)*
3. *Normal birth* (p62 Beech and Phipps 2004).

The definition of normal birth is inextricably linked with the concept of interventions in childbirth. The National Institute for Health and Clinical Excellence (NICE) defines interventions as '*a healthcare action intended to benefit the patient, for example a drug treatment, psychological therapy or surgical procedure'* (p xv NICE 2007). Interventions can be any behaviour or action by the health professional. One leading obstetrician is quoted as saying: '*when you are dealing with normality, even shaking a pregnant woman by the hand is an intervention*' (Murray Enkin quoted p208 in Anderson 2002), '*the midwife herself is a significant intervention*' (p208 Anderson 2002). It can be argued that interventions in childbirth should not be categorised simplistically as good or bad, but that all interventions should be recognised as such, considered carefully and be evidence-based.

In seeking to develop a robust definition of normal childbirth for the purposes of this thesis, an exploration of the debate about the nature of 'normality' in the broader literature outside maternity was undertaken. This found three key approaches to defining normality: statistical, physiological and evaluative. Statistical definitions of normality are based on the distribution of particular characteristics in a particular population (Clegg 1982, Watson et al 2000). If a characteristic is normally distributed, it is possible to define a mean and outer deviations from the norm using centiles or standard deviations (Clancy and McVicar 2002). A number of characteristics of childbirth have been defined statistically to assist clinical decision-making, including length of pregnancy and length of labour. The lower and upper 5 or 10% of a

characteristic in a population are generally used to identify risk of a pathology and instigate particular approaches to care to attempt to manage these risks (for example use of continuous electronic fetal monitoring and syntocinon to augment labour). The statistical framework defines a pregnancy and labour as normal if all characteristics fall inside the mid 80-90% range for the general population. On its own, the statistical approach is helpful but can provide only a partial description of normality in childbirth, as it excludes 'unusual normality' (Wachbroit 1994).

A physiological definition of childbirth, however, acknowledges that normality is that which is functional rather than simply usual (Wachbroit 1994). This approach identifies that most women can give birth vaginally without medical intervention, that the maternal-fetal system has evolved to instigate, sustain and complete the birth process preserving maternal and fetal health, and that care provided will seek to support this physiology and assist the maintenance of homeostasis. The physiological definition can be helpful in assessing whether the care provided is based on the best available evidence on the physiology of childbirth and its maintenance.

The evaluative definition of normality recognises that any definition of normality involves an assessment and appraisal of what happens during labour and birth by those involved in the process (Malim and Birch 1998). The society and culture in which birth takes place affect what is considered to be natural and normal:

'*Normality is, of course, culturally defined and, in seeking to fix it we are taking part in that cultural process*' (p32 Downe 2001b).

Women's responses to their childbirth experience play a central part in the definition of a birth as 'normal' or 'abnormal'.

For the purpose of this thesis, the definition of normal childbirth employed incorporates statistical, physiological and evaluative approaches. Normal birth is defined as:

A physiological, social and psychological process which results in the spontaneous birth of a baby at term. The woman commences labour spontaneously between 37 and 42 weeks of pregnancy with a singleton fetus presenting by the vertex. The mother receives continuous care during labour which supports the physiological and psychological process. Careful

monitoring reveals no significant deviations from the norm and therefore no medical interventions are instigated. Following the birth, both mother and baby are satisfied and well without the need for on-going medical care.

It is this definition which provides the 'indicators of success' in the assessment of whether normality has been successfully promoted during the labour and birth and thus provides the ultimate benchmark for the impact of the central construct studied in this research.

1.4 PROMOTING NORMAL BIRTH AND REDUCING INTERVENTIONS

The evidence is clear that normal birth without unnecessary medical interventions has benefits for women, their families and therefore for society. Systems of care in the developed world have led to a reduction in the frequency of normal birth and the identification of approaches to reverse this trend is a priority for research and academic study.

A review of current evidence highlights a number of elements which positively influence the reduction of medical interventions and the increase of normal birth rates. These include the adoption of evidence-based maternity care practices (Chalmers et al 1989, Flamm et al 1998, NICE 2007, Khunpradit et al 2011), the provision of midwife-led care and continuity of carer during pregnancy and childbirth (Homer et al 2001, Walsh and Downe 2004, Hatem et al 2008) and the provision of continuous one to one support of women during labour (Hodnett et al 2011).

Of these, continuous support during labour appears to have the greatest positive effect on outcomes. A systematic review of twenty one randomised controlled trials including more than 15,000 women, comparing intermittent with continuous support during labour (Hodnett et al 2011) found that women who received continuous support were significantly more likely to have a shorter labour and a spontaneous vaginal birth, and less likely to have analgesia and to report dissatisfaction with the birth experience (see pages 36-41, Chapter Two).

To reduce unnecessary medical interventions and increase normal birth rates, evidence suggests that healthcare systems should ensure that all women are provided with continuous support when they are in active labour. Midwives are the main provider of maternity care to women in the UK (Devries et al 2001, DoH 2010). The provision of one to one continuous intrapartum midwifery support is a key aspiration in UK health policy and professional guidance (SEHD 2001, DoH 2007, NICE 2007, DoH 2010). Evidence suggests that one to one midwifery support during active labour is not universally provided to all women in the UK and that the quality of the support provided is variable (Healthcare commission 2008, Care Quality Commission 2010). To date, no research has been undertaken in the UK to explore the extent and quality of midwifery intrapartum support. All of the research relating to the impact of continuous support on outcomes has taken place outside the UK in very different healthcare systems (Hodnett et al 2011).

1.5 THESIS STRUCTURE

The thesis which follows sets out to contribute to knowledge of the role of midwifery support in labour in promoting normal birth and reducing unnecessary medical interventions. This is done by making an original contribution to knowledge of the professional support provided to women during labour and childbirth, in order to improve the quality of clinical care and women's experiences.

The thesis reports a series of studies to achieve this goal. Chapter Two details the literature review undertaken into intrapartum support and finishes with the identification of the central research questions resulting from this review. Chapter Three describes the decision making process in choosing the central quantitative research methodology. The chapter details a further literature review undertaken which focuses on the evidence relating to observational studies in maternity care, systematic observation techniques and the measurement of quality in healthcare interactions. Chapter Four describes Study One, the development of a new

systematic observation instrument and the specific research questions for this thesis are defined. Chapter Five sets out the method and results of Study Two, which undertook initial testing of the content validity of the new instrument using a card sorting exercise with a group of student midwives. Chapter Six describes Study Three which used a detailed questionnaire with an expert panel to further test face and content validity of the instrument. Chapter Seven describes the method and results of Study Four. This study tested inter-rater and intra-rater reliability of the new instrument. Chapter Eight sets out the methods and detailed analysis plan for the final and largest study. This study tested the new instrument in the clinical setting for validity, feasibility, usability and acceptability. Chapter Nine reports the results of Study Five. Chapter Ten discusses and sets out the thesis conclusions in relation to the results of the interlinked studies, their implications in terms of their contribution to knowledge, practice and future research and the strengths and limitations of the research.

CHAPTER TWO – A REVIEW OF THE LITERATURE RELATING TO SUPPORT DURING CHILDBIRTH

2.1 INTRODUCTION

The aim of the literature review was to critically appraise current knowledge to enable the development of a theory based and evidence based research project. The review sought to establish the current state of knowledge of intrapartum support, both that which has been substantially studied and is well established as well as that which appears to be incomplete and uncertain. The review is presented below in terms of the key themes identified in the review which provided the necessary foundations for the proposed studies: the historical context of intrapartum support, the theoretical background, the definition of support, women's views of labour support, the impact of labour support on other outcomes, midwives' views of their support role, the role of fathers and other companions in labour support, the mechanism by which support has an effect on outcomes, the measurement of professional intrapartum support, and the current provision of intrapartum professional support in the UK National Health Services.

A comprehensive review of the literature relating to support during childbirth was undertaken in July 2009 using the CINAHL (Cumulative Index for Nursing an Allied Health Professionals) and Psychinfo search databases, drawing on 165 databases. This search was cross-referenced with a search using the NHS Scotland Electronic library database to ensure completeness. The search terms 'Support + childbirth or labo*' were employed, limiting results to articles available in English and published since 1980. Eighty six articles were selected for detailed review. Secondary searches were undertaken for key cited articles and related search topics identified in the initial review. This thematic review included 'women's experience + childbirth', 'satisfaction + childbirth', 'post traumatic stress + childbirth', 'fathers + childbirth', 'Doula', 'social support + health', 'companions + childbirth', 'maternity + quality', 'social support + theory', led to the critical review of a further 60 papers . Papers and position statements from UK

Governments, national and international maternity care professional bodies and lay childbirth organisations over the last ten years were reviewed. The literature search was repeated in September 2011 to include material from mid 2009 - 2011, which led to the review of 52 further papers.

The final 198 sources reviewed included six books, nine literature reviews, three meta-analyses, 24 randomised controlled trials, 34 studies exploring women's views of support in labour, 21 non-randomised studies which included five direct observation studies of support in labour, nine qualitative studies exploring care providers' views of support, six papers focusing on fathers, seven articles relating to doulas, 21 studies of the psycho-social impact of childbirth and seven papers relating to social support theory. The remaining 51 articles were commentaries and educational pieces on intrapartum support. As these 51 papers were not research papers, they are not discussed in the review below.

2.2 THE HISTORICAL CONTEXT OF INTRAPARTUM SUPPORT

The review identified a high level of interest in intrapartum support. One of the key motivations cited for the study of support is the concern that the changing nature of maternity care during the 20th Century in developed countries has led to a deterioration in the quality and quantity of support women receive during labour (Tew 1998, Davis-Floyd 2001).

The movement of the normal birth place from the home to the hospital, before the Second World War in the United States and after the Second World War in Europe, removed women from their domestic support networks. Throughout history and in different cultures, women have generally been supported during labour by other women: family members or women from the local community with experience of childbirth (Jordan 1980, Tew 1998). An anthropological study found that in 127 of 128 non-industrialised societies, women giving birth in non-medical settings are supported by female companions throughout labour (Meyer et al 2001). It has been argued that the increased medicalisation of the labour and birth process during the post-war

period led to a different emphasis in the care provided by obstetric nurses and midwives (Gale et al 2001). Activities such as continuous electronic fetal monitoring and intravenous oxytocin administration, which became widespread in the 1970s, diverted caregivers from offering continuous support (Hodnett 1996). Women's unhappiness with this medicalised and fragmented system of care led to the establishment of lay movements such as Lamaze and the National Childbirth Trust. These lay movements argued that women should be allowed to be accompanied by their partners during hospital labour, with the husband's role generally identified as one of 'coach'. By the 1980s it had become the norm in most Western developed countries for women to be accompanied by their partners in labour, though this has been much slower to change for women attending medical institutions to give birth in the developing world (Maimbolwa et al 2001, Devries et al 2001, Bruggeman et al 2007, Morhason-Bello et al 2008, Banda et al 2010). Researchers in this area argue that this exclusion of supportive companions in labour has a detrimental impact on women's emotional and physical well-being both during and after labour (Kennell et al 1991). Research into the impact of support for women in labour over the last 30 years has examined the role of partners, lay women, professional nurses and midwives in providing support.

2.3 THEORETICAL BACKGROUND

The roots of current theories of support in labour lie in theories of social support developed in social psychology since the 1970s. The concept of social support refers to '*some type of positive interaction or helpful behaviour provided to a person in need of support*' (p5 Rook and Dooley 1985). Social support has been theorised as a multi-faceted concept that encompasses social networks, supportive behaviours and subjective appraisals of the support (Cohen and McKay 1984, Vaux 1988). Two main theories have sought to explain social support and its positive effect on health. The 'buffer theory' hypothesises that social support 'acts as a buffer to protect people from the stresses of life' (p206 Callaghan and Morrissey 1993) and 'attachment'

theory speculates that secure attachments formed in childhood are the basis for an adult's ability to form socially supportive relationships (Callaghan and Morrissey 1993). Social support from nurses is defined as '*intentional human interaction, in which nurses provide concrete, material help and offer their time to their clients*' (p266 Kahn 1979). A large body of research has been undertaken that has identified clear connections between the provision and experience of positive social support in many contexts and positive effects on physical and mental health (Asher 1984, Ganster and Vicker 1988, Callaghan and Morrissey 1993, Vinokler and Variryh 1993, Vandervoort 1999, Lakey and Orenek 2011, Thoits 2011).

Theories of social support specific to labour and childbirth (Bryanton et al 1994, Corbett and Callister 2000) adhere largely to the 'buffer' theory of social support and have developed from the '*cognitive-phenomenological model of stress, appraisal and coping*' (p1 Lazarus and Folkman 1984). This model hypothesises that '*coping with the stress of labor can be enhanced by personal and environmental coping resources or it can be impeded by coping constraints*' (p638 Bryanton et al 1994). Professional support can be considered as an environmental coping resource, and negative professional support as a coping constraint.

The literature review undertaken identified that although social support is considered to be a multi-faceted concept, many studies into intrapartum support have focused solely on one facet of social support, either the woman's perception (Lesser and Keane 1956, Shields 1978, Fields 1987, Kintz 1987, Bryanton et al 1994, Bryanton and Gagnon 2008, Tarkka and Paunonen 1996, Holroyd et al 1997, Waldenstrom 1999, Corbett and Callister 2000, Sauls 2004a), the impact on clinical outcomes (Sosa et al 1980, Klaus et al 1986, Cogan and Spinnato 1998, Hodnett and Osborn 1989, Hofmeyr et al 1991, Kennell et al 1991, Langer et al 1998, McGrath and Kennell 2008) or the measurement of behaviours (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2001, Miltner 2002, Barnett 2008), with no research seeking to examine all of these components of social support.

A large number of studies have explored the recipients' perceptions of support (Lesser and Keane 1956, Shields 1978, Kintz 1987, Bryanton et al 1994, Tarkka and Paunonen 1996, Holroyd et al 1997, Waldenstrom 1999, Corbett and Callister 2000), drawing on the proposition that *'the support activity per se is not as important as how the activity is perceived and interpreted'* (p468 Heller et al 1986). This literature has led to a rich and detailed understanding of what women consider to be supportive and unsupportive during their labour, but has not identified how these perceptions are associated with what is actually provided, the perceptions of the caregivers or with other clinical outcomes.

Similarly, those studies which have sought to identify links between support in labour and measurable health benefits have provided very limited insight into the content of the support provided. The randomised controlled trials only identify two variations in the support provided, whether it was 'continuous' or 'intermittent' (Hodnett et al 2011). The support offered in the intervention arm of the studies is usually described in very general terms in the studies as being the provision of continuous presence, emotional and physical support (Hodnett and Osborn 1989, Breart et al 1992 a & b, Kennell et al 1991, Dickinson et al 2002, Morhason-Bello et al 2009). Some studies provide a little more detail, such as '*close physical proximity, touch and eye contact, teaching, reassurance and encouragement*' along with the use of hot and cold packs and massage (p199 Kashanian et al 2010). Only a small number of studies have examined intrapartum support as behaviours to be observed and measured (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2001, Miltner 2002, Barnett 2008), with only one of these studies combining the examination of the support behaviours with women's perceptions (Barnett 2008).

Another concept developed in the social support theories that has not been tested in earlier studies of labour support is that of 'veridicality', that is the congruence of perceptions of support between recipients and someone else (Antonucci and Israel 1986). It is hypothesised that in order to understand how to improve how supported women feel it is necessary to identify what

that support would look like from an observer's perspective, in order to allow a more detailed description of behaviours than may be possible when only considering a woman's perspective.

The contribution made by earlier studies to our knowledge of intrapartum support as a theoretical construct is therefore fragmented as each study has focused on one facet of intrapartum support rather than on intrapartum support as a whole: the behaviours that express it, the perception of those behaviours by the recipients and observers and the impact of those behaviours on measurable outcomes.

From the theoretical standpoint, it can therefore be argued that in order to fully understand social support, other aspects should be considered and explored including '*the interaction between the provider and recipient, the extent to which the support provided matches need, is offered at the appropriate time and for the proper length of time, the perceptions of support received versus what was actually provided and negative support, such as non-reciprocity*' (p15 Cohen and Syme 1985). It is through exploring these facets of support in labour that this thesis hopes to make its contribution to knowledge.

2.4 DEFINITIONS OF INTRAPARTUM SUPPORT

A number of overarching definitions of intrapartum support are provided in the literature:

'*Labor support is a repertoire of techniques the nurse can use to help women during one of the most memorable and personally challenging experiences of their lives. The goal of labor support is to help a woman achieve her wishes during labor, through offering companionship, attention to her emotional needs and active helping'* (p257 Hodnett 1996).

'*Supportive care may be defined as non-medical care that is intended to ease a woman's anxiety, discomfort, loneliness and exhaustion, to help her draw on her own strengths and to ensure that her needs and wishes are known and respected. It includes physical comfort*

measures, emotional support, information and instruction, advocacy and support for the partner' (p721 Simkin 2002).

Such definitions are rooted in the social support theories developed by Kahn and Lazarus in the 1970s and 1980s. A consensus exists in the academic literature that labour support consists of the three sub-categories of emotional, physical and informational support (Bryanton et al 1994, Hodnett 2002, Miltner 2002, Sauls 2002). Affect or emotional support is defined as expressions of love, admiration, liking, reassurance and respect, spending time with the client and making them feel cared for. Tangible or physical support includes direct assistance and informational support includes advice, information and feedback (Kahn 1979, Lazarus 1991). Over time, the categories of advocacy and partner support have been added in some studies to reflect research findings (Hodnett et al 2007). One study which used a factor analysis with 146 intrapartum nurses to define labour support, further sub-divided the emotional support category into three different kinds of emotional support: '*creating control; reassurance and nursing care behaviour, promoting comfort and reassurance through monitoring the condition of mother and baby*' (p40 Sauls 2006).

2.5 WOMEN'S VIEWS OF INTRAPARTUM SUPPORT

A large body of quantitative and qualitative research, with women antenatally and postnatally, has sought to explore and define the professional labour care behaviours that women experience as being supportive (Lesser and Keane 1956, Shields 1978, Kintz 1987, Bryanton et al 1994 and 2008, Tarkka and Paunonen 1996, Holroyd et al 1997, Brown 2000, Corbett and Callister 2000, Small et al 2002, Sauls 2004 and 2010, Takacs and Kodysova 2011, Mbye et al 2011). This extensive body of research, undertaken over several decades with women from different countries and cultures using a variety of methodologies, has produced a remarkably consistent list of priorities identified by women:

'Research on women's views of their intrapartum care is compelling for the consistency it reveals about what women want from, and appreciate about, their care' (p266 Small et al 2002)

When analysing the evidence for what women experience as being supportive during labour, the 'hierarchy of evidence' (NHS Centre for Reviews and Dissemination 1996) provided a helpful framework. The review of women's views therefore first identified systematic reviews or meta-analyses of randomised controlled trials, explored individual randomised studies, then identified any systematic reviews of non randomised research studies, both quantitative and qualitative and finally explored the contribution to knowledge of individual non-experimental studies.

The Cochrane meta-analysis of randomised controlled trials is considered to be a 'gold standard' in the analysis of current evidence. The systematic review most relevant to this thesis, comparing the impact of continuous and intermittent support, identified that women receiving continuous intrapartum support were significantly less likely to report dissatisfaction with the birth experience than women receiving intermittent support (Hodnett et al 2011). Data on women's overall satisfaction with the birth experience were collected in eleven trials with 11,133 participants in total. Reported negative ratings of or negative feelings about the childbirth experience were significantly lower among women who received continuous support (RR 0.69, 95% CI 0.59 to 0.79).

Only a minority of the randomised controlled trials included in the review collected any further data relating to women's feelings about the support received and were therefore unable to identify what aspects of the continuous support were of particular importance to the participants. In Hodnett and Osborn's 1989 study comparing continuous support by a monitrice (n=49) with usual care by an obstetric nurse (n=54), women in the intervention group reported significantly higher quantities of physical, emotional informational and advocacy support in a postnatal questionnaire: the average number of support actions by the monitrice was 15.1 while the average by a nurse in the control group was 8.6 (p180 Hodnett and Osborn 1989). Fewer than

one third of control subjects reported receiving any physical comfort measures from the nurse. However, the study's authors concede that the postnatal questionnaire employed was a 'crude measure' as it did not measure perceived helpfulness or the relative importance of each type of support.

One of the studies reported in the Cochrane review undertook detailed qualitative postnatal interviews with a small sub-group of the women involved in the trial, n=16 ('Alone I wouldn't have known what to do' Campero et al 1998). This identified the comfort experienced by the women in the intervention arm of the trial receiving continuous support and the importance of the information and reassurance that those providing continuous support were able to provide.

A large UK pilot randomised controlled trial with 615 women, designed to compare the impact of partogram action lines on labour management, explored women's views of their labour using an open-ended question in a postnatal questionnaire (Lavender et al 1999). The six key themes identified from the 412 respondents were the importance of professional support, information, decision-making, interventions, a sense of control and pain relief (Lavender et al 1999).

Thus, though viewed as the highest level in the hierarchy of evidence, the meta-analysis and randomised controlled trials in this area provide us with only limited information about what behaviours women experience as being most supportive in labour. These studies highlight that continuous support is valued by women above intermittent support and that the higher quantity of supportive behaviours is valued, but provide us with very little evidence about the optimal content of support.

Review was therefore undertaken of reviews of non-randomised studies. Five reviews of research into women's views of and satisfaction with care and support in labour were identified (Watkins 1998, Bowers 2002, Hodnett 2002, NICE 2007 and Larkin and Begley 2009), though they cannot all be described as systematic in their approach.

Watkins' review, limited to seven studies focusing on intrapartum care (Mackey and Lock 1989, Beaton 1990, Green and Coupland 1990, Bramadat and Driedger 1993, Bryanton et al 1994,

Gagnon and Wagnorn 1996 and Tarkka and Paunonen 1996), identified the importance of individualised care as a central theme of all of the included studies. The review is described as an 'integration and synthesis' of the studies, however the very limited number and the high level of heterogeneity between the included studies, with very variable methodologies, call into question the ability of the review to effectively or meaningfully integrate and synthesise findings. Watkins states, for example, that the review identified that the perspectives of women and caregivers on the nature of intrapartum support are quite different (p15 Watkins 1998), a view which is not supported by other evidence which suggests that caregivers' and women's definitions and expectations of intrapartum support largely concur (Miltner 2000, Sauls 2006, Payant et al 2008, Thorstensson et al 2008).

A more comprehensive approach was taken by Bowers in a systematic review and synthesis of 17 qualitative studies of women's perceptions of professional support in labour including 533 women. This review identified that the continuous presence of a nurse or midwife during labour, physical comfort measures and emotional support were key elements in women's responses to birth (p742 Bowers 2002). Bowers' review included six phenomenonological studies, one study using a grounded theory approach, one ethnographic study and nine content/thematic analyses of interviews or questionnaires with women. The support described was provided by nurses in seven of the studies, by midwives in five of the studies and by a mixture of doulas and nurse-midwives in the final five. The studies took place in the UK, USA, Canada, Finland, Sweden, Iceland, Mexico and Taiwan. The study responses were analysed through categorisation into the four established theoretical dimensions of intrapartum support: emotional, tangible, informational and advocacy. Bowers identified three other categories required to fully represent the qualititative data presented in the included studies: the caregiver's communication style, women's antenatal expectations and the caregiver's professional competence. A 'recurrent theme' (p747 Bowers 2002) was the importance of the caregiver being friendly, open and gentle, communicating a warm positive regard and being able to convey a sense of security and tranquility:

'What you do doesn't matter as much as how you do it', said one mother' (p748 Bowers 2002).

Words of praise, constant presence along with technical competence and advocacy were considered important aspects of care by many. The review also linked the perception of care to a woman's overall experience of childbirth:

'Women who perceived their nurses as negative or uncaring tended to have more negative perceptions of the labor experience' (p750 Bowers 2002).

Bowers identified that the review was limited by the lack of contextual cultural descriptions in the studies, which limit the reader's ability to assess transferability of the findings. It is also of note that Bowers' review did not contain any critical analysis of the quality of the included studies beyond identifying this lack of contextual context.

A systematic review of 137 methodologically varied studies exploring pain and women's satisfaction with their birth experience was undertaken by Hodnett in 2002. This review included descriptive studies, randomised controlled trials and systematic reviews of intrapartum interventions. The findings of each of these three key types of research were synthesised separately and then summarised qualitatively. Twenty nine studies of satisfaction with intrapartum care were reviewed, ranging from small qualitative studies (n=16) to large population based surveys (n=>2000), including more than 14,000 women in nine countries (ten of the included studies were undertaken in the UK). Hodnett describes two of the larger population based surveys undertaken in the UK (Green and Coupland 1990 and Green et al 1998) as among the most rigorous. The review of these studies highlighted that supportive care was the most helpful nursing measure. Strong predictors of dissatisfaction with the birth experience were a lack of involvement in decision-making, insufficient information, obstetric interventions and caregivers that were perceived as unhelpful. The review concluded that four key factors were so important in women's evaluation of their birth experience that they outweighed the effects of all other variables (age, ethnicity, socio-economic status, birth environment, medical interventions, attendance at antenatal education, pain perception,

continuity of care and mobility) (Hodnett 2002). These four factors were personal expectations, amount of support from caregivers, the quality of the caregiver-patient relationship and the involvement of the woman in decision-making. This finding led the author to conclude:

'The influences of pain, pain relief and intrapartum medical interventions on subsequent satisfaction are neither as obvious, as direct nor as powerful as the influences of the attitude and behaviours of the caregivers' (p160 Hodnett 2002).

The review also identified that professional caregiver support is complementary but distinct from the support from a partner:

'although the support of people who love her undoubtedly is of great benefit to the woman, it is no substitute for the nurse's support' (p258 Hodnett 1996).

The National Institute for Health and Clinical Excellence is a UK organisation which undertakes systematic reviews of current literature and evidence to provide national guidance on many healthcare topics and interventions. The 2007 NICE guideline on intrapartum care of low risk women included a review of studies relating to intrapartum communication and psychosocial outcomes for women (NICE 2007). 182 papers were initially retrieved, with 19 papers selected for detailed review as they described studies in settings considered to be generalisable to women in the UK and considered to be methodologically sound (NICE 2007).

NICE employs a 'hierarchy of evidence' approach to evaluating evidence from 1++ (high quality meta-analyses and systematic reviews of randomised controlled trials with a very low risk of bias) to 4 (expert opinion). The highest level of evidence relating to the topic of communication and psychosocial outcomes reported in the intrapartum guidance is 2+ (high quality case control or cohort studies). This included a Swedish longitudinal cohort study of 2541 women measuring their global experience of labour and birth (Waldenstrom et al 2004) and a UK prospective study with 1146 women using antenatal and postnatal questionnaires with women about their birth experiences and psychosocial outcomes (Green and Baston 2003). Both of these studies are assessed by NICE to have used high quality methodology and analysis using multiple logistic

regression to measure the strength of the association between intrapartum variables and women's feelings postnatally. Both studies identify a strong association between feelings of control during labour and the level of perceived support from the caregiver and women's feelings about their birth experience.

The other studies included in the NICE analysis are evaluated at Evidence Level 3. They include a number of large scale population based survey studies in Sweden and Australia including between 790 and 1336 women (Brown and Lumley 1998a and b, Waldenstrom 1999, Waldenstrom et al 2004) which support the finding that professional support is a key factor in women's feelings about their birth and that negative experiences of caregivers have a strong association with dissatisfaction. The NICE guideline also includes a number of smaller qualitative studies with women in the analysis (Berg and Lundgren 1996, Halldorsdottir and Karlsdottir 1996, Vandevusse 1999) highlighting a number of 'strong common themes': the importance of feeling treated as an individual, the need to feel guided and supported and to have caregivers who demonstrate positive, caring and empathic traits during labour (NICE 2007).

A further, more recent, review of the literature relating to women's feelings about support was undertaken by Larkin and Begley in 2009 as part of an evolutionary concept analysis of women's experiences of labour and birth. This review sampled 62 papers from 180 papers identified as being relevant, including 30 qualitative and 30 quantitative studies. The studies were undertaken in the United Kingdom (n=22), North America (n=13), Sweden (n=9) and Australia (n=7). The most commonly identified themes in the sample of papers were control, support, the relationship with the caregiver and pain (p53 Larkin and Begley 2009).

While the reviews provided further information about the importance of positive support behaviours to women in labour, they did not provide detailed descriptions of what is and is not supportive for women in labour. Further analysis of individual qualitative and quantitative studies with women was therefore required.

Since the 1950s research has identified the key role that professional support plays in women's overall satisfaction with and perception of their childbirth experience. The earliest research into women's priorities for care during labour was by Lesser and Keane in 1956 in the United States. Sixty six women were interviewed in mid-pregnancy and then postnatally about what they expected from nurses during labour. These women identified the need to be sustained by another human being through nursing presence, to have relief from pain, to have a safe outcome, to have their attitudes and beliefs accepted and to receive bodily care (Lesser and Keane 1956).

Another early North American study was conducted by Shields in 1978. Eighty women were interviewed postnatally about their satisfaction with the labour. No association was found between variables such as the woman's age, educational status, parity and analgesia used and her satisfaction with labour (Shields 1978). Of all the variables measured, the type of nursing care was most strongly associated with satisfaction. Presence of the nurse was the most helpful nursing measure, the majority of women wanted the nurse in the room most or much of the time. The presence of other supporters, such as the partner or mother, did not alter the woman's need for the presence of the nurse. Shields categorised the types of nursing care into seven categories: physical care only, supportive care only, medications only and then combinations of physical and supportive, supportive and medications and physical and medications and all three. Combined care was found to be the most satisfying type of care, while supportive care only was considered more satisfying than physical care only. The supportive care category included assistance with breathing exercises, holding the woman's hand, staying with the woman, encouragement, physical comfort, explanations, talking as a diversion and being reassuring, calming and patient (p535 Shields 1978).

An study which has influenced the development of knowledge of women's priorities for care was that by Kintz in the United States in 1987, in which she developed 'The Nursing Support in Labour Questionnaire'. This questionnaire has formed the basis for a number of subsequent studies. The questionnaire, devised by the author and based on the research available at the

time, provided women with a list of nursing behaviours which they were asked to rate postnatally in terms of their importance to them (Kintz 1987). This questionnaire was adapted and further tested in a subsequent study by Bryanton into the BANSILQ (Bryanton Adaptation of the Nursing Support in Labour Questionnaire) which provided women with a list of 25 possible nursing behaviours. The BANSILQ was tested in Bryanton et al's study with 80 postnatal women. The top ten most rated behaviours were:

'1. Made me feel cared about as an individual

2. Kept me informed about progress

3. Touched me

4. Treated me with respect

5. Praised me

6. Appeared calm and confident

7. Provided a sense of security

8. Spent time in the room

9. Instructed me in breathing

10. Made me physically comfortable' (p642 Bryanton et al 1994).

The behaviours chosen least frequently were providing pain medication, explaining hospital routines, encouraging my partner, familiarising me with my surroundings, including me in decisions and distracted me by talking (p642 Bryanton et al 1994).

Bryanton concluded '*these findings suggest that emotional support during labor is more helpful to women than informational or tangible support'* (p643 Bryanton et al 1994).

The BANSILQ has been used in a number of subsequent studies with women from a range of cultural and ethnic backgrounds (Holroyd et al 1996, Corbett and Callister 2000, Ip 2003, Sauls 2004 and 2010, Mbye et al 2011).

Holroyd et al used a Chinese language translation of the BANSILQ with a purposive sample of 30 Hong Kong Chinese women in the 24-36 hours after birth. The women's most highly rated behaviours had a high number of commonalities with the US women in the Bryanton study, though some differences were apparent: the provision of information was rated more highly and the provision of touch was the least rated behaviour (Holroyd et al 1996).

Sauls used the BANSILQ in two studies with adolescents in the USA to identify whether their support needs were different from older women. The most helpful behaviours identified by the 185 participants were providing pain medication, treating me with respect, praise and supporting my partner (Sauls 2010). The emphasis on the provision of pain relief is distinct from the other studies using the same questionnaire and suggest some differences in the needs of the younger women, though the importance of the provision of emotional support is shared with the other studies.

Mbye's study with 120 women in the Gambia using the BANSILQ found that women valued emotional support behaviours most highly and informational support the least.

The BANSILQ approach to ascertaining women's views of which behaviours are most important to them during labour may be criticised as a list of previously defined behaviours is provided to women, thus reducing women's freedom to identify their priorities for care. A number of studies have been undertaken which did not suggest the behaviours to women but enabled the women to list key behaviours themselves.

An antenatal study with fifty seven nulliparous women in the USA found nine items that were listed most frequently:

' 1. Making me as comfortable as possible

2. Support

3. Keeping me calm

4. Reassurance

5. Answer questions

6. Helping me with breathing and relaxation

7. Helping my partner

8. Monitoring the baby' (p54 Tumblin and Simkin 2001).

It is interesting to note the consistency and similarities of this study's findings with the findings of the BANSILQ based studies.

A recent Czechoslovakian study also took a qualitative approach, developing written childbirth narratives with 189 women and interviewing 44. This found seven key dimensions of satisfaction with the healthcare:

1. *Staff attitude and behaviour*
2. *Staff communication*
3. *Participation in decision-making*
4. *Support of early mother-baby contact*
5. *Breastfeeding support*
6. *Mother and baby friendliness of the maternity unit*
7. *Clarity of information* (p202 Takacs and Kodysova 2011).

There are some variations in the priorities identified by women in different studies, while most of the studies reviewed emphasised the centrality of emotional support (Bryanton et al 1994, Corbett and Callister 2000, Mbeye et al 2011), two studies were found which emphasised the importance of the health professional's technical skills and knowledge (Schultz et al 1998, Manogin et al 2000). Manogin's U.S study used a structured questionnaire design to ask 31 women following a vaginal birth to rank a list of the most important nursing behaviours experienced in labour. Technical skills were rated as the top three most important behaviours: 'knowing what they are doing, knowing how to handle equipment and giving treatments and medications on time', followed by 'being there when I need them, treating me with respect' (p155 Manogin et al 2000). It is possible that these women's responses were affected by the

nature of the list with which they were provided and having experienced a labour in the highly technical and medicalised maternity care system of the United States.

Several large population based studies have been undertaken to identify women's priorities for care. A recent nationwide cross-sectional study of 739 women's feelings and perceptions of intrapartum care in Sweden identified the importance of feeling in control, including being treated with respect and involved in decision-making, in women's assessment of their birth experience (Wilde-Larsson et al 2011). Maternity care in Sweden is more akin to the British system than the North American systems, with midwives as the key providers of maternity care for the majority of women (Devries et al 2001) and thus research findings may be considered to be of considerable relevance to the British setting.

Several large quantitative studies drawing on representative samples of women have also been undertaken in the UK. These studies have emphasised the important impact of the caregiver relationship and communication during childbirth (Green and Coupland 1990, Garcia et al 1998, Green et al 2003, Healthcare Commission 2008, Care Quality Commission 2010).

A large scale study, 'Greater Expectations', including 1286 women who gave birth in 2000 in eight maternity units in the South and North of England (four units in the South were matched with four units in the North) used two antenatal and one postnatal postal questionnaire to identify women's feelings about their maternity care (Green et al 2003). The results were compared with a similar study by the same group of researchers with 825 women in 1987 (Green and Coupland 1990). The study found that women's priorities and needs for care during labour had remained very similar between the two time points, though women in the later study worried significantly more about pain in labour than the women in the earlier study and were more willing to accept medical interventions, particularly epidural analgesia (Green et al 2003). The study found that women felt more satisfied with the communication and care with caregivers in the later study, with higher proportions satisfied with the amount of information they were given, more women described the midwives as 'sensitive', more felt that they were

treated with respect and as an individual during labour. Multiple logistic regression analysis of the results found clear links between women's satisfaction with their experience and greater feelings of being in control, being treated with respect by staff and being able to get into comfortable positions of their choice (Green et al 2003). Women were less satisfied when the staff caring for them in labour were considered to be less helpful and when they were left alone (Green et al 2003).

The importance of a sense of control to women during their childbirth experience has been found in repeated studies (Coyle et al 2001, Green et al 2003, Larkin and Begley 2009, Namey and Lyerly 2010, Wilde-Larsson et al 2011). Enabling a sense of control appears to be a key element of professional support in many of the reviews and studies, irrespective of methodology (Lavender et al 1999, Waldenstrom 1999, Bryanton et al 2008). One interesting example of the inter-related nature of women's feelings of control and the role of the caregiver is provided in a small qualitative study comparing women's experiences of birth centre and hospital based care in Australia (Coyle et al 2001). The nature of the relationships is described on a continuum from collaborative to provider-dominated. In provider-dominated relationships women tend to experience a lack of information and communication which in turn leads to a lack of real involvement in decision-making which leads to a sense of a lack of control and reduced satisfaction:

'These findings also revealed that one of the major factors influencing women's perceptions of control over the pregnancy and birth was the nature of the relationship between the women and their carers. Women who had a collaborative relationship with their midwife indicated a sense of control over their experience' (p191 Coyle et al 2001).

The literature identified that generally women are very satisfied with their childbirth experience and the care received (Waldenstrom 1999, Ortega et al 2001, Green et al 2003, Care Quality Commission 2010, Records and Wilson 2011, Wilde-Larsson et al 2011). Waldenstrom's Swedish study of 1111 women randomised to usual or birth centre care undertook

questionnaires with women in pregnancy and in the postnatal period. The study identified that 50.3% of women had a very positive overall experience with 3.2% reporting a very negative one. The five variables in a logistic regression analysis which contributed to women's birth satisfaction scores were a sense of involvement in the birth process, anxiety experienced during the labour, pain, parity and the midwife's support. The partner's support was not significantly linked with satisfaction scores (Waldenstrom 1999).

More recently, more evidence has emerged about the detrimental impact of poor perceived support on women's postnatal mental health. Women have detailed life-long memories of their children's births (Simkin 1991, Beech and Phipps 2004). Positive childbirth experiences are linked to more positive feelings about motherhood and parenting stress and lower anxiety levels (Takehara et al 2009). Poor experiences contribute significantly to perinatal mental health problems including postnatal depression (Beck 2002, Leeds and Hargreaves 2008, Hunker et al 2009) post-traumatic stress disorder (Soderquist et al 2006, Davies et al 2008, Zaers et al 2008, Elmir et al 2010, McDonald et al 2011) and fear of subsequent childbirth (Pang et al 2008, Nilsson et al 2010):

'Regardless of the type of labor or the outcome of the labor, the quality of support a woman receives can make the difference in whether she recalls her experience as depersonalising and degrading or as one that increased her self-esteem and self-confidence' (p257 Hodnett 1996).

Unplanned events in labour, such as emergency caesarean section, are also linked to the development of perinatal mental health problems (Hunker et al 2009, Dencker et al 2010), though it appears that the impact of these adverse events may be mediated and lessened by the provision of high quality intrapartum support that reduces feelings of being out of control, being alone and fear (Tham et al 2010). While other factors play an important role in the development of postnatal mental health problems including woman's personal mental health history, stressful life events, a poor social support network and perceived low levels of partner

support, the nature of the childbirth experience represents a key risk factor or, conversely, if positive, may serve as a protective factor:

'*Positive experiences act as a buffer against later physical and emotional stress'* (p1 NCT 2002).

Several high quality studies have explored the relationship between birth experiences and the development of post traumatic symptoms (Creedy et al 2000, Olde et al 2005, Stevens et al 2011a & b, Stramrood et al 2011, Yang et al 2011). A well conducted Australian study including 499 women gathered information through antenatal questionnaires including demographic details, antenatal risk factors, relationship status and state and trait anxiety scores (Creedy et al 2000). The women participated in detailed telephone interviews 4-6 weeks postnatally. Women were not prompted to refer to stressful or traumatic events, but 33% of women identified a traumatic birthing event and reported the presence of at least 3 trauma symptoms. More detailed post-traumatic symptom questions identified 5.6% of the women as meeting the DSM-1V criteria for acute post-traumatic stress disorder (PTSD) (The Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association). Using multiple logistic regression techniques, the authors concluded:

'Antenatal variables (partner support, antenatal risk factors, state and anticipatory anxiety scores measured antenatally) did not contribute to the development of acute or chronic trauma symptoms. The level of obstetric intervention experienced during childbirth and the perception of inadequate intrapartum care during labor were consistently associated with the development of acute trauma symptoms' (p104, Creedy et al 2000).

These findings reflect those of other large studies of PTSD following childbirth (Olde et al 2005, Stevens et al 2011 a & b, Stramrood et al 2011, Yang et al 2011).

The impact of women's childbirth expectations on their perceptions of their birth experience has been examined in a number of studies (Green et al 1998, Hauck et al 2007, Bryanton et al

2008, Kuo et al 2010, Records and Wilson 2011). Green's 'Great Expectations' study found that women with higher expectations of the birth had higher levels of satisfaction (Green et al 1998), a finding which is echoed by Bryanton et al's considerable body of work including a large prospective cohort study with 652 women in Canada (Bryanton et al 2008). Studies suggest that women identifying their positive expectations and aspirations for the birth to the person caring for them can have a positive impact on feelings of satisfaction and fulfillment (Green et al 1998, Kuo et al 2010). One study, in which twenty women were interviewed in depth, concluded that women's evaluation of their birth experience as positive or negative is dependent on whether their priority expectations are met (Hauck et al 2007). This study found that the role of the midwife is central in helping a woman to 'frame' her birth experiences:

'Care givers become even more important when expectations are not able to be realised...Supportive behaviours of maternity healthcare providers assisted women to evaluate their birth experience as positive even when expectations could not be achieved' (p235 Hauck et al 2007).

This finding appears to link well with the research on PTSD which suggests that difficult labours with numerous medical interventions are made much more difficult for women if there is a perceived lack of care or support from health professionals (Niven 1988).

The relationship between continuity of carer and the quality of support is explored in a number of studies. Some maternity care systems have sought to provide women with a higher degree of continuity of carer than in the standard maternity service. These systems allocate women one midwife or a small group of midwives during their pregnancy who also provide intrapartum and postnatal care. Studies evaluating the impact of continuity of midwifery care schemes have identified that the development of a trusting relationship between the woman and the midwife appears to facilitate the conditions which influence satisfaction with care (McCourt and Page 1998). An evaluation of a pilot team midwifery project identified a number of factors which contributed to maternal satisfaction (Tinkler and Quinney 1998): the nature and quality of

information provided, choices about the type of care, congruence between expectations and reality, relationships with caregivers and a sense of control over the birth process (p34 Tinkler and Quinney 1998). Women interviewed from the continuity of care scheme compared to those receiving usual care indicated that they felt more able to access information and ask questions whenever they needed, felt that they were offered a wider range of choices and felt treated more as individuals.

Several studies have specifically focused on women's reactions to and feelings about medical interventions in labour (Oakley 1980, O'Hara 1986, Green et al 1998, Clement et al 1999). Clement et al asked 1,714 women at 6 weeks postnatally to rate 20 intrapartum interventions according to how much of a medical intervention they perceived them to be. The highest mean score (9 out of a possible 10) was for caesarean section, followed by fetal blood sampling, epidural anaesthesia, forceps, ventouse and general anaesthetic which all scored 8. Episiotomy and sutures were rated 7, syntocinon 6, vaginal examinations 5, amniotomy 4 and TENS pain relief 1.6 (Clement et al 1999). This tool, known as the Intrapartum intervention score, was the first interventions scoring tool to be based on women's assessments and was the first to include vaginal examinations. Women in this study clearly perceived a number of interventions which are generally carried out by midwives and are often considered to be a part of 'routine care' as highly medicalised. While most studies seem to suggest a negative impact of medical interventions on women's sense of control and satisfaction with the birth experience, one study, undertaken as part of a randomised controlled trial into the use of partogram action lines in labour, identified that a significant proportion of the 519 women in the study welcomed intervention to hasten a slow labour (Lavender et al 1999).

In summary, a large body of empirical research has been undertaken with women about the key factors in their birth experiences. Though a research aim of establishing what is of central importance to women in their childbirth experience does not lend itself to exploration using what is considered to be the highest level of evidence (meta-analyses of well conducted randomised controlled trials), robust well-conducted reviews and studies using quantitative and qualitative

techniques were identified through this review. This research has spanned decades, crossed geographical and cultural barriers and methodological approaches. The key finding from the review of this varied research was the remarkable consistency found about the key factors in promoting a positive birth experience. The nature of the support offered to women by their caregivers during labour was consistently identified as a key factor in their assessment of the birth experience. Being treated as an individual, having a sense of control and being involved in decision-making were also repeatedly identified.

The number and type of interventions also appear to influence women's responses, particularly if a large number of interventions take place in a context where the support and relationship are also perceived as poor. None of the studies reviewed suggest that more than a very small minority of women wish to have a highly medicalised or operative birth, the majority of women appear to wish to have as normal an experience as possible. It is clear when viewing the issue from the perspective of women's experiences that the provision of high quality intrapartum support and the promotion of normality in childbirth and the reduction of unnecessary medical interventions in the labour process are valuable and necessary aims.

2.6 THE IMPACT OF SUPPORT IN LABOUR ON OUTCOMES

In addition to its impact on women's satisfaction with the birth experience, the nature of intrapartum support offered to women during labour effects other key birth outcomes. The evidence for the positive impact of support on birth outcomes is of the highest level in the hierarchy of evidence. Robust, high quality meta-analysis of twenty one methodologically sound randomised controlled trials carried out over the last thirty years involving over 15,000 women has concluded that continuous support has considerable benefits when compared to intermittent support (Hodnett et al 2011).

Women who received continuous support during labour rather than intermittent support were

- More likely to have a spontaneous vaginal delivery (18 trials, n= 14,005, RR (risk ratio) 1.08),
- Less likely to have intrapartum analgesia or anaesthesia (13 trials, n=12,169, RR 0.90),
- Less likely to report negative feelings about their childbirth experience (11 trials, n=11,133, RR0.69),
- More likely to have a shorter labour length (11 trials, n=5269, mean difference -0.58 hours),
- Less likely to have an instrumental birth (18 trials, n=14,004, RR0.9),
- Less likely to have a caesarean birth (21 trials, n=15,061, RR0.79)
- Less likely to have a baby that received a low apgar score (rating for indicators of health including respiration, heart rate, colour, tone and reactivity) at 5 minutes after birth (12 trials, n=12,401, RR0.7) (p11 Hodnett et al 2011).

The author of this review concluded:

'*The review provides evidence of a dose-response phenomenon: a strong and prolonged 'dose' of continuous support may be most effective'* (p10 Hodnett et al 2007).

All of the trials compared birth outcomes between an intervention group that received one to one continuous support in labour and a control group that received 'usual' care (see table included as appendix one for summary of trials and results). All three meta-analyses of the randomised controlled trials (Zhang et al 1996, Scott et al 1999, Hodnett et al 2011) conclude that continuous support during labour has a significant impact on a number of key labour and birth outcomes.

However, the effects of the intervention are not consistent across all the trials and several large randomised trials show only very limited effect on outcomes. The trials varied in a number of respects. Firstly, in relation to who provided the continuous support during labour, either lay

women unknown to the woman (Sosa et al 1980, Klaus et al 1986, Cogan and Spinnato 1988, Hodnett and Osborn 1989, Kennell et al 1991, Hofmeyr et al 1991, Langer et al 1998, Gordon et al 1999, McGrath and Kennell 2008), partners or family members (Madi et al 1999, Campbell et al 2006, Bruggemann et al 2007, Morhason-Bello et al 2009) or trained maternity care professionals (obstetric nurses, student midwives or midwives) (Hemminki et al 1990,Breart et al 1992 a and b, Gagnon et al 1997, Dickinson et al 2002 a and b, Hodnett et al 2002) . The trials also vary greatly in terms of the context in which the trial took place. The trials with the greatest effects took place in contexts where women were generally deprived, were labouring in crowded conditions with little privacy and where their partners were not allowed to be present (Sosa et al 1980, Klaus et al 1986, Kennell et al 1991, Kashanian et al 2010), while in other trials all women laboured in more favourable conditions, with partners accompanying women in the control group (Gagnon et al 1997, Dickinson et al 2002, Hodnett et al 2002). Some trials took place in conditions where medical interventions in labour were generally high including routine provision of epidural analgesia (Cogan and Spinnato 1988, Hodnett and Osborn 1989, Kennell et al 1991, Gagnon et al 1997, Langer et al 1998, Gordon et al 1999, McGrath et al 1999, Dickinson et al 2002 a and b, Hodnett et al 2002, Campbell et al 2006, Bruggemann et al 2007, McGrath and Kennell 2008), while others had no epidural service available and had generally lower rates of medical intervention (Sosa et al 1980, Klaus et al 1986, Hemminki et al 1990, Hofmeyr et al 1991, Madi et al 1999, Morhason-Bello et al 2009). The way in which the trials were conducted varied considerably, with different levels of training provided to the birth supporters, varying degrees of continuousness of support and differences in whether the support was instigated early or late in active labour.

With such a variety of conditions it is not surprising that the results also varied widely. Some studies show much stronger effects on outcomes (Sosa et al 1980, Klaus et al 1986, Kennell et al 1991, Madi et al 1999, Dickinson et al 2002, McGrath and Kennell 2008, Morhason-Bello et al 2009, Kashanian et al 2010) than others, which showed quite limited effects (Hemminki et al 1990, Gagnon et al 1997, Langer et al 1998, Hodnett et al 2002, Bruggemann et al 2007).

The differences in results between the trials can lead to a number of observations. The first is that the results indicate that non-professional lay people offering continuous support have more beneficial outcomes than when support is provided by professionals. The second is that the trials where support was offered in 'higher dose' had greater impact on outcomes. In some of the trials, even though the support was described as 'continuous', supporters were allowed to be out of the room for considerable periods of time (Hemminki et al 1990, Hofmeyr et al 1991) or support was started quite late in the labour (Hemminki et al 1990, Breart et al 1992 a and b, Hodnett et al 2002). There appears to be a link between studies where support was provided by professionals and those that provided less continuous and later support (Hemminki et al 1990, Breart et al 1992 a and b, Hodnett et al 2002) and fewer positive effects on outcomes. The third is that the context in which support is offered is key confounder, with differences in thresholds and availability of medical interventions having a considerable impact on the effectiveness of support.

Sub-group analysis of the findings led the authors of the Cochrane systematic review to conclude that continuous support was most effective when it was provided by a woman who was neither part of the hospital staff nor the woman's social network and in settings in which epidural analgesia was not routinely available (Hodnett et al 2011). The reason for this difference, it was suggested, was that hospital employees

'*often have simultaneous responsibility for more than one labouring woman, spend a large proportion of time managing technology and keeping records and begin or end work shifts in the middle of women's labour. They may lack labor support skills or work in short-staffed environments*' (p4 Hodnett et al 2011).

The results of the very earliest randomised controlled trials using non-professional trained birth companions or 'doulas' (Klaus et al 1986 and Kennell et al 1991) and the analysis presented in the Cochrane library meta-analysis above have led to a growth in interest in the role of 'doulas' (a Greek word meaning 'handmaiden' coined by Klaus in 1991 to describe a non-professional

trained birth support companion) in supporting women during labour. The use of doulas has developed significantly in the last twenty years, particularly in the USA (Nolan 1995, Deitrick and Draves 2008, Mottl-Santiago et al 2008). The question of who is best placed to provide continuous high quality support to women in labour in the UK midwife-led system of care currently remains unanswered in the literature. The extrapolation of the randomised controlled trials' results to the UK has led to the establishment of doula training programmes and doula schemes (Stockton 2003 and 2010). It is argued that the studies show that doulas are best placed to provide continuous labour support and have the best effect on outcomes in comparison to midwives (Stockton 2003 and 2010).

However, the extent to which the specific analysis of the Cochrane review group are applicable to the UK system of maternity care is questionable. None of the randomised controlled trials included in the review were conducted in the UK, where midwives are the lead providers of intrapartum care. The majority of the studies were undertaken in countries where physicians are the lead providers of maternity care, assisted by obstetric nurses (Klaus et al 1986, Cogan and Spinnato 1988, Hodnett and Osborn 1989, Hofmeyr et al 1991, Kennell et al 1991, Breart et al 1992 a and b, Wolman et al 1993, Gagnon et al 1997, Langer et al 1998, Madi et al 1999, Torres and Kopplin 1999, Hodnett et al 2002, Campbell et al 2006, Bruggemann et al 2007, McGrath et al 2008, Morhason-Bello et al 2009). The training, culture and professional role of obstetric nurses generally differs substantially from that of midwives (Devries et al 2001, Sauls 2002). The provision of support is a central part of midwifery training and considered to be a core midwifery role (ICM 2011), but is not necessarily for obstetric nurses. In the United States, for example, support skills are not a core part of all labour and delivery nurse training programmes (Jordan et al 2008). Where obstetric nurses are required to provide continuous intrapartum support as part of a study (Hodnett et al 2002), they may feel less confident and have fewer developed support skills than midwives, reducing their efficacy. A substantial proportion of the studies were in systems where other birth companions were not permitted to accompany women in labour, while in the UK it has been normal practice for the last thirty years

for women to be accompanied during labour by a companion of their choice. The impact of a doula is likely to be greater for a woman who is unaccompanied and thus the applicability of the study results to the UK is reduced. In a number of the studies where support was provided by professional employees rather than lay doulas, close examination reveals that what is described as 'continuous' support is actually intermittent and late in onset (Hemminiki et al 1990, Hofmeyr et al 1991, Hodnett et al 2002). This will reduce the 'dose' of support provided by professionals compared to lay supporters and thus reduce the impact on outcomes. Finally, all of the studies were undertaken in maternity systems where intermittent support was 'usual care' and continuous support was the innovative intervention. In UK Government policy and all UK clinical guidance there is a commitment to one to one continuous midwifery support of all women in active labour (DoH 2007 and 2010, NICE 2007, RCOG 2007) and continuous care in active labour is considered 'usual care'.

The findings of one study are in contrast to the suggestion that healthcare professionals have little influence on the reduction in medical interventions. A retrospective review of the birth records of 405 women in the United States found highly significant differences in the caesarean section rates for women cared for by different nurses. Multiple regression techniques identified that the nurse caring for a woman outweighed all other variables in determining the likelihood of a caesarean section including the attending physician, type of health insurance and maternal and fetal characteristics (Radin et al 1993).

Though it is suggested by some commentators (Stockton 2003, Hodnett et al 2011) that the results of the randomised controlled trials indicate that lay supporters are more effective than professionals in improving outcomes, the alternative explanation proposed in this thesis is that the differences in outcome are as a result of the dose, quality and context of support rather than the lay or professional status of the supporter. It is proposed that high quality continuous one to one support with beneficial outcomes can be provided by midwives in the UK setting.

2.7 CARE PROVIDERS' VIEWS OF THEIR SUPPORT ROLE

A handful of studies have explored the views of maternity care providers about their professional support role and factors affecting how they carry out this role (Collins 1986, Miltner 2000, Sauls 2006, Payant et al 2008, Thorstensson et al 2008). Professional views of support largely reflect those of women (Sauls 2006). In a three round Delphi study with 87 labour ward nurse-midwives in the US, the key support methods were defined as:

1. *Staying with the woman,*
2. *Coaching the woman to enable her to relax,*
3. *Praising the woman*
4. *Advising the woman about progress and coping strategies* (p495 Miltner 2000).

A Delphi designed study exploring midwives' views of the definition of exemplary midwifery practice identified three key dimensions which appeared to be of equal importance: 'therapeutics' (includes skilled practice to optimise health outcomes for the woman and baby), 'caring' (ensuring that the woman feels safe, well cared for, satisfied and empowered by her birth experience) and 'profession' (the environment in which the midwife practices which enables high quality practice) (p7 Kennedy 2000). The role of support is at the centre of midwives' definitions of good midwifery care (Butler and Jackson 1998, Ralston 1998, Fraser 1999):

'*This 'one to one' midwife and woman relationship is the essence of good maternity care'* (p11 Ralston 1998).

An integrative systematic review of literature relating to definitions of 'a good midwife' identified good communication skills as making the greatest contribution to being a good midwife, while being compassionate, kind and supportive also made a major contribution (p427 Nicholls and Webb 2006).

The provision of effective intrapartum support can be hindered on several levels: a whole system level, an individual institutional level and at a personal practitioner level. Maternity systems which are 'obstetric led' rather than 'midwife led' have been found to provide care that offers less continuity of care and is generally considered to be less supportive by women (Homer et al 2001, Walsh and Downe 2004, Hodnett 2006, Hatem et al 2008). Where significant staff shortages exist in a system, provision of one to one intrapartum care is undermined (Care Quality Commission 2010). At an institutional level, staff may experience social pressures that undermine their ability or desire to provide continuous intrapartum care. Managers and colleagues may indicate that supportive care is less highly valued than technical care (Gale et al 2001, Davies and Hodnett 2002, Lundgren and Dahlberg 2002, Sleutel 2002 and 2003, Payant et al 2008, Halperin et al 2011). At a personal level, maternity care providers may feel they lack training and skills in providing supportive care (Hodnett et al 2011). Where staff are not well supported to enable them to cope with the pressures and stress of their role, they may suffer 'burn out' which reduces their ability to provide care that responds effectively to women's needs (Hunter 2000, 2002, 2006 and 2008, Deery 2005, John and Parsons 2006). The maternity care system and cultural context in which support is provided is a key element in any exploration of intrapartum support.

2.8 FATHERS AND OTHER BIRTH COMPANIONS

Though the focus of this thesis is on the support of women by midwives, the role of women's chosen lay birth companions is a key theme in the literature on intrapartum support.

The role of the father in supporting the woman during labour was a focus of academic and lay attention in developed countries during the 1970s (Heggenhougen 1980) and since that time has generally become the norm in Western societies. A range of studies have identified the benefits of partner attendance during labour including greater psychological well-being for women (Szeverenyi 1989, Gungor and Beji 2007, Kainz et al 2010) and a feeling of involvement

and a successful transition to fatherhood for the fathers (Vehvilainen-Julkunen and Liukkonen 1998). The impact of fathers or family members as support figures on clinical outcomes such as use of pain relief and type of birth appears to be less than the impact of professional or doula support (Gungor and Beji 2007, Hodnett et al 2011). The presence of fathers and other family members to support women does not appear to reduce women's need for professional presence and support (Bowers 2002, Hauck et al 2007, Larkin and Begley 2009).

The admission of fathers or other family members into the labour room as supporters in developing countries remains an issue of debate and research and is not universally implemented. Studies in these countries generally identify that schemes to introduce partner or family members are successful and acceptable (Bruggeman et al 2007, Morhason-Bello et al 2008, Banda et al 2010).

The perspective of fathers and the impact of professional support on their views of the birth of their child are explored in a handful of studies. These studies demonstrate consistency between the views of fathers and women about the nature of intrapartum support. As in studies with women, the majority of fathers report a positive birth experience. The factors associated most strongly with a positive experience are midwifery support, the midwife's presence in the room and information provision about the progress of labour (Vehvilainen-Julkunen and Liukkonen 1998, Hildingsson 2011). Fathers feel most supported themselves during their partner's labour if they are allowed to ask questions, are able to interact with the midwife and their partner, are given information about progress and advice on how to help and when they can choose to be involved or step back (Vehvilainen-Julkunen and Liukkonen 1998, Hallgren et al 1999, Hildingsson 2011). When fathers feel excluded this can lead to feelings of helplessness and panic (Backstrom and Wahn 2011).

2.9 THE MECHANISM OF ACTION OF INTRAPARTUM SUPPORT

This is the question that the literature review was least able to answer. There has been very little research undertaken to investigate the mechanism by which support may affect outcomes in labour, promote normality and reduce interventions:

'*There is no direct evidence of the process or the way in which the effect [of support] on labour is mediated. If there were, perhaps it could be included into midwife education'* (p42 Alder 2000).

The theoretical explanations proposed in the literature on childbirth generally lean towards the 'buffering' explanation. As part of their randomised controlled trial of continuous support on labour outcomes, Hofmeyr et al (1991) hypothesised that:

'*during labour women may be uniquely vulnerable to environmental influences: modern obstetric care frequently subjects women to institutional routines, high rates of interventions, unfamiliar personnel, lack of privacy and other conditions that may be experienced as harsh. These conditions may have an adverse effect on the progress of labour and on the development of feelings of competence and confidence. This process may to some extent be buffered by the provision of support and companionship during labour'* (p757 Hofmeyr et al 1991).

This 'buffering theory' of social support suggests that support does not have a direct physiological effect but rather '*it may be that the presence of the support person did little more than render the hostile labour environment marginally less inhumane'* (p672 Mander 2000). Support may operate by helping to break what Dick-Read described as the fear-tension-pain cycle (Dick-Read 1951), so that the intensity of the woman's reaction to her pain sensation may be better controlled when she is supported (Edgar and Smith-Hanrahan 1992, Mander 2000). The sense of competence and control that a woman experiences is carried on through labour and into the early parenting period and helps to explain the findings of some studies showing

longer term impact on mother-infant interaction and breastfeeding (Hofmeyr et al 1991, Langer et al 1998).

In presenting a randomised controlled trial of continuous support in labour in 2002, Hodnett draws on the work of Lederman (1978,1981 and 1996). Lederman suggests a direct relationship between support and maternal anxiety and hormonal responses. If women are unsupported, a higher level of catecholamines are produced which in turn inhibit oxytocin production and thus the frequency and strength of contractions is reduced, leading to a longer labour (Lederman et al 1978). Lederman's work measured plasma epinephrine, norepinephrine and cortisol levels among 32 primigravida women with no complications at 31 and 36 weeks gestation and then at four stages during labour. Maternal anxiety levels were measured at each stage using the State-Trait anxiety inventory. This is a rare piece of research assessing the physiological responses of women during labour. This research found a link between stress response and abnormal fetal heart rate activity and a reduction in uterine activity and therefore between stress and medical interventions (Lederman et al 1978 and 1981).

The only other experimental study in this area was a small randomised controlled trial of 16 women carried out in 1998, which provided women with one hour of continuous support. Following the intervention the women's oxytocin level assays were then compared to women without support. Unsurprisingly, given the very short period of the intervention and the very low numbers of women, no difference was found in oxytocin levels between the two groups (Lindow et al 1998).

Some more recent work on the way that women in particular respond to stressful situations has been undertaken. This work, by Taylor et al (2000) explores the hypothesis that biobehavioural response to stress in women may have evolved differently from those in men, and that rather than a 'fight or flight' response, women may exhibit a 'tend and befriend' response (p411 Taylor et al 2000). This theory draws on research that suggests that women particularly seek out affiliation and support, particularly from other women, in times of stress (Gerin et al 1995, Taylor

et al 2000) and that this support leads to an increased production of oxytocin (Turner et al 1999), which is the key hormone in labour progress and maternal attachment behaviours.

2.10 MEASURING SUPPORT

Five studies were identified which most closely related to the central topic of this thesis (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2001, Miltner 2002, Barnett 2008). These studies aimed to describe in detail how obstetric nurses provided care during labour and what proportion of their time was spent in providing support, through direct observation on labour wards. Their methods and designs are summarised in Appendix Two.

The first three studies (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2001) were conducted in Canada and employed a checklist of direct and indirect care activities developed by McNiven. Direct care was divided between supportive direct care and other care. Supportive direct care was subdivided into four categories: physical comfort (including eight specific behaviour categories), emotional support (three sub-categories), instruction and information (four categories) and advocacy (two categories). The studies used a work sampling approach in which researchers observed and recorded at regular observation points the behaviours of all nurses working at any time on the labour ward using the checklist. These studies identified a very low percentage of the nurses' time spent in direct support activities: six per cent (Gagnon and Waghorn 1996), 9.2% (McNiven et al 1992) and 12.4% (Gale et al 2001). Nurses were observed to spend an average of 79% of the time out of the labour rooms (Gagnon and Waghorn 1996), even when the workload allowed one to one care to be provided.

The study by Miltner was undertaken in the USA and used a different observational method, with the observer remaining in the labour room to undertake two hour periods of observation of care (Miltner 2002). This study employed an original 'intrapartum nursing observation tool' which was based on an earlier Delphi study with obstetric nurses. The tool allowed 23 behaviours to be documented every minute. These included thirteen supportive activities (five

informational, four emotional and four physical support), six surveillance activities and four indirect care activities. This study found that nurses spent 31.5% of their time providing at least one supportive care intervention (Miltner 2002).

The most recent study was also undertaken in the United States (Barnett 2008). A computer programme was devised to enable an observer present in the labour room to record the amount of time the nurse spent in the labour room and the type of activity the nurse engaged in. The study identified that nurses were in the room for 31% of the observation period and during their time in the room, the nurse was engaged in supportive activities for 40% of the time.

The five studies described have made an important contribution to knowledge about the quantities of support provided to women in labour in the North American systems. The methods used were appropriate to answer research questions relating to the quantity of supportive and other caring behaviours provided to women during labour. However, the studies have a number of limitations. The studies all measured the quantity and not the quality of support during labour. The work sampling observation studies only provided brief snapshots of tasks, actions and behaviours without being able to describe in more depth and detail the quality of interactions, the tone of conversation, the provision of quiet supportive presence without providing any specific care or the impact of women's behaviours on professionals' behaviour. The three earlier studies only recorded one activity at a time and thus were unable to provide a full representation of the nurse's activities as they did not demonstrate multi-tasking or where a non-supportive behaviour was accompanied by a supportive behaviour. In the three earlier studies, it is not clear the extent to which the observation instruments used were developed using a robust evidence-based approach and very little evidence of validity or reliability testing is described. The relevance or transferability of the findings of the five studies to the UK setting is very limited due to the very different maternity care systems and the very different role of obstetric nurses to midwives.

2.11 PROVISION OF INTRAPARTUM SUPPORT IN THE CURRENT UK NATIONAL HEALTH SERVICE

The maternity services of the UK National Health Services provide care to pregnant women and newborns by multi-disciplinary teams of health professionals including the woman's general practitioner, community and hospital-based midwives, obstetricians, anaesthetists, paediatricians, neonatal nurses and health visitors. The midwife is designated as the lead professional for the care of the majority of women. Where a woman has specific needs that require her to be reviewed or cared for by other members of the healthcare team, the midwife maintains a coordinator role (DoH 2010). Healthcare is an element of government that is devolved, that is the National Health Service in each of the four countries making up the UK has their own management and professional guidance bodies. In Scotland, where the thesis studies were undertaken, national guidance recommends that women are carefully assessed at each encounter during pregnancy, labour and the postpartum period to establish any risk factors and the appropriate care pathway for that woman. If a woman does not have any of the specific risk factors identified in guidance, the woman is assigned to the 'green' care pathway and as such she is provided by midwife-led care. If a woman is identified as having specific care needs or risk factors, she is assigned to the 'amber' or 'red' care pathway, in which she will continue to be cared for by a midwife, but with the involvement of other appropriate members of the professional team, such as the obstetrician (NHS QIS 2009).

The provision of one to one continuous midwifery support for all women in active labour is identified as a central tenet of maternity service provision by Governments in all four countries of the UK (Scottish Government 2001 and 2011, Welsh Assembly Government 2002, DoH 2007 and 2010), in clinical guidance (NICE 2007, NHS QIS 2009) and by all professional and lay bodies (NCT 2002, RCM 2005, MCWP 2007, RCOG 2007).

The ability of the service to provide this level of care is variable across the UK. A recent Centre for Workforce Intelligence report identified significant variations in midwifery staffing levels across the UK (CFWI, Dunkley and Haider 2011). The Royal College of Midwives recommends

an overall standard of one midwife per 28 hospital births. Though this standard was achieved in Scotland, the rate in England is on average one midwife per 33 births. The Royal College of Midwives estimates that vacancy rates in London are 15% (CFWI, Dunkley and Haider 2011).

A national review of maternity services standards in Scotland in 2007 identified that fourteen out of the then fifteen health boards had provided evidence that they provided one to one midwifery care to all women in active labour (NHS QIS 2007).

An independent inquiry into the safety of maternity services in England in 2008 identified a shortage of midwives and a failure to provide one to one care in active labour in England (King's Fund 2008). A national review of maternity services in England in the same year undertook a large scale survey with service users. This found that women generally rated the care they received during labour and birth as 'good' or better (89%), but that there were significant differences between trusts, with a range of 67-96% in satisfaction with labour care. Around one in five women identified having been left alone at some point in labour when it worried them. This figure rose to 40% in one trust. Where women were left alone more, they were also more likely to report feeling they were not treated with respect and dignity or given the explanations or information they needed (Healthcare Commission 2008). Similar results were found in the follow-up study with 25,000 mothers in England in 2010 (Care Quality Commission 2010).

National UK wide data on the provision of one to one midwifery care during labour are not currently routinely collected or reported.

2.12 SUMMARY

The literature review identified an established body of theory relating to the nature of social support in labour and broad consensus about definitions of support in labour. Social support during labour is defined as emotional, tangible, informational and advocacy behaviours which can enable or undermine a woman's ability to cope with the emotional and physical demands of

labour and childbirth. The thesis which follows drew on these theories of social support as a multi-dimensional concept where the type of support provided, recipients' perceptions of that support, the behaviours of the provider and the reciprocity of the exchange are all studied to provide new knowledge about the means by which benefits and positive outcomes may be maximised (Hupcey 1998). This theoretical framework informed the development of the research questions, design, methodology and analysis of the results of the study.

The review identified the central importance placed on professional support by women in their assessments of their childbirth experiences. What women value and what women find unsupportive in labour has been evidenced in the literature. A large number of studies using a variety of qualitative and quantitative methodological approaches with women from many different backgrounds have been undertaken. Systematic review of studies with a large number of women has identified a high degree of commonality in the priorities of women for care and support during labour, irrespective of the maternity care system in which they find themselves (Hodnett et al 2002). These well established findings, along with the research identifying fathers' support needs in labour, provide the structure for the content of the evidence based systematic observation instrument developed for this study.

The positive impact of continuous support in labour has been substantially researched and there is strong evidence to support the contention that continuous support improves a range of clinical outcomes. However, the question of whether the identity or role of the supporter effects outcomes differently, particularly in relation to the contribution of midwives and the question of what type of continuous support has the most beneficial effect on outcomes remain unanswered.

The critical review of the existing most comparable studies highlighted some significant gaps in knowledge about professional intrapartum support. The content and quantity of support by obstetric nurses in North America had been explored, but the contribution of midwives in providing continuous labour support had not yet been researched. The nature and content of

intrapartum support by midwives, and specifically by midwives offering care to women in hospitals in the National Health Services in the UK had not been the subject of research. Questions about the impact of the quality of support and the effect of negative support have also not yet been answered empirically. Review of the large body of research with women postnatally identified these elements of professional support to be significant in their assessment of the support provided. No previous observational studies exploring professional support in labour had sought to explore the role of the demeanour and behaviours of the woman and her birth partner in the interaction. There have been no studies which sought to measure intrapartum professional support and identify links between the observed care, women's perceptions of the care received and other clinical outcomes. These identified gaps enabled the development of the key research questions and informed the content of the data collection tools.

There is a lack of research or audit undertaken across the National Health Service to identify the proportion of women who receive continuous midwifery support in labour. This study provided new detailed information about the level of provision in four maternity units in Scotland and tested an instrument which could provide this information across the UK.

Unfortunately, it was felt to be outside the scope of this study to seek to answer the large number of questions remaining about the physiological mechanism and biochemical pathways through which support in labour has an effect on outcomes, though it is hoped that its findings contribute to the debate.

The current 'state of the nation' of knowledge relating to intrapartum support has identified that support is a key concept that is central to women's feelings about childbirth, central to reducing the number of medical interventions, central to caregivers' perceptions of their role and central to definitions of normal childbirth. There are clear and substantial benefits to women of continuous rather than intermittent support in terms of shorter labours, fewer caesarean and operative births and greater satisfaction. The nature and quality of the support provided has

clear links with women's feelings about the birth and has implications for their perinatal mental health. This knowledge has led to the development of international (WHO 1996) and national policies (DoH 2007 and 2010) and clinical guidance (NICE 2007) identifying one to one high quality support for all women in active labour as a key aspiration.

What has not yet been explored in research is the extent to which the aspirations of high quality continuous support are realised in current practice and what the definition of high quality support should be. These gaps are identified by leading researchers in the field:

'*although the randomised controlled trials have told us a great deal about the effects of labor support, they can tell us little about the art of providing it'* (p257 Hodnett 1996),

'*we should aim to have care giving techniques applied in a systematic organised fashion based on research...Defining women's preferences in support during the birth process and implementing and evaluating the results of those interventions remain significant challenges for researchers'* (p15 Watkins 1998),

'little is known about the quality and quantity of supportive actions currently used by nurses' (p3 McNiven et al 1992),

'*studies are needed that investigate the components affecting a woman's satisfaction with her birth experience'* (p58 NICE 2007).

2.13 THE RESEARCH AIM AND QUESTIONS

The aim of the thesis was to provide greater understanding of the professional support provided by midwives to women during labour and childbirth in order to support the successful enablement of normal birth, improve the quality of clinical care and women's experiences.

The literature review undertaken into labour support provided the theoretical and empirical framework for the thesis and identified gaps in our current knowledge. The key questions identified were:

1. Do midwives working the in Scottish National Health Service provide continuous one to one care to women in active labour?
2. How does the support offered by midwives in Scotland compare to the support provided by maternity care providers in other maternity systems outside the UK?
3. What are the quantities of different types of support provided by NHS midwives in Scotland?
4. What is the quality of the support provided by NHS midwives in Scotland?
5. What are women's perceptions of the support provided by the midwives caring for them?
6. Are there associations between the quantity and quality of the support provided by midwives and women's perceptions and other clinical outcomes?

In order to answer these questions, a further exploration of the literature was required. This secondary literature review, detailed in the following chapter, focused on the choice of an appropriate methodology to answer the above questions. This identified that an observational approach was most able to address the questions successfully. It was then necessary to identify existing intrapartum observation instruments and assess these instruments to identify their suitability for use in the UK to address the identified gaps. This secondary review identified that a new observation instrument was required to address the research questions. This secondary literature review and the subsequent development of the instrument therefore led to the specific research questions for the thesis (see section 4.8.1).

CHAPTER THREE – CHOICE AND DEVELOPMENT OF THE METHODOLOGY

3.1 INTRODUCTION

The preceding chapter documented the comprehensive literature review undertaken to identify the current state of the nation of knowledge in relation to intrapartum support. This review identified the central importance of support in the childbirth process in terms of women's experience and clinical processes and outcomes. The review identified an established theoretical framework that explained and defined intrapartum support as a range of emotional, tangible, informational and advocacy support behaviours that seek to enable a woman to cope with the challenge of childbirth. Women's views of what kind of support is important to them have been explored in depth. Some research has been undertaken that seeks to measure the quantity of different support and non support behaviours by health professionals during labour. The optimum content of intrapartum support and the nature of intrapartum support provided by midwives in the UK have not yet been studied.

Decisions about the research methodology stem directly from the research questions identified at the end of the preceding chapter. The following chapter describes the process followed to choose the appropriate methods, the review of literature relating to the chosen methods, the stepped approach to the development of the central data collection instrument and the development of the specific research questions for the thesis.

3.2 FRAMEWORKS FOR THE DEVELOPMENT OF AN APPROPRIATE METHODOLOGY

The overall aim of this research was to contribute to knowledge about the intervention of professional intrapartum support in order to optimise its beneficial impact in improving normal birth rates. The way in which the true impact of any intervention can be measured most robustly is, ultimately, in a large scale randomised controlled or cohort trial. Such a trial was

beyond the scope of this thesis, however the research described may be considered to be the early preparatory stages required before embarking on such a large scale trial.

In order to provide robust foundations for a future larger study, a clear structured approach to the development of the methodology was chosen. The methodology was informed by two methodological frameworks which complimented each other: the Medical Research Council (MRC 2000, 2008) framework for the development of trials of complex interventions, which guided the overall programme of work from the initial theoretical basis for the intervention through the early stages of trial development. During the early stages of reviewing previous research, it became apparent that it would be necessary to develop a new instrument . To guide the instrument development, the framework for the development of health measurement instruments devised by Streiner and Norman (2003) was then also employed.

Professional intrapartum support and the measurement of the quantity and quality of intrapartum support match the Medical Research Council (MRC) definition of a 'complex intervention', that is an intervention with several interacting components (MRC 2000 and 2008). The complexity of an intervention is related to the range of possible outcomes, the variability of the target population and the number of elements in the intervention package itself (MRC 2000 and 2008). The approach taken in the studies was informed by this guidance to ensure a robust research design and to ensure that any subsequent trial or large scale evaluation testing the impact of midwifery support on outcomes would have strong foundations. The MRC framework includes the following stages:

- *Identification/development of a coherent theoretical basis for the intervention,*
- *Identification of evidence to suggest that the intervention is likely to be effective,*
- *Systematic use of the theory to develop the intervention,*
- *Full description of the intervention,*
- *Modelling the process and anticipated outcomes (paper or fieldwork)*

- *Initial piloting and feasibility testing of the intervention*
- *Feasibility and piloting to estimate recruitment and determining sample size for the later full study*
- *Assessing the effectiveness of the process and intervention* (MRC 2000 and 2008).

The MRC framework was first applied to the complex intervention of intrapartum support. The initial literature review detailed in the preceding chapter identified the clear theoretical framework for intrapartum support and the evidence that continuous support has significant positive impact on outcomes when compared to intermittent support. Studies Two, Three and Four, testing the newly developed instrument for validity and reliability, may be viewed as part of the 'modelling' stage described in the earlier MRC Framework of 2000. This modelling is concerned with 'unravelling and distinguishing the key components in a complex intervention' (p8 MRC 2000) and may be undertaken as a paper, computer based or fieldwork exercise:

'*The most challenging part of evaluating a complex intervention and the most frequent weakness in such trials is defining the actual intervention, that is, standardising the content and delivery of the intervention by determining the critical components of the intervention and how they relate to, and impact on, each other' (p9 MRC 2000).*

The final clinical study using the newly developed instrument and gathering postnatal outcomes data represents the piloting and feasibility stages, through the testing of the feasibility of the systematic observation approach in testing the impact of the complex intervention of intrapartum support.

3.3 CHOOSING THE THESIS METHODOLOGY

Consideration was given to several methodological approaches. Firstly, an exploration of the nature of intrapartum support as described by women and midwives in the UK using antenatal and postnatal quantitative and qualitative questionnaires and interviews. A considerable body

of research, explored in the previous chapter, has been undertaken using these approaches and has provided valuable insights into what women and their caregivers consider to be the most important aspects of intrapartum support (Brown and Lumley 1998, Garcia et al 1998, Bowers 2002, Hodnett 2002, Green et al 2003, Larkin and Begley 2009). These approaches cannot fully answer the questions posed. Firstly, women's descriptions of the care they received during labour, while of central importance, are by their nature subjective and are open to influence from many factors including the woman's overall experience of her pregnancy and antenatal care, her current emotional state, the outcome of the birth and her own personal support networks. Some research has identified what is called the 'halo effect' where the experience is described more positively by the participant reflecting the happiness and relief of having a healthy baby (Simkin 1991, East and Colditz 1997, Stelmack et al 2006). Secondly, when asking caregivers to describe the care they give, it is recognised that they may provide a positive description of their practice, described as 'the social desirability bias' (p316 Robson 2000) which may not always reflect the actual care given. 'Questionnaires measure what people say they do or believe, but not what they actually do' (p3 Sackett 1978).

Another approach considered was a retrospective review of intrapartum records to identify the support provided. Previous research has identified that maternity records do not provide a complete record of care provided:

'*It is often difficult to assess from case notes what communication actually takes place between professionals and the woman they are caring for, as what is said may not necessarily be written down and written notes may not capture well the nature of the interaction'* (p23 McCourt and Beake 2001).

Maternity care records tend to describe some activities, such as auscultation of the fetal heart, but may not record other 'softer' elements of care. Midwives do not generally record in detail either the amount of time spent in the labour room or provide written accounts of reassurance or comfort measures provided.

This then leads to the necessity to observe intrapartum support in some way to establish what is provided in practice. '*Many questions about behaviour are most appropriately answered by observational research'* (p16 Martin and Bateson 1986).

Observational research can be defined as *'the collection of data that are visible to visual sensors, whether that consists of the researcher's eyes or the use of video'* (p140 Rees 2003). Observational research seeks to observe behaviour in its natural setting rather than in an experimental or laboratory setting, in order to provide an accurate picture of what actually happens:

'*Virtually no other data collection method can provide the depth and variety of information as observation. With this approach, humans the observers are used as measuring instruments and provide a uniquely sensitive and intelligent tool*' (p286 Polit et al 2001).

Historically, there have been two key approaches to observational methods of enquiry. The first, participant observation, is an essentially qualitative style, while the second, structured or systematic observation produces quantitative data. Traditionally, advocates of qualitative or quantitative approaches to research have maintained that these methods reflect incompatible paradigms, though this mutual exclusivity of methodologies has more recently been questioned by researchers. It is possible for creative researchers to use elements of both approaches in an observational study, either in separate phases of the research or by developing quantitative indicators that seek to capture richer more qualitative information (Hall et al 1996).

3.3.1 Qualitative Ethnographic observation

Qualitative observational approaches were first developed by anthropologists and sociologists to examine the actions and interactions of animals and people in their natural social world. Several approaches to human observation were developed which sought to define the position of the observer in relation to the group she observed: this ranged from the researcher as 'complete participant' where she would be part of the group observed, carrying out covert observation, through 'participant observer' where the observation is overt and carried out by the

researcher who is an insider, to 'observer as participant' in which the researcher does not have any real involvement in activities but is present and finally to 'complete observer' where the researcher is at a distance from the setting and is unnoticed by the subjects, this can be carried out through means such as two-way mirrors or the use of video.

Several influential ethnographic studies have been undertaken in labour settings in the United Kingdom. Kirkham's 1989 exploration of information provision in the labour room provided extensive and rich new knowledge about the interaction between women and midwives in the UK. The continuous observation undertaken during 113 labours used a 'grounded theory' approach. Key themes identified were the central importance of information provision for women and midwives, the different levels of information provided to women depending on their perceived social and educational status, the role played by the midwives' behaviours on women's information-seeking behaviours, the impact of power structures on the labour ward on patterns of information provision, the role of humour in the labour room interactions and the 'verbal asepsis' or poor communication techniques observed on occasion (p125 Kirkham 1989).

Another ethnographic exploration of midwifery care was undertaken in the 1980s. This study, undertaken over six months on two labour wards in the UK, sought to explore the culture of these labour wards in order to understand the social meaning of midwifery (Hunt and Symons 1995). The study focused particularly on the observed cultural influences on the midwives' behaviours in the labour ward setting but did not undertake any observations of labour care. This study highlighted the importance of social norms in shaping the midwives' attitudes to care and caring behaviours and the influence of the systems and organisation of care on their ability to provide continuity of care.

In 1998 McCrea et al published a qualitative observational study of eleven midwives caring for fifteen women in the first stage of labour, focusing on their varying approaches to pain relief. This study postulated that there were three categories of midwife in their approach to pain relief

in labour: the ‘cold professional’, the ‘warm professional’ and the ‘disorganised carer’ (p179 McCrea et al 1998).

The most recent observational study in an intrapartum setting was undertaken in a stand alone midwife led unit in the Midlands of England. The aim of the study was to ‘*explore the culture, beliefs, values, customs and practices around the birth process within a free-standing birth centre’* (p216 Walsh 2007). The study findings identified the particular culture of the midwife led unit, in which women’s choice and agency were prioritised by the midwives and in which midwives’ perspectives on risk and normality were observed to be at odds with the dominant medical culture of hospital based maternity services.

While these studies have contributed valuable insights into midwifery culture in the UK and midwife behaviours in childbirth settings, there are some limitations to the qualitative observational approach. The approach relies very heavily on the observer's judgments about what is important in what they observe and the meanings they give to what they observe. A narrative account of the events observed is written in detailed field notes and then generally a 'grounded theory' approach is taken to the development of hypotheses (Glaser and Strauss 1966). Hypotheses are developed as a result of the findings rather than before the research begins. This requires the observer to *'perform difficult tasks of synthesis, abstraction and organisation of data. The observer is the instrument'* (p320 Robson 2000). The centrality of the single observer’s judgments has led to concerns about the reliability of the findings of such approaches and certainly limits the ability to generalise any findings or replicate the study beyond the specific setting of the particular piece of research.

3.3.2 Systematic Observation

The systematic or structured approach to observation of behaviour developed in the discipline of psychology. The systematic approach seeks to reduce the impact of the personal judgments of the observer by developing a clear coded schedule of observations, where predetermined categories of behaviour and interaction are noted. These coding schemes are developed early

in the research process generally through an exploratory, unstructured observation stage, which seeks to clarify and focus the research questions and, potentially, the hypotheses. The coding scheme is developed to incorporate the behaviours and distinctions which the observer feels are important in providing answers to the research questions. A number of observers are then trained to use the coding scheme.

The coding system and training should be devised so that the same results are derived when different observers are observing an interaction ('inter-observer reliability') and when the same observer reviews an interaction at two different times ('intra-observer validity'). This reliability can be tested using an 'index of concordance' (p80 Bakeman and Gottman 1997).

The systematic approach to interactional observation has been widely used in developmental psychology: studies have observed the interaction between a mother and her baby at different ages, leading to a huge growth in understanding of human development and the establishment of a number of key theories such as attachment theory and concepts of infant mental health (Brazelton 1974, Cohn and Tronick 1987).

The systematic observation approach has also been used widely in research in education, particularly looking at classroom interactions between teachers and their pupils. An early example of a systematic coding scheme is the 'Flanders Interaction Analysis System' (Flanders 1976). The system is used as an 'interval coding system', the observer notes down in one of ten categories the observed behaviours in the classroom at regular set intervals This allows the observer to record only the behaviours that have been considered to be of central importance during the development of the coding scheme (Bakeman and Gottman 1997). The schemes aim to reduce the amount of inference that needs to be made by the observer when coding the interaction. It is considered 'highly desirable' in systematic observation to have more than one observer involved in gathering data as this increases the validity of the findings as they are not relying on one individual's inferences (Bakeman and Gottman 1997).

There has been some limited use of systematic observational techniques in the labour setting with a handful of studies identified using systematic observation of second stage care and behaviours (Beaton 1990, Mackay and Smith 1993, Thomson 1995). In one study, thirty three women and thirty nurses providing care in labour were observed, using a schedule to categorise the 'verbal response modes'. This identified the way in which nurses used communication and language to maintain professional control (Beaton 1990). In 1995 a pilot study for a randomised controlled trial to compare spontaneous and directed pushing in the second stage of labour was published. Thirty two women were observed by a researcher once the second stage of labour had been diagnosed. The women were randomised at the point of diagnosis of second stage to either spontaneous pushing or directed pushing. A proforma coding sheet was completed by the researcher which recorded the time of the contractions, the number of pushes made by the woman in each contraction, the instructions given to the woman by the midwife, the woman's actions and the positions adopted by the woman (Thomson 1995). The focus of this research was the woman's 'natural' pushing behaviour if left undirected by the midwife which identified that women will naturally use shorter 'open glottis' pushes rather than the long 'closed glottis' pushing prescribed by many midwives in 'directed pushing' (p1027 Thomson 1995). This provided important additional information to inform practice change in second stage labour care. None of the studies specifically focused on observing or recording the support behaviours of the midwives.

One study sought to compare the professional intrapartum supportive behaviours of midwives in public and private hospital settings in Africa. This study employed an adaptation of the BANSILQ (Bryanton Adaptation of the Nursing Support in Labor Questionnaire, Bryanton 1994) to record 37 midwife-woman interactions in labour alongside interviews and focus groups (Eustace and Lugina 2007). The BANSILQ is a questionnaire validated for the description of labour support received by women as a postnatal questionnaire. This study adapted the questionnaire to serve as an observation instrument with the observer identifying each behaviour on a scale from one, 'not done', to five, 'done very well'. This study has a number of

methodological limitations. Reliability testing of this adapted instrument was not described, the observers were described as 'concealed participant observers' without fully describing how the observation was carried out, other than saying that the observers were members of unit staff, and no details were given of the duration of each observation period. This study suggested marked differences in approach between the public and private setting, with more information giving, listening and back massages observed in the private setting than the public hospital setting (p8 Eustace and Lugina 2007).

A handful of other studies have employed a systematic observation approach to the study of professional support of women in labour. These five systematic observational studies are described in detail below (page 66, section 3.4.1) and in Appendix Two (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2001, Miltner 2002, Barnett 2008).

3.3.3 Potential for use of a systematic observational approach to provide new knowledge about professional support in labour

A number of potential benefits of using a structured systematic approach for this study were identified. Firstly, it may reduce the very time-consuming labour intensive nature of observational studies, as the observational fieldwork can and should be divided between a number of observers rather than just one observer. Secondly, the development of a systematic tool allows replication of the study in different settings and at different times. Thirdly, a systematic observation reduces the impact of the individual judgments of the observer and the need for inference to interpret the meaning of behaviours. Finally, the systematic observational approach produces quantitative data which has the potential to be used to identify correlations between the quantities of particular supportive behaviours and clinical outcomes.

In order to explore the use of this methodology for the thesis study, a further literature review was carried out. This review included earlier studies that had employed a systematic observation approach to study intrapartum support and the literature relating to the observation

and recording of the quantity and quality of care in other healthcare situations. This review is described in the following sections.

3.4 STAGES IN THE DEVELOPMENT OF A SYSTEMATIC OBSERVATION INSTRUMENT

The data collection instrument for a systematic observation study is the observation instrument, which is a paper or computer based checklist in which the behaviours of interest can be noted in mutually exclusive categories as they are observed. Guidelines have been developed to ensure a robust design of measurement scales in healthcare settings (Streiner and Norman, 2003, 'Health measurement scales: a practical guide to their development and use'. 2nd Ed. Oxford: Oxford university press).

The stages of this development can be summarised as follows:

1. *Elucidation of theory,*
2. *Review of the relevant research in the field,*
3. *Location of previous instruments and assessment of their suitability for the study,*
4. *Development of a draft instrument,*
5. *Review of the draft instrument by an expert panel to establish their views of the content validity and suggestions about gaps,*
6. *Testing of the instrument for reliability and validity (*Streiner and Norman, 2003).

These guidelines have been successfully used in a number of studies developing healthcare observation instruments (Bradley et al 2009, Hanks 2010) and were followed to ensure a clear and robust approach for this thesis study.

The first stage, elucidation of theory, was described in the preceding chapter in relation to the review of social support theory generally and intrapartum social support theory specifically. The second stage, review of relevant research in the field, was also described in the previous

chapter, this review identified a substantial body of empirical and theoretical research giving clear definitions of intrapartum support, with a high degree of consensus between women and caregivers. It was therefore not felt necessary to carry out original research, such as a Delphi study, in order to identify a clear definition of intrapartum support. The third stage, location of previous instruments and assessment of their suitability for the study, is addressed immediately below.

3.4.1 Review of other systematic observation instruments

The literature review of observational studies of intrapartum support detailed in the previous chapter identified only five previous studies focusing on the description and recording of professional support in labour (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2001, Miltner 2001, Barnett 2008). Specific details of the five studies are given as Appendix Two.

All five of the studies were undertaken in North America and so focus on the behaviours of obstetric nurses rather than midwives. The role of obstetric nurses and the systems in which they work differ significantly from midwives in the UK National Health Services and thus the results of the studies are likely to differ significantly from a comparable study in the UK. However, while the results of the studies may not be transferable to the UK setting, the methods employed are. The research design of the studies, systematic observation of labour support, matched the chosen design for the thesis study. Despite the differences in the context of the care observed, the research method used and the instruments employed were considered to be of such close relevance to the thesis study that they warranted detailed consideration.

The studies by McNiven, Gagnon and Waghorn and Gale et al used the same observation schedule to record care provided by obstetric nurses in three Canadian maternity units. The schedule used in the study by Gagnon and Waghorn in their 1996 study is reproduced below in Table One.

Table One – Intrapartum Observation Schedule Gagnon and Waghorn 1996

1.Supportive direct care activities **Category** **Category 1: Physical Comfort Measures**	**2.All other activities** **Category 1: Direct care activities with woman**
Use cool cloths, warm compresses	Includes all other activities in the presence of the patient e.g. physical assessments, performing procedures
Bathing, assisting with shower	**Category 2: Indirect care activities in room**
Linen and under pad changes	Assisting with procedures
Offer ice chips, fluids	Washing hands
Position (for comfort)	Talking to partner
Massage back or other body parts	Charting
Assist with ambulation	**Category 3: Postpartum**
Give reassuring touch	Care of mother and baby
Category 2: Emotional Support	**Category 4: Indirect not in room**
Reassurance, encouragement, praise	Preparing medications
Be with the patient to keep her company	Washing hands
Laughter, joking, social chitchat	Preparing equipment
Category 3: Instruction/Information	Teaching other than with patients
Instruct or coach e.g. with breathing or relaxation or pushing techniques	. Charting, documenting care (not in presence of patient),
Give advice	Discussing care with other members of the team
Explain, provide information e.g. about progress, fetal well-being	Attending caesarean section
Interpret physician's findings to woman	. Social discussions
Instruction to partner	**Category 5: Other non-care activities off unit**
Category 4: Advocacy	Meetings
Listening to woman's requests	In general operating suite
Support woman's decisions	Meal breaks
Negotiate patient's wishes with other team members	In other units
Discussion with visitors about woman's wishes	

The content of the schedule included was largely relevant to a UK setting but included elements not relevant to the current study including postnatal observations and observations of the nurse's behaviour outside the labour room.

The observation schedule used in the study by Miltner was based on a Delphi study with intrapartum nurses (Miltner 2000) which suggested that nurses viewed surveillance interventions as overlapping and linked with supportive interventions rather than completely separate. This led to an observation schedule with a slightly different format, presented below as Table Two.

Table Two - Intrapartum Nursing Observation Tool, Miltner 2001

Surveillance	**Care management**	**Informational support**	**Emotional Support**	**Physical Support**
History/Admission	Documentation	Relaxation techniques	Remaining with mom	Comfort positions
Assessment	Procedure preparation	Pain relief measures	Coach	Urine output
Maternal Vital signs	Assisting other health professionals	Fetal status	Praise	Pelvic rock/tilts
EFM Interpretation	Discuss with other health professionals	Procedures	Encourage/ Reassure	Ambulation
Medication Effects	Other care management	Pushing	Other emotional support	Other physical support
Post-epidural care		Other Information		**In any patient room** **Care of other patient**
Fetal resuscitation				**Non-productive time**
Other assess/Technical				**Other RN with patient**

The content included in Miltner's schedule appeared to be relevant to the current study as it placed the supportive activities of the professional in the context of other caring behaviours. Barnett's computer based observation schedule was the simplest, with the inclusion of just seven categories, presented below as table three.

Table Three – Observation Schedule, Barnett 2008

1.Time in room	3. Professional activities	5. Physical support	7. Advocacy support
2.Time out of room	4.Emotional support	6.Instructional support	

Barnett provided more detailed descriptions of the behaviours in the seven categories in her published research report and PhD thesis. These described emotional support as 'physical presence, verbal affirmation, reassurance, encouragement, distraction, attention, eye contact, visualisation, expressions of concern or caring, humor, social interaction, encouragement of the support person, praise' (p202 Barnett 2008). Physical support included 'assisting with

positioning, giving massage, offering a reassuring touch, holding, promoting relaxation, promoting hygiene, giving heat or cold compresses, offering food or fluids, providing acupressure, providing hydrotherapy' (p202 ibid). Instructional/informational included 'directing, coaching, giving advice, teaching, explaining, offering options' and advocacy 'supporting behaviors and decisions, conveying or negotiating client's wishes' (p202 Barnett 2008).

On review, it became apparent that though the content of these observation schedules had some transferability for a study of support in the UK, the observation schedules employed in some of the studies (McNiven et al 1992, Gagnon and Waghorn 1996 and Gale et al 2001) were not subject to a rigorous process to ensure validity and reliability. The content of the observation schedule used in all three of these studies was based largely on the schedule employed by Hodnett and Osborn for a randomised controlled trial of support (Hodnett and Osborn 1989). This schedule was in turn based on one study described in an unpublished Master's thesis. The process of developing the observation schedule was not described as being systematically based on the large body of research with women and maternity care providers identifying the key elements of supportive behaviour during labour. None of the studies, including the original work by Hodnett and Osborn, described any process to assess the validity of the content of the list of activities. None of the studies described a structured approach to developing a measurement instrument.

A more robust approach to the development of the observation instrument was described in Miltner and Barnett's studies. The study by Miltner employed a theoretical framework which referred to social support literature, but drew more directly on the 'quality of care framework' (Donabedian 1966a and b and 1988). This framework suggested that the structures of care influence the processes of care which in turn affect patient outcomes. The processes of care include both technical and interpersonal elements, which are not mutually exclusive, the interpersonal aspects of care (communication and relationship building) are the vehicles by which technical care is delivered. The success of technical care is dependent on the

interpersonal elements of care. Miltner developed this framework into an 'Intrapartum care management model' which identified the two categories of surveillance and supportive interventions provided by intrapartum nurses which overlap considerably. This framework led to the development of a different observation schedule than those employed in the earlier studies, which allowed for the recording of more than one activity at one time. The decision making process about the content of the observation schedule appears to be more robust, based largely on a well-conducted Delphi study with American intrapartum nurses (Miltner 2000). The three round Delphi study asked intrapartum nurses to identify the activities they perceived to be the most important supportive activities. The list of 55 activities with which they were provided in the first round of the study was based on a thorough review of the qualitative studies identifying the activities women found to be most supportive.

There are some shortcomings in the Delphi study: the participant nurses were self-selected volunteers and not a stratified sample, the sample of 87 was much lower than originally planned, the participants were all obstetric nurses working in the USA, and so the list produced is likely to reflect an approach to care shared by this particular group. It did not include the perspective of women or the perspective of midwives or other maternity care professionals working in systems outside the USA. Miltner developed the observation schedule by including the elements of care identified in the Delphi study, but then made additions to this list 'based on practice guidelines or professional standards of care, because they consume large amounts of nursing time, or because the intervention is a possible indicator for assessing the quality of nursing care' (p756 Miltner 2000). Such an approach to the content of the schedule is less robust: it is not based on a systematic review of the literature, but rather on what is 'normal' care at the time of the study in the particular location of the study. No validity testing of this modified list of activities to be observed is described in Miltner's published paper. Miltner tested the observation instrument for reliability by 'simultaneous coding of the observation period by another trained but a registered nurse observer. Interrater agreement was 0.95' (p756 Miltner 2002). No further details are provided.

The observation instrument devised by Barnett is based on the theoretical framework of social theory (Schaefer et al 1981, Lazarus and Folkman 1984, Lazarus 1991). The tool used by Barnett is very simple, defining only six categories: presence, emotional, tangible, informational and advocacy support and non-supportive care. No validity testing is described. Reliability was tested by two observers recording simultaneously for three observation periods, leading to good reliability coefficients of .93, .89 and .96. What may be described as a test of construct validity was carried out in the Barnett study: a postnatal satisfaction questionnaire was carried out with women. However, no correlation was found between women's satisfaction with care and the amount of time spent engaged in supportive activities by the nurse. The reason for this lack of correlation could be that the instrument lacked 'construct validity', that is, that it did not satisfactorily measure the construct of support in labour, as evidence suggests that women are more satisfied with their birth experience if they receive a greater level of support (Lavender et al 1999, Goodman et al 2004). Barnett acknowledged that factors such as empathy by the nurse and the nurse's ability to promote self esteem were not measured by the tool and may be of more significance in affecting women's perceptions than the amount of time the nurse spent engaged in particular activities (Barnett 2008).

Miltner and Barnett took a direct observation approach based in the room of the woman receiving nursing care. These observations therefore recorded the frequencies of particular types of care received by an individual woman. Barnett's study also timed the amount of time spent engaged in the different types of nursing activity. The data presented represent the amounts of different types of care that individual women received from individual nurses. This approach is more appropriate when the aim of the research is to assess the quantity and quality of support that a woman receives and to identify any correlations with outcomes, than the random work sampling approach of the earlier three studies which cannot assess an individual woman's experience of support.

The next stage in the assessment of the suitability of the earlier instruments for use in the thesis research was to establish the extent to which any of the existing tools could record all the key

elements of support identified in the literature review. This mapping exercise is summarised and included as Appendix Three.

A number of particular areas highlighted the way in which the existing instruments did not include all the key elements of support defined in the literature. Nursing presence is one of the key components of support identified in the literature exploring women's and nurses' definitions of intrapartum support (Lesser and Keane 1956, Shields 1978, Miltner 2000, Tumblin and Simkin 2001, Bowers 2002, Matthews and Callister 2004). Only Barnett's instrument recorded the amount of time the nurse spent in a woman's room as a proportion of the woman's active labour (Barnett 2008). The presence of the nurse in the room with no task being performed or 'keeping company' was recorded by McNiven (1992), Gagnon and Waghorn (1996), Gale et al (2001) and Miltner (2002). The description of presence in the literature refers not only to physical presence, but to the emotional presence or attentiveness of the caregiver. However, none of the instruments included any behaviour variables relating to the quality or affect of the nurse's presence. The literature review indicated that showing undivided attention through the use of eye contact, woman-directed gaze, forward leaning and proximity were considered to be important components of 'presence' (Haldorsdottir and Karlsdottir 1996), but this is not measured by any of the existing instruments.

Enabling the woman to have a sense of control or empowering women was also identified as a key component of nursing support in the literature (Lavender et al 1999, Kennedy 2000, Matthews and Callister 2004, Sauls 2006, Bryanton et al 2008). This was also only partially recorded in the existing instruments. Gagnon and Waghorn included 'listening to the woman's requests, supporting woman's decisions' (p3 Gagnon and Waghorn 1996). All of the instruments included the provision of information in their tools, which may be considered one element in ensuring that women are well-informed so that they are able to participate in decision-making and feel more in control. However, other elements described in the literature which may contribute to a sense of being in control or empowered were not included. These are giving the woman the opportunity to express her expectations, attitudes and beliefs;

encouraging the woman to do whatever feels right or helpful; attempting to carry out the woman's expressed wishes; presenting options and choices and checking out with the woman and her partner what their views or feelings are about particular situations as they arise (Watkins 1998, Lavender et al 1999, Kennedy 2000, Tumblin and Simkin 2001, Matthews and Callister 2004, Sauls 2006, Bryanton et al 2008).

A number of studies highlighted the centrality of the woman feeling 'treated with respect' (Kintz 1987, Bryanton et al 1994, Abushaikha and Oweis 2005) as a component of intrapartum support. This element is addressed partially by the existing instruments in 'discussing the woman's requests' (Gagnon and Waghorn 1996) and 'explaining and providing information' (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2000, Miltner 2002, Barnett 2008). However, there are other ways in which a woman may be helped or hindered to feel respected during her labour. These may include actions taken to ensure her privacy and modesty (such as knocking on the door before entering, using curtains around the door or bed, using covers during examinations, minimising interruptions and introducing all staff that attend the labour room), attempting to carry out the woman's expressed wishes (or failing to do so,) presenting the woman with options and choices rather than decisions that have already been made and demonstrating undivided attention and active listening (through verbal and non-verbal communication such as head nodding, reflection and responding to cues) (Fields 1987, Kintz 1987, Bryanton et al 1994, Watkins 1998, Tumblin and Simkin 2001, Bowers 2002, Adams and Bianchi 2008, Ford and Ayers 2009).

Each component of support identified in the literature was listed individually and mapped across to the existing observation tools to identify which of the elements were fully operationalised or actively included in the existing instruments. This included 28 components of emotional support. Generally the existing instruments only included three or four different elements of emotional support. For each of the 28 components, where earlier instruments had not identified them, an attempt was made to describe how this component may be operationalised or what behaviour could be directly observed to demonstrate that this component had been provided.

These additions are included and referenced as ‘Ross-Davie’ in the second column of the table (Appendix Three).

The literature identified the negative impact on women of negative behaviours by the caregiver (Halldorsdottir and Karlsdottir 1996, Soderquist et al 2006, Davies et al 2008, Zaers et al 2008, Hunker et al 2009, Leeds and Hargreaves 2008, Elmir et al 2010, McDonald et al 2011). The inclusion of negative behaviours was felt to be necessary to reflect all of a woman’s possible experiences of professional care as fully as possible. If negative demeanour or behaviours were not included, a true reflection of the quality of the support provided may not be given. A simple absence of a behaviour would not identify when a midwife had said or done something that was ‘actively unsupportive’, for example belittling the woman’s partner is likely to be perceived differently than simply ignoring the partner. None of the earlier instruments included negative behaviours. These negative observable behaviours are included in the far right hand column of the table (Appendix Three).

Review of the earlier North American systematic observation studies of intrapartum support identified the potential of the quantitative methodology to provide meaningful data about the quantity of different support behaviours of caregivers. These early studies also suggested that such an approach to measure supportive behaviours in the intrapartum setting could be acceptable to women and staff and feasible from a researcher’s perspective.

The mapping exercise clearly identified that none of the existing instruments were adequate to address the research questions. The existing instruments did not include all behaviours identified as central to women’s experience of professional support in the literature. The instruments were not designed for use in the United Kingdom and did not seek to measure the quality of professional support as well as the quantity of particular behaviours.

The earlier intrapartum support observation instruments did not include measures of quality or negative behaviours. The substantial body of research with women suggests that these are important elements of professional intrapartum support. In order to ensure that a newly

developed systematic observation instrument was based on good evidence, it was necessary to review observation instruments developed in other relevant contexts, outside of the maternity setting, that have sought to record and measure elements of the quality in healthcare interactions and delivery.

3.4.2 Systematic Observation instruments in other healthcare contexts – measuring quality as well as quantity, verbal and non-verbal behaviours

A considerable body of high quality research with health professionals outside the maternity care setting has succeeded in systematically recording and measuring the quality of interactions as well as simply recording the quantity of certain behaviours (Booth 1995, Jarrett and Payne 1995, Roter and Larson 2002, Caris-Verhallen 2004).

One of the most widely used and validated observation instruments is the 'Roter Interaction Analysis System' (RIAS, Roter and Larson 2002) devised to code video or audio recordings of doctor-patient interactions, used in more than 75 studies and substantially tested for validity and reliability. The RIAS has 34 mutually exclusive verbal categories and allows the observer to also record a general assessment of the atmosphere of the interaction. Some studies have added further non-verbal categories including patient directed eye gaze, affirmative head nodding, forward leaning, smiling and affective touch to the original RIAS (Caris-Verhallen et al 2000, Kruijver et al 2001).

Some observational instruments have been developed and validated to record and measure one particular aspect of a healthcare interaction. The 'Euro-Communication rating scale' was developed to rate a doctor's patient-centred behaviour from 0 (poor) to 5 (excellent) across five dimensions: involving the patient in problem definition, involving the patient in decision making about management, picking up cues about hidden aspects, exploring issues of patient ambivalence and the doctor's overall 'responsiveness' (p74 Mead and Bower 2000). The importance of humour has been explored in one study examining videotapes of 92 doctor-

patient visits (Sala et al 2002). Tests identified a high level of inter-rater reliability in categorising humour as negative, positive or general. It was found that humour had more of an impact on satisfaction than the length of the visit, the demographics of the patient or doctor and the health of the patient (p278 Sala et al 2002).

Several approaches to measuring quality within interactions were identified in the literature. These included categorisation of particular elements of interaction as either positive, neutral or negative, such as that described in the study above examining the use of humour. Other studies have used a Likert scale to enable observers to rate a behaviour from 'poor' to 'excellent'. A potential problem with the use of ratings scales in observational studies is the danger that they are open to error and bias, observers may have a tendency to rate everything according to a general impression, so this may lead to an 'error of central tendency', ' an error of severity' or an 'error of leniency' (p495 Kerlinger 1995). It was therefore decided for this study, that rating scales would not be used but rather simpler judgments about the presence or absence of a behaviour.

One element of the assessment of the quality of interactions is the ability of observers to record accurately and reliably non-verbal elements of interactions such as facial expression and vocal tone and pitch. There is evidence that these elements of an interaction are key in a patient's assessment of an interaction. A participant observation study of 245 patient-nurse interactions found that when patients were asked about what happened when the nurse was taking care of them, the nurse's interactive style was the primary focus, not what the nurse was doing. Building rapport, which included personal sharing and 'kidding' were valued, patients also mentioned smiling and whether the nurse looked them in the eye (p1085 Fosbinder 1994).

'Research findings indicate that the patient's perception of quality care is related to interpersonal relationships, and suggest that personal interactions between caregivers and patients significantly influence patient satisfaction' (p1085 Fosbinder 1994).

One study of particular interest and relevance describes the development of an observation instrument to observe the quality of nursing care on a psycho-geriatric ward. The authors first identified the central concepts of high quality nursing in this environment from the literature. These were autonomy, individuality and dignity. The concepts were 'operationalised' as the level of choice, information and attention given to patients by the nurses:

'The measurement of the quality of care requires a descent of the 'ladder of abstraction' from concepts, such as autonomy and dignity through dimensions of these concepts, such as choice and independence, to indicators, such as whether patients are given the opportunity to choose where they sit for a meal' (p273 Gilloran et al 1993). This study reports positive results when testing face and content validity of the instrument and inter-rater reliability.

Further examples of systematic observation measuring the expression of abstract concepts in clinical practice come from a considerable amount of research that has sought to assess and measure empathy in clinical interactions. Such research begins by seeking to define the concept of empathy as a specific set of behaviours. For example clinical empathy has been defined as the ability to:

'understand the patient's situation, perspective and feelings; to communicate that understanding and check its accuracy; to act on the understanding with the patient in a helpful way' (p9 Mercer and Reynolds 2002).

The level of empathy expressed by clinicians in an interaction has been found to be linked with improved health outcomes. Studies with nurses and cancer patients have found that where nurses expressed high levels of empathy in observed interactions, their patients showed significant reductions in anxiety, depression and hostility (p699 Mercer et al 2004).

A widely used instrument to measure empathy in nurse-patient interactions was developed drawing on clients' descriptions of behaviours that they found helpful or unhelpful in establishing a feeling of empathy, resulting in twelve categories of behaviour, which were recorded as present or absent:

1. *Attempts to explore and clarify feelings (positive)*

2. Leads, directs, diverts (negative)

3. Responds to feelings (positive)

4. Ignores verbal or nonverbal communication (negative)

5. Explores personal meaning of feelings (positive)

6. Judgmental and opinionated (negative)

7. Responds to feelings and meaning (positive)

8. Interrupts and seems in a hurry (negative)

9. Provides client with direction (positive)

10. Fails to focus on solutions, does not answer direct questions (negative)

11. Appropriate voice tone, sounds relaxed (positive)

12. Inappropriate voice tone, sounds curt (negative)' (p227 Reynolds and Scott, 2000).

The review of other instruments developed to measure the quality of healthcare interactions identified that a considerable body of high quality research has been undertaken which appears to successfully define particular aspects of healthcare quality and which enable an observer to reliably measure these aspects.

3.5 SUMMARY OF CHOICE OF METHODOLOGY

A number of methodological approaches were considered to explore the research questions identified. A quantitative study design employing systematic observation of professional intrapartum support behaviours as the central method was chosen as the most appropriate to adequately address the key research questions identified (p58).

The initial comprehensive review of the literature (Chapter Two) relating to intrapartum support identified that a large body of research of adequate quality and quantity had provided a robust theoretical framework, a clear shared definition of intrapartum support and an empirically based large knowledge base about women's needs and preferences for professional intrapartum support. This literature review identified a lack of research exploring the impact of specific behaviours within intrapartum support on birth outcomes.

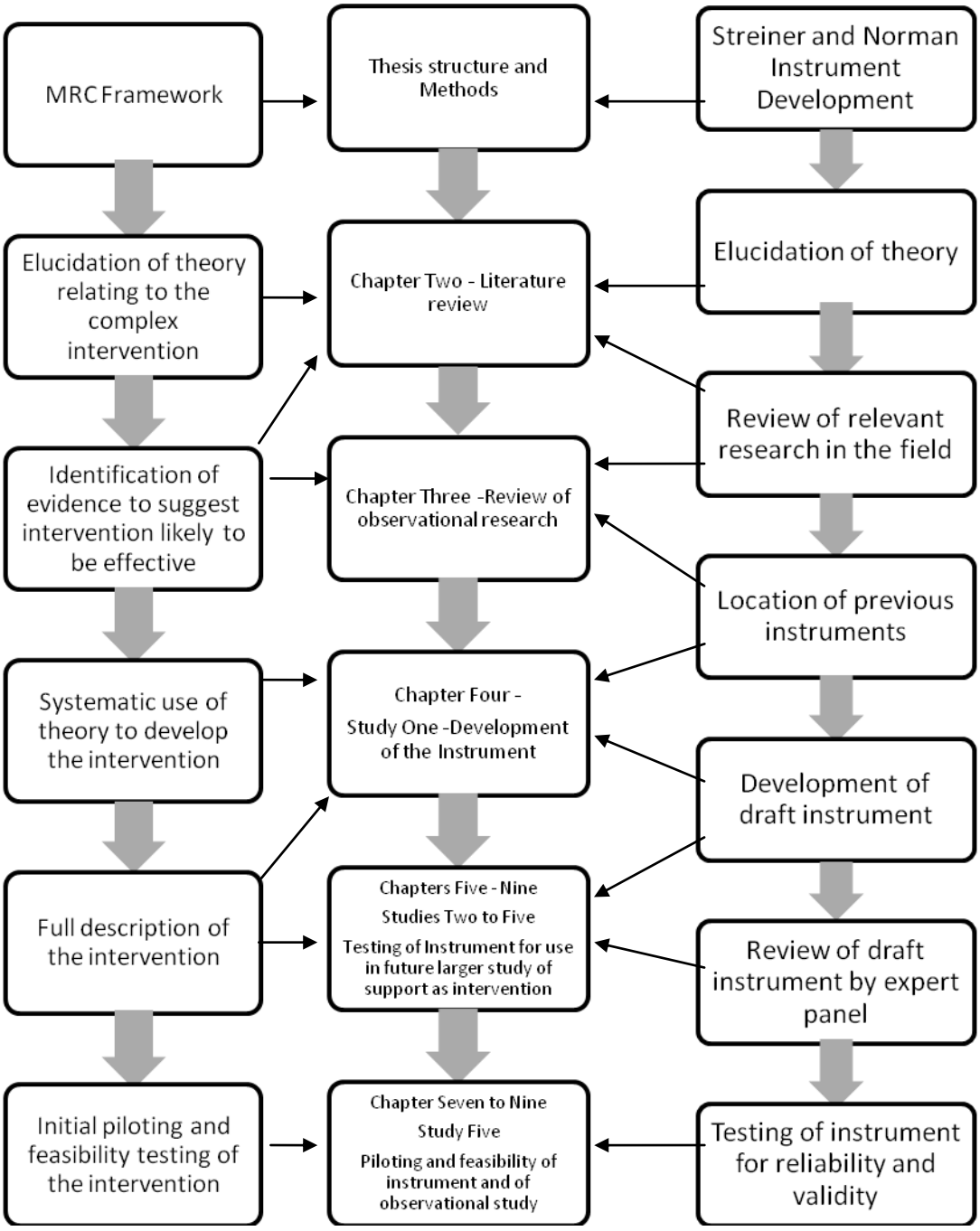
A methodology was therefore sought that could best address this gap through enabling the identification and quantification of specific support behaviours. An observational study of actual care provided was necessary to identify the presence of particular behaviours in the labour room. In order to be able to explore the correlation between specific behaviours and outcomes, it was identified that a quantitative approach to observation was required rather than a qualitative approach. While ethnographic studies of labour interactions would provide very valuable data about labour support, it would not be possible to undertake statistical analysis in relation to outcomes.

Five quantitative systematic observations of labour support were identified. These studies provided a very helpful starting point for the thesis study. Though the studies provided a great deal of new information about the nature of intrapartum professional support in North America, the instruments developed in these studies were not adequate to address the identified research questions. The instruments were not systematically developed and did not include key elements identified in the literature review as being essential components for the measurement of support in labour. The earlier instruments did not measure quality, did not identify negative behaviours and did not include the role of the mother and her birth partner in shaping the supportive care provided. The review of these studies led to the conclusion that the systematic observational approach was the right one to address the research questions, but that a new systematic observational instrument was required.

A review of non-maternity systematic observational instruments from education, behavioural psychology and health research provided evidence that it is possible to reliably measure the quantity of behaviours that operationalise concepts of quality such as empathy, respect and patient centredness and the quality of interactions through the recording of non-verbal and paralinguistic behaviours, negative behaviours and humour.

The development of this new quantitative data collection instrument is described in the next chapter as the first of the series of five studies detailed in the thesis. This process is shown graphically as Figure One to demonstrate the way in which the particular methods were informed by both the MRC framework and the Streiner and Norman guidelines for the development of healthcare measurement instruments.

Figure One: Use of the MRC Framework and Streiner and Norman guidelines to inform the study design and thesis structure



CHAPTER FOUR – STUDY ONE

DEVELOPMENT OF A NEW SYSTEMATIC OBSERVATION INSTRUMENT TO MEASURE THE QUANTITY AND QUALITY OF INTRAPARTUM SUPPORT

4.1 INTRODUCTION

Following the review of earlier systematic observation instruments from maternity and non-maternity settings, it was decided that a new systematic observation instrument designed to measure the quantity and quality of midwifery intrapartum support was required. The review of studies in other healthcare settings identified that systematic observation of interactions can reliably measure key elements of quality such as the presence or absence of positive and negative verbal and non-verbal behaviours (Booth 1995, Jarrett and Payne 1995, Roter and Larson 2002, Mercer and Reynolds 2002, Caris-Verhallen 2004).

4.2 DEVELOPMENT OF THE CONTENT OF THE OBSERVATION INSTRUMENT

The key decisions in relation to the development of the content of the new instrument were undertaken as part of the mapping exercise described in section 3.4.1 of the previous chapter and shown in Appendix Three. The exercise ensured that all defining elements of intrapartum support were included. The mapping exercise identified that while the previous observation instruments included most measures of quantity of behaviours they did not include measures of quality of those behaviours, which were clearly highlighted in the literature as being an important element of women's experience of childbirth.

Measurement of the key indicators of quality was achieved through the 'descent of the ladder of abstraction' (p269 Gilloran et al 1993), where key concepts were operationalised as observable behaviours (Appendix Three).

In order to develop an instrument to measure quality of support, clear criteria to define quality in intrapartum support were needed. The definitions of high and poor quality support used in the

study are based on the theoretical framework, the literature review identifying women and caregivers' assessment of key behaviours, the review of studies in other healthcare settings measuring quality in healthcare interactions and the Institute of Medicine definition of healthcare quality.

The internationally recognised six dimensions of healthcare quality set out by the Institute of Medicine are:

- *Person-centred*
- *Safe*
- *Effective*
- *Efficient*
- *Equitable*
- *Timely* (p3 Institute of Medicine 2001).

Unlike the measurement of the quantity of support behaviours, the calculation of the quality of the midwifery intrapartum support cannot be a simple presentation of the frequency with which certain behaviours are displayed. The assessment of quality in healthcare combines the presence or absence of positive and negative behaviours, the evaluation of those behaviours by the recipient of care and the clinical outcomes.

Using these frameworks, high quality intrapartum support will be patient-centred and include the demonstration of emotional, tangible, informational, advocacy and partner support behaviours by the midwife, the midwife will provide support to all women when they need it, the midwife will display a positive attitude and will remain with the women they are caring for. Using this theoretical framework, if these criteria are reached, the woman will describe feeling well supported and positive clinical outcomes are more likely. If the quality of support is low, there will be an absence or low level of these behaviours demonstrated, the midwife will display a neutral or negative demeanour, will engage in negative unsupportive behaviours and will not remain with the woman continually. Employing the current theoretical and empirical knowledge

of intrapartum professional support, if these criteria are reached, the woman will assess the level of support she received as poor and clinical outcomes are likely to be less favourable.

Measurement of the quality of intrapartum support employing the theoretical framework seeks to measure the extent to which the key elements of the presence of the midwife in the room, any negative behaviours, emotional, tangible, informational, advocacy and partner support are displayed in the midwife-woman interaction, and correlate these with the woman's perceptions of the support received and other clinical outcomes.

4.3 IDENTIFYING THE UNIT OF BEHAVIOUR TO BE OBSERVED AND RECORDED

When developing a new systematic observation instrument, it is necessary to consider the 'unit of behaviour' to be recorded. Quantitative approaches to observing interactions can take a molecular approach where every unit of the behaviour of interest is recorded or a more molar approach where larger units of behaviour are recorded, for example the scope of a conversation. Both approaches bring with them advantages and disadvantages. Larger more molar approaches require a greater degree of inference from an observer. So, for example in an observation of children's behaviour, if the behaviour category is 'aggression' the observer would need to place a meaning on a behaviour, such as 'hitting another child'. The weakness of this approach is that observers can make incorrect inferences from the observation. When an interpretative burden is put on the observer it is argued that validity and reliability may suffer (Kerlinger 1995). In order to reduce this danger it is necessary to 'define precisely and unambiguously what is to be observed' (p485 Kerlinger 1995). However, if behaviours are described in too much detail on a molecular level, there is a danger that some possible behaviours may not be included as an option and that the observation becomes so complex that the observer misses some behaviours. To overcome the disadvantages of the two approaches, it is suggested that an observation schedule should require a 'medium degree' of inference 'to

avoid ambiguity and uncertainty but to also conversely avoid being too inflexible or even trivial' (p491 Kerlinger 1995).

One way of reducing the possibility of incorrect inference is to choose observers with knowledge and skills in the behaviour to be observed: 'Observations of human behaviour requires competent knowledge of that behaviour and even of the meaning of that behaviour' (p487 Kerlinger 1995). It was therefore decided to recruit midwives as the observers for the main clinical study.

4.4 OTHER SOURCES OF CONTENT DECISION MAKING

Following the mapping process undertaken to define the behaviours to be included in the observation instrument, a first draft of the instrument content was devised. In order to identify potential gaps in this draft instrument and to review the relevance of its content, commercially available films depicting intrapartum care were sought by the researcher.

The films viewed were those that were available to the researcher at this stage in the research process. At this time, a new TV documentary series was being screened on national TV, entitled 'One Born Every Minute' (Channel 4, series 1, 2009-10). This series used a 'fly on the wall' documentary approach to present the labour and birth stories of women and their partners in one English obstetric maternity unit. The screening of this series provided the researcher with the opportunity to view a variety of labour care episodes in the context of seeking to record the care demonstrated by the midwives in the series.

The other films observed were obtained from the Stirling University Nursing and Midwifery department, the researcher's personal collection and contacts with parent education midwives. The films observed were:

- 'Having a baby' presented by Sue Cook, from the BBC series 'Having a baby', UK, 1988
- 'Water and birth' Janet Balaskas, Active Birth Videos, UK, 1992

- ‘Birth: eight women’s stories’ Nancy Durrell McKenna, B-Line productions, UK, 1993
- ‘Water babies: the aqua natal experience in Ostend’ Thierry Devillet, Jade Productions, Belgium, 1994
- ‘Gentle birth choices’ Global maternal/child health association, USA, 1994
- ‘Giving birth: challenges and choices’ Suzanne Arms, Birthing the Future, USA, 1998
- ‘I’m pregnant, now what?’ Social work department Westmead Hospital, Western Australia, undated
- ‘Different experiences of birth’ no other information provided, from television
- ‘Happy Birthday – how to have the best possible pregnancy and birth’ The National Childbirth Trust, 2007

The films were chosen pragmatically, that is those films that were readily available to the researcher. Most of the films showed labour care in UK settings, though two showed North American care. The films showed a variety of different contexts of care including home birth, water birth and conventional mainstream obstetric hospital births. The films were watched by the researcher with the draft observation instrument available for reference.

The experience of viewing the films emphasised a number of issues that were expressed in the qualitative research with women but were not included in earlier observation tools. These were the importance of a number of non-verbal behaviours, including the posture, positioning and proximity of the midwife, the tone and intonation of the midwife’s speech, the responsiveness of the midwife to a cue or plea from the woman, the timing of the midwife’s words, the use of humour and the role played by the woman’s and birth partner’s behaviours and demeanour in shaping the interaction. These observations did not lead to the inclusion of any new content to the draft instrument but confirmed the view of the researcher that qualitative, non-verbal elements of care were an essential element of the instrument and that it was important to include some observation of the woman and birth partner’s behaviours to place the midwife’s behaviours in context.

4.5 DECISIONS ABOUT THE OBSERVATION APPROACH

A number of decisions were made about the overall approach to the observation before attempting to develop the instrument itself.

Firstly, whether observations would take place with an observer present in the labour room or whether video recordings of labour care would be taken to be analysed after the event. Many of the previously developed interaction observation instruments, such as the RIAS, analyse video or audio recordings of interactions. This analysis is a lengthy process, generally requiring one to two hours of analysis for each fifteen minute recording. This allows a 'molecular' level of analysis to be carried out, describing each individual turn of speech. This study is the first to seek to record and measure professional support in labour in the UK setting and it was therefore felt that an approach providing an overall measurement of the quality and quantity of support behaviours was required at this early stage, which could prepare the ground for more specific sequential analyses of labour interactions in future research. This approach made the need for a video recording of the labour less essential. The decision to carry out direct observations rather than use video recording was further reinforced by pragmatic considerations. It was suggested that recruitment of women and midwives to be filmed during labour and birth may be more difficult than recruiting them to have an observer present, as this had been the experience of a researcher from the department in an earlier study (Jauncey 2008).

The second decision relating to the development of the observational approach centred on the usability of a data collection instrument, consideration of issues relating to concentration and fatigue of the observer and the very large amount of data that would be generated. Some quantitative observational studies of nursing care have sought to streamline the process by being selective about how observations are undertaken. Some choose to only record the first ten minutes of any interaction, some only record in detail during specific events of interest and some combine molar and molecular approaches for different parts of an interaction (Caris-

Verhallen 2004). It was anticipated that questions about how long observations can realistically be and how many different elements of an interaction an observer can be expected to record would only be answered in the actual clinical testing phase. Based on the earlier intrapartum research by Kirkham (1989), which identified that midwives were on 'their best behaviour' for the first one hour of an observation, it was decided to have a three hour observation period. In order to avoid observer fatigue and a reduction in accuracy of recording it was decided not to attempt an observation of a whole labour episode which may last for many hours.

Consideration was given to attempting only molar observations for the majority of the observation with molecular observations during periods of particular interest or intensity; for example, only recording the presence or absence of the midwife and very broad categories of behaviour for the majority of the time and recording behaviours in more detail during key events such as an emergency, the carrying out of a vaginal examination, when the woman is requesting further pain relief or during the birth. It was decided that such an approach would not adequately answer the research questions. Support is an ongoing process that continues throughout the labour, certain aspects of support may be demonstrated more strongly in the less intense periods of a labour, for example more informational support is likely to be given between contractions when the woman is not distressed and no procedures are being carried out; calm quiet presence where the midwife keeps the woman company may be an important element of emotional support that would not be demonstrated during more active or intense periods of a labour. Any observation that focused on specific events would miss important elements of support.

Earlier intrapartum observation studies of professional support focused on the nurses' behaviours and did not include any of the woman or her partner's behaviours. It was felt to be evident that a nurse or midwife's behaviours are directly influenced by the behaviours of the woman and her birth partner and an important contextual element of the midwife's behaviour would be excluded if these were not recorded.

The large number of elements included in the observation made a continual observation of behaviour unrealistic. It was therefore decided to employ the 'interval coding system' used in schedules such as the Flanders interactional system (p47 Flanders 1974). This style of observation allows the observer to record the presence or absence of a behaviour in more than one animal or person at a set time interval. The observation is repeated at this set interval. Though this approach means that some behaviours will be missed, it enables repeated 'snapshots' of behaviours to be taken, which when aggregated build up an overall picture of the most frequent behaviours (Martin and Bateson 1986). Decisions about the length of time at which this interval would be set were made during the validity and reliability testing phases of the study.

Based on these considerations, the approach of the observational study was set as an observer to be present in the labour room recording supportive care intermittently over a three hour period. The units of observation would include both molar and more molecular levels of observation and would include verbal and non-verbal behaviours of the midwife, the woman and her birth partner.

4.6 DEVELOPING A USABLE INSTRUMENT

The next phase in the development of the observation instrument was to ensure that the content could be presented in a way which would make it possible to record all the observational units of interest. It was decided at an early stage that a computerised instrument would be most appropriate rather than a paper based checklist as this would allow the recording of specific timings and could facilitate the recording of a high number of observations most efficiently. An initial draft of the observation instrument based on the literature review, the operationalisation of the components of support as observable behaviours and viewing of birth films was devised.

Careful consideration was given to the name of the instrument. The researcher felt that the name of the instrument should be as simple as possible, memorable and explain as far as

possible the purpose of the instrument. The name chosen was the 'Supportive Midwifery in Labour Instrument', described by the pneumonic 'SMILI' (pronounced 'smiley').

The SMILI was co-developed with a member of the university mathematics department teaching staff. Meetings between the researcher and the information technology specialist continued regularly for a nine month period allowing the instrument to be developed, tested and refined in an iterative process. At the outset some key requirements were identified:

- The necessity to place the care episode in a context, with an introductory section to be completed that provided some details about how busy the labour ward was at the time of the observation, any risk factors that the woman had and the number of years of experience that the midwife had.
- The facility to record the absence and presence of the observation midwife in the room in order that at the end of the observation period an overall figure for the length of time the midwife was present in the room can be calculated.
- The facility to record any other people entering and leaving the room including the woman's own partner and supporters as well as other professionals.
- The ability to record whether a midwife's actions occurred when a woman was having a contraction or not.
- The setting of a timer to ensure that each observation episode took place at regular intervals. This timer would ensure that the observer was aware how much time they had left to complete the remaining observation screens before the next observation episode. The timer would also ensure that the observer was aware when a new observation episode had begun.
- The facility to record some key overall elements including position, verbal communication, demeanour, touch and facial expression displayed by the woman, her birth partner and the midwife.

- The facility to record specific observable behaviours of the midwife including type of verbal communication, type of touch, information given, physical care provided and assessments undertaken.
- The facility to record in free text any unusual situation that arose, such as a medical emergency.

Copies of the pages of the SMILI are included as Appendix Four to show the content and layout of the programme.

4.7 DECISION MAKING ABOUT OUTCOME MEASURES

In order to measure the quality of the intrapartum support observed, establish construct validity of the SMILI and to explore all elements of intrapartum support defined in the theoretical framework, it was necessary to gather information about women's views of the support offered to them and record key clinical outcomes.

To test construct validity, that is to establish whether the instrument is able to measure the quantity and quality of midwifery support in labour successfully, it is necessary to identify if the woman's assessment of the support she received correlates with the data recorded using the SMILI. A review of the literature relating to instruments to assess women's satisfaction with their intrapartum care was undertaken to identify a suitable existing instrument. A number of instruments were located that seek to record women's feelings about their maternity care. These include the 'Labor Agentry Scale' (Hodnett 1987), the 'Labour and Delivery Satisfaction Index' (LADSI) (Lomas et al 1987), the 'Childbirth self-efficacy inventory (CBSEI) (Lowe 1993), the 'Caring behaviours assessment tool' (Manogin et al 2000), the 'Care in Obstetrics Measure for Testing Satisfaction' 'COMFORTS' (Janssen et al 2006), the 'Positive Presence Index (PPI) (Hunter 2009) and the 'Support and Control in Childbirth' (SCIB) measure (Ford and Ayers 2009). A number of new validated measures have been developed and reported since this stage in the development process and so could not be employed for this study but may be

considered for future work: the 'Childbirth experience questionnaire' (Dencker et al 2010), the 'Birth satisfaction scale' (Martin and Fleming 2011), the 'Multi-dimensional health locus of control scales for labor and delivery' (Stevens et al 2011b) and the Intrapartal Specific Quality from the Patient's Perspective Questionnaire (QPPP-I) (Wilde-Larsson et al 2011). Generally the developed instruments did not focus on intrapartum support and were considered to be either too general for the purposes of the study (Lavender et al 1999, Janssen et al 2006) were based on a very different maternity system (Manogin et al 2000) or more focused on another aspect of care such as control (Hodnett 1987, Lowe 1993). The most appropriate instrument identified was the 'SCIB' or 'Support and Control in Birth' measure. This measure was developed and fully tested for validity and reliability in the UK setting and includes 21 items relating to the woman's feelings of being in control during her labour followed by 11 items relating to the support she received from staff. These 11 items cover all the key elements of support identified in the literature review and included in the Supportive Midwifery in Labour Instrument (SMILI): the perceived helpfulness and encouragement of the midwife, the midwife's responsiveness to the woman's needs, the midwife's attempt to make the woman more comfortable, the midwife's suggestions to help the woman cope and the expression of empathy and concern (p250 Ford and Ayers 2009). The questionnaire is succinct, is not unduly taxing for the woman to complete and has been fully validated. Permission was sought from the authors to use the measure in the study, and this permission was provided. The SCIB is attached as Appendix Five.

The other outcomes that were relevant to the study were the clinical processes and outcomes of the birth. Several measures were identified in the literature which seek to measure process and outcomes in maternity care. The 'Optimality Index' (Wiegers et al 1996), the 'Optimality Index-US' (Cragin and Kennedy 2006, Murphy and Fullerton 2006) and the 'Bologna Score' (Chalmers and Porter 2001). The outcomes measured in these scales do not match the outcomes generally used as the outcome measures in the randomised controlled trials measuring the impact of labour support: length of labour, medical interventions such as

augmentation, type of pain relief received, type of birth and immediate maternal and neonatal well-being. A simple postnatal clinical outcomes data sheet was therefore developed for the purposes of this study (Appendix Six).

4.8 SUMMARY

Study One of the series of interlinked studies described in this thesis undertook to develop a new systematic observation instrument for the recording of the quantity and quality of professional support in labour.

The overall study design was chosen as the most appropriate to answer the research questions arising from the literature review (page 58). The quantitative approach selected included systematic observation using a newly developed systematic observation instrument in the clinical setting followed by a postnatal questionnaire completed by the women participants and a postnatal clinical outcomes data sheet completed by the observer after completion of the observation.

A review of the literature identified that there were no suitable existing observation instruments and that a new instrument was required. The development of the new instrument, study one, was undertaken in line with the guidelines for healthcare instrument development of Streiner and Norman. Theory and relevant research relating to social support, intrapartum support and systematic observation were identified. Next, earlier systematic observation instruments were located and assessed for their suitability. Finally, a draft instrument was devised based on the theory and relevant research.

This new instrument, the 'SMILI' or 'Supportive Midwifery in Labour Instrument' was developed, informed by social support and quality in healthcare theories, research with women and caregivers about the key elements of support, earlier maternity observation instruments measuring the quantity of different supportive behaviours and earlier observation instruments developed in other disciplines to measure quality in interactions.

The most appropriate and relevant validated postnatal questionnaire was identified for the assessment of women's views of the care they received and a simple data sheet was devised for the recording of clinical outcomes.

The next stage in the development of a new research or healthcare instrument is a thorough process of testing to ensure that the instrument is valid and reliable for the purpose for which it has been designed (Streiner and Norman 2003). This then led to the identification of new thesis-specific research questions to be addressed before being able to address the research questions identified at the end of Chapter Two (p53).

4.8.1 The Thesis Questions

These are:

1. Is a systematic observation study of intrapartum support feasible and acceptable in the intrapartum setting in the National Health Service in Scotland?
2. Can a systematic observation instrument be developed that is valid and reliable in its ability to record intrapartum midwifery support?
3. Can a systematic observation instrument record and measure the quantity and quality of midwifery support in labour?

The following chapters describe the method and results of the subsequent four inter-linked studies undertaken to address these three thesis-specific research questions. An overall summary of the method and design of these interlinked studies is given below graphically as Figure Two.

Figure Two: Summary of the studies described in the thesis

Study Number	Main Method	Aims	Sample
One	Staged development of systematic observation instrument	To develop robust evidence and theory-based comprehensive instrument	Literature review 1980 -present, 192 papers
Two	Card sort exercise	Initial content validity testing of observable behaviours developed in study one	11 student midwives Convenience sample Volunteers
Three	On line questionnaire, calculation of Content Validity Index	To further test face and content validity of the items and the instrument as a whole	11 members expert panel Purposive sample to ensure balance – lay members, academics and clinical midwives
Four	Real-time use of instrument while watching labour care videos	To test the usability of approach and instrument To test whether the instrument enables observer to fully record what is observed To test inter- and intra-rater reliability of the instrument	Part One: Convenience sample of 3 volunteers from expert panel, started as a reliability testing session became a usability and feasibility session. Part Two: Convenience sample of 3 volunteer clinical midwives from NHS Scotland (different from part one of study four, same volunteers as for study five). Training session and then reliability testing.
Five	Systematic observation, postnatal questionnaire and postnatal clinical outcomes data collection	To test the usability, feasibility and acceptability of the approach and instrument in the clinical setting To further test other aspects of validity and reliability	Target sample of 50 observations. All women in early established labour who met inclusion criteria, all registered midwives working in four participating NHS maternity units.

CHAPTER FIVE – METHOD AND RESULTS OF STUDY TWO
INITIAL VALIDITY TESTING OF THE OBSERVATION INSTRUMENT

5.1 INTRODUCTION

A quantitative study design was selected as the most appropriate to answer the central research questions. This included systematic non-participant observation of intrapartum support, followed by a postnatal questionnaire with women about the support received and recording of key clinical outcomes. Study One, detailed in the preceding chapter, followed a structured approach to the development of the instruments required (Streiner and Norman 2003). A review of previous comparable research and earlier observation instruments identified that a new instrument was required to record the quantity and quality of intrapartum support adequately. The content of the new instrument was based on a review of a substantial body of earlier research which had identified the key components of intrapartum support from both the woman and caregiver's perspectives. The development of the new instrument led to three thesis specific research questions about the feasibility, usability, validity and reliability of the instrument to be answered before the central research questions relating to the content and outcomes of midwifery support could be addressed.

Studies Two and Three aimed to test the content validity and identify any gaps in the SMILI, through two interlinked studies. Study Two tested content validity through a card-sorting exercise with student midwives. Study Three further tested face and content validity of the SMILI through a detailed questionnaire with an expert panel.

5.2 AIM

To identify whether the decisions made by the researcher in translating the research based categories of intrapartum support into observable behaviours were supported by a sample group with knowledge of intrapartum support.

5.3 OBJECTIVES

1. Test with a group of student midwives whether the midwifery support behaviours chosen were considered to be comprehendible and comprehensive,

2. Test whether there was agreement about how the observable behaviours fitted within the theoretical categories of support defined in the literature.

5.4 STUDY DESIGN

A card-sorting exercise was developed to establish the level of inter-rater agreement among the participants and between the participants and the researcher when categorising behaviours. Participants were asked to place cards describing observable supportive behaviours beneath cards bearing broader support category headings.

5.5 RESEARCH SITE

The participants and the study were located in the nursing and midwifery department of the University of Stirling, Scotland. This site was chosen for convenience as it is the site at which the researcher is based.

5.6 POPULATION

All students currently studying for a degree in midwifery at the University of Stirling were approached to participate in the study. Students were given the information sheet (Appendix Seven) by their midwifery lecturers. The information sheet was posted on the university interactive blackboard system, handed in paper form to some of the students by their lecturer or sent as an attachment to an email. The students were invited to contact the researcher directly either by telephone or by email if they wished to participate.

Student midwives were chosen to participate in this part of the validation process for several key reasons: the students were readily accessible for the researcher who was also studying at the same university and the students represented a group of individuals with a degree of knowledge about and demonstrated interest in, labour support. It was felt that the role of students in the early part of their training, as observers of care, enabled them to understand the observational approach and to have a certain level of clarity or fresh eyes about what high quality midwifery support may look like, without having become conditioned by the NHS system.

5.7 THE SAMPLE

Eleven student midwives volunteered to participate in the study. Of these, eight were in the first year of their studies, two were in the second year and one was in the final year of her studies.

5.8 THE INSTRUMENTS

The researcher designed and produced the materials for the study. Three sets of colour coded cards were produced:

1. Broad categories of intrapartum support. Five cards each bearing the title of one of the broad theoretical categories of support derived from the literature (emotional support,

tangible/physical support, informational support, advocacy and partner support), with an additional card for 'non support' activities.

2. Sub-categories of intrapartum support. Thirteen cards each describing key elements of intrapartum care and support identified through the literature review: presence of the midwife, helping the woman cope, building rapport, conveying a sense of warmth, confidence and security, supportive touch, creation of an appropriate environment, providing for the woman's bodily needs, providing adequate information, being an advocate, caring for the woman as an individual and enabling a sense of control, supporting the partner, non-supportive activities and relief from pain.
3. Observable Behaviours. Fifty three cards each describing a specific observable behaviour that may be displayed or carried out by a midwife providing labour care.

5.9 DATA COLLECTION PROCEDURES

Once the volunteer student had contacted the researcher, a date and time to meet to carry out the exercise was agreed. The data collection took place on five occasions: two occasions with one participant, once with two participants present, once with four and once with three participants.

The researcher explained the aim of the study on each occasion, answered any questions that were raised and asked the participants to complete and sign the informed consent sheet (Appendix Eight).

The card sorting exercise was divided into two parts. Firstly, the student midwife was asked to place the thirteen sub-category cards beneath the overall category card to which they felt it was most closely linked.

In the second part of the exercise the student midwives were asked to place the 53 'observable behaviour' cards under one of the 13 support category cards to which they felt it was most

closely linked. During this part of the exercise the thirteen sub-category cards and the five overarching category cards remained on the table as placed in the first part of the exercise by the participant. They were advised that if they felt the behaviour belonged in more than one category they could tell the researcher which categories and then place the card in the category it suited most.

When categorising the observable behaviours into support categories, the researcher had often placed the behaviours in more than one support category (for example 'keeping company' or 'undivided attention' belonged in 'presence', 'building rapport' and 'conveying a sense of warmth, confidence and security'). The researcher imposed a 'forced choice' upon herself and chose one 'first choice' category for each behaviour.

Once the participants had completed the exercise, the researcher recorded their decisions using a table specifically designed to record the results. The researcher asked each student two standard questions: 'Do you feel the cards describe what you understand to be support provided by a midwife during labour?' and 'Do you feel there is anything that is missing in seeking to describe what midwifery support in labour involves?' Their answers were recorded contemporaneously by the researcher in a fieldwork journal.

5.10 ETHICAL CONSIDERATIONS

A proposal for this study was submitted to and approved without amendment by the Department of Nursing and Midwifery Research Ethics Committee in April 2010 (letter of approval, Appendix Nine).

The study was designed to protect the dignity, rights and privacy of the participants. This included no direct initial approach to the students by the researcher to avoid any sense of coercion, a clear and structured information sheet and written consent procedure and the

anonymisation of all data recorded through the provision of identification codes to each of the participants.

5.11 DATA ANALYSIS

The answers to the overall questions relating to the comprehensiveness of the cards in describing the concept of intrapartum support were recorded and are reported in full in the results.

The decisions made by the participants in categorising the cards were entered by the researcher from the results table into the SPSS (v17) database. A measure of interrater reliability, the Cohen's Kappa, was calculated for each data point to measure the degree of agreement between each participant and the researcher. Of the 11 students, Kappa scores were able to be calculated for nine. For student midwives numbers 10 and 11 no Kappa score could be calculated as they did not categorise any of the support categories into the 'other non-support activities', category. In order to calculate a Kappa correlation, both sorters have to sort the same variables.

Cohen's Kappa is the most appropriate means to identify levels of agreement between raters when the results are categorical rather than continuous and where the data is not a 'rating' scale. It is commonly used to measure the level of agreement between two sets of dichotomous scores. The result is the amount by which the observed agreement exceeds that expected by chance alone, divided by the maximum which this difference could be. Only values between 0 and 1 have any useful meaning. For perfect agreement Kappa or K would equal one. When there is no agreement in the sense that there is no relationship beyond that of chance then Kappa would be zero (K=0). Different medical and psychological diagnostic tests set different levels of Kappa that represent an adequate level of agreement, this varies between .4 and .9 depending on the nature of the test (Wood 2007). Levels of reliability have been defined in the literature for Kappa correlations ranging from slight (0-0.20) to almost perfect (0.81-1).

These categorisations of Kappa reliability are employed in analysing the results of studies three and four.

Table Four - 'Kappa Coefficients and Reliability' (Landis and Koch 1977):

Kappa Coefficient	**Reliability**
0.81 - 1	Almost perfect
0.61 - 0.8	Good
0.41 - 0.6	Moderate
0.21 – 0.4	Fair
0 – 0.20	Slight
<0	Poor

5.12 RESULTS OF STUDY TWO

In response to direct questions, all of the participants stated that they felt the cards adequately described support provided by a midwife during labour. None of the participants identified any gaps in the description of midwifery support in labour provided by the cards.

5.12.1 Results of Study Two, Part One

The first part of the exercise showed a good level of agreement between the participants and the researcher and among participants in categorising the thirteen sub-categories into the five overall categories of support.

Table Five below shows the percentage of support between all twelve participants (eleven students and the researcher). Four of the thirteen categories had complete support from all twelve scorers. The category with the lowest level of agreement was number eight, 'providing a setting to meet the woman's needs'. Four agreed with the researcher that this was physical/tangible support, three categorised this as emotional support, two categorised it as other non-supportive care and one described it as advocacy support. For the category

'providing individualised care, giving the woman a sense of control', six agreed with the researcher in categorising this as emotional support, but five categorised this as advocacy support. For the category 'helping the woman cope', seven agreed with the researcher categorising this primarily as emotional support, but four placed this in the physical support category.

Table Five- Percentage agreement in placement of support categories into overarching categories

Support category	**Percentage agreement**
1.Presence	75% Emotional Support
2. Helping woman cope	67% Emotional Support
3. Building rapport	75% Emotional Support
4. Warmth, confidence and security	100% Emotional Support
5. Individual care, sense of control	58% Emotional Support (42% advocacy)
6. Supportive touch	75% Tangible support
7. Providing pain relief	92% Tangible support
8. Setting to meet needs	42% Tangible support
9. Physical needs	92% Tangible support
10. Adequate information	100% Informational support
11. Advocate	100% Advocacy
12. Supporting partner	100% Partner support
13 Surveillance, monitoring and other non-support care	83% Non-support activities

The Cohen's Kappa correlations for this first part of the exercise are given below in Table Six.

Table Six – Kappa agreement between participants and researcher on placement of support categories in overarching categories

Participant	1	2	3	4	5	6	7	8	9	10	11
Kappa with researcher	.802	.898	.515	.724	.893	.795	.626	.898	.702	None	None

Using the Landis and Koch definitions of the strength of the Kappa correlation, all of the results here show a moderate to very good level of agreement. The literature generally agrees that for validity testing purposes an agreement of at least 50% or a Kappa of .700 and above are valid. For this exercise there was more than 50% agreement for twelve out of the thirteen categories

and a Kappa of more than .700 for seven of the nine participants, which demonstrates a satisfactory level of agreement (Landis and Koch 1977, Cohen 1988).

5.12.2 Results of Study Two, Part Two

For the second part of this exercise, the participants sorted the 53 observable behaviours into the thirteen sub-categories of support and levels of agreement between each student and the researcher were calculated using a Kappa correlation coefficient. Table Seven below shows that there was an adequate level of agreement between participants above the level that would expected by chance.

Table Seven – Kappa agreement between participants and researcher on placement of observable behaviours in support sub-categories

Participant	1	2	3	4	5	6	7	8	9	10	11
Kappa with researcher	.733	.896	.628	.524	.566	.420	.501	.627	.603	.589	.711

Overall, the results of this part of the exercise show a moderate to good level of agreement between the participants and the researcher in placing the observable behaviours within the 13 larger sub-categories. The Cohen's Kappa correlation was above .420 for all participants. The percentage levels of agreement between all participants showed a high level of agreement with the majority of participants agreeing for the majority of behaviours. However, the levels of agreement for this part of the exercise were lower than for the first part of the study (placing the 13 sub-categories into the five overall categories) and for the final part of the study (identifying the five overall categories into which the 53 observable behaviours fall).

As the overarching category cards remained on the table for this part of the exercise, levels of agreement were calculated between the participants when placing the 53 observable behaviours into the five overarching categories. The results are shown as Table Eight below. A simple percentage level of agreement was employed for this part of the study as it was felt to be

most meaningful to analyse the level of agreement among the whole group of respondents rather than just between each student and the researcher. This showed the highest level of agreement among all the parts of this study (study two part a) with more than 50% agreement for 51 out of 53 behaviours.

Table Eight – Percentage agreement between participants placement of observable behaviours into five overarching categories of support (all 12 participants)

	Observable behaviour → Support Category ↓	**Emotional support**	**Physical support**	**Informational support**	**Advocacy**	**Partner support**	**Non-support**
1	Keeping company – undivided attention	100%	0	0	0	0	0
2	Coaching	100%	0	0	0	0	0
3	Giving pain relief	0	100%	0	0	0	0
4	Encouraging partner	0	0	0	0	100%	0
5	Positively assertive	90%	0	0	10%	0	0
6	Humorous/ Jokey	100%	0	0	0	0	0
7	Position change	30%	70%	0	0	0	0
8	Soft vocal tone	100%	0	0	0	0	0
9	Describing progress	40%	0	40%	0	0	20%
10	Empathy/ comfort	100%	0	0	0	0	
11	Touch	0	100%	0	0	0	0
12	Ensuring privacy	50%	40%	0	10%	0	0
13	Building nest	10%	90%	0	0	0	0
14	Helping to toilet	10%	90%	0	0	0	0
15	Encouragement /praise	100%	0	0	0	0	0
16	Changing clothing/ bedding	0	100%	0	0	0	0
17	Fetal monitoring	0	0	10%	0	0	90%
18	Helping bath	10%	80%	0	0	0	10%
19	Role modeling for partner	0	0	0	0	100%	0
20	In room	90%	0	10%	0	0	0
21	Massage/hot and cold compresses	10%	90%	0	0	0	0
22	Asking partner about feelings/ views					100%	
23	Fluid/nutrition		100%				
24	Partner's physical needs					100%	

	Observable behaviour → Support Category ↓	**Emotional support**	**Physical support**	**Informational support**	**Advocacy**	**Partner support**	**Non-support**
25	Preparing equipment						100%
26	Maternal vital signs		10%				90%
27	Pain relief options discussed		40%	60%			
28	Discussion with other hp			10%	50%		40%
29	Social chat with woman	90%				10%	
30	Medical intervention		10%	10%			80%
31	Calm positive demeanour	100%					
32	Negotiating/supporting woman's decisions				90%		10%
33	Asking woman about her feelings	80%			20%		
34	Resolving conflict	50%			40%		10%
35	Suggestions about coping strategies	70%	10%	20%			
36	Documenting care			10%			90%
37	Assisting other hp	10%			10%		80%
38	Explaining labour process	30%		70%			
39	Responding to contraction	100%					
40	Explaining hospital procedures	10%		70%			20%
41	Answering question	10%		90%			
42	Showing woman and partner facilities			40%		10%	50%
43	Pleasant facial expression	100%					
44	Supportive discussion of birth plan	50%			50%		
45	Listening to woman or partner	40%			40%	20%	
46	Cue response	70%	10%		10%		10%
47	Discussing options/next steps	30%		60%	10%		

	Observable behaviour → Support Category ↓	Emotional support	Physical support	Informational support	Advocacy	Partner support	Non-support
48	Encouraging to adapt facilities	20%	80%				
49	Involving couple in decision making	50%		10%	40%		
50	Using appropriate language	40%		60%			
51	Carrying out woman's wishes	40%			60%		
52	Carrying out assessment – e.g. VE			20%			80%
53	Staying close to woman	100%					

5.13 DISCUSSION AND SUMMARY OF STUDY TWO

This study established some initial elements of content validity of the SMILI. All participants were asked whether they felt that the exercise and the cards described midwifery support in labour and all of the participants stated that they felt it did and that no elements were missing. The earlier stages of the study with the first two participants allowed the researcher to change the wording of some of the cards to ensure that there was no confusion about the meanings of the observable behaviour cards. The card sorting exercise has suggested that the validity of the instrument content is of an adequate to good level through analysis of the Kappa correlation and percentage agreement between all participants.

It is interesting to note that there was a higher level of agreement when sorting the observable behaviours into the five overarching categories than when sorting either the sub-categories into the overarching categories or the behaviours into the sub-categories. This suggests that the most helpful units of observation and analysis are the observable behaviours and the overarching categories rather than employing the 13 sub-categories. It appeared that the intermediate 'sub-category' level was more likely to lead to different interpretations and personal judgments as their meaning was perhaps less clear or concise. This exercise therefore assisted

in confirmation of the researcher's decision to have specific micro-units of behaviour to be observed and recorded rather than employing a larger macro unit of behaviour.

The analysis of the final part of the study, detailed in Table Eight, revealed some differences in categorising a significant minority of behaviours. For example, 'describing progress' was categorised by 40% as emotional support and 40% as informational support. 'Ensuring privacy' was categorised by 50% as emotional support and 40% as physical support, 'helping woman bathe' and 'massage and reassuring touch' were both classified by 10% as emotional support. These results point to the overlapping nature of the different categories of support and hint at the arbitrary nature of the categories. It is correct that all of the above behaviours could be experienced as emotionally supportive by the woman, but the decision was made by the researcher to continue to place the behaviours in other categories (informational support and physical support respectively) in order to allow analysis of the observation in the higher level categories to allow comparisons with earlier observational studies.

An unanticipated finding of the study was the emphasis placed by the student midwives on the category of 'advocacy'. In the earlier observational studies reviewed, 'advocacy' was rarely seen and was classified as conflict resolution, highlighting the woman's preferences and supporting the woman's decisions in discussions with other health professionals. However, the participants in this study identified a wider range of behaviours as being examples of advocacy support: 60% categorising 'carrying out the woman's wishes' as advocacy, 40% 'involving the couple in decision making', 50% 'supportive birth plan discussion', 40% 'listening to the woman or her partner' and 20% 'asking the woman about her views and feelings'. The researcher categorised these behaviours as examples of emotional support in line with previous studies. It is apparent that there may be considerable overlap between advocacy and emotional support. These findings suggest that consideration should be given when analysing the observational data to the categorisation of emotional and advocacy support as one category.

CHAPTER SIX – STUDY THREE – TESTING OF FACE AND CONTENT VALIDITY OF THE NEW INSTRUMENT WITH AN EXPERT PANEL

6.1 INTRODUCTION

This next study built on the first two studies. Study One had used the established literature to develop an evidence based observation instrument, Study Two aimed to assess whether the researcher had operationalised the concepts derived from the literature in a way that was comprehensible and appropriate to a group with some knowledge of and interest in labour support and the next study aimed to further test the content and face validity of the new instrument.

A well established method in the literature for the testing of face and content validity of any new research or health measurement instrument is the use of an expert panel. Use of an expert panel is an accepted strategy in the validation of the content domain of instruments (Fitzpatrick 1996 and 1997, Streiner and Norman 2003). The experts are asked to evaluate the validity of items in the instrument individually and as a set (Lynn 1986). The expert panel was made up of eleven members chosen from a group of thirteen volunteers. Experts writing in the field of instrument development differ in their recommendations for the number to be included in an expert panel from two to twenty (Lynn 1986, Tilden et al 1990).

6.2 AIM

To ensure that the presentation and content of the systematic observation instrument is comprehensive and understandable.

6.3 OBJECTIVE

To test the level of agreement among an expert panel about the face and content validity of the draft SMILI. Face validity indicates whether an instrument appears to either the users or designers to be assessing the right qualities and content validity is similarly a 'judgment by one or more 'experts' as to whether the instrument samples the relevant or important 'content' or domains within the concept to be measured' (p27, Elwyn et al 2005).

6.4 STUDY DESIGN

This study used a questionnaire design inviting the members of an expert panel to rate the clarity and relevance of each item of the SMILI and then to give an overall rating of the comprehensiveness of the instrument and the extent to which the panel members believed that the SMILI would be successful in measuring the quality and quantity of intrapartum midwifery support.

6.5 RESEARCH SITE

This part of the study was completed electronically by members of the expert panel at their own place of work or at home.

6.6 SAMPLE

The literature suggests that an expert panel should consist of members who have the relevant training, experience and qualifications to understand the central concept. This may be as a result of carrying out research or publishing peer reviewed journal articles in the subject area, through clinical experience and expertise or through personal firsthand experience (p383 Lynn 1986). It was therefore decided to seek to appoint a panel that would include a balance of

people with knowledge of intrapartum support through academic exploration, through clinical experience, and including lay people who had experience of receiving intrapartum support from a midwife.

No definitive evidence-based recommendation was found in the literature for the ideal size of the expert panel. A small literature search using the Web of Science search database was undertaken using the search terms 'Expert Panel' + 'Instrument Development', restricting the search to papers published in the year prior to the study (mid 2008-mid 2009). This yielded ten papers describing the development and initial validity testing of a range of instruments relating to healthcare where the full paper was available on line. Two of the papers described using an expert panel but did not describe the number of experts (Hollenbeck et al 2008, Walsh et al 2008), the remaining eight papers described panels ranging in size from three to fifteen members, with a mean membership among the eight papers of 8.8 (Edelen et al 2008, Muller et al 2008, King et al 2008, Ning et al 2008, Ruiz et al 2008, Mahboobeh et al 2009, McCormack et al 2009, Pelander et al 2009).

In order to obtain a balance in the membership a number of approaches were taken to recruitment. These included general emails sent to appropriate established professional networks across Scotland (the 'Lead midwives Scotland network' which includes leading midwifery educationalists, policy makers and managers; the shared midwifery space on the NHS Education for Scotland E-library website which includes members of the national Scottish midwifery practice development network and the Consultant Midwives network) and an approach to the lay organisation the NCT or National Childbirth Trust to ask for volunteers. In addition, personal approaches were made by email to a number of people known to the researcher that were felt to offer particular expertise. These included an independent midwife practising in Scotland, two women who had recently had a baby and who had been approached by their independent midwife to ask if they would be happy to be involved, a leading UK researcher in maternity and women's health issues who has published widely in this area, and

two practicing midwives who had recently completed their PhD studies. All of those approached were sent a copy of the information sheet about the study (Appendix Ten).

In order to maintain a balance in the composition of the panel, it was decided to not include two of the volunteers. These volunteers were consultant midwives which would have led to the panel having a membership of six consultant midwives which was felt to be unbalanced.

The final membership of the panel consisted of four consultant midwives working in NHS Scotland in a combined leadership and clinical role specialising in the promotion of normal birth, three academic midwifery researchers, one independent midwife and three lay representatives. Seven members of the panel were known personally to the researcher and four were not.

6.7 THE INSTRUMENTS

Each member of the panel was sent electronically and in paper form the information sheet about the study (Appendix 10), a written consent form (Appendix 11), a covering letter (Appendix 12) and instructions for the use of the SMILI and for completing the questionnaire (Appendix 13).

Panel members were sent the draft SMILI on a compact disc or a memory stick (based on their expressed preference) and a paper copy of the SMILI screens for reference while completing the online questionnaire. The electronic version of the SMILI was a functioning prototype of the computer programme including a timer to allow the panel members to use the programme and therefore understand how the programme would function in the clinical setting.

The panel members were given a hyperlink to access the online ‘Survey Monkey’ questionnaire. The questionnaire was devised specifically for the study by the researcher and consisted of ten questions asking panel members to rate on a Likert scale for clarity and relevance all individual items included in the SMILI.

6.8 DATA COLLECTION PROCEDURES

Panel members were asked to complete and return the written consent forms and the discs and memory sticks of the SMILI to the researcher.

The panel members completed the online survey monkey questionnaire over a period of one month. The questionnaire responses were not named, though it was possible from the information provided to identify which 'group' any respondent belonged to: research, clinician or lay person.

Only the researcher had access to all of the responses on the survey monkey website, which is password protected.

6.9 ETHICAL CONSIDERATIONS

A proposal for this study was submitted to and approved without amendment by the Department of Nursing and Midwifery Research Ethics Committee in April 2010 (letter of approval Appendix Nine).

The study was designed to protect the dignity, rights and privacy of the participants. Members of the panel were not told the identities of other members of the panel and the report sent to the panel detailing the results did not identify individual responses. Members of the expert panel were asked not to share the content of the draft SMILI with others at this stage.

6.10 DATA ANALYSIS

A number of different approaches to assessing content validity by an expert panel are suggested in the literature. In some similar studies, an item requires agreement among 75% of the panel for it to be removed or added (Bryanton et al 1994, Miltner 2002). Other studies impose a statistical analysis of the results known as a 'content validity index' (Polit and Beck

2006). The individual content validity index is computed as the number of experts rating any item quite or highly relevant, divided by the total number of experts. The content validity of a whole scale is calculated either as 'the proportion of total items judged content valid' (p384 Lynn 1986) or 'the proportion of items on an instrument that achieved a rating of quite or highly valid by the content experts' (p207 Beck and Gable 2001d).

For this study, all of these approaches to analysis were employed.

6.11 RESULTS OF STUDY THREE

The Survey Monkey questionnaire consisted of ten questions with the opportunity to complete free text responses for each. Respondents completed the questionnaire between the 3rd June and 5th July 2010.

Two types of content validity index are generally calculated: the content validity of individual items (I-CVI) and the content validity of the whole scale (S-CVI) (p489 Polit and Beck 2006).

There is general agreement about the calculation of the I-CVI. A panel of content experts is asked to rate each scale item in terms of its relevance to the underlying construct. These items are typically on a four point scale to avoid having a neutral and ambivalent midpoint (Lynn 1986) though a five or three point scale may be used. An example of the descriptors of the scales given in the literature is 1=not relevant, 2=somewhat relevant, 3=quite relevant and 4= highly relevant (p490 Polit and Beck 2006). Then for each item the I-CVI is computed as the number of experts giving a rating of either 3 or 4 divided by the total number of experts. So if 4 out of 5 experts rated a scale item as 3 or 4, the I-CVI for that item would be 0.80.

For the SMILI validation process, the eleven members of the expert panel were asked to complete a ten question on-line 'survey monkey' questionnaire. The results are described in detail and then summarised in Table Nine below.

The first question asked the raters to identify their designation (consultant midwife, midwifery researcher, lay representative or other). Four of the respondents were consultant midwives (36.4%), one is a midwifery researcher (9.1%), three were lay representatives (27.3%) and three were 'other', a researcher and lecturer, an independent midwife and a researcher in social sciences and women's health.

The second question asked the panel to rate the four different elements of the 'context' page of the SMILI: midwife demographics, women's demographics and history, unit information and the physical environment. Nine of the eleven rated the midwife demographics as 'completely relevant' with two choosing 'some irrelevant/some relevant'. This gives an I-CVI of 0.82 if a strict definition of validity is used only including those that chose completely relevant. It was suggested that for this item it would be helpful to note if the midwife was direct entry or dual qualified, the grade of the midwife, which country she trained in, gender and ethnic origin of the midwife. For the women's demographic information and history the I-CVI was also 0.82. Suggested additions to this item were whether the woman had met the midwife before, woman's ethnic origin and socio-economic status. Unit information was rated by all as 'completely relevant' with an I-CVI of 1.0. It was suggested that number of births a year, rural/inner city location, and type of unit (consultant led or midwife led) be added. For the physical environment item, the I-CVI was 0.82. Suggestions made were to have an option for bed not in the room, mats on floor, birthing pool, ensuite facilities and if the midwife has a chair to sit on.

The third question asked the experts to rate five items that note particular events and start the programme on the opening page of the SMILI. These were the 'during contraction', 'start', 'midwife present or absent', 'other member of staff' and 'emergency/error' touch pad. The raters were given three options: completely irrelevant/unclear, somewhat relevant/clear and completely relevant/clear. For these five items, all raters rated the five items as 'completely relevant/clear' giving these items an I-CVI of 1.0.

The next question asked the panel to rate the five items relating to the woman's demeanour, position, verbal communication, facial expression and touch. For the items 'woman's position and touch' all of the raters considered the item to be completely relevant and clear and so had an I-CVI of 1.0. For the items 'woman's verbal communication and facial expression' ten of the raters chose 'completely relevant and clear' with one rater choosing 'somewhat relevant/clear'. This gives these items an I-CVI of 0.9. For the item 'woman's demeanour' nine of the eleven experts chose 'highly relevant/clear' giving the item an I-CVI of 0.82. The suggestions made here were for 'withdrawn' to be moved from demeanour to communication, to add 'silent, laughing, speaking calmly and quietly and talking with midwife/partner' to verbal communication, to change 'neutral' facial expression to 'relaxed' and to add 'agitated' to 'anxious/distressed' and to include 'leaning on partner/furniture'.

In question five the panel rated the five items relating to describing the partner: demeanour, verbal communication, facial expression, position and touch. Again position and touch received 100% agreement with an I-CVI of 1.0. Ten agreed with the general demeanour and facial expression descriptors, an I-CVI of 0.9 and nine agreed fully with the verbal communication descriptors, an I-CVI of 0.82. Suggestions made here were for 'neutral' facial expression to be changed to 'relaxed, to add 'holding/supporting partner's weight' and add 'ignoring partner, chatting on mobile phone, chatting to other birth partners'.

In question six all of the panel agreed that the midwife position and demeanour descriptors were highly relevant and clear, ten agreed fully with the midwife's facial expression descriptors (I-CVI 0.9) and nine fully agreed with the vocal tone descriptors (I-CVI 0.82). Suggestions made here were to include 'calm, relaxed, reassuring' in vocal tone. A lack of clarity about what a 'professional' facial expression would be was expressed.

Question seven included thirty behaviour descriptors for midwife behaviours during a contraction. For fourteen of these, all eleven raters described them as 'highly relevant' giving an I-CVI of 1.0 for keeping company, talking woman through contraction, giving

encouragement/praise, expressing empathy/reassurance, bringing the woman back if she is losing control, holding hand/reassuring touch, massage/hot and cold compresses, ensuring privacy, helping with position change, showing the partner how to help, encouraging the partner, monitoring fetal well-being, monitoring maternal vital signs and documenting care. For thirteen items, ten described the behaviours as 'highly relevant' with one person describing the behaviour as 'somewhat relevant'. This gives an I-CVI of 0.9 for ignoring the contraction, responding to the contraction, talking over the contraction, telling the woman not to do something, directing the woman forcefully, restraining/directional touch, administering pain relief, building a nest, assisting with shower/bath, asking the partner about their views/feelings, ensuring the partner has something to eat, checking equipment and carrying out an assessment. For the remaining three items, nine of the raters described the behaviours as highly relevant with two raters describing them as 'somewhat relevant'. These behaviours with an I-CVI of 0.82 are: helping the woman to the toilet, changing clothes/bedding and getting food or fluid.

Question eight included 56 behaviour descriptors for midwife behaviours between contractions. Of these, 100% of the raters described twenty four of the behaviours as 'highly relevant' giving an I-CVI of 1.0 for asking about the birth plan in a supportive way, asking the woman about her feelings, listening to the woman or partner, encouraging/praising, expressing empathy/reassurance, making suggestions about what might help, positive humour, reassuring touch, ensuring privacy, building a nest, helping with mobilisation, showing the partner how to help, encouraging/praising the partner, monitoring fetal well-being, monitoring maternal vital signs, documenting care, explaining the labour process fully, explaining hospital procedures fully, answering a question fully, describing progress positively, discussing pain relief options, encouraging the couple to adapt the facilities to their needs, presenting a decision to the couple and involving the couple in decision making. For 22 of the behaviours, ten raters described the behaviours as 'highly relevant' giving these an I-CVI of 0.9 These were social chat (about herself), social chat (about the couple), dismissive discussion of the birth plan, telling the

woman not to do something, directing the woman to do something forcefully, bringing the woman back if she has lost control, belittling humour, restraining/directional touch, hot and cold compresses, assisting with shower or bath, asking the partner about their feelings, ensuring the partner has a break, checking or preparing equipment, carrying out an assessment, assisting another health professional, defusing a difficult situation, discussing possible next steps, providing a limited explanation of the labour process, providing a limited explanation of the hospital procedures, partially answering a question, describing progress negatively and showing the couple the facilities. For ten of the behaviours, nine raters described the behaviours as 'highly relevant' with two raters describing these behaviours as 'completely irrelevant' (three behaviours) or 'somewhat relevant' (seven behaviours). The items with an I-CVI of 0.82 were keeping company, distracted by another activity, giving pain relief, helping the woman to the toilet, changing clothes/bedding, giving food or fluid, carrying out a medical intervention, carrying out a woman's wishes, suggesting a medical intervention without indication and suggesting pharmacological pain relief. Two suggestions for further additions were made: doing something to the woman without the couple's permission and providing positive pain talk.

Question Nine asked the raters to rate the clarity and usability of the SMILI in the clinical setting. None of the panel rated the SMILI as unusable, unrealistic or very unclear. Eight rated the SMILI as quite usable and quite clear and Three rated the SMILI as highly usable, realistic and very clear. As this rating sought to provide an overall assessment of the usability and clarity of the SMILI, it is not appropriate to calculate an item content validity index for this question as it does not refer to one specific content item. As a proportion of the panel, 72.7% of the panel found the SMILI highly usable, realistic and clear, 27.3% rated it as quite usable and clear and 0% rated it as unusable or very unclear. Several issues were raised by raters: these focused on the wordiness of the program within such a short time frame, some technical issues with the computer programme freezing and some issues with layout including the small font and dark purple screen.

The final question asked raters if they felt the SMILI would measure the quantity of midwifery support not at all, partially or successfully. Nine raters felt that it would successfully measure the quantity of support and two felt that it would partially measure the quantity of support. When asked whether they felt the SMILI would measure the quality of midwifery support, seven felt that it would do so successfully and four felt it would do so partially. As these questions asked for overall assessments rather than specific item content validity, it is not appropriate to calculate an item content validity index. 81.8% of the panel felt that the SMILI would successfully measure the quantity of midwifery support, 18.2% felt that it would partially measure the quantity of support and 0% felt that it would not measure the quantity of support. 63.6% of the panel felt that the SMILI would successfully measure the quality of midwifery support, 36.4% felt that it would partially measure and 0% felt that it would fail to measure the quality of midwifery support. These proportions represent a good level of agreement among the panel that the SMILI would be usable and would measure what it is setting out to measure.

Table Nine - Expert panel questionnaire on SMILI content

Qu. 1	Context page	Midwife demographics	Woman details	Unit information	Physical environment	
	I-CVI	0.82	0.82	1.0	0.82	
2	**Opening Screen**	**During contraction**	**Start button**	**Midwife present**	**Other people**	**Emergency Error**
	I-CVI	1.0	1.0	1.0	1.0	1.0
3	**Woman screen**	**Position**	**Touch**	**Verbal**	**Facial**	**Demeanour**
	I-CVI	1.0	1.0	0.9	0.9	0.82
4	**Partner screen**	**Position**	**Touch**	**Verbal**	**Facial**	**Demeanour**
	I-CVI	1.0	1.0	0.82	0.9	0.9
5	**Midwife contraction behaviours**	**14 items – emotional and tangible**	**13 items negative behaviours**	**3 items – non-support**		
	I-CVI	1.0	0.9	0.82		
6	**Midwife between contractions**	**24 items**	**22 items**	**10 items**		
	I-CVI	1.0	0.9	0.82		
7	**Usability and clarity**	**Highly usable and clear**	**Quite usable and clear**	**Unusable and unclear**		
	%	27.3% (n= 3)	72.7% (n= 8)	0		
8	**Will measure quantity of support?**	**Successfully**	**Partially**	**Not at all**		
	%	81.8% (n= 9)	18.2% (n= 2)	0		
9	**Will measure quality of support?**	**Successfully**	**Partially**	**Not at all**		
	%	63.6%(n=7)	36.4% (n=4)	0		

The lower level of agreement about whether the SMILI would effectively measure the quality of support reflects the more complex concept of 'quality'. Some concerns were expressed that some of the subtleties of providing high quality support may not be captured and that the instrument would not be able to fully capture the 'filtering' role of the woman's perceptions about the support. The employment of the post-natal questionnaire with women (the Support and Control in Birth questionnaire) will be an important addition to the SMILI in seeking to measure the perceived quality of support offered.

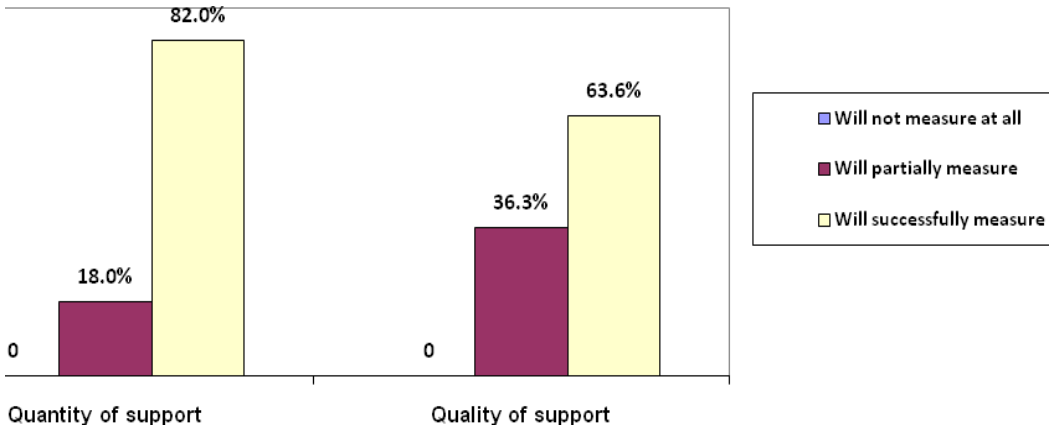
One concern raised about the CVI is that it is an index of interrater agreement that simply expresses the proportion of agreement, which can be inflated by chance factors. One response to this is to have different thresholds of acceptability for different numbers of raters. Lynn (1986) recommends that for five or fewer experts all must agree on content validity. When there are six or more judges, the standard can be relaxed, with Lynn recommending an I-CVI of no lower than .78. Using this criterion, all of the individual content items – woman, partner and midwife behaviours all had an I-CVI of between 0.82 and 1 and thus there is no necessity to remove or amend any individual items.

When calculating the Content Validity Index for a whole scale or instrument, there are several definitions employed when there are more than two raters. Either 'the proportion of total items judged content valid' (p384 Lynn 1986) or 'the proportion of items on an instrument that achieved a rating of 3 or 4 by the content experts' (p201 Beck and Gable 2001d) and 'the proportion of experts who score items as relevant or representative with a 3 or 4' (p269 Grant and Davis 1997). There are two approaches to calculating these scores, one is a strict definition which counts only the items judged valid by all of the experts (Scale content validity index, universal agreement or S-CVI – UA). This has the disadvantage that disagreement can be inflated by chance factors as the number of experts on a panel rises (Polit and Beck 2006). The other approach is the average proportion of items rated as relevant across the judges (S-CVI – Ave). Polit and Beck recommend that for a scale to have excellent content validity, it would be composed of items with I-CVIs of a minimum of .78 for 6-10 experts and it would have an SCVI/Ave of .90 or higher.

When calculating the scale content validity index, the responses to questions two to eight were included. Question one was not a question about the scale, but was about the raters and so is not relevant to include. Questions nine and ten asked the raters to provide overall ratings of the scale and so are not individual content items. Questions 2-8 asked raters to score a total of 109 items for relevance and clarity. Of these, 51 had an I-CVI of 1 (with total agreement about the relevance of the item among all of the raters). Forty items had an I-CVI of .9 (with 10 out of 11

raters scoring them as highly relevant) and eighteen items had an I-CVI of .82 (with 9 out of 11 raters scoring them as highly relevant). To calculate the S-CVI –Ave, all of the I-CVIs were totaled and then divided by the number of items. The I-CVIs totaled 101.76 (that is 51 x 1=51, 40 x 0.9=36, 18 x 0.82=14.76). 101.76 divided by 109 items= 0.93. The scale content validity index (S-CVI-Ave) for the draft SMILI was 0.93, composed of items with item content validity indexes (I-CVIs) of a minimum of 0.82 and can thus be judged to have 'excellent content validity' (p496 Polit and Beck 2006).

Figure Three - Overall assessment of the SMILI by the expert panel



Some positive overall comments were given:

'I am very glad that this incredibly important aspect of midwifery is being studied with what seems to be a very comprehensive tool. As well as research applications, I'm sure it could ultimately be used for training purposes too'. 'Well done, excellent so far, just some wee tweaks. Can this information be made available for students and midwives as soon as you have the outcomes?', 'I think it's excellent'. No negative comments were given.

6.12 AMENDMENTS TO THE INSTRUMENT BASED ON THE EXPERT PANEL RESULTS

Following Study Three, a number of amendments were made to the SMILI to incorporate suggestions made by the expert panel. These included some additions to the context page to include ethnic and socio-economic factors and some additions to the physical environment descriptors. Some of the wording was amended to describe the woman, partner and midwife's demeanour and facial expressions and vocal tone. Two additions were made to the midwife behaviour's list: carrying out a procedure without asking the couple's permission and engaging in 'positive pain talk'. An attempt was made to reduce the wordiness of the behaviour screens to make completion more straightforward. The problems relating to the layout and running of the computer programme were fed back to the IT expert and appropriate amendments made to enable the smooth running of the programme.

6.13 DISCUSSION AND SUMMARY OF STUDY THREE

The two studies detailed in this and the preceding chapter aimed to test the face and content validity of the SMILI. The number of student and expert panel members compared favourably to the size of expert panels in other instrument development studies (Lynn 1986, Tilden et al 1990, Edelen et al 2008, Muller et al 2008, King et al 2008, Ning et al 2008, Ruiz et al 2008, Mahboobeh et al 2009, McCormack et al 2009, Pelander et al 2009). The studies found a good level of agreement between both the student group and the expert panel and the researcher about the content of the instrument. The draft instrument was judged to be valid by the expert panel. The studies were an essential stage in the development of a robust instrument as they not only confirmed the researcher's decisions about approach and content but also identified changes required to be made to the computer programme to make it comprehensive and usable.

CHAPTER SEVEN – STUDY FOUR

RELIABILITY TESTING OF THE OBSERVATION INSTRUMENT IN THE PRE-CLINICAL SETTING

7.1 INTRODUCTION

The final two of the series of interlinked studies were designed to complete the testing of the Supportive Midwifery in Labour Instrument in both the non-clinical and clinical environments to ensure that it is a valid, reliable and usable tool to record the quantity and quality of midwifery intrapartum support. Study four was the final pre-clinical study, using a panel of volunteer observers to test the SMILI for reliability by observing commercially available labour care films. The testing of reliability is a vital stage in the development of the observation instrument:

'*The extent to which any method of observation can be called objective depends on the degree of agreement between two observers using the observational method'* (p253 Cormack 1996).

It was decided to carry out this stage of the reliability testing using films rather than in the clinical setting as it was felt that the recruitment of women and midwives in the clinical setting was a substantial undertaking for an instrument that was completely new and untested. It was felt that recruiting midwives and women to test the instrument at such an early stage in its development could raise ethical issues when a reasonable alternative, watching labour care films, was available to the researcher.

7.2 AIM

To test the reliability of the SMILI in enabling an observer to record the quantity and quality of support provided by the midwife in real time. The reliability of an instrument refers to the consistency of a measurement or the degree to which an instrument measures the same way each time it is used under the same conditions with the same subjects, that is the repeatability

of a measurement. Reliability may be estimated in two ways: test-retest and internal reliability. This part of the study sought to estimate reliability using the test-retest approach.

7.3 OBJECTIVES

- To replicate as far as possible in the non clinical setting the conditions in which the SMILI was designed to be used,
- To test whether the observers were able to use the instrument effectively and to complete all of the observation screens in the allocated time,
- To identify any problems with the SMILI when used in near real-life conditions before entering the clinical setting,
- To test inter-rater reliability of the instrument, by comparing the observations recorded by two observers observing the same three labour care films.
- To test whether one observer recording care observed in three labour care films on two different occasions two weeks apart obtains reliable results using the SMILI, that is whether there is adequate intra-rater reliability.

7.4 STUDY DESIGN

The study was a small scale pilot for the full-scale clinical feasibility testing study, taking place in conditions that aimed to be as similar to the real-life clinical environment but without requiring the recruitment of study participants. Volunteer observers received written information and a short training session in using the SMILI. The observers were shown three short videos showing real-life labour episodes.

Three different labour care episodes were chosen by the researcher for this study. Two of the excerpts were from the Channel 4 series ‘One Born Every Minute’ and one was from an older

video used in antenatal education called ‘Eight Births’. The three different excerpts were chosen as they showed British midwives working in the NHS and so were relevant to the context for which the SMILI had been designed. ‘One Born Every Minute’ examples were chosen as they were the most up to date examples available to the researcher. The three different excerpts were felt to provide a good variety of behaviours to be recorded: one of the midwives demonstrated a very positive and caring approach and provided a great deal of supportive care (film two), one provided very little supportive care and showed some more negative and directive behaviours and speech patterns (film one) and the final video was chosen as it depicted a home rather than a hospital birth (film three).

The ‘One Born Every Minute’ series is presented in a highly edited format on the television. Different women’s labours and births are woven through a whole programme with very short two minute excerpts of a woman’s labour shown before moving on to observe a different labour. In order to provide observers with a longer period of observation more akin to the real life observation, the separate excerpts were edited by a university technician to provide one continuous longer excerpt. In the case of film one the final excerpt viewed was thirteen minutes long, while film two was four minutes and film three was six minutes. In total, then, reliability was tested for twenty three minutes of observations.

The observers were asked to use the SMILI in real-time while watching the videos to record the support that they observed.

7.5 RESEARCH SITE

Initially one half day session was set aside to provide training and carry out the testing with the four volunteer observers in August 2010. Following this session, two further training and testing sessions took place in University teaching facilities in September and December 2010.

7.6 POPULATION AND SAMPLE

The population and sample used to test the instrument for reliability were a convenience sample of clinical midwives currently working in NHS Scotland who volunteered to be involved.

All professional members of the expert panel involved in Study Two were invited to volunteer to take part in the next stage of the study. Three members of the panel volunteered to assist with the reliability testing. All of these volunteers worked as consultant midwives within NHS Scotland. After the first of the training and testing sessions in August 2010, a number of changes were made to the SMILI.

At the time that volunteers were sought to join the expert panel, a request was also sent to all Heads of Midwifery in Scotland to forward an email to all midwives asking if they would be interested in volunteering their time to be involved in the clinical study as observers. Four clinical midwives working in NHS Scotland volunteered to be part of the study. One of the four was a member of the expert panel who was also involved in the initial training and testing session, however prior to the final pre-clinical reliability testing she had to withdraw due to work commitments. Of the three remaining volunteers, one was not known to the researcher prior to the study and was working as a community midwife. The two remaining volunteers were known to the researcher as senior clinical midwives. All three midwives had more than twenty years clinical experience, though variable amounts of research and information technology experience.

Following the changes, the reliability testing was undertaken with the three midwives who had volunteered to carry out observations in the clinical setting. It was felt that the training for the reliability testing and the testing process itself would provide them with good experience for the clinical study. The final training and testing session in September and December 2010 involved these three participants and the inter-rater reliability results presented below are for these midwives at these sessions.

7.7 THE INSTRUMENTS

The volunteers were each provided with a laptop loaded with the latest version of the SMILI. The data recorded were saved onto the laptop's desktop in the form of Microsoft Excel spreadsheets. Verbal feedback and comments were sought on each occasion from the volunteers which were noted down by the researcher at the time of each of the sessions.

7.8 DATA COLLECTION PROCEDURES

Further written information about this next stage of the research was given to the prospective participants by the researcher by email (Appendix 15). Prospective participants were asked to contact the researcher if they wished to participate in the next stage of the research. A further verbal explanation of the use of the observation instrument and an opportunity to ask further questions were provided. Written consent was requested at the time the participants attended to observe the videos (Appendix 16). The participants agreeing to be involved in observing the intrapartum video excerpts and recording the care observed on the observation instrument were asked to set aside a total of two hours. This included half an hour to describe the process and the instrument and an opportunity to ask questions, an hour to complete the observation exercise and half an hour to discuss any issues arising from the testing. The location of the exercise was at the convenience of the participant.

The first reliability testing session in August 2010 identified a number of problems with the use of the instrument in real-time, described in the results section below. Though it had been planned that this would be a reliability testing session, it became clear that the session was a feasibility and usability session. This led to the decision to make some significant changes to the layout of the SMILI and to ensure that observers had more time to become familiar with the SMILI and practice using it prior to any reliability testing. Once the changes had been made to the SMILI by the researcher and IT expert, the new version was sent in memory stick form to the four original volunteers who were then asked to provide feedback about the changes.

Following positive feedback about the changes, the four midwives who had volunteered to take part in the clinical observations were sent a training manual and invited to participate in a combined training and reliability testing session in December 2010. The participants were sent a copy of the new version of the SMILI and encouraged to practice using the instrument prior to attending the training day. One of the volunteers withdrew from the study at this stage due to work commitments.

At the training and testing session in December 2010, the researcher provided a presentation setting out the key findings of the literature search and the stages of the development of the instrument. The three participants practiced using the SMILI first by responding to a verbal description of labour events by the researcher, followed by observing several labour film excerpts in which the participants were encouraged to say out loud what they were observing and recording. Once all three participants stated that they felt confident in using the SMILI in this way, reliability testing of the instrument was carried out observing the three labour care excerpts.

7.9 ETHICAL CONSIDERATIONS

All women and midwives featured in the labour care films had agreed to the public distribution and use of the films. Permission to use the 'One Born Every Minute' episodes were sought from the producers and a DVD of two of the episodes was purchased from the producers.

The participants were volunteers from the expert panel and, subsequently, from the population of NHS Scotland midwives who had been informed about the study by email and who had volunteered. The participants' anonymity was protected through the use of individual codes to identify the data they recorded. All participants were provided with written information about the study and signed written consent forms before commencing the testing process. Completed consent forms were stored in a locked cabinet separately from the data obtained.

Data was recorded by participants directly into the computer based software. Responses were anonymised and were traceable only by the researcher through the use of a coding system. The list linking the codes and names of participants was kept securely and separately from the data collected. This data was transferred by the researcher into SPSS on a password protected computer.

7.10 DATA ANALYSIS

Verbal feedback from the volunteers at the first session was documented by the researcher contemporaneously to ensure all important points were recorded.

Data recorded during the testing sessions were recorded onto data sticks and uploaded into the SPSS programme by the researcher. The statistical test used was the Kappa correlation, as described in Study Two (p101). The data recorded by each of the participants for each of the three video excerpts were compared with the data recorded by the researcher. The Kappa calculation identified the level of agreement between each observer and the researcher above a 50% chance correlation level, giving a measure of inter-observer reliability. Similarly, a Kappa correlation co-efficient was used to measure the level of agreement between the same observer observing the same video footage on two separate occasions, to measure the intra-observer reliability of the SMILI.

7.11 RESULTS OF STUDY FOUR

The initial reliability testing session with the three members of the expert panel in August 2010 revealed a number of difficulties with the SMILI. It was decided that these difficulties and issues had compromised the ability of the participants to carry out the reliability testing as planned and the session was therefore used as a test of the instrument's usability and an opportunity for participants other than the researcher to 'road test' the instrument and to provide detailed

feedback. The feedback related almost exclusively to the layout and practical usability of the instrument rather than the content, so a decision was made to incorporate all of the suggestions made by the volunteers as it was apparent that this did not compromise the evidence-based content.

7.11.1 Amendments to the instrument based on Study Four

The feedback provided at this session led to a number of changes being made to the SMILI:

1. The font used throughout the instrument was enlarged to facilitate the observer's ability to read the instrument with ease,
2. The observation period set for the observer to work through all the observation screens was changed from two minutes to three to enable the observer to complete all of the screens,
3. The programme had been set up so that it took the observer automatically through all of the screens at set intervals. This was changed to allow the observer to move freely through the different screens at their own pace and in their preferred order by clicking on the tabs,
4. The midwife behaviour screens had been presented as long lists of possible behaviours divided between five tabs (emotional, tangible, informational, advocacy, partner and non-support). Following feedback, these behaviours were reduced to much shorter lists divided between eleven tabs and screens to ensure that the observers could locate behaviours more easily. These tabs were labeled presence, verbal, advocacy, touch, physical care, assessment, environment, care of partner, indirect care, information and decision making,
5. The 'contraction'/'between contraction' button and the 'midwife enters/leaves' button were made larger and more distinctive using colour and pictures to remind the observers to use them during the observation.

7.11.2 Inter-rater reliability

The data recorded during the testing process was initially saved onto Microsoft Excel spread sheets, these were then converted into SPSS by the researcher. The Kappa correlation coefficient and percentage agreement was then calculated between each of the three observers and the researcher for each of the three labour care films. The results are shown in the table below:

Table Ten: Inter-rater reliability of the SMILI between observers and researcher

Film number	Observer One Kappa (%)	Observer Two Kappa (%)	Observer Three Kappa (%)
1	.642 (86.9)	.517 (76.2)	.581 (83.4)
2	.552 (80.1)	.484 (70.1)	.520 ((75.3)
3	.574 (81.8)	.500 (74.4)	.570 (82.6)

The level of agreement is moderate, providing an acceptable level of inter-rater reliability. It is interesting to note that there were slightly higher rates of reliability for film one. This film was the longest in length (13 minutes v four and six minutes) and depicted less supportive and more negative behaviour by the midwife.

7.11.3 Intra-rater reliability

The reliability of the researcher recording support in the same three films observed on two separate occasions separated by two weeks was also measured. It had initially been hoped to test intra-rater reliability for one or more of the volunteer observers but this proved to be unfeasible due to the work commitments of the volunteers. The results were converted into SPSS and the Kappa correlation and percentage agreement between the two different observations was then calculated. The results are shown in the table below:

Table 11 : Intra-rater reliability of the SMILI

Film number	Kappa correlation between 1st and 2nd observation by researcher (%)
1	.696 (88.4)
2	.776 (95)
3	.682 (92.4)

This test therefore identified a good level of intra-observer reliability of the SMILI for the researcher.

7.12 DISCUSSION AND SUMMARY OF STUDY FOUR

The reliability testing of the draft instrument was successful in further refining and developing the usability of the instrument. Testing was initially delayed as it was identified that observers required further training and to become more familiar with the SMILI before being able to test its reliability successfully. Some changes to the layout and speed of the observation were identified to make it usable for all of the observers.

Once these changes had been made and the observers had been given an opportunity to practice using the SMILI, the inter-observer and intra-observer reliability were found to be moderate to good. The extent of inter-rater and intra-observer reliability testing were limited by time constraints and further testing may be considered to be beneficial in future studies. The volunteer observers expressed the view that they now felt confident and competent to use the SMILI. It was now possible to proceed to the next stage of the instrument development: testing the SMILI in the clinical environment.

CHAPTER EIGHT – STUDY FIVE

METHOD AND DATA ANALYSIS PLAN

FEASIBILITY AND PILOT TESTING OF THE SUPPORTIVE MIDWIFERY IN LABOUR INSTRUMENT IN THE CLINICAL SETTING

8.1 AIM

The principal aim of Study Five was to test whether the newly developed systematic observation instrument, the 'Supportive Midwifery in Labour Instrument' (SMILI), could reliably record and measure the quantity and quality of midwifery support during labour in order to provide detailed information about professional intrapartum support.

8.2 OBJECTIVES

This aim was achieved through the specific study objectives:

1. To test the feasibility and acceptability of a direct observational study and the SMILI in the intrapartum setting.
2. To complete the testing of the validity and reliability of the SMILI in the clinical setting.
3. To explore the ability of the SMILI and outcome measures to measure the quality and quantity of midwifery support in labour in the clinical setting.
4. To undertake initial analysis of the study data to explore the ability of the study methods to identify correlations between midwifery support and clinical outcomes.

8.3 STUDY DESIGN

The methodology chosen for this study was a quantitative one. The research design was a non participant observation of behaviour in the clinical setting recording the care observed using a newly designed computer based instrument, the 'SMILI' and the collection of postnatal data

through a validated postnatal questionnaire with women and the recording of clinical outcomes data.

The SMILI was designed to set the context of the observation, recording key details about the woman, the midwife and the labour ward environment. The SMILI assists the observer in intermittently recording the key behaviours of the woman, her birth partner and the midwife every 3 minutes. Screens allow the observer to record the demeanour, position, verbal communication, facial expression and touch of the woman and her birth partner by providing a number of options which can be ticked to identify their presence. Subsequent screens allow the observer to record in more detail the position, vocal tone, demeanour, facial expression, level of attentiveness, verbal communication, advocacy, touch, direct physical care, environment, indirect care activities, and information provision by the midwife.

In addition to the data collected using the SMILI, data relating to the feasibility of the instrument in the clinical setting and outcomes were collected. The observer asked the midwife and woman if they were happy to be contacted by the researcher separately following the birth. The participant woman and midwife were asked postnatally about their feelings about being observed and whether they found the presence of the observer disturbing. The responses to these questions were recorded on the standard postnatal outcomes data sheet by the researcher (Appendix Six).

The observer completed questions on the postnatal outcomes data sheet relating to whether they found the SMILI usable and whether they encountered any problems with its use in the clinical setting. In order to record birth outcomes, the observer completed some clinical outcomes data on this postnatal sheet including type of birth, length of labour and use of analgesia. Women's feelings about the support they received were measured through a short validated self-complete written postnatal questionnaire called the 'Support and Control in Childbirth' questionnaire (Ford and Ayers, 2009).

8.4 RESEARCH SITES

In order to test the new instrument effectively, four contrasting maternity units within NHS Scotland were chosen: one midwife-led unit offering intrapartum care to low risk women suitable for midwife-led care (the community midwife unit at Royal Alexandra Hospital, Paisley), one unit with a consultant-led unit offering care to all women and a separate alongside midwife-led unit, providing care for low risk women (Crosshouse Hospital, Kilmarnock), one obstetric consultant-led maternity unit providing care for all women regardless of risk (Wishaw General Hospital) and one consultant- led unit providing care for all women regardless of risk, but without the facility of an intrapartum epidural service (Cresswell maternity unit, Dumfries).

8.5 POPULATION AND SAMPLE

To obtain the required data, three populations of participant were required. These were the observers, the midwives being observed and the women and their partners being cared for in labour.

8.5.1 The Observers

The three observers were a convenience sample of clinical midwives currently working for NHS Scotland, who responded to a call for volunteers to participate in the study. A group of four volunteers was initially identified who wished to be involved in carrying out a proportion of the observations, along with the principal researcher. Prior to the commencement of the study, one of the volunteers had to withdraw due to work commitments. Permission was sought from the volunteers' line managers to be released for five days of research observation.

All of the volunteers received a training pack, the opportunity to practice using the SMILI at home for several weeks and a half day training in using the SMILI in the clinical setting and giving information to women and midwives about the research study. The researcher was

always available at the research sites when the other observers were present to carry out observations to answer any questions or assist with any problems.

8.5.2 The Midwives

Written information was sent to the Heads of Midwifery at the four maternity units about the research. The researcher offered to meet with the Head of Midwifery and midwives at the units to discuss the research and answer any questions. This offer was taken up in all four of the units and the researcher attended each unit to make a presentation to staff about the background to the study, the development of the SMILI, the information, recruitment and consent procedures and to answer any questions about the study.

All midwives regularly providing intrapartum care at the maternity units where ethical approval had been granted were sent written information about the study in the weeks before commencement of the observations (Appendix 21) by the local collaborator at each of the four units. The local collaborator was the consultant midwife at each of the units.

The sample of midwives was a convenience sample drawing on volunteers who had provided consent, who were on duty to provide intrapartum care at the time of the researcher's attendance and who were caring for a woman meeting the inclusion criteria who consented to participation. It was decided to allow a midwife to consent to participate in the study on more than one occasion when caring for different women.

Decisions about the planned sample size were based on a number of considerations (described below in Section 8.8 in more depth). The target sample size was chosen as 50 observation episodes. The number of midwives in this sample would depend on the number of midwives who agreed to participate on more than one occasion, but was anticipated to be in the region of 45. It was felt that it would be of interest to observe a minority of midwives on more than one occasion but to obtain as broad a spread of examples of support as possible, this would not be a high proportion.

8.5.3 The Women and their birth partners

The population was all pregnant women booked to give birth at the maternity units during the months of the pilot study who met the inclusion criteria. The inclusion criteria for participation in the study were women who had reached term (37-42 weeks of pregnancy), were not booked for an elective caesarean and who had a singleton fetus presenting by the vertex. The exclusion criteria were any woman aged under 16 years, any woman with a learning difficulty or mental health problem that precluded her from providing informed consent and any woman who was known to be carrying a baby likely to experience significant medical problems.

All eligible women booked at the maternity units due to have their babies during the months when observations were to take place were provided with written information about the study at around the 36 week appointment by their midwife (Appendix 16 and 17). The researcher offered to attend group antenatal education sessions to provide women with information about the research and answer any questions; however this offer was not taken up by any of the participating units.

The sample of women was planned to be between 45 and 50 women who provide informed consent to participate upon admission to the maternity unit in early active labour or for induction of labour. It was anticipated that some women would be asked to provide consent for their care to be observed for two observations (that is when they were being cared for by two successive midwives during their labour), and thus the sample may be less than the planned observation sample of 50.

For the purposes of this study, 'early active labour' was defined as a woman who is experiencing regular contractions that are resulting in dilatation of the cervix of at least 3cm but less than 8cm. This ensured that an observation was not started when a woman was in the 'latent phase' of labour when hospital admission and continuous midwifery care are not generally advised and also that the observation was not commenced when the woman was in very advanced labour and therefore may find the consent procedure and introduction of an observer particularly intrusive.

Most women are accompanied in labour by a birth partner; this may be a life partner or another relative or friend. If a woman was not accompanied by a birth partner during her labour this did not exclude her from inclusion in the study. It is likely that the behaviour of the birth partner has an impact on the course of events in the labour room, including the behaviour of both the woman and the midwife, and so it was considered important that the study included some observation of the partner's overall demeanour and behaviour. The person that the woman identified as her main birth partner was therefore also informed about the research soon after her admission to the maternity unit and asked for their written consent to participate in the study.

8.6 THE INSTRUMENTS

The instruments used in the study were the newly developed 'Supportive Midwifery in Labour Instrument' (SMILI) to record the labour care observed, the Support and Control in Birth (SCIB) postnatal questionnaire (Ford and Ayers 2009) self-completed by each woman involved in the study within the first 24 -48 hours after the birth and the postnatal outcomes data sheet, designed specifically for this study.

8.7 DATA COLLECTION PROCEDURES

8.7.1 Informed consent

Written information leaflets were provided to all of the participating units and distributed by the consultant midwives to all of the midwives involved in providing antenatal care. The midwives were advised to give all women the information leaflet at the woman's 36 week antenatal appointment. The leaflet included contact details of the researcher. Posters were also distributed to be placed in the waiting areas of all antenatal clinics to raise local awareness about the research study.

The researcher met with staff from each of the participating units in the weeks prior to the commencement of the study and agreed a start date for the study at each site.

At the beginning of each observation session, the researcher and/or trained observer would make their presence known to the shift coordinator. The researcher would sit either at the nurses' station or in the staff room to provide the midwives with further verbal information about the study, answer any questions and ask the midwives on duty for their written consent to participate.

The shift coordinator would advise the researcher which women on the maternity unit would fit the inclusion criteria for the study. The coordinator approached the woman and her partner to provide them with written and verbal information about the study. The couple were given time to read and consider the information and were asked if they would be happy to participate by the midwife caring for them. If they were happy to participate, the midwife would ask them to complete the written consent forms. The midwife coordinators and midwives involved in the consent procedure were given verbal and written information about the study and how to obtain informed consent (Appendix 20).

The women and her birth partner participating in the study were observed in the course of their labour. The information sheet was given to women during a routine antenatal appointment and the consent process took place upon admission to the labour unit and lasted less than 15 minutes.

The midwives participating in the study were observed in the course of their usual shift of work. The researcher provided them with time to ask any questions about the research before the observation began and asked a short list of demographic questions, such as number of years qualified at this point.

8.7.2 Systematic Observation

Following the completion of the informed consent procedure, the researcher or trained observer entered the labour room and introduced herself. She explained that she would be in the room

for the next three hours, unless the woman, midwife or the woman's partner asked her to leave at any point. She explained that she would not be offering care and would not join in conversations, but that she could summon help for the woman or midwife when asked.

The researcher or observer wore 'theatre scrubs' when carrying out the observation in order to assist in them becoming 'part of the background' for the couple and their midwife. The observer would choose a spot to sit in the room where she was not in the direct sight line of the woman if possible and not in the way of staff providing care. The observer sat silently throughout the observation and avoided eye contact with participants. This approach was in line with guidance available in the literature about conducting direct observational research:

'*Although the entry of an independent observer to the research setting can have an initial disturbing effect, providing that certain considerations are applied this disruption will be short lived'* (p257 Cormack 1996).

The computer based observation instrument was then employed. The SMILI runs directly from a data stick in a laptop and records results directly and contemporaneously onto the data stick. The data can only be recorded if the observer has recorded a unique midwife identifier code. No personal identifiable data was recorded on the SMILI. The woman and midwife's names and contact details were recorded and stored separately on paper.

The data collection process assessed the practicality of the instrument in the clinical setting, and any problems, issues and gaps were recorded by the researcher as contemporaneously as possible in a field work diary.

At the end of the observation, on some occasions the woman had not yet given birth and so the observer simply thanked the woman and her partner for allowing her to be present and asked her permission to visit her after the birth.

8.7.3 Postnatal data collection

Once the woman had been transferred to the postnatal ward or was suitable for discharge home, the researcher asked permission to speak to the woman again. The researcher or

observer provided the woman with the opportunity to ask any further questions, asked her about her feelings about having an observer present and thanked the couple for their participation. The researcher or observer provided written information about how to contact the researcher should they wish to at a later time. The researcher or observer also gave the woman the validated postnatal questionnaire to complete, to assess her feelings about how in control and well supported she felt during the labour. The observer or researcher showed the woman how to complete it and provided her with an envelope in which to return the questionnaire. The meeting generally took five minutes and the completion of the questionnaire also took less than five minutes. The researcher or observer recorded the woman's expressed feelings and any questions on the postnatal birth outcomes form (Appendix Six).

The researcher or observer recorded key clinical outcomes of the labour and birth on a standard birth outcomes form (Appendix Six) including length of labour, analgesia used, medical interventions performed and type of birth.

The researcher or observer was also asked to record their overall 'global' ratings of the quality and quantity of midwifery support provided during the observation period on the standard form with the clinical outcomes data (Appendix Six).

The researcher or observer completed a question on this same data sheet about how successful they felt that the SMILI was in recording the quantity and quality of support observed (Appendix Six).

8.8 SAMPLE SIZE CONSIDERATIONS

Decisions about the planned sample size were based on a number of considerations. Little evidence was available to allow precise sample size calculations as this was the first study using this particular approach with systematic observation followed by postnatal follow-up data. It was unknown prior to the commencement of data collection how problematic recruitment would be. Advice from a leading health statistician suggested that sample size could be based

on pragmatic considerations relating to the time available for data collection (four months) and the sample size used in the most comparable studies.

The work sampling and observations studies carried out previously in this area have included highly variable numbers in their samples. The observational studies of second stage behaviour included between 20 and 32 women (Sampselle et al 2005, Thomson 1995). The random work sampling studies carried out by McNiven et al (1992) and Gagnon and Waghorn (1996) were based on 616 and 3,367 individual random observations respectively. These represent single time point observations with one observation every 15 minutes for all the nurses on shift at that time. Thus, if there were ten nurses on shift, 616 observations represent 15.4 hours of observation and 3,367 represent around 84 hours of observation. Miltner (2002) and Barnett (2008) carried out periods of continuous systematic observation in labour rooms, which are the most comparable to this study. Miltner observed 24 nurses caring for 75 women for a two hour period of observation. This represents 150 hours of observation. Barnett observed 17 nurses caring for 30 women for variable lengths of time. Barnett reports that this represented 85 hours of observation.

A substantial review of studies employing assessment instruments to measure nurse-patient interactions in oncology (Caris-Verhallen 2004), identified 21 studies using a quantitative systematic observation approach. The observation periods in these studies varied between two and four hours and the average number of nurse-patient interactions observed for each study was 40.6 (Caris-Verhallen 2004).

The decision was therefore taken to aim to undertake fifty labour care observation episodes. If observations were three hours long this would represent 150 hours of observation. It was felt that this number of observations would ensure that this study was of at least a comparable size to similar systematic observation studies in the maternity and non-maternity settings reviewed.

8.9 ETHICAL CONSIDERATIONS

The research was carried out in accordance with the University of Stirling 'Code of Good Research practice' (2009). The dignity, rights, safety and well-being of the participants will be the primary concern of the researcher throughout the study.

The study received ethical approval from the University of Stirling Nursing and Midwifery Department ethics committee (letter included as Appendix 23) in June 2010.

The study received ethical approval from the Tayside B NHS ethics committee in August 2010, with only very minor amendments suggested to the information leaflets for women (letter included as Appendix 24).

The study received research and development approval from all four participating units (included as Appendix 25).

Women with particular vulnerabilities were not eligible for inclusion in this study. The study excluded women with learning disabilities, women under the age of 16, women where it had been identified that the fetus had potentially serious medical problems and women with severe mental health problems as these may impair the woman's ability to provide informed consent. All women are emotionally vulnerable in the early stages of labour. In order to ensure that women did not feel pressure to be involved in the study, the consent procedure was carried out by a member of the midwifery staff on duty at the time and not the researcher. Women who were in very advanced labour or distressed were not eligible for inclusion in the study as this would not be an appropriate time to seek informed consent for participation. A review of other intrapartum studies identified that gaining informed consent in early labour is an acceptable approach when managed with sensitivity (Hundley and Cheyne 2004). On occasion, while a woman was happy to consent to participation in the study, her birth partner or other members of her birth support were unhappy. In order for the observation to commence, all of the woman's birth supporters had to be in agreement.

The researcher was aware of the intrusive potential of being present in a labour room. During the observation period, a woman may no longer wish to have the researcher present. This

possibility was discussed with the woman prior to consent, so that she was aware she was able to terminate her participation in the study at any time or that she could ask the researcher to leave the room for a period and that this would not affect the care she received.

Prior to commencement of the study, it was recognised that it would be possible that the care observed during the observation period was considered by the observer to be sub-standard in some way. As the observers are registered midwives they are bound by their professional rules and code of conduct (NMC 2008). It was clarified with the observers prior to the study that if they observed care that they considered to present a risk to the well-being of the baby or mother, they would be obligated to report their findings as soon as possible to the person in charge of the maternity unit at the time. There was therefore a recognised potential conflict of interest between the research interests and professional duty of the researcher, but it was explicit that the professional duty would take precedence.

It was also recognised that the midwife participants in the trial may feel uncomfortable and that their practice was under scrutiny. These feelings may be particularly acute if they were aware that the researcher was a senior professional peer. The consent and information procedure prior to consenting to participate in the study sought to reassure the participants that the focus of the observation was not the assessment of their technical capabilities in carrying out procedures and that the results of the observation would not be reported back to any senior colleagues or supervisors unless unsafe practice had been observed. In the event that unsafe practice had been considered to be observed, the researcher would discuss her thoughts with the midwife involved before referring to a senior colleague. It was emphasised to the midwife participant that the aim of the study was to provide further information for the midwifery profession about what kinds of midwifery support appear to be most effective and that the observer would not be critiquing the care provided by the midwife on any individual basis. The study hoped to identify the most positive aspects of midwifery care so that these can be replicated.

If any other professional or lay person entered the room to provide care or support, their presence was recorded using the observation tool but no other observations about their actions

or behaviour was recorded unless they had already provided written consent to participate in the study.

The processes for anonymising data and protecting the privacy of the participants, both women and midwife, was explained and emphasised to all the participants. All participants were given information about how to contact the researcher, her supervisors or an independent university sponsor in the future if they had any concerns or questions about either the conduct of the research or events observed.

Prior to commencement of the study it was identified that it was possible that the observer could be present when an emergency occurred. The researcher would be required by her professional code of conduct to respond appropriately to any emergency, to call for help and assist other health professionals. All of the observers were registered midwives with current notification of their intention to practice and had been appropriately updated in responding to obstetric emergencies. This could lead to the possibility that the researcher could be called to give evidence or report her findings in a clinical risk investigation or legal investigation of an incident. The researcher in these cases would need to participate in any such investigation in accordance with her professional code of conduct.

The presence of the observer may change the behaviours of the midwife, woman and birth supporters. The behaviour of the observer when she was in the labour room was an important factor in ensuring that participants felt as relaxed as possible. The observer made herself as unobtrusive as possible, making as little noise as possible and sitting in a way that allowed the woman and her birth supporters freedom of movement and privacy.

It was a potential risk that a woman could experience trauma or distress as a result of her experience of being observed during the birth process. It was hoped that this risk would be minimised by the informed consent process and by the appropriate unobtrusive behaviour of the observer. It was necessary to ensure that any woman that agreed to participate in the study was aware how she could contact the researcher to discuss any issues that arose during the postnatal period in relation to having participated in the research.

While the observers were themselves experienced midwives, it was possible that they may observe events that could be upsetting or even traumatic. This was discussed with the observers as part of their preparation for the study. The observers were advised to be aware of their emotional response to events and to ensure that they sought any necessary debriefing or assistance with their feelings after any such event.

No incentives to participate in the study were given to any of the participants.

All participants in the study were aware that they were participants in a research study. No deception was involved.

8.10 THE ANALYSIS PLAN

The overall data analysis plan is included below. The plan was developed to ensure that the study aims and objectives (p134) were fully addressed.

1. Calculate overall figures for the study including
    - the number of separate observations,
    - the number of women participants,
    - the number of partner participants,
    - the number of midwife participants,
    - the number of hours of observations carried out,
    - the number of observations at the different sites,
    - number of midwives seen more than once,
    - number of women seen more than once,
    - total observation time and number of midwives observed at each of the four units,
    - numbers for the postnatal follow-up – clinical outcomes data complete and postnatal questionnaire complete
    - numbers where problems occurred with data collection.
2. Collate the information collected about women participants including age, first language, ethnic origin, risk factors, gestation.
3. Collate the information collected about midwife participants including age, years of registration, type of training, ethnic origin.

4. Collate the collected information about the environment and context of care.
5. Calculate the rates of clinical interventions including pain relief and type of birth for the study as a whole.
6. Collate the information gathered during the data collection period relating to the feasibility of a systematic observation study in the clinical environment, including any barriers to access and recruitment.
7. Analyse the observer comments about the usability of the SMILI to identify the completeness and usability of the SMILI in the clinical setting,
8. Analyse the midwife and woman's responses to the questions about their involvement in the study to identify the acceptability of the research method in the clinical setting,
9. Calculate the length of each observation, the total number of hours of observation in the whole study and the average length of an observation.
10. Calculate the length of time and the proportion of the overall time that each midwife was:

- present in the room,
- engaged in each type of observable behaviour,
- engaged in each of the five overarching categories of support (emotional, tangible, informational, advocacy and partner support),
- engaged in non-support activities including indirect care and assessment activities,
- exhibiting a positive supportive manner and demeanour,
- behaving in a negative or unsupportive manner.

11. Calculate the mean for each of the above calculations for all of the midwives observed,
12. Identify any correlations between the quantity and quality of midwifery support and the workload of the observed midwife during the observation period (that is, the number of women that the observed midwife was caring for at one time during the observation period).
13. Identify the satisfaction of women with the support received through the calculation of scores for the SCIB questionnaires.
14. Identify any correlations between the data recorded using the SMILI with the postnatal SCIB questionnaire results, through the calculation of correlational coefficients.
15. Identify whether any other non-support variables (such as parity, type of birth, pain relief, assessment activities of the midwife, partner behaviours) are correlated with women's views of their labour care recorded in the SCIB.
16. Identify the overall assessment of the quantity and quality of the support by the observers through the analysis of their responses to two Likert scale questions.

17. Identify any correlations between the data recorded using the SMILI with the overall global ratings scales given by the observer, through the calculation of correlational coefficients.
18. Test the 'veridicality' of the SMILI through the comparison of the women's SCIB results and the observer overall assessment results.
19. Identify the level of internal consistency of the SMILI, through the calculation of Cronbach's alpha reliability statistics for related variables.
    Identify any correlations between the data recorded using the SMILI and the postnatal clinical outcomes data including medical interventions and type of birth.

8.11 DESCRIPTION OF THE DATA ANALYSIS PROCESS

Prior to data collection an overall plan for the analysis of the data was drawn up, as shown above. However, on completion of the data collection period and commencement of the analysis process, it became clear that the analysis process would be a lengthy and involved one. In order for the results detailed in chapter seven to be meaningful, a detailed description is given in the following pages to describe the step wise approach to cleaning, managing and finally analysing the data.

The data collected during the observation period using the SMILI were saved directly onto the desktop of the laptop used in Microsoft Excel spreadsheets. For each observation, four separate Microsoft Excel spreadsheets were generated and automatically saved to the computer laptop. These were the 'Context' sheet, the 'Log', the 'Between Contractions' data and the 'Contractions' data. All were labeled with the midwife's individual code (001 – 053). Following each observation, these four spreadsheets were saved onto the researcher's password protected data stick and then transferred to the double password protected office computer.

8.11.1 The Context sheet

The context sheet was completed by the observer before, during and after the observation period to ensure that background information was available for each observation. The data items included in this sheet are given below as Table 12. In order to analyse the results of the context page, it was necessary to convert answers into numerical responses, so for example ' ensuite in room', the response 'yes' was entered as '1' and 'no' as '0'.

Table 12 – The context page data items

Context page data item
Chair for midwife in the room
Ensuite in room
Pool
Position of bed
Beanbag/Birthing ball out in room
Natural Light
Bright Light
Soft Light
Unit Music
Relaxation CD
Woman's own music
Number of births at unit
Unit Type
Number of women allocated to observation midwife
Unit Code
English woman's first language
Woman's ethnic origin
Cervical dilatation at last Vaginal Examination
Risk Factors identified
Allocated care pathway
Pain relief administered before start of observation
Pain relief received at start of observation
Woman Age
Woman's Parity
Midwife's Ethnic Origin
Midwife's Training
Midwife's Experience in years
Midwife's age in years
Midwife's working hours
Number of hours midwife had been on duty at start of observation

8.11.2 The Log

The second Microsoft Excel spreadsheet generated for each observation was the log. This recorded several different elements. Firstly, the presence or absence of the midwife. This was recorded as 'midwife leaves' 'midwife enters' and recorded beside the number of seconds after the start of the observation that this event happened. The log also recorded the presence or absence of other lay birth companions for the woman and other members of staff. This was recorded as 'partner/mother/student midwife/paediatrician/anaesthetist etc arrives/leaves', providing a detailed record of who was present in the room at what times during the observation. Finally, the log recorded any free text added by the observer to the box 'Emergency/Error'. Observers were instructed to record in this box if they made an error when recording behaviours that they could not undo and to note down any events of particular note, especially an emergency. In practice, two of the observers also used the free text box to record contextual detail and thoughts about the observation. These observations were very helpful for the researcher when analysing the data to understand the situation more fully and, if it was an observation carried out by the observer, served as a helpful aide memoire to enable the observer to recall the particular observation.

An example of the log of one observation is given below as Appendix 26.

The data collected in the log enabled the researcher to provide answers to one of the key research questions about the presence of the midwife including the amount of time each midwife spent in and out of the room, the proportion of the observation each midwife spent in or out of the room and the frequency that the midwife left the room. The log also provided information about who else was supporting the woman, the number of interruptions from comings and goings in the room and the number of other staff involved in each woman's care. The additional notes enabled the researcher to record specific phrases used by the midwife, the woman or her partner to provide some interesting more qualitative data about some of the communication which took place.

8.11.3 The 'Between Contractions' and 'During Contractions' Spreadsheets

During the early development stages of the SMILI it was decided to identify if a behaviour was recorded during or between a contraction. This would ensure that the level of support provided could be contextualised in terms of the individual woman's labour. One option considered was having 'contraction begins' and 'contraction ends' as an event which would appear on the log. It was felt that this may lead to difficulties in analysing the data. By storing the results on two separate spreadsheets the data could either be analysed separately for during or between contractions or be merged to allow joint analysis. The step wise process taken to interpret, clean and analyse the between and during contraction spreadsheets is described below:

8.11.3.1 The process of cleaning and collating the between and during contraction data sheets

In practice, the analysis of the two separate spreadsheets and the attempt to merge them identified a number of issues. The list of behaviours available to be recorded between and during a contraction were different. For example, 'ignoring contraction' was only available to be recorded during a contraction. Where there were matching behaviours available in the 'between contractions' and 'during contractions' lists they did not always appear in the same order. This was only identified at the analysis stage. Considerable time was taken to re-order the behaviour lists and results to merge the lists when joint analysis was required. These problems were noted by the researcher and fed back to the technical co-developer of the SMILI to ensure that the lists were re-ordered to make merging and joint analysis more straightforward in subsequent studies.

8.11.3.2 The calculation of the frequency of behaviours to allow comparison between observations and between studies

When beginning the process of reviewing and cleaning the data following completion of the data collection period, a number of decisions were needed to ensure that the analysis of the data reflected as closely as possible the care observed.

As the observations varied considerably in length, it was clear that it would not be possible to simply add up the number of times a behaviour was seen during an observation and compare that directly with the number of times the behaviour was seen in other observations. Consideration was given to comparing the frequency that a behaviour was seen in a set period (for example in a thirty minute period). This would have been possible if observations between and during contractions were only recorded at a set regular period, however, as discussed below, in practice the data was not recorded by the SMILI in this way. In order to present frequency data as a percentage, it is necessary to decide how the denominator is calculated in order to calculate the proportion of an observation that a behaviour or demeanour was seen.

The observation process and timer on the SMILI programme were designed to allow the observer to record all of the screens every three minutes. However, the way in which the SMILI programme was devised led to data being recorded whenever data was noted and not only every three minutes. This meant that the frequency of observations was not presented in the results spreadsheets at regular intervals.

The way in which data were recorded was affected by the individual nature of women's labours. It became clear when assessing the data for the first time that an observation would, for example, begin between a contraction. The observer would begin to record in the first minute the woman, partner and midwife's demeanours, vocal tone and position. The woman would then begin to have a contraction, the observer would click on the contraction button and then the subsequent behaviours of the midwife screens completed by the observer during the next one to two minutes would be recorded on the 'contractions' spreadsheets. The midwife behaviours on the 'between contractions' spreadsheet for that three minute period would all therefore be blank. The original analysis plan to use the three minutes as the denominator for calculating the frequency and proportion of any observation that a midwife was engaged in a particular activity was therefore inadequate. If the three minute plan was used, this could significantly underestimate the proportion of time that a midwife was displaying a particular behaviour as it would not take into account the time when the woman was having a contraction and therefore

the midwife was not able to display the 'between contractions' behaviours. As contractions became longer and more frequent during a labour, more and more observations would take place during contractions and fewer between contractions. The calculations needed to reflect this in order to provide a true reflection of care.

In practice, midwives came and went from the room at different intervals and for different lengths of time. If the frequency of a behaviour was noted at every 3 minute period, this could include a period when the midwife was out of the room. This would also underestimate the proportion of time that a midwife was spending engaged in an activity when she was in the room. Though this would accurately reflect the proportion of her labour that the woman experienced the particular supportive behaviour, it would not facilitate the analysis of whether it is the quantity or quality of the behaviours that is most important in affecting outcomes. The researcher wished to be able to differentiate between the effects of the midwife's absence from the room on outcomes, and the quantity and quality of the care provided when she was in the room on outcomes. Thus it was felt to be best to exclude the periods when the midwife was out of the room in the analysis of the frequency of the behaviours.

The calculation of the denominator was based on careful individual assessment of the spreadsheets for each observation.

In order to help clarify these issues, an example for one observation of a section of a between contraction spreadsheet is given below as Table 13. Where '0' was recorded for every behaviour at a particular time period, this time period was not included in the calculation of the appropriate denominator.

The top row of the table indicates the number of seconds into the observation that the particular behaviour was noted, that is 180 seconds, 201, 360, 368, 540 and 552. The table represents the data resulting from completion of the midwife's behaviour screens relating to emotional, advocacy and touch behaviours. A '1' indicates that the behaviour has been seen, a '0' indicates that it has not been seen. In the table below, on the 'between contractions'

spreadsheet, no midwife behaviours are recorded at 201, 368 or 552 seconds. The denominator used for this ten minute period is therefore three rather than six. Thus, if a behaviour was seen twice it was said to have been seen 66% of the times it was possible to be seen. The denominator for calculating proportions would be three in ten minutes and ten in thirty minutes. Thus, 'chatting to the couple about them' occurred twice out of a possible three occasions in the ten minutes of observation recorded here and thus was observed 66% of the possible times it could have been observed.

Table 13 - Example Between Contraction spreadsheet for initial ten minutes of observation 100

Time (seconds)	**180**	**201**	**360**	**368**	**540**	**552**
Quietly being with woman keeping company	0	0	0	0	0	0
Distracted/engaged in other activity in room	0	0	0	0	0	0
Listening to woman or partner	0	0	1	0	0	0
Midwife chats about self	0	0	0	0	0	0
Chatting to couple about them	1	0	1	0	0	0
Critical or dismissive birth plan discussion	0	0	0	0	0	0
Supportive birth plan discussion	0	0	0	0	0	0
Checking out woman's view	0	0	0	0	1	0
Asking for consent to do something	0	0	0	0	0	0
Stopping/criticising woman	0	0	0	0	0	0
Encouraging/praising woman	0	0	0	0	1	0
Talking positively about pain and coping	0	0	0	0	1	0
Forceful direction	0	0	0	0	0	0
Advice/suggestions	0	0	0	0	0	0
Empathy/comfort/reassurance	0	0	1	0	0	0
Re-focusing woman	0	0	0	0	0	0
Gentle/positive humour	0	0	0	0	1	0
Negative humour	0	0	0	0	0	0
Being an advocate	0	0	0	0	0	0
Discussing care with other health professional	0	0	0	0	0	0
Attempting to defuse a difficult situation	0	0	0	0	0	0
Restraining/directional touch	0	0	0	0	0	0
Holding hand, reassuring touch	0	0	0	0	0	0
Massage/counter-pressure/hot and cold compresses	0	0	0	0	0	0

8.11.3.3 The Calculation of the frequency and percentages of observed behaviours

Once the decision was reached about the calculation of the number of observation points, totals were calculated for each observation. Results were totalled for between contractions, during contractions and then for the observation as a whole. Two examples are given below as Tables 14 and 15 to illustrate how this part of the analysis was carried out, using midwives 'A' and 'B'. The individual midwife codes used in the study have been changed here to further protect the anonymity of the midwife participants.

Only one section of the behaviours observed is illustrated, those behaviours linked to the category of emotional support. The first column represents a combined list of behaviours including those from the between contractions and during contractions spreadsheets. The next column titled 'between contraction n=24' shows the number of times that the particular behaviour was seen during this whole observation. Where there is a dot in the cell it is because these behaviours could not be observed either between or during a contraction. The n=24 means that there were 24 separate observation points during this observation between contractions, that is each of these behaviours could have been observed and recorded a maximum of 24 times during this observation.

The next column titled 'between contraction %' is the percentage calculated by dividing the frequency that the behaviour was seen by the number of observations (24) and multiplying by 100. The behaviour 'quietly being with the woman' was seen on three occasions which is 12.5% of the overall possible during this observation. The next column 'during contractions n=11' shows the frequency of behaviours seen during contractions out of a possible 11 occasions during this observation and the final column is the percentage that any behaviour was seen during a contraction.

Table 14 - Totals and percentages for emotional support behaviours observation A

Responsiveness/ Emotional support	**Between Contraction n/24**	**Between contraction %**	**During contraction n/11**	**During contraction %**
Ignoring contraction	.	.	3	27.2
Distracted/engaged in other	0	0	1	9
Responding to contract	.	.	0	0
Quietly being with woman	3	12.5	3	27.2
Talking over contraction	.	.	1	9
Talking woman through contraction	.	.	0	0
Listening to woman	1	4.1	.	.
Mw chats about self	1	4.1	.	.
mw chatting to couple about them	0	0	.	.
critical birth plan discuss	1	4.1	.	.
supportive birth plan discuss	0	0	.	.
checking out woman's view	1	4.1	.	.
asking for consent to do something	2	8.3	0	0
stopping/criticising woman	0	0	0	0
Encouraging woman	0	0	0	0
Talking positively about pain and coping	0	0	0	0
Forceful direction	0	0	0	0
Advice/suggestions	0	0	0	0
Empathy	0	0	0	0
Refocusing woman	0	0	0	0
Gentle positive humour	0	0	1	9
Negative humour	1	4.1	0	0
Being an advocate	0	0	0	0
discussing care with other hp	1	4.1	0	0
defusing a difficult situation	0	0	0	0

Table 15 shows the same behaviours as Table 14 for a different observation. As this was a longer observation and the contractions were more frequent there were 59 observation points between contractions and 54 during contractions, compared to the 24 and 11 of observation A.

Table 15 - Totals and percentages of emotional support behaviours for Observation B

Responsiveness/ Emotional support	**Between contraction n/59**	**Between contraction %**	**During contraction n/54**	**During contraction %**
Ignoring contraction	.	.	0	0
Distracted/engaged in other activity in room	0	0	0	0
Responding to contract	.	.	43	79.6
Quietly being with woman keeping company	13	22	3	5.5
Talking over contraction	.	.	0	0
Talking woman through contraction	.	.	35	64.8
Listening to woman or partner	12	20.3	.	.
Midwife chats about self	6	10.1	.	.
Chatting to couple about them	12	20.3	.	.
Critical or dismissive birth plan discussion	0	0	.	.
Supportive birth plan discussion	2	3.3	.	.
Checking out woman's view	6	10.1	.	.
Asking for consent to do something	7	11.8	1	1.8
Stopping/criticising woman	0	0	0	0
Encouraging/praising woman	16	27.1	43	79.6
Talking positively about pain and coping	17	28.8	26	48.1
Forceful direction	1	1.6	0	0
Advice/suggestions	8	13.5	4	7.4
Empathy/comfort/reassurance	11	18.6	40	74
Re-focusing woman	15	25.4	18	33.3
Gentle/positive humour	23	38.9	0	0
Negative humour	0	0	0	0
Being an advocate	0	0	0	0
Discussing care with other health professional	0	0	0	0
Attempting to defuse a difficult situation/resolve conflict	0	0	0	0

The two example observations given, A and B, were of two very different midwives. Midwife A gave very little emotional support as illustrated by the low percentages both between and during

contractions. Midwife B gave a great deal of support and the percentages reflect this contrast. Midwife A did not give any verbal empathy, comfort or reassurance either between or during contractions throughout the whole observation and so the percentage is 0, while midwife B gave this kind of support at 18.6% of observation points between contractions and 74% of observation points during contractions.

8.11.3.4 Managing the data to allow between case and between study comparison

The SMILI recorded a very large number of variables, producing a large amount of data. In order to manage and analyse the data it was felt necessary to order and group the results into categories. Table 16 below shows the way in which the midwife's demeanour, vocal tone, position and behaviours were re-ordered so that they could be grouped into categories for further analysis.

The SMILI programme differs from any previous systematic observation instruments developed for the recording of intrapartum care by enabling the inclusion of negative behaviours. The first three categories in the table, 'lack of attentiveness',' neutral/professional attitude' and 'negative/authoritarian behaviour' group together those behaviours of the midwife which are the opposite of the aspects of care women highlighted as being important in the literature, such as showing a positive attitude and being responsive.

The following category is that of Emotional Support. This includes the positive options relating to the midwife's demeanour, vocal tone and facial expression and to the proximity of the midwife to the woman. It then includes 24 of the behaviours grouped into five 'sub-categories':

1. Attention: defined by four behaviours 'responding to a contraction', 'seeking eye contact', 'quietly being with the woman, keeping company' and 'listening to the woman'.
2. Verbal Support: defined by six possible behaviours.
3. Rapport building, defined by four behaviours.
4. Enhancing the woman's sense of control, including eight behaviours.
5. Creating a positive birth environment, including two categories.

The sub-categories developed were felt to reflect the main aspects of emotional support identified in the earlier studies (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2001, Miltner 2001, Barnett 2008). 'Attentiveness' covered presence, eye contact, 'remaining with mother' and attention behaviours from the earlier studies; 'verbal support' covered coaching, reassurance encouragement and praise; 'rapport building' covered 'social interaction' 'laughter and chitchat' and 'humour'. The other sub-categories of 'enhancing a woman's sense of control' and 'creating a positive environment' included elements which were not included in the earlier studies but which were felt to be key aspects of emotional support based on the literature review.

Following the category of emotional support, there is then informational support (including nine behaviours), advocacy (two behaviours), physical support (eight behaviours) and partner support (five behaviours).

The five overarching categories of emotional, information, advocacy, physical/tangible and partner support are, as described in earlier chapters, well established in the literature. The grouping of the behaviours beneath the overarching categories was established as valid during study one with the student midwives group.

Table 16 - Categories of midwife behaviours and midwife demeanour

Category	**Individual behaviour**
Lack of attentiveness	Ignoring contraction
	Distracted/engaged in other activity in room
	Talking over contraction chatting/ giving explanation
	Other side of room (>2m), back to woman
	Other side of room
Neutral/Professional attitude	neutral, professional demeanour
	neutral verbal tone
	neutral, professional facial expression
Negative/Authoritarian behaviour	
Negative demeanour	cold, disinterested, angry
	panicky, anxious,
Negative verbal tone	Shouting, harsh, curt
	Shrill, nervous

Category	Individual behaviour
Negative verbal tone ctd	Disinterested, flippant
Negative facial expression	Cold, disinterested, angry
	Panicky, anxious,
Emotional negative	Critical or dismissive birth plan discussion
	Stopping/criticising woman
	Negative humour
Tangible negative	Restraining/directional touch
Partner negative	Belittling/criticising partner
Information negative	Ignores question or partial answer
	Describing progress - negative or neutral terms
Taking control negative	Doing something to woman without consent/warning/against wishes
	Forceful direction
	Suggests intervention/no indication or no discussion
	Presents decision to woman and her partner
	Suggests pharmacological pain relief
Emotional Support	
Positive demeanour	light, chatty, jokey
	Warm, friendly, calm
Positive verbal tone	positively assertive
	Light / chatty
	Soft, warm, calm, reassuring
Positive facial expression	Warm, smiling, calm
Attentiveness	Near woman 1-2m
	Next to woman (close enough to touch) standing
	Next to woman - sitting
	Responding to contraction non-verbally - moves closer, undivided attention
	Quietly being with woman keeping company
Attentiveness contd	Listening to woman or partner
Verbal support	Talking woman through contraction - coaching breathing, relaxation etc
	Encouraging/praising woman
	Talking positively about pain and coping
	Advice/suggestions
	Empathy/comfort/reassurance
	Positively assertive/Refocusing woman
Rapport building	Midwife chats about self
	Chatting to couple about them
	Gentle/positive humour
	Asking woman about her history
Enhancing woman's sense of control	Supportive birth plan discussion
	Checking out woman’s feelings/view

Category	Individual behaviour
Enhancing sense of control contd	Asking for consent to do something
	Discusses options for next steps, explains indications for an intervention
	Full range of pain relief options and choices offered
	Involves woman and partner in decision-making
	Doing as woman asks
	Encouraging woman and partner to adapt facilities to their needs
Creating environment	Ensuring privacy - knocking, using curtains, covers
	Changing environment to make it more comfortable, building nest
Informational support	Partial labour process information
	Full labour process information
	Partial hospital procedures information
	Full hospital procedures information
	Full answer to a question
	Describing progress - as positively as possible
	Showing woman and partner facilities
	Giving information about fetal well being
Advocacy	Being an advocate
	Attempting to defuse a difficult situation/resolve conflict
Physical support	Holding hand, reassuring touch
	Massage/counter-pressure/hot and cold compresses
	Preparing or administering pain relief
	Helping woman to toilet
	Changing clothes/bedding/pads
	Helping with position change/mobilising
	Assisting with shower or bath
	Getting or giving fluid or food
Partner support	Chatting to partner
	Explaining situation to partner
	Showing partner how to help/ Encouraging/praising partner
	Asking partner about their views/feelings
	Ensuring partner is comfortable/has breaks/something to eat
Non-support direct care	Carrying out a medical intervention
	Delivering baby
	Delivering placenta
Assessment	Monitoring fetal well-being
	Monitoring maternal vital signs
	Carrying out assessment - vaginal or abdominal
Indirect care	Checking or preparing equipment
	Documenting care
	Assisting other health professional
	Discussing care with other health professional

8.11.4 The calculation of descriptive statistics for the behaviour categories

The next stage in understanding and analysing the data was to calculate descriptive statistics for each category for each observation. For most of the observed behaviours the mean of the percentages that a behaviour or a category of behaviours was seen between and during a contraction was calculated to provide an overall figure for the observation. Where comfort and reassurance was given 5% of the time between a contraction and 10% of the time during a contraction, the overall figure for the observation was 7.5%. For those behaviours only recorded between or during a contraction, the percentage it was observed at either of those time points was taken rather than creating a mean between and during contractions as it was felt this would give a more accurate reflection of the frequency of that category of behaviour. If 'describing progress positively' was seen 5% of the time between contractions, this was described as being seen 5% of the time for the whole observation, rather than 2.5%, as this information giving behaviour was only recorded between contractions and not during contractions. The overall results for each behaviour were added to create the overall frequency for the category. To identify the frequency that 'verbal support' occurred, the percentage figures for 'talking woman through a contraction', 'encouraging/praising', 'talking positively about pain and coping', 'advice suggestions', 'empathy comfort and reassurance' and 'being positively assertive/ refocusing' were added. As seen below, this could create a figure of greater than 100% as several of these behaviours could be observed at one observation point as a midwife may, for example, encourage the woman, express empathy and advise her how to breathe through the contraction in a very short space of time.

8.11.5 The other data collection instruments

The postnatal questionnaire with women (the SCIB) and the postnatal data outcomes sheet were in paper form and were transferred to a locked filing cabinet in the research office.

Women's views of the support they received during labour were captured through completion of the validated 'Support and Control in Birth (SCIB)' questionnaire (Appendix Five). The SCIB is a

33 item questionnaire with a 5-point response scale (1 to 5) with high scores indicating more support or control. The questionnaire has three subscales:

1. *Internal Control,* 10 items, average score calculated, range 1 – 5
2. *External Control,* 11 items, average score calculated, range 1 - 5
3. *Support*, 12 items, average score calculated, range 1 - 5

Total scores range from 3 to 15. The average scores for each woman who completed the SCIB were calculated for each of the three subscales. A score of 5 indicates the maximum possible score and 1 the lowest (Ford and Ayers 2009).

To obtain the observers' global assessments of the quantity and quality of the support observed, two questions with Likert scale responses were included in the postnatal data outcomes sheet. The responses enabled a score range of between 0 (poor support observed) to 4 (excellent). For each observation a global observer score was calculated for the quantity and quality of the support observed.

The researcher carried out the process of 'cleaning' the excel spreadsheet data and inputting the paper stored data onto excel spreadsheets. Following this process of preparation and cleaning, the researcher transferred the data to the computer based statistical software package SPSS 17 for further analysis.

8.11.6 Measuring the construct validity and internal reliability of the SMILI

Testing of the construct validity of the SMILI in the clinical setting was undertaken through the identification of correlations between the behaviour variables recorded and women's and observers' views of the support received or observed. If the SMILI was not effectively measuring the central construct of support, the data produced using the SMILI would not correlate significantly with women's and observers' overall assessments of the midwifery support.

In order to identify the existence of relationships between variables measured 'correlation coefficients' are calculated. This is a numerical index that indicates the strength and direction of a relationship between two variables. The Spearman's Rho is the appropriate test for the data produced in this study as it is a non-parametric test that allows for the calculation of correlations between ordinal data (such as Likert scale results in the SCIB and postnatal data sheet responses), that is not necessarily normally distributed. The test evaluates the degree to which individuals or cases with high rankings in one variable were observed to have similar rankings in another variable. Associations between variables may be negative or positive. The test applied here is 'one tailed' rather than 'two tailed' as the study hypothesis is that negative behaviours will have a negative effect on women's feelings of support and positive behaviours will have a positive effect.

A correlation is always expressed as a figure between 0 and 1 if positive or 0 and -1 if the correlation is a negative one. The correlation is stronger the closer the figure is to 1 or -1. The level at which a correlation is considered to be 'weak', 'moderate' or 'strong' varies with the type of study and the number of variables (Cohen 1988). If the study explores a large number of variables and/or variables that may be more difficult to categorise such as demeanour, facial expressions, tone of voice, lower figures are considered to be moderate or strong than in a study with only a few variables and comparing clear scientific or mathematical categories of variables. For this study, Cohen's classification of strength has been employed (Cohen 1988):

Table 17 - Cohen's definition of correlational strength

Strength of correlation	**R (correlation coefficient)**	**R2**
Weak	.1 to .3	1 to 10%
Moderate	.3 to .5	10 to 25%
Strong	>.5	>25%

R2 indicates that if there is a correlation of .3 then 10% of the variance in this variable may be explained by the correlation with the other variable.

Statistical significance was calculated by the SPSS statistical software package. Where there is a statistically significant correlation the figure is followed by ** or *. Two asterix signify that only 1% of variance may be explained by chance, that is that the correlation is significant at p=0.01. One asterix signifies that 5% of variance may be explained by chance, that is that correlation is significant a p=0.05.

In order to test the internal reliability or consistency of the SMILI it was necessary to test the relationship between related variables. If no relationship was found between the frequency that related variables were recorded using the SMILI (such as midwife's positive demeanour and midwife's positive facial expression), this would bring into question the internal reliability of the instrument. The testing of the internal consistency of the instrument was undertaken using the Cronbach's Alpha test. This analysis seeks to identify whether there is a significant level of consistency between variables that would be expected to be related. The strength of the relationship between the variables is, as with Kappa and Spearman's Rho correlations, expressed as a figure between 0 and 1. The closer the figure is to 1, the stronger the correlation.

8.11.7 The analysis process to measure the quality of the support observed

In order to identify whether the SMILI was able to measure the quality of midwifery support in the clinical setting, correlations were sought between key supportive, negative and non-support midwifery behaviour variables and women's views of the support they received expressed in the SCIB, again using the Spearman's Rho correlation coefficient.

The strength of these key correlations found using the non-parametric Spearman's Rho correlation coefficient were then further analysed. The relationship between women's SCIB responses and the amount of emotional support and the proportion that the midwife was out of the room were analysed using a multiple regression analysis in the SPSS programme. Multiple

regression analysis models and analyses several variables when the focus is on the relationship between a dependent variable (in this case women's assessment of the support received) and one or more independent variables (in this case the amount of emotional support and the presence of the midwife). The analysis helps us to understand how the typical value of the dependent variable changes when any of the independent variables is varied, while other independent variables are held fixed.

8.11.8 Initial exploration of relationships between support variables and clinical outcomes

This study was not designed as an experimental study powered to identify causal relationships between variables and clinical outcomes. However, in order to test the ability of the SMILI to measure quality of support, relationships between the quantity of support behaviours and women's views expressed using the SCIB were explored. Also, an exploration of correlations between data collected using the SMILI and clinical outcomes was undertaken to identify the ability of the SMILI to produce data in future larger scale studies that could test for such relationships.

Initially Spearman's Rho correlational coefficient calculations were undertaken. Multiple regression calculations were undertaken where possible. Data for type of birth was not suitable for testing using multiple regression due to the small number of outcome variables (vaginal or operative delivery) and so a Mann Whitney U test was undertaken to further assess the strength of any correlations identified. The Mann Whitney U test is a non-parametric statistical hypothesis test for data that is not necessarily normally distributed. It calculates whether one of two samples of independent observations tends to have larger values than the other sample. In this case the sample of those who had normal births was compared with the sample of those who had operative deliveries to identify whether one group received greater quantities of emotional support and midwife presence. The null hypothesis is that both groups will have the same amounts of the predictor variables.

8.12 SUMMARY OF METHOD AND ANALYSIS PLAN FOR STUDY FIVE

A study to test the newly developed systematic observation instrument in the clinical setting was devised. A research protocol was drawn up and ethical and Research and Development approvals were obtained. Information leaflets were distributed to women and midwives at the four participating units and the researcher attended each of the units to talk with managers and staff about the study and answer their questions. Three volunteer observers were trained by the researcher to undertake the study in the clinical setting. Data collection took place at the four maternity units by the four observers (the three volunteers and the researcher) over a four month period. Recruitment and consent of women and their birth partners was carried out by midwives at each of the participating units when a woman meeting the inclusion criteria was admitted to the maternity unit in early labour or for induction. Recruitment and consent of the midwife participants was undertaken by the researcher.

The analysis of the data collected was undertaken by the researcher over a five month period in a step wise approach described above to enable transparency of the results given in the chapter which follows. The analysis of the data collected in the clinical study sought to identify whether the study had been feasible and acceptable, whether the SMILI was valid and reliable in the clinical setting, whether the SMILI was successful in measuring the quantity and quality of midwifery support observed and whether the SMILI had potential to be used in a larger scale experimental study to identify correlations between support variables and clinical outcomes.

CHAPTER NINE – STUDY FIVE

RESULTS OF FEASIBILITY AND USABILITY TESTING OF THE SMILI IN THE CLINICAL SETTING

9.1 INTRODUCTION

In this chapter the results of Study Five, the main clinical study, are detailed. The analysis plan described in the previous chapter (pp147-149) was followed in order to achieve the study aim. The aim of Study Five was to test whether the newly developed systematic observation instrument, the 'Supportive Midwifery in Labour Instrument' (SMILI), can reliably record and measure the quantity and quality of midwifery support during labour in order to provide detailed information about professional intrapartum support.

This aim was achieved through the specific objectives for Study Five:

1. To test the feasibility and acceptability of a direct observational study and the usability of the SMILI in the intrapartum setting
2. To complete the testing of the validity and reliability of the SMILI in the clinical setting.
3. To explore the ability of the SMILI and outcome measures to measure the quality and quantity of midwifery support in labour in the clinical setting.
4. To undertake initial analysis of the study data to explore the ability of the study methods to identify correlations between midwifery support and clinical outcomes.

9.2 THE SIZE AND SCOPE OF THE STUDY

A sample size of 50 intrapartum observations was chosen to ensure that the study was feasible in the four month data collection period and of a comparable size to other systematic observation studies in the maternity and non-maternity setting. The study was successful in completing the maximum planned number of observations. Data was collected in four maternity units chosen to represent the range of maternity locations in Scotland.

Fifty two observations of intrapartum care were observed during the four month data collection period. Data were lost in three observations due to user error which led to the data not being saved correctly. Full data was recorded and analysed for forty nine observations with complete data (summarised in Table 19).

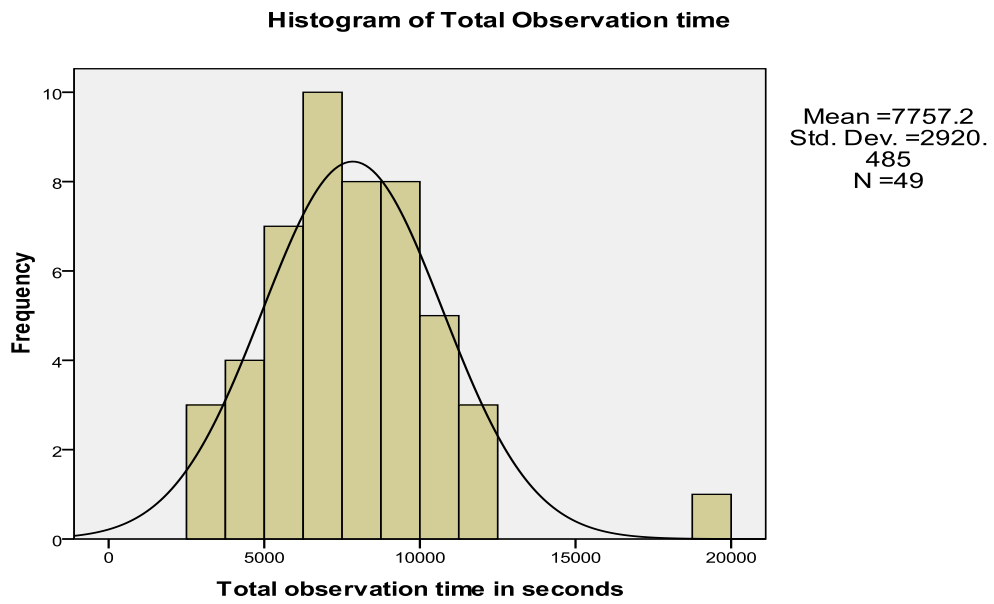
One hundred and eleven hours of direct intrapartum observation were undertaken, the average length of each observation was 127.7 minutes (range 45.8 minutes – 318 minutes). Full data were available and analysis was carried out for 104.3 hours of observation.

Observations were often shorter than the planned three hour period as women progressed quickly through labour and to the birth of their baby in one third of the observations.

Table 18 – Overall Study Figures for Observations

Number of observations with complete data	**N= 49 (missing data n=3)**
Total hours of observation	104.3 hours
Average length of observation	127.7 minutes
Range of observation length	45.8- 318.0 minutes
Number of observations by unit type and size	
Annual births >3000 Consultant led unit	38 (77.6%)
Annual births 1500-3000 Alongside midwife led unit	8 (16.3%)
Annual births <500 Community midwifery unit	3 (6.1%)

Figure Four – Frequency Distribution curve for length of observations



9.3 THE STUDY PARTICIPANTS

The study included three groups of participants: the women in labour, their birth partners and the midwives caring for them. Written consent was obtained from all participants.

9.3.1 The women and their birth partners

Forty four women participated in the study, this is less than the number of observations as five women agreed to have an observer present for two sequential observations, when they were cared for by two different midwives during their labours.

All of the women spoke English and were white European in ethnic origin. 65.3% were in early active labour at the start of the observation, 32.7% of the women were in more advanced labour (>5cm) at the start of the observation. 44.9% of the women were identified as being allocated to the 'green' care pathway, that is without significant risk factors and suitable for midwife led care in labour, 16.3% were on the 'amber' pathway where some risk had been identified which had

required consultation with medical staff but had not led to the need to hand over care from midwife to maternity care team care, the remaining 38.8% were on the 'red' pathway with identified risks requiring them to have consultant led care during labour. This distribution of women across the risk pathways reflects the general risk distribution of women admitted in labour in Scotland (unpublished data KCND evaluation, Abhyankar et al 2011).

The demographic distribution of the participants broadly reflects national Scottish figures in terms of age distribution, with around 16% under twenty years, the majority of women aged between 20 and 35 and around 18% of women over 35 years of age. First time mothers are somewhat over-represented in the study at 56.8% compared to less than 50% of births in Scotland in total (ISD, 2011). The sample may be considered to be less than representative of the whole Scottish population as none of the women observed were from an ethnic minority or did not have English as a first language.

All of the women were accompanied by at least one birth partner during their labour. Generally this was their life partner. On nine occasions, the woman had two birth partners present: the woman's mother was present as well as her life partner for four observations, for three observations the woman had her sister or a close friend present as well as her life partner, on one occasion the woman's mother in law was present for some of the labour and on one occasion the woman's father was present for some of the labour. All of the units where observations took place had a policy that the woman could be supported by a maximum of two birth partners at any time, this policy was adhered to in all observations. Consent was obtained from all birth partners as well as the women. These results are summarised in Table 19 below.

Table 19 - The Women and birth partner participants

Characteristics of woman and birth partner participants	**Number (%)**	
Number of women observed	44	
Women observed on two occasions	5	
English woman's first language	44 (100%)	
Woman's ethnic origin	White European	44 (100%)
Cervical dilatation at last Vaginal Examination (n=49)	<3cm	12 (24.5%)
	3-5cm	20 (40.8%)
	>5cm	16 (32.7%)
	Unknown (no VE carried out)	1 (2.0%)
Allocated care pathway (n=49)	Red	19 (38.8%)
	Amber	8 (16.3%)
	Green	22 (44.9%
Pain relief administered before start of observation (n=49)	Yes	34 (69.4%)
	No	15 (30.6%)
Pain relief received at start of observation (n=49)	None	15 (30.6%)
	Entonox	16 (32.6%)
	Pool	3 (6.1%)
	DF118	4 (8.2%)
	Diamorphine	4 (8.2%)
	Epidural	7 (14.3%)
Woman Age (n=44)	<20	7 (15.9%)
	20-25	13 (29.5%)
	26-35	16 (36.4%)
	>35	8 (18.2%)
Woman's Parity (n=44)	0	25 (56.8%)
	1	9 (20.4%)
	2	5 (11.4%)
	3+	5 (11.4%)
Birth partner present (n=44)	44 (100%)	
	Life partner only birth partner	34 (77.3%)
	Mother only partner	6 (13.6%)
	Life partner + mother	4 (9.1%)

9.3.2 The midwives

Forty five midwives participated in the study. Four midwives allowed observers to be present on two different occasions when they were caring for different women.

The age distribution differed somewhat from the overall figures for UK midwives, though it shows a fairly even distribution across age groups: 2.2% of midwives in the study were aged 20 to 25, compared to 3.3% nationally; 13.3% of the study midwives were aged 26 to 30, compared to 10.3% nationally; 28.9% of study midwives were 31-40 compared to 22.9% nationally; 24.4% were aged 41-50, while nationally the figure is 40%; 31.2% of the midwives were over 51, which is higher than UK rates of around 23% (DoH, 2010). Part-time midwives make up 62% of the midwifery population in Scotland generally and so were somewhat underrepresented in this study (53.3%) (DoH 2010).

The high proportion of older midwives and midwives of white European racial origin reflect the midwifery working population in Scotland. All of the midwives observed were caring for only one woman throughout the observation period without responsibilities towards any other women on the unit.

Table 20 - The midwife participants

Midwife characteristics n=45	**Categories**	**Number (%)**
Midwife's Ethnic Origin (n=45)	White European	44 (97.7%)
	Asian	1 (2.3%)
Midwife's Training (n=45)	Pre-registration long course	26 (57.8%)
	Short course (dual qualified)	19 (42.2%)
Midwife's Experience in years (n=45)	0-5	11 (24.4%)
	6-10	8 (17.8%)
	11-15	6 (13.3%)
	16-20	7 (15.6%)
	>20	13 (28.9%)
Midwife's age in years (n=45)	20-25	1 (2.2%)
	26-30	6(13.3%)
	31-40	13 (28.9%)
	41-50	11 (24.4%)
	51-65	14 (31.2%)
Midwife's working hours (n=45)	Part time	24(53.3%)
	Full-time	21 (46.7%)
Number of women allocated to observation midwife (n=45)	One woman	45 (100%)
	>1	0

9.4 THE ENVIRONMENT OF CARE

The environment in which all of the observations took place was single labour or birthing rooms. All of the rooms were large, comfortable and clean with ensuite toilet and shower facilities.

The consultant unit labour rooms were set up in a uniform clinical fashion with the bed in the centre of the room, clinical equipment such as the neonatal resuscitation equipment, the cardiotocograph machine for monitoring of the fetal heart rate, electronic monitors for monitoring of maternal blood pressure and pulse rates and oxygen and suction facilities visible at all times. All rooms had a comfortable, usually reclining, chair available for the partner along with a stool generally used by the midwife or for a second birth partner. The rooms did not as a rule have other mats, bean bags or birthing balls on display, though on occasion these were brought into the room. None of the rooms in which observations took place had any art work on display. One of the large consultant units (004) had televisions mounted on high brackets available in each room. These televisions were often switched on. Radios were present in some of the other labour rooms, but no other facilities for playing music were seen.

The midwife led unit rooms were generally set up so that the bed was not in the centre of the room. At the community maternity unit, there were no beds in the rooms where observations took place, instead there were comfortable mats and beanbags covered with sheets placed in the room alongside the birth pool. These rooms were more likely to have soft lighting and to have clinical equipment less visible, either as equipment was not kept in the room or because it was obscured from view by curtains.

The other key environmental difference noted by the researcher between the consultant led and midwife led units was the level of noise. The midwife led unit rooms were much quieter: the doors were always shut, sound levels in the corridors outside were much lower and the midwives generally spoke in more hushed tones than on the consultant led units.

The findings relating to environment of care are summarised in Table 21 below.

Table 21 – Features of the labour rooms in which the observations took place

Features in labour room	**Results (Total number 49)**	
Chair for midwife in the room	Yes	35
	No	14
Ensuite in room	Yes	49
	No	0
Pool	Yes	4
	No	45
Position of bed	Centre of room	43
	No bed	2
	Side of room	4
Beanbag/Birthing ball out in room	No	37
	Yes	12
Natural Light	No	34
	Yes	15
Bright Light	No	39
	Yes	10
Soft Light	No	22
	Yes	27
Unit Music	No	47
	Yes	2
Relaxation CD	No	49
	Yes	0
Woman's own music	No	48
	Yes	1

9.5 CLINICAL OUTCOMES OVERALL FIGURES

Clinical outcomes data were completed by the observer or researcher for 100% of observations undertaken. The data are summarized below in Table 22. These data broadly reflect current national statistics, the spontaneous vaginal delivery rate in this study was 65.9%, with an emergency caesarean section rate of 15.9%. Latest figures for Scotland (ISD 2011) report a spontaneous vaginal delivery rate of 60.5%, ventouse deliveries 3.3%, forceps deliveries 9.7% and emergency caesarean section rates of 14.8%. The induction rate of 27.2% in this study was somewhat higher than the recorded induction rate nationally, which is 21.8% across Scotland (ISD 2011). Available figures for England suggest an overall rate of around 33% for opiates, entonox 80% and epidural 16.2% (Healthcare Commission 2008). The epidural rate of

45.4% in the study is high. Across the UK, the epidural rate rises to 42% among first time mothers, the higher epidural rate in the study population will in part reflect the higher proportion of primiparous women in the study and perhaps also the higher induction rate.

Table 22 - Clinical Outcomes

Clinical Outcome	**Categories**	**Number (%)**
Type of pain relief (n=44)	Breathing and relaxation	14 (31.8%)
	Self-hypnosis	0
	Entonox	33 (75%)
	TENS	1 (2.2%)
	Birthing pool	5 (11.4%)
	Opiates	15 (34.1%)
	Epidural	20 (45.4%)
Medical interventions (n=44)	No medical interventions	14 (31.8%)
	Amniotomy	22 (50%)
	Prostaglandin	7 (15.9%)
	Syntocinon	21 (47.7%)
	Episiotomy	5 (11.4%)
	Fetal Scalp Electrode	1 (2.2%)
	Induction	12 (27.2%)
Type of birth (n=44)	Spontaneous Vaginal Birth	29 (65.9%)
	Ventouse/Forceps	8 (18.2%)
	Emergency Caesarean	7 (15.9%)

9.6 FEASIBILITY OF THE SMILI SYSTEMATIC OBSERVATION STUDY IN THE CLINICAL ENVIRONMENT

Feasibility was assessed by the ease of recruitment of maternity units, midwives, women and birth partner participants, acceptability of the observation process to midwives and women and the usability of the instrument in the real life setting.

It was planned to recruit the same number of participants at each of the four participating units. The researcher arranged with the local collaborator to spend blocks of one week at a time at each unit.

Twenty four of the observations took place at unit 001, a large consultant led unit with over 5000 births a year with an alongside midwife led unit. Ten of these observations were carried out by the other volunteer observers and fourteen by the researcher.

Twenty four observations took place at unit 004, another large consultant led unit with around 6000 births a year. Two of the observations were carried out by one of the volunteer observers, the remaining twenty two were carried out by the researcher.

Three observations were carried out by the researcher at unit 003, a small community midwifery unit with 300 births a year. One observation was carried out at unit 002 by the researcher, a smaller rural consultant led unit with around 2000 births a year.

The uneven distribution of figures between the units is due to a number of factors: Recruitment at the larger units (001 and 004) was generally easier as there were more women who fitted the study criteria present on the maternity unit on any day that the observers were present.

Recruitment at both of the large consultant led units progressed very smoothly. All of the midwives approached to participate in the study by the researcher consented to participate. A high proportion of women approached by the unit midwives to participate agreed to take part. Figures and reasons for the decision not to participate were not routinely collected, but verbal feedback from the midwives to the researcher identified that on occasion the woman provided

consent but her partner did not agree and on other occasions the midwives reported that the woman was ‘very anxious’ and so did not want another person present in the room.

Recruitment at the smaller remote rural consultant led unit (002) where only one observation took place was affected by a number of factors. The study took place during the winter months, weather conditions hampered the researcher’s ability to undertake the substantial drive to the unit. On the two days that the researcher spent at the unit there were no women on the unit who fitted the criteria for participation. It was then decided that the researcher would attend the unit on an ‘on-call’ basis rather than waiting on the unit. This led, it is felt, to fewer women being approached to participate in the study as the researcher was not a visible presence on the unit to remind midwives to ask women for consent. The lack of onsite presence of the researcher may have affected the acceptability of the research to the midwives. At the larger units, the researcher spent long periods of time on the units and in the staff rooms, the midwives became more relaxed with the researcher and understood more about the research. It was only at this small consultant unit that any negative views of the study were expressed to the researcher, where one midwife declined to discuss or participate in the study.

Midwives and management at the small community maternity unit expressed a high level of enthusiasm for the study to the researcher. However, recruitment at this unit was hampered largely by the small scale of the unit. A majority of the women booked to give birth at the unit were multiparous and so were admitted and gave birth very quickly without time to be recruited to the study. Another factor was a higher proportion of women and their birth partners declining to participate. Data was not routinely collected for numbers and reasons for not wishing to participate.

Verbal feedback was sought from all of the observers about their experience of being involved in the study and any problems they encountered in carrying out the direct observations in the clinical setting. All three of the volunteer observers reported feeling very positive about their

involvement in the study, being surprised with the ease with which they were able to gain consent from participants and how accepted and welcomed they felt by staff.

There were no problems experienced during the data collection period in gaining access to the ward areas or to midwifery staff to explain the study and to ask them to discuss participation with women. Staff were generally enthusiastic and positive about the study and interested in the outcomes. Following the end of the data collection period, the local collaborators at each of the sites were asked to talk informally to staff about the study and identify any problems or concerns that staff had not felt able to share with the research team. All the feedback given to the local collaborators was positive and no concerns or problems were raised.

9.7 THE FACE AND CONTENT VALIDITY, USABILITY AND COMPLETENESS OF THE SMILI IN THE CLINICAL SETTING

Following each observation the observers completed a question on the postnatal outcomes sheet identifying the extent to which the SMILI enabled them to record the midwifery support observed. The results identify that the SMILI was generally felt to be a very effective tool to record the quantity and quality of midwifery support in labour, with only a few problems and gaps identified in the earlier observations. Additions were made as a result of the comments and no further problems were identified after these changes were made.

Table 23 – Observers' views of efficacy of SMILI

Observer global view of SMILI efficacy	Response category	Number =49 (%)
The SMILI helped me to record the midwifery support I observed	Inadequately	1 (2%)
	Partially	1 (2%)
	Well Enough	0
	Very well	19 (38.8%)
	Fully	28 (57.2%)

Problems identified by the observer:

- Need to have the information list available during a contraction, as some information is given during contractions,
- Need to add 'describing fetal heart rate, asking about history' and other physical care such as feeling for contractions, looking for advancing head, delivering placenta.
- Programme crashed, so had to close and re-start using a different midwife code.
- Comments box not easy to use, unable to spell check without losing all text.
- Need to have 'teaching student' as option.
- Memory stick crashed, had to revert to paper SMILI.

On two occasions during observations, a problem arose with the memory stick that led to the programme crashing. On one occasion the observer reverted to completing a paper version of the SMILI and on another occasion the observer opened a new data collection sheet. No data were lost for these observations.

On three occasions data were lost. On one occasion the observer left the room while the midwife was having a break and turned off the computer in error on her return without saving the earlier data. On another occasion the observer overwrote the data from the previous observation by inadvertently using the same midwife code. On a third occasion, the observer was using the programme for the first time for a very short observation (33 minutes) and data were not saved correctly.

Problems with the programme were rare during the 111 hours of observation and overall the programme proved very reliable and usable in the clinical setting.

9.8 ACCEPTABILITY OF THE SMILI OBSERVATIONAL STUDY TO PARTICIPANTS

The midwife and woman participants responded positively to a postnatal question about the presence of an observer during the labour.

Table 24 – Observation midwife and woman's feelings about participation

Participant question	Feelings about involvement in study	Frequency
How the midwife felt	Distressed, very uncomfortable	0
	Uncomfortable	0
	Mildly uncomfortable	0
	OK	16 (35.6%)
	Fine, enjoyed it	29 (64.4%)
Would you participate again?	No	1 (2.2%)
	Maybe	0
	Yes	44 (97.8%)
How the woman felt	Distressed, very uncomfortable	0
	Uncomfortable	0
	Mildly uncomfortable	0
	OK	5 (11.4%)
	Fine	39 (88.6%)
Would you participate again?	No	0
	Maybe	0
	Yes	44 (100%)

Midwife comments: 'Felt a bit odd at first, but then fine. The chat before with the researcher helped.' 'A bit strange at first, then I relaxed'.

Woman comments: 'Forgot she [the observer] was in the room' (n=5).

All the midwife and woman participants who completed this part of the postnatal outcomes data sheet said they would be happy to participate in a similar study in the future.

9.9 ASSOCIATIONS BETWEEN RELATED VARIABLES TO TEST INTERNAL CONSISTENCY

In order to test the internal consistency of the SMILI it was necessary to test the relationship between related variables. If no relationship was found between the frequency that related variables were recorded using the SMILI (such as midwife's positive demeanour and midwife's positive facial expression), this would bring into question the internal reliability of the instrument.

The testing of the internal consistency of the instrument was undertaken using the Cronbach's Alpha test. This analysis seeks to identify whether there is a significant level of consistency between variables that would be expected to be related.

Using George and Mallery's accepted definition for strength of a Cronbach's alpha, with >.8 good, >.7 acceptable and >.6 questionable, the variables show an acceptable to good level of agreement (George and Mallery 2003), with the exception of the negative variables of the woman and partner which show a weaker correlation. These results generally show an acceptable level of internal consistency between related variables using the SMILI. The consistency is higher for positive variables than for negative variables. This suggests that either the SMILI is less reliable at measuring negative behaviours or may reflect the low frequency that negative variables were observed. The results are summarised below in Table 25.

Table 25 - Internal Consistency of the SMILI

Variables tested for internal consistency with one another	**Cronbach's alpha**
Woman – negative demeanour, neutral demeanour, negative and neutral vocal, negative and neutral facial	.563
Woman – positive demeanour, positive vocal, positive facial	.857
Partner – negative demeanour, neutral demeanour, far from woman, negative verbal, neutral verbal, negative facial, neutral facial, not touching, ignoring woman	.449
Partner – positive demeanour, next to woman, positive verbal, positive facial, supportive touch, engaging with woman	.836
Midwife – negative and neutral demeanour, far from woman, negative and neutral vocal, negative and neutral facial, proportion out of room	.688
Midwife – positive demeanour, next to or near woman, positive vocal and facial	.840
Midwife - positive demeanour, next to or near woman, positive vocal and facial and emotional support	.710

9.10 THE MEASUREMENT OF THE QUANTITY OF MIDWIFERY SUPPORT

One of the key objectives of the study was to test whether the SMILI is able to measure the quantity of support provided. The quantity of support was measured in this study through identifying the proportion of the observation that the midwife was in the room with the woman

and then measuring the proportion of that time that the midwife was engaged in supportive activities.

9.10.1 Presence and absence of the midwife

The data collected in the log enabled the researcher to provide answers to one of the key research questions about whether the midwives provided continuous or intermittent support to the women observed. This was achieved through the measurement of the amount of time and the proportion of each observation each midwife spent in and out of the room and the frequency that the midwife left the room. These data are presented in the tables below for all observations.

Table 26 - Physical Presence of the midwife for all observations

Midwife number	Total observation time in minutes excluding break	Proportion mw out of room, excluding breaks (% of total observation)	Frequency mw left room (as average number of minutes between exits)
1	93	4.20	20
2	51	0	Did not leave
3	129	13.7	18
4	154	7.8	19
5	103	26.9	12.8
6/7	112	12.9	18.6
8	170	10.3	15
9	111	9.7	27.7
10	162	0.5	54
11	52.5	0	Did not leave
12	80.5	No data	No data
13	145.5	6.8	18
14	169.5	17	28
15	Missing Data	Missing Data	Missing Data
16	87.1	0	0
17	105	6.3	35
18	63	0	Did not leave
19	45.8	2.4	15
20	101	4.4	33.6
21	78	15.4	13
22	144	9.4	18
23	201	10.6	16.7
24	318	8	12
25	101	15.8	33.6

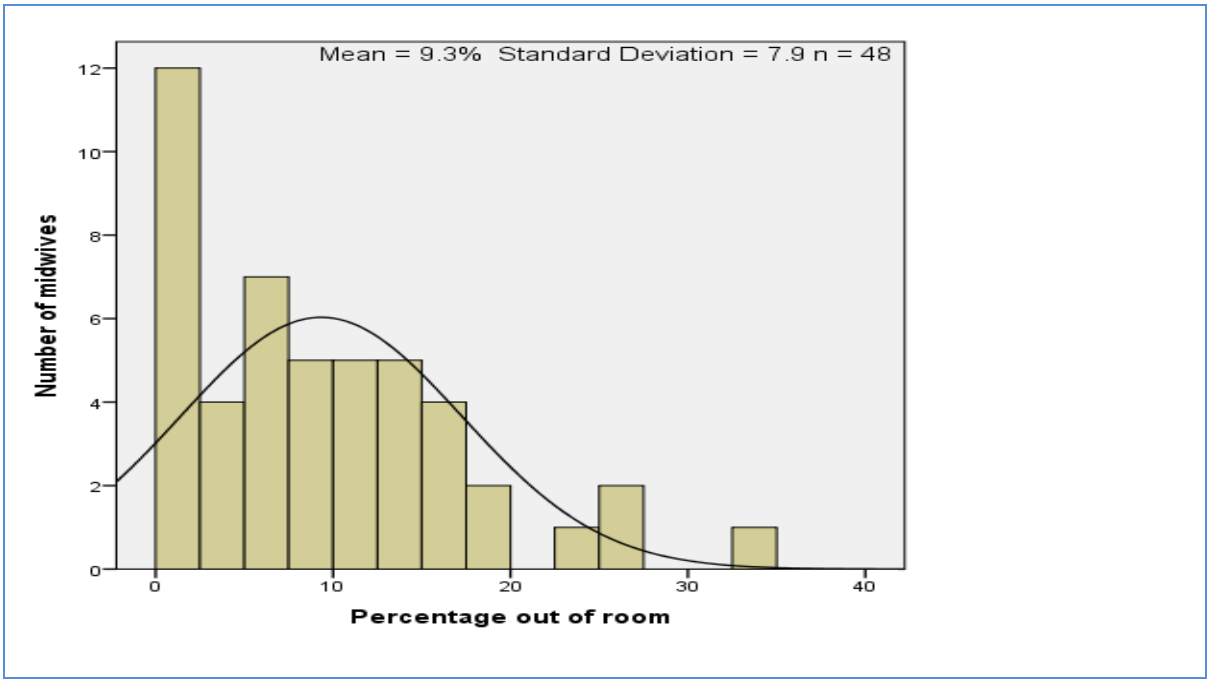
Midwife number	Total observation time in minutes excluding break	Proportion mw out of room, excluding breaks (% of total observation)	Frequency mw left room (as average number of minutes between exits)
26	92.9	24.9	15.4
27	165	0	Did not leave
28	112	5.5	22.4
29	164	1.4	41
30	146.1	3.7	36.5
31	157.9	2.6	39.4
32	197.3	10	24.6
33	105	1	52.5
34	49	25	49
35	105.8	11.1	17.6
36	126	19.4	9.6
37	165	33.8	18
38	140	0.82	70
39	169	16.1	16
40	106	6.5	26.5
41	118	5.4	23.6
42	Data missing	Data missing	Data missing
43	127	12.9	9.7
44	200	6.2	15.3
45	133	12.3	12
46	66.6	9.8	22.2
47	87	18.7	9.6
48	156	14.6	22.2
49	178	1.6	89
50	113	13.8	16
51	181.5	7.1	20
52	Data missing	Data missing	Data missing
53	106	1.6	35.3
Mean	127.5 (SD 49.1)	**9.33 (SD 7.9)**	**25.7 (SD 17.1)**

During observation 6, the computer programme crashed. The programme was closed and a new observation record was opened. Results named 6 and 7 recorded one observation.

Observation 12 was the first observation for one observer. The midwife's presence or absence was not recorded consistently and data was incomplete.

The frequency curve below in Figure Five shows that most midwives (92%) were in the room for more than 80% of the observation, with around one quarter of midwives present for 98% of the observation.

Figure Five - Frequency distribution curve of percentage of time midwife out of the room (n=48)



Ten of the observations included observation during the second stage of labour and the birth (1, 2, 16, 17, 18, 29, 35, 38, 44 and 53). The average proportion that the midwife was out of the room during these observations was substantially lower than the study average at 3.1% of the observation. The midwife was out of the room for an average of 10.9% during the thirty nine observations which took place only during the first stage of labour.

The analysis of the log results above give the following overall results for the forty nine observations:

- The total observation time with complete data was 104.3 hours.
- The mean length of each observation was 127.7 minutes. Observations ranged from 45.8 minutes to 318 minutes in length.

- The mean length of time that a midwife was out of the room excluding breaks was 11.5 minutes, which is 9.3% of the observation time. This ranged from 0% to 33.8% of the observation.
- The average number of times that the midwife left the room was six. Midwives left the room on average every 25.7 minutes, with a range from every 9.6 minutes to 165 minutes without leaving the room.
- Midwives remained in the room for a higher proportion of the observation when the woman was in the second stage of labour during the observation (96.9%).

9.10.2 Quantity of different midwife behaviours

The quantity of the midwives' behaviours were calculated in a number of ways and a number of stages, as detailed in the description of analysis in the previous chapter. For each midwife, the following figures were calculated to identify the quantity of different behaviours:

- The number of times each behaviour was recorded during and between a contraction,
- The percentage that these behaviours were observed between and during a contraction as a proportion of the number of observation points,
- The overall percentage that these behaviours were displayed,
- The overall percentages that categories of behaviour were displayed when individual behaviours were grouped into categories.

9.10.3 The Quantity of supportive behaviours

The tables below indicate the frequency with which the categories of supportive behaviours (summarised Table 16) were seen during each of the forty nine observations for which complete data is available. The tables have been colour coded to facilitate interpretation of the results. Green identifies when a supportive behaviour was recorded above the overall study average. Amber identifies a result around the study average. Red highlights where a midwife demonstrated a positive supportive behaviour less than the study average. Advocacy has not

been allocated a colour coding due to the rarity with which it was seen. It was considered by the observers that where advocacy was not seen this was generally because there was no requirement for advocacy during that observation period rather than a lack of advocacy when required.

The results included in Table 27 below demonstrate the percentage that each of the categories of support was observed for each observation. More than one behaviour could be observed at each observation point, this therefore leads to the possibility of a figure of more than 100%. Where emotional support is recorded as being observed 300%, this indicates that three emotionally supportive behaviours were observed on average at each observation point during this observation.

The table shows a high level of variance in the frequency that the different behaviours were observed. This high level of variation can be considered an indicator of the success of the SMILI in measuring the quantity of behaviours, as the instrument demonstrates adequate sensitivity to differences between midwives.

The colour coding enables the identification of patterns of behaviour. It identifies that six midwives provided higher than average amounts of all the categories of support (10, 16, 41, 45, 46, 51). Nine midwives provided lower than average amounts of all of the categories of support (4, 5, 13, 21, 32, 33, 34, 40, 48). The majority of midwives provided some elements of support more than average and some less than average.

Table 27 - Overall frequency of categories of support behaviours for all observation midwives

(Figures represent percentage behaviour seen in each observation)

Midwife number	Emotional Support	Informational Support	Tangible Support	Partner Support	Advocacy
1	326.2	78	16	2	0
2	478.5	93	30	8	0
3	247.3	14	34	2.5	0
4	223.5	25.9	6.1	4.2	0
5	98.9	16.5	12.8	0	2.05
6	243.2	22.7	38.65	0	0
8	484.7	53.4	24.7	2.5	0
9	460.2	54	29.7	5.4	0
10	608.6	70.9	31.55	14.6	0
11	518.0	50	10	0	0
12	476.6	38.1	9.4	8.7	0
13	348.7	35.4	3.3	0	0
14	453.1	9.3	16.7	5.6	0
16	575.8	62.3	56.8	10.3	0
17	372	48.3	20	0	0
18	371.5	48.3	5.95	10.5	0
19	387.1	40.9	16.1	14.6	0
20	306.0	54.8	16.5	10.8	1.35
21	377.2	36	16	0	0
22	377	38	42.3	8.4	0
23	289.8	28	14	10.1	0
24	503.4	56.2	15.8	18	3.625
25	384.4	28.4	22.05	0	1.65
26	293.8	48	16.5	8	0
27	629.7	51.5	14.9	12.5	0.55
28	351.3	6	7	7	0
29	323.9	24	19.4	7.8	0
30	451.9	44.8	8.1	14.3	0
31	382.9	25.0	18.5	9.4	0
32	186.7	36.5	6.9	0	2
33	288.5	12.7	6.3	2.5	0
34	327.6	10	5	2.5	0
35	560.4	37.8	14.3	1.8	0.9
36	362.6	23.3	19.5	4.35	0
37	401.5	36.9	6.65	7.6	0
38	480.8	27.5	25.9	3.8	0
39	472.4	9.2	23.75	9.85	0
40	336.4	20.8	7.5	5.8	0
41	516.3	59.2	23.5	18.8	0
43	348.2	45.9	20.7	8.45	0
44	356.3	21.7	37.75	2.45	0

Table 27 contd

Midwife number	Emotional Support	Informational Support	Tangible Support	Partner Support	Advocacy
45	424.2	58.6	22.9	12.5	0
46	496.5	53.4	30.5	30.6	0
47	395.0	57.4	14.9	12.25	0
48	305.9	33	7	3.6	0
49	511.4	41.3	10.25	4.2	0
50	332.4	38.5	10.1	1.6	0
51	427.5	64	23.5	35.7	0
53	506.4	18.9	31.8	6.15	0
Mean	**395.5**	**38.9**	**18.8**	**7.5**	**0.2**

The relationship between the provision of the different categories of support for all of the midwives observed is presented below in Table 28. A Spearman's Rho correlation coefficient was calculated to identify whether higher levels of one type of support (for example emotional support) were generally correlated with a higher level of another type of support (such as tangible support).

This table demonstrates the relationships between the different categories of support. Midwives providing more emotional support were more likely to provide more informational, tangible and partner support at a moderate statistically significant levels. Statistically significant correlations were also found between partner support and informational support. Advocacy support did not correlate with any of the other types of support. Tangible support only correlated significantly with emotional support and not with the other categories of support.

Table 28 - The relationship between different categories of support

(** = significance at p value of <0.01, * = significance at p value of <0.05)

Behaviour category		Emotional Support	Informational Support	Advocacy	Tangible support	Partner support
Emotional support	Correlation p value	1.0 000	.462** .000	-.020 .445	.329* .011	.409** .002
Informational support	Correlation p value	.462** .000	1.0 000	.047 .374	.215 .069	.445** .001
Advocacy	Correlation p value	-.020 .445	.047 .374	1.0	-.145 .160	-.107 .233
Tangible support	Correlation p value	.329** .011	.215 .069	-.145 .160	1.0	.196 .089
Partner support	Correlation p value	.409** .002	.445** .001	-.107 .233	.196 .089	1.0

Table 29 below identifies the overall average frequency of the supportive behaviour categories for the study along with the lowest and highest frequency that these behaviours were observed.

Table 29 - Quantities of categories of support behaviours for overall study, n=49

Behaviour category	Study Mean %	Standard Deviation	Lowest frequency %	Highest frequency %
Emotional Support	395.5	109.2	98.9	629.7
Informational Support	38.9	19.1	6	93
Advocacy	0.2	0.7	0	3.6
Tangible support	18.8	11.2	3.3	56.8
Partner support	7.5	7.3	0	35.7

It is helpful to view the distribution of support behaviours graphically in terms of a normal distribution curve (Figure Six). These graphs demonstrate that emotional and informational support are close to being normally distributed. Advocacy, tangible and partner support were not distributed normally and were skewed in frequency to the left.

Figure Six – Frequency distribution curve of all emotional support behaviours by midwives, n=49

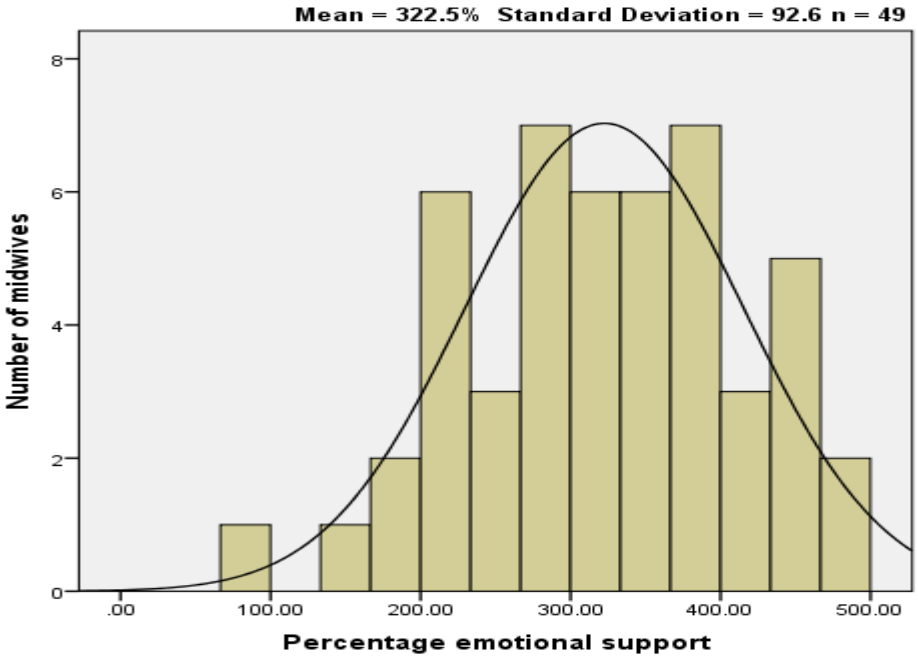
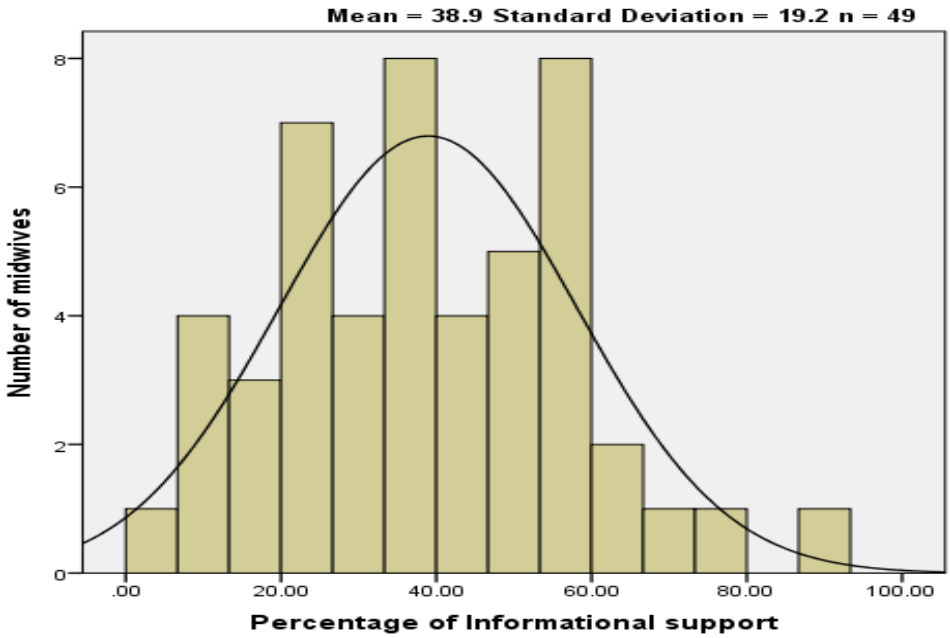


Figure Seven - Frequency distribution curve of all informational support behaviours by midwives, n=49



In order to identify variations in the pattern of supportive behaviours, a sub-group analysis was undertaken to compare the proportions that behaviours were observed when the woman entered the second stage of labour and gave birth during the observation with observations where the woman was in the first stage of labour only.

These results suggest a changing pattern of support behaviours by the midwife as the labour progressed (Table 30). The results suggest that higher levels of rapport building were used during the earlier stages of labour than in later labour. In later labour more verbal support, attentiveness during contractions, informational support and tangible support were provided. Support for the partner appeared to decrease as the labour progressed.

Table 30 – Comparison of frequency behaviours seen in study mean, observations including 2nd stage (n=10) and observations in 1st stage only (n=39)

Behaviour category	Study Mean %	Observation including 2nd stage/birth %	Observation first stage only %
Emotional Support	395.5	435	385.4
Attentiveness	93.5	97.9	89.7
Verbal support	78.6	120.8	60.8
Rapport building	36	27.5	38.5
Informational Support	38.9	45.9	37.1
Tangible support	18.8	25.7	17
Partner support	7.5	5.2	8.1

The above tables and figures identify a number of key results:

- Emotional support is the most frequently observed category of support. Emotional support was observed on average 395.5% of an observation, that is an average of around four emotionally supportive behaviours were observed at every observation point.
- The frequency of all supportive behaviours varied very widely between midwives. Emotional support varied between 98.9% to 629.7%, informational support varied between 6% and 93%.

- Significant positive correlations were found between the quantities of emotional, informational, tangible and partner support behaviours.
- After emotional support the most frequently observed category of support was informational support, followed by tangible support and support of the partner. Advocacy was only very rarely seen.
- A different pattern of support behaviours were observed in the later stages of labour than earlier active labour, with much higher levels of verbal support provided to women in the second stage of labour than the first.

9.10.4 The quantities of neutral/professional and negative behaviour categories

The quantities of neutral/professional and negative behaviours by the midwives in the study are summarised below as Table 31. This Table again identifies significant variations in behaviour between midwives and enables the identification of some patterns of behaviour. There were nine midwives who had below study average frequency of all of the neutral and negative behaviours included above (1, 2, 10, 16, 25, 31, 35, 39 and 53). There were two midwives who had above average frequency of all of the neutral and negative behaviours (12 and 23). In a similar manner to positive support behaviours, the majority of midwives (n=37, 75.5%) showed a mixture of behaviours, displaying some neutral or negative behaviours.

The negative behaviours category included negative demeanour (cold, disinterested, angry, panicky or anxious), a negative verbal tone (shouting, harsh, curt, shrill, nervous, disinterested, flippant), a negative facial expression (cold, disinterested, angry, panicky or anxious), emotionally negative behaviours (a critical or dismissive birth plan discussion, stopping or criticising the woman and negative humour), restraining or directional touch, belittling or criticising the partner, negative informational behaviours (ignores question or partial answer, describing progress negatively or in neutral terms) and taking control in a negative manner (doing something to the woman without consent or warning, forceful direction, suggesting an

intervention with no indication or discussion, presenting a decision to the woman or her partner and suggesting pharmacological pain relief).

In Table 31 green indicates where a behaviour was displayed less frequently than the study average and red indicates where a behaviour was displayed more frequently.

Table 31 – Quantity of neutral/professional and negative behaviours

Midwife number	Neutral professional demeanour %	Lack of attentiveness %	Lack of proximity %	Negative behaviours %
1	14.95	9	0	7.5
2	16.6	12.5	3.3	6.5
3	61.5	16.5	2	6
4	15.7	25.9	12.2	2.1
5	44.5	40.7	4.4	31.2
6	56.2	31.9	10.75	7.1
8	36.6	11.3	4.7	10
9	58	2.7	6	0
10	9.0	0	3.1	0.8
11	14.9	6	14.4	5
12	41.6	56.5	31.6	21.4
13	14.1	24.2	14.2	0
14	41.0	15.7	7	3.4
16	1.6	0	0	3.7
17	22.5	0	6.2	29.2
18	34.0	0	3.3	22.1
19	20	7.4	10	2.9
20	2.2	7.1	0	0
21	43.3	8	26.6	0
22	44	4.2	16	2
23	39.9	32.1	12.1	13.9
24	11.3	2.5	5.4	4.9
25	8.7	1.6	1.2	0
26	19.1	51.2	19.1	0
27	8	3.1	2	11.9
28	26.2	26.0	5	0
29	16	18.1	7.8	0
30	60	0	1.5	0
31	16.3	3.4	0	0
32	83.4	41	3.4	11.2
33	111.7	10.9	1.25	37.8

Table 31 contd Midwife number	Neutral professional demeanour %	Lack of attentiveness %	Lack of proximity %	Negative behaviours %
35	10	7.7	5.55	3.8
37	33.7	97.9	1.2	27.9
38	26.6	3.6	7.5	0
39	29.0	13.9	4.9	0
40	59.3	67.2	6.7	11.2
41	15.7	0	5.2	0
43	20.0	24.9	13.5	2.05
44	83.5	56.5	3.6	2.4
45	21.9	0	12.1	0
46	45.4	0	0	9.0
47	63.7	18.7	21.0	13.3
48	122.2	112.7	0	2.4
49	43.5	20.5	8.8	8.3
50	65.1	70.3	2.7	0
51	39.2	63.7	2.5	0
53	5	0	5	0
Mean	**37.7**	**26.2**	**6.9**	**11.6**

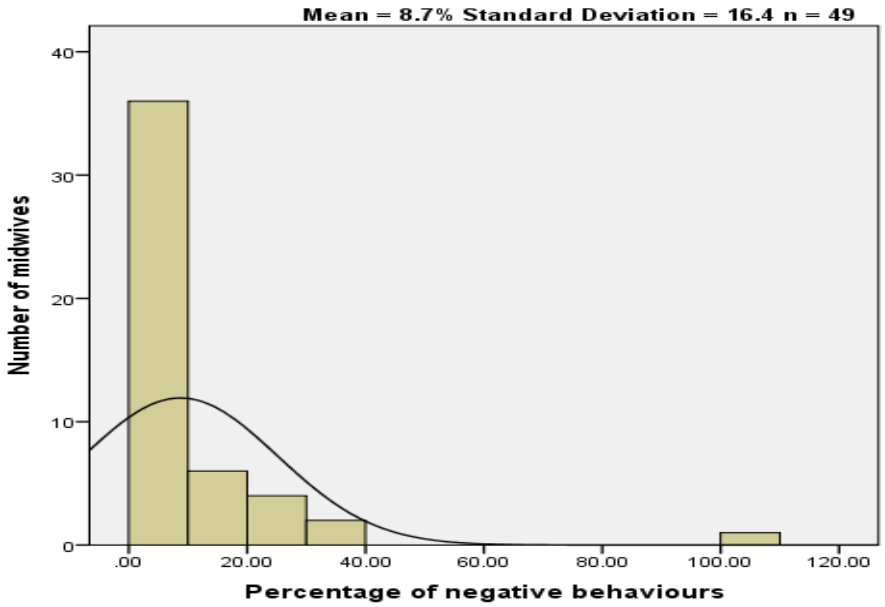
The quantities of neutral/professional and negative behaviours by the midwives are further summarized in Table 32 below. This table presents the study mean, highest and lowest frequencies and standard deviation that these behaviours were recorded.

Table 32 – Quantity of neutral/professional and negative behaviours

Behaviour	Study Mean	Standard Deviation	Lowest frequency	Highest frequency
Neutral professional demeanour	37.7	29.3	1.6	122.2
Lack of attentiveness	26.2	26.4	0	112.7
Lack of proximity	6.9	6.9	0	31.6
Negative behaviours	11.6	16.3	0	101.4
Negative demeanour	2.6	12.1	0	83.9
Negative emotional	3.2	2.0	0	10.7
Negative tangible	0.3	1.5	0	10.7
Negative partner	0.09	0.3	0	1.9
Negative Information	1.3	2.8	0	15
Negative taking control	3.9	6.3	0	34.1

The distribution of the negative behaviours category of behaviours is presented below in Figure Eight as a frequency distribution curve. This demonstrates that negative behaviours were seen infrequently and so the curve is skewed heavily to the left.

Figure Eight - Frequency distribution curve of negative behaviours by the midwife (n=49)



Internal consistency of the SMILI was further tested by identifying any correlations between negative and neutral behaviours. These are shown in Table 33 below. Table 33 demonstrates some moderate significant correlations between neutral demeanour and negative behaviours: a higher frequency of a neutral professional demeanour is significantly correlated with an increased rate of negative behaviours and a negative demeanour. A higher frequency of negative demeanour is moderately correlated with negative behaviours.

Table 33 – Correlations between neutral and negative variables

(** = significance at p value of <0.01, * = significance at p value of <0.05)

Behaviour category		**Neutral professional**	**Negative behaviours**	**Negative demeanour**
Neutral professional	Correlation	1.0	.328*	.282*
	P value	000	.011	.025
Negative behaviours	Correlation	.328*	1.0	.480**
	P value	.011		.000
Negative demeanour	Correlation	.315*	.480**	1.0
	P value	.014	.000	

The above tables and graph again show significant variations in the frequency that different behaviours were recorded between different midwives.

- Negative behaviours were seen 11.6% of the observation period ranging from 0 - 101.4%.
- The most frequently observed negative behaviour was the 'taking control negative' category which included forceful direction and presenting decisions to the couple. This was seen on average 3.9% of all observations.
- Neutral and negative demeanour and behaviours were associated with each other.
- Positive behaviours by the midwife were far more frequently observed and recorded than negative or neutral behaviours.
- When comparing the patterns of midwives' support behaviours, two midwives were found to have shown below the study average of all neutral and negative behaviours and above the study average for all positive support behaviours, midwives 10 and 16.

9.10.5 Quantity of non-support behaviours – non-support direct care, assessment activities and indirect care

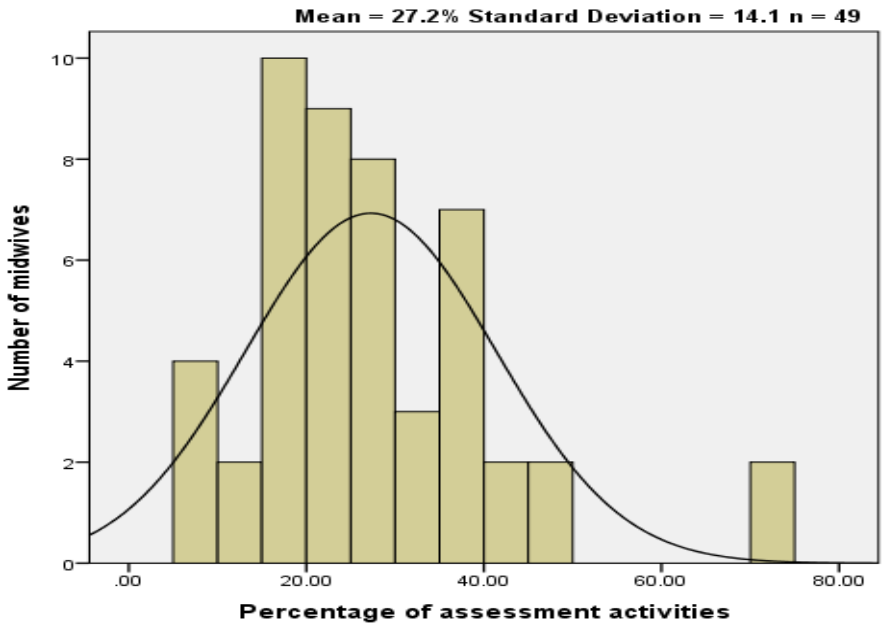
The frequency of the other non-support activities of the midwife are presented as Appendix 27. As with positive support and negative behaviours, the frequency of non-support activities varied considerably between midwives. These results are summarised in Table 34 below.

Table 34 – Quantity of non-support activities

Non-support behaviour	Study Mean %	Standard deviation	Lowest frequency %	Highest frequency %
Non-support direct care	2.9	3.1	0	13.4
Assessment	27.7	14.1	5	73.2
Indirect care	40.4	21.2	13.9	99.9

The frequency distribution curve presented below as Figure Nine demonstrates that non-support behaviours were more normally distributed than some of the other behaviours.

Figure Nine - Frequency distribution curve of assessment activities (n=49)



A sub-group analysis found that non-support direct care was increased in observations in the later stages of labour compared to earlier labour (average 4.8% versus 2.2%) and that assessment activities and indirect care activities were reduced (19.1% versus 27.7% assessment, 22.2% versus 40.4% indirect care).

9.10.6 Relationships between different elements of care: positive support, negative behaviours, non-support activities and presence in room

Analysis of the frequency data was undertaken to identify any correlations between the quantities of positive support behaviours (emotional, physical, partner, informational and advocacy support) and the quantities of negative behaviours and non-support behaviours and the proportion of the observation that the midwife was present in the room, in order to identify any clear patterns of midwives' behaviours.

This analysis found no correlations between the amount of positive emotional, informational, partner and advocacy support behaviours and negative behaviours. A significant inverse

correlation was found between the quantity of tangible support and negative behaviours (Spearman's Rho correlation coefficient -.326*, p=.011).

No correlations were found between the quantities of emotional, tangible, partner and advocacy support and the quantities of non-support activities (non-support direct care, assessment and indirect care). A significant correlation was found between the quantity of informational support and the amount of direct care (Spearman's Rho correlation coefficient .328*, p=.017).

No correlations were found between negative behaviours and non-support activities.

A considerable number of correlations were found between the proportion of time that the midwife was out of the room and other positive support, negative and non-support behaviours. These findings suggest that the midwives who spent more time out of the room, when they were in the room presented a less supportive demeanour, showing less attentiveness, less verbal support, maintained a more neutral attitude and were more frequently engaged in non-support indirect care activities such as documentation.

Frequency data was based on the proportion of time that a behaviour was seen when the midwife was in the room, not as a proportion of the observation time overall, so the behaviours of the midwives who were out of the room more are not unfavourably reduced.

These findings are shown in Table 35 below.

Table 35 - Correlation between time out of room and midwife demeanour and behaviour variables.

(** = significance at p value of <0.01, * = significance at p value of <0.05)

Variables	Spearman's rho	Midwife out of room
Midwife inattentiveness	Correlation P value	.509** .000
Midwife neutral professional demeanour	Correlation P value	.430** .001
Midwife neutral facial	Correlation P value	. 522** .000
Midwife neutral vocal	Correlation P value	.412** .001
Midwife attentiveness	Correlation P value	-.398** .003
Midwife verbal support	Correlation P value	-.480** .000
Midwife emotional support	Correlation P value	-.374** .004
Midwife informational support	Correlation P value	-.323* .012
Indirect care activities	Correlation P value	.393** .003

9.10.7 Summary of quantity of support results

The results provided in table and graphic form above provide clear data about the presence and absence of the midwife, and the quantity of support, negative and non-support behaviours for individual midwives and for the study as a whole. The results show considerable variations between midwives and identify some patterns of behaviour for particular midwives. No clear pattern emerged in the analysis for the whole study in the relationships between positive, negative and non-support behaviours. Clear relationships were found between the amount of time the midwife was absent from the room and fewer positive support behaviours when the midwife was in the room.

These results not only relate to the quantity of supportive and non-supportive behaviours observed and recorded but also contribute to the analysis of the quality of the support observed. When considering whether the quality of the care observed may be considered to be 'high', the very wide variation in the frequency of different behaviours, the absence of some positive

behaviours in the care provided by some and the prevalence of negative behaviours in the care provided by some midwives do not match the six dimensions of healthcare quality defined by the Institute of Medicine (person-centred, safe, effective, efficient, equitable and timely). The variance in the care suggests that the quality of the support provided was not always person-centred and was not equitable as not all women were provided with comparable quantities of support.

9.11 MEASUREMENT OF THE QUALITY OF INTRAPARTUM MIDWIFERY SUPPORT

The analysis of the quality data required the exploration of relationships between recorded behaviours and women's assessment of the care received. The measurement of the instrument's construct validity is also tested through the identification of relationships between the SMILI data and the women's assessment and observers' overall assessments of the quantity and quality of the support they observed. This was calculated using the Spearman's Rho correlation coefficient test using the SPSS .17 statistical software package.

9.11.1 Women's assessments of the midwifery support provided

Women's assessments of the midwifery support they received were measured using the validated 'Support and Control in Birth' (SCIB) questionnaire. The questionnaire calculates three scores for each woman, one for their sense of internal control, one for external control and one for support. Each score has a possible range of 1-5. The individual results are attached as Appendix 28. The overall mean results are shown below in Table 36.

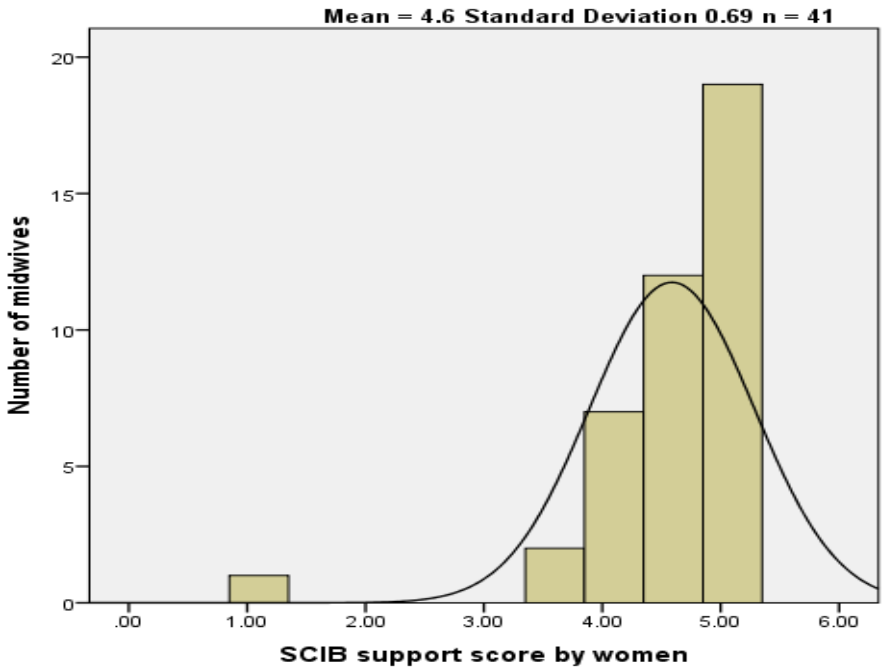
The SCIB was completed fully for 42 of the 49 observations, that is for 85.7% of observations. Where a woman was observed being cared for by two different midwives she was asked to complete two SCIB questionnaires. Four additional forms were only partially completed, with no support questions completed.

Table 36 – Summary of overall study results of the Support and Control in Birth Questionnaire

Responses	Internal Control (range 1-5)	External control (range 1-5)	Support (range 1-5)
42	Mean 3.6	Mean 4.1	Mean 4.6

The frequency distribution curve below clearly demonstrates that the SCIB responses were heavily skewed to the positive.

Figure Ten- Frequency distribution of Support and Control in Birth Questionnaire results relating to support , n=42



9.11.2 The Observer's overall assessment of the quantity and quality of the support observed

Each observer (including the researcher) completed two questions about the quantity and quality of the midwifery support they had observed using a Likert scale at the end of each observation. These questions were completed for 100% of the observations.

The observers' global assessments of the quality and quantity of care observed were generally skewed to the positive. The quality of the support provided was generally rated highly by the

women participants (average 4.6 out of a possible 5) and in the global ratings by observers (average 2.7 out of a possible 4).

Table 37 - Observer global assessments of support

Global observer assessment question	Response	Frequency(n=49)
The quantity of midwifery support I observed was	Poor	0
	Adequate	3 (6.2%)
	Good	7 (14.2%)
	Very good	20 (40.8%)
	Excellent	19 (38.8%)
The quality of midwifery support I observed was	Poor	3 (6.1%)
	Adequate	2 (4.1%)
	Good	9 (18.3%)
	Very good	19 (38.8%)
	Excellent	16 (32.7%)

These responses were included in the next stages of the analysis to identify whether the assessment by the observer corresponded with the results recorded in the SMILI and with women's assessment of care recorded in the SCIB questionnaire. The comparison of the observer and women's assessments of the support functions as a further test of the instrument's validity and 'veridicality'. Veridicality refers to the level of congruence between the perceptions of support of the recipients and someone else, in this case, the observers, who may be considered experts in intrapartum midwifery support (Antonucci and Israel 1986).

9.11.3 Associations between negative behaviours and woman and observer assessments

Spearman's Rho correlation coefficients were calculated between rates of negative behaviours by the midwife recorded in the SMILI and the assessments of support recorded by the woman in the SCIB and the observer in the global ratings questionnaire. Negative behaviours and inattentiveness by the midwife showed significant inverse correlation with the assessment of the midwifery support by women and observers.

Table 38 – Correlations between negative behaviours and inattentiveness and assessment of support.

(** = significance at p value of <0.01, * = significance at p value of <0.05)

Midwife behaviours	Spearman's rho	Woman's assessment SCIB Support	Observer's Global rating of quality
Negative behaviours	Correlation coefficient P value	-.311* .024	-.385** .006
Inattentiveness	Correlation coefficient p value	-.284* .036	-.500** .000

9.11.4 Associations between midwife's presence and ratings of support

One of the key elements of support derived from the literature is the importance of the continual physical presence of the midwife to woman's feelings of being supported. The results of the analysis to test the association between these elements are given below. This analysis sought to test whether the quantity of presence or attendance by the midwife is an element in the assessment of the quality of the support. These results (presented in Table 39 below) show a strongly significant inverse correlation between the amount of time that the midwife spent out of the room and the woman and observer's assessments of support. The higher the proportion of the observation that the midwife was out of the room, the lower the assessment of the support offered.

Table 39 - Correlations between midwife's absence and views of support

(** = significance at p value of <0.01, * = significance at p value of <0.05)

Midwife's behaviours	Spearman's rho	Woman's assessment SCIB Support	Observer global rating of quality
Proportion out of room	Correlation coefficient Sig (1 tailed) P value	-.503** .001	-.516** .002

9.11.5 Association between positive behaviours and woman and observer assessments

Correlation coefficients were calculated between positive midwifery support behaviours and the assessments of support by the woman and observer, in order to test whether the quantity of positive midwifery support behaviours is a key element in the measurement of the quality of

midwifery support. These results show a significant correlation between women's assessment of the support they received and the overall measurement of emotional support.

Table 40 – Correlations between positive behaviours and assessments of support

(** = significance at p value of <0.01, * = significance at p value of <0.05)

Midwife behaviours	**Spearman's rho**	**Woman's SCIB score**	**Observer's global rating of quality**
Emotional support	Correlation P value	.299* .029	.505** .000
Informational support	Correlation P value	.248 .059	.364** .009
Tangible support	Correlation P value	.195 .111	.307* .024
Support for partner	Correlation P value	.428** .003	.376** .007
Advocacy	Correlation P value	-.210 .094	.089 .285

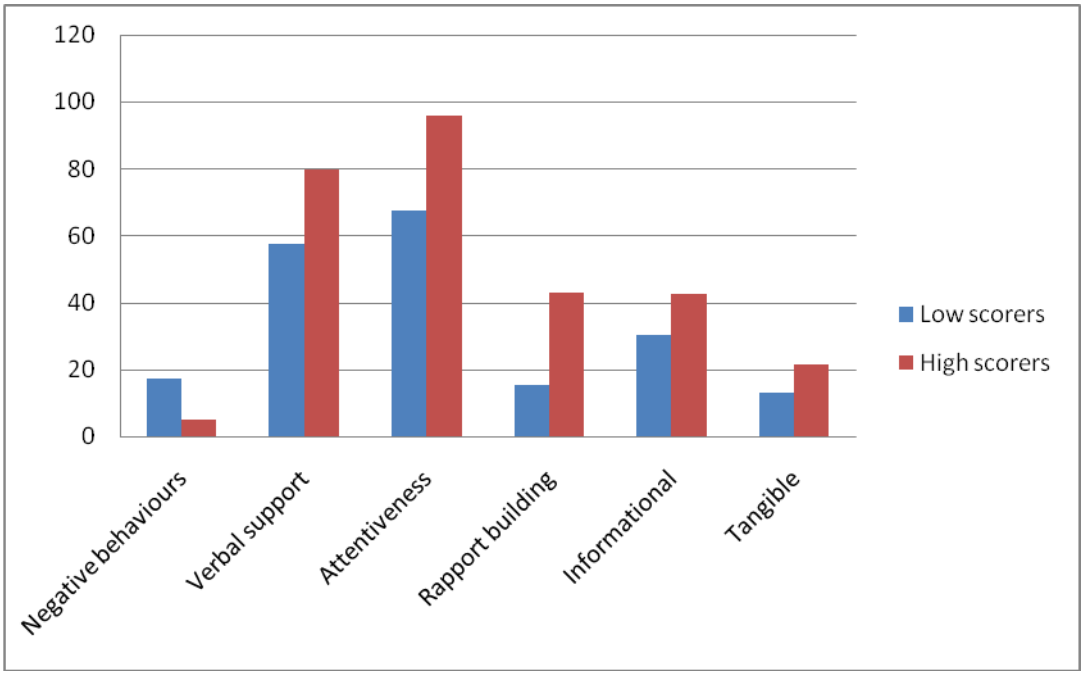
Analysis of the data for the sub-categories of emotional support found that the most significant element of emotional support for women appeared to be rapport building (Spearman's Rho correlation with SCIB score .432**, p=.002) and support for the birth partner (Spearman's Rho correlation with SCIB score .428**, p=.003).

The observers also show a significant correlation between their assessment of support and the overall emotional support category and informational support. Analysis of the sub-categories of emotional support found highly significant correlations between the observer assessments and higher levels of attentiveness (.401** p=.004), verbal support (.517** p=.000), enhancing a woman's sense of control (.380** p=.013) and creating a positive environment (.363** p=.009). Tangible support was also associated with higher assessments of support by the observers.

Figure 11 below shows the frequency with which support behaviours were displayed by two groups of midwives. The blue column shows the figures for the midwives that received low SCIB scores (lower than 4.0) from the women they cared for and the red column shows the figures for midwives that received high scores (higher than the study average of 4.59) from the

women they cared for. The figure graphically depicts the associations demonstrated in Table 41. The figure shows that where women rated the support they received highly (that is with a score above the study average of 4.59 in the SCIB, the red column), the SMILI had recorded higher levels of verbal support, attentiveness, rapport building, informational and tangible support. There were lower levels of negative behaviours. Where the women rated the support received at a lower level (with a score below 4 in the SCIB, the blue column), the SMILI had recorded lower levels of supportive behaviours and higher levels of negative behaviours.

Figure 11 - Frequency of support behaviours where the woman rated the support low (<4) and those where the woman rated support above the average



The differences in the frequency of behaviours of midwives rated high for support (that is above the average of 4.5) or low by the women (that is below 4.0) they cared for is provided in Table 41 below.

These results show very clear differences in the presence and behaviours of the midwives that women rated very highly (using the SCIB support questionnaire) and those that the women rated below average. Midwives rated below average were out of the room almost twice as long as the most highly rated midwives (13% v 7.5%). They were almost twice as likely to be

inattentive (36.3% v 19.9%) and showed three times as many negative behaviours (17.2% v 5%). High rated midwives offered the partner support four times as frequently (8.7% v 2.3%). The differentials are less marked when comparing positive demeanour and information provision between the groups. Little difference was seen between the groups in providing non-supportive care (non-supportive direct care 2.9% v 3.1%, assessment 29.1% v 23.2%, indirect care 39% v 33.7%).

Table 41 - Comparison of midwives by SCIB scores

Variable	Low scoring midwives (n=7) %	Overall study mean (n=49) %	High scoring midwives (n=32) %
Proportion of total observation time mw out of room excl breaks as	13.0	9.3	7.5
Overall observer assessment of quality	1.2	2.7	3.1
Neutral professional demeanour	49.9	37.7	29.8
Lack of attentiveness	36.3	26.2	19.9
Negative behaviours	17.2	11.6	5.0
Emotional Support	280.1	395.5	422
Rapport building	15.4	36.0	42.9
Informational support	30.1	38.9	42.5
Advocacy	0.5	0.2	0.2
Physical support	13.1	18.8	21.4
Partner support	2.3	7.5	8.7
Non-support direct care	3.1	2.9	2.9
Assessment	23.2	27.7	29.1
Indirect care	33.7	40.4	39.0

The SMILI demonstrates good sensitivity to differences in behaviour by midwives that result in different assessments of support by women and observers. It is therefore possible to begin to build a clearer picture of the details of what may be described as high quality midwifery support, that is support that is woman-centred, safe and evidence-based.

9.12 ASSOCIATIONS BETWEEN WOMEN'S AND OBSERVERS' ASSESSMENTS OF SUPPORT

In order to test whether women and observers have comparable definitions of midwifery support and that the SMILI has 'veridicality', analysis was undertaken to identify associations between women's assessments of support and the global assessments undertaken by the observers. These results (presented in Table 42) show highly significant correlations between women's views of support and those of the observers, and thus further support the veridicality and validity of the SMILI.

Table 42 – Associations between women's and observers' assessments

(** = significance at p value of <0.01, * = significance at p value of <0.05)

Assessment tool	**Spearman's rho**	**SCIB Support**	**Global rating of quantity**	**Global rating of quality**
SCIB support	Correlation P value	1.00 .000	.569** .000	.584** .000
Global rating of quantity	Correlation P value	.569** .000	1.00 .000	.862** .000
Global rating of quality	Correlation P value	.584** .000	.862** .000	1.00 000

9.13 THE CONSTRUCT VALIDITY OF THE SMILI

A key question for this study was to identify whether the SMILI was able to measure the central concept of intrapartum midwifery support, that is, whether the instrument has construct validity. The main way to test this is to identify whether women's views of the support correlate significantly with the data collected using the SMILI. These links have been clearly identified in the previous section, with significant correlations between women's views and the quantity of positive and negative behaviours recorded.

However, women's views of the support they received may not only be influenced by the supportive and non-supportive behaviours recorded using the SMILI, but may be also

significantly influenced by other elements of the experience. For example, a woman may describe the support she received less positively if she has had a more difficult labour and birth experience in terms of more medical interventions. These other possible influences and their impact on women's and observers' views of the support provided were examined (presented in Appendix 30).

This analysis found that there were no correlations between women's views of the support they received and their parity, allocated care pathway, analgesia used, number of medical interventions, type of birth, amount of non-support care and assessment activities, maternity unit and number of years the midwife had been qualified. This may be seen as further evidence to support the construct validity of the SMILI.

In summary, the SMILI demonstrates a high level of construct validity. Women's views of the midwifery support received correlate well with the supportive behaviours recorded using the SMILI and do not show correlations with other non-support aspects of care and the birth experience.

9.14 DESCRIBING THE QUALITY OF THE INTERACTIONS USING THE SMILI

The SMILI programme provided observers with a free text box which was designed to allow observers to note down when an error in recording care was made or when an emergency arose which would affect the care provided. Two of the observers, including the researcher, also used the free text box to describe certain aspects of care and the interaction more fully than was possible by simply ticking the behaviour boxes.

This included overall observations of any difficulties or tensions observed in the room which were not completely described by the specific categories of behaviours. One example of this is where the woman was initially on her own during the observation being supported by the midwife and student midwife. She was then joined by her mother and mother in law. The two

birth partners did very little to support the woman, they chatted to one another and texted on their mobile telephones. The midwife and student caring for the woman did not feel able to ask the birth partners to leave or to behave differently and spent their time trying to offer the woman as much comfort and support as possible. However, the atmosphere in the room was completely changed and the woman, who had been coping with labour very well and was using the birthing pool for pain relief, became increasingly distressed over the following fifteen minutes and then asked for an epidural.

Another aspect of support included in the free text box were specific phrases that the midwife used and interactions between the woman and the midwife that were particularly striking to the observer as being very supportive or very unsupportive. One example of positive verbal support from the midwife while the woman was experiencing transition was recorded as below:

'Lots of nodding and eye contact 'You're a star, you're doing brilliantly...Everything is absolutely perfect... [all maternal and fetal observations])...What do you feel?...The baby's moving down and you're doing beautifully, you're helping the baby here because your its mum...Fantastic, excellent that's so good...Let's just work together for a couple more and see how it goes...We're just doing a couple of contractions at a time...You're moving the baby down, you couldn't do any better' (010).

An example of a woman's needs not being fully met was recorded:

'I want more now, I've had enough' (to partner). Midwife distracts by asking about baby names. (To midwife) 'You need to help me now'. Midwife replies: 'What pain relief would you want?'. Woman replies 'You need to help me now, please help me' . Midwife doesn't say anything but stays close, 'Please help me somebody'. No answer, no response (011).

The final aspect of the observation included regularly in the free text box was the number and nature of disturbances in the room. Though this was recorded partially using the log to note when anyone came in or out of the room, the free text box was used to describe more fully the nature of the disturbance and reason for it. For example, in one unit it was normal practice to

allow cleaners into the rooms during a woman's labour to dust and empty bins. It was also normal practice in this unit to have one of the labour room doors open throughout labour, which meant that noise levels were high in the unit. These important environmental aspects of the observation, though not specifically describing the support given to the woman, were considered to be important to describe the context in which support was provided and the possible inhibitors to the support being provided.

The free text box therefore appears to be an important aspect of a systematic observation instrument in order to contextualise more fully the support observed.

9.15 IDENTIFICATION OF ASSOCIATIONS BETWEEN THE QUANTITY AND QUALITY OF SUPPORT AND OUTCOMES

This study was chiefly designed to identify whether the SMILI was reliable, feasible and valid in the clinical setting and to identify whether it is possible to measure the quantity and quality of midwifery support during labour using such an instrument. The SMILI was developed to be a robust instrument for future larger scale studies and trials of intrapartum support. Such large scale studies would, it is anticipated, seek to identify the most effective elements of intrapartum support in improving clinical outcomes. Initial exploration of the study data was therefore undertaken to identify any correlations between support behaviours and clinical outcomes, to inform future full-scale studies.

The observational data were analysed to identify if there were associations between the support recorded and the key outcomes of women's views, number of medical interventions and type of birth.

9.15.1 Association between the quantity and quality of midwifery support and women's views of care

As detailed above in the exploration of the SMILI's validity, significant associations were found between the support recorded and women's views. Table 40 demonstrates construct validity of the instrument and also shows statistically significant links between women's feelings about the support they received and the support recorded. Where the midwife was out of the room for longer, had a neutral or negative demeanour and engaged in negative behaviours, the woman was less happy with the support she received. The more emotional, tangible, informational and partner support the midwife provided, the happier the woman was with the support she received.

Further analysis of this association was undertaken using an ordered logistic regression model with women's views (the SCIB support result) as the dependent outcome variable. The explanatory variables were emotional support and the proportion the midwife was out of the room. The overall model was found to be statistically significant (Chi square =12.2, degree of freedom=2, p=.002) and both the predictor variables were also found to be statistically significant. Emotional support was statistically significant at p=.002 and proportion the midwife was out of the room was also significant (p=.049).

9.15.2 The association between the quantity and quality of support and type of birth

A Spearman's Rho correlation coefficient analysis was undertaken to identify any associations between the SMILI data and the type of birth that women had.

This analysis identified relationships that would be expected between the parity and age of the woman and type of birth (the fewer previous births and the older the woman the more likely the woman is to have an operative delivery), analgesia (if the woman had an epidural she was more likely to have an operative delivery) and medical interventions (the more of these kinds of care the woman received, the more likely she was to have an operative delivery).

What is of particular interest in relation to support was the statistically significant correlations found between the time the midwife was out of the room and type of birth (the more the midwife was out of the room the more likely the woman was to have a caesarean) and verbal and emotional support and type of birth (the more of these kinds of support the less likely the woman was to have a caesarean). No correlation was found between other types of support including informational and tangible support and the type of birth. These data are summarised in Table 43 below.

Table 43 – Correlations between type of birth and other variables

(** = significance at p value of <0.01, * = significance at p value of <0.05)

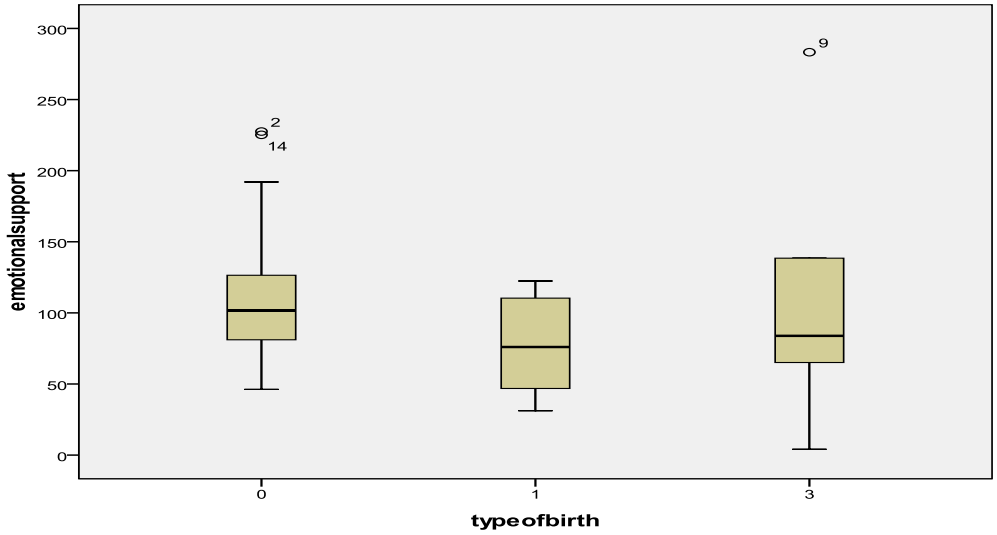
Variable	**Spearman's rho**	**Type of birth**
Midwife out of room	Correlation coefficient P value	.342** .009
Verbal support	Correlation coefficient P value	-.526** .000
Emotional support	Correlation coefficient P value	-.461** .001
Informational support	Correlation coefficient P value	.205 .081
Tangible support	Correlation coefficient P value	.010 .476
Analgesia	Correlation coefficient P value	.437** .001
Medical Intervention	Correlation coefficient P value	.539** .000
Indirect care	Correlation coefficient P value	.414** .002
Parity	Correlation coefficient P value	-.308* .031
Woman age	Correlation coefficient P value	.455** .009

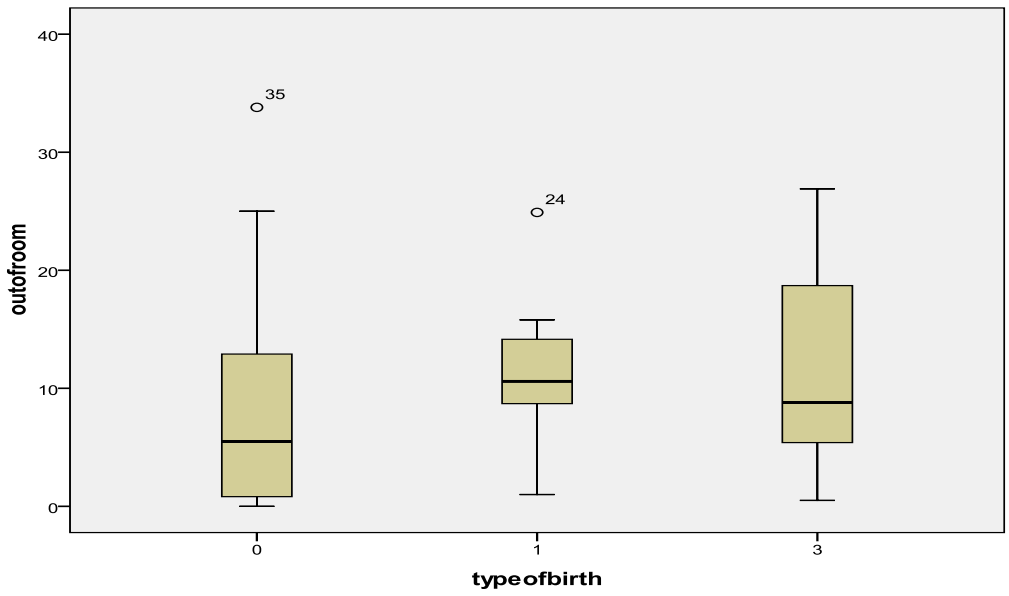
These relationships between emotional support and type of birth and time the midwife was out of the room and type of birth are graphically depicted in the box plot diagrams below, presented as Figure 12. The first of the charts graphically depicts the relationship between the levels of emotional support and the type of birth. Where higher levels of emotional support were recorded, the woman was more likely to have a spontaneous vaginal birth. Lower levels of

emotional support were associated with operative deliveries (ventouse, forceps and caesarean section). The second chart demonstrates the association between the proportion of the observation that the midwife was out of the room and the type of birth. Spontaneous vaginal births were associated with the midwives being out of the room less and the operative deliveries with the midwife being more likely to be out of the room for longer.

Figure 12 - The relationship between emotional support and type of birth and time midwife was out of the room and type of birth.

0=normal delivery, 1=ventouse or forceps delivery, 3=caesarean birth





The strength of these correlations was further tested using a Mann-Whitney U test. For normal birth (n=31) compared with assisted birth (n=18), the proportion the midwife was out of the room was mean = 7.1 (sd=7.9) and 12.1 (sd = 7.7) respectively. This shows a statistically significant difference (z=2.16, p=0.024).

A Mann-Whitney U test was also undertaken to examine the relationship between emotional support and the type of birth. This found that for normal birth (n=31) compared with assisted birth (n=18) the mean emotional support was 128.1 (sd=58.4) and 77.7 (sd=34.5) respectively. This shows a Mann-Whitney test that is significantly different (z= -3.15, p=0.002).

9.15.3 The association between the quantity and quality of support and the number of medical interventions

Correlations were sought between support behaviours and the number of medical interventions as the other key outcome variable. This analysis identified the expected correlation between the amount of analgesia and medical interventions (epidurals have been found in earlier studies to be associated with an increase in medical interventions such as syntocinon augmentation and operative deliveries). A significant correlation was also found between the amount the midwife was out of the room and more medical interventions. There was a significant negative correlation between the amount of emotional support and the number of medical interventions. There were no correlations found between other types of support including informational support and tangible support and the number of medical interventions. These findings are summarised in Table 44 below.

Table 44 – Correlations between midwife behaviours and number of medical interventions

(** = significance at p value of <0.01, * = significance at p value of <0.05)

Variable	Spearman's rho	Medical Interventions
Midwife out of room	Correlation P value	.488** .004
Emotional support (verbal and rapport building)	Correlation P value	-.404** .004
Neutral professional	Correlation P value	.454** .008
Lack of attentiveness	Correlation P value	.353* .033
Analgesia	Correlation P value	.401* .017
Informational support	Correlation P value	.135 .247
Tangible support	Correlation P value	-.224 .126

Further analysis of the data relating to correlations between medical interventions and support behaviours was undertaken using logistic regression. Medical interventions were the outcome variable with the predictor variables of emotional support (verbal support and rapport building) and proportion of time that the midwife was out of the room. This found that the overall model was statistically significant (p=0.025), as was the variable emotional support (p=0.037). Proportion of time that the midwife was out of the room was not significant in this analysis.

9.16 SUMMARY OF RESULTS OF STUDY FIVE

The results of Study Five are summarised in relation to the study objectives.

1.To test the feasibility and acceptability of a direct observational study and the usability of the SMILI in the intrapartum setting

The study was successful in recruiting participants across the four participant sites and achieved the maximum goal for numbers with forty nine complete observations analysed. Some difficulties were experienced in achieving recruitment at the two smaller participating units. The resulting 104.3 hours of observational data means that the study is the largest intrapartum

observational study undertaken in the UK since Kirkham's 1989 study of information provision and the largest ever UK study of intrapartum support (Kirkham 1989). The study compares favourably in size with the most comparable studies undertaken in North America (Miltner 2002, Barnett 2008). The Miltner study undertook 150 hours of observations of 24 nurses caring for 75 women, the Barnett study undertook 75 hours of observations of 17 nurses caring for 30 women.

The study demonstrated that the direct observational approach was feasible, understandable and acceptable to the majority of women, their birth partners and midwives in the clinical setting. Women's and midwives' views were actively sought and no problems with the approach were identified.

The SMILI worked well in the clinical setting with loss of data in only three cases due to user error. The SMILI worked from an inexpensive memory stick on standard personal computer laptops without any special adaptation and so did not represent a costly method.

The use of the SMILI in the clinical context produced a large amount of comprehensible and usable data relating to intrapartum midwifery care. The analysis process did reveal difficulties in the ease with which the data could be analysed. The analysis process was made more complex and lengthy by the way in which the programme recorded data, that is as it was seen rather than at regular set intervals. This finding has been noted and will be incorporated into future amendments to the programme prior to its use in future studies.

2.To complete the testing of the validity and reliability of the SMILI in the clinical setting

The observers rated face validity of the SMILI high in the clinical setting. A number of small gaps in content were identified in the earlier stages of the study which were addressed. Following these amendments, content validity of

the SMILI was found to be high by the observers using the instrument in the setting for which it was designed.

Good levels of internal reliability of the SMILI were found using a Cronbach's alpha analysis. Different aspects of 'attitude' correlated highly with each other for the woman, her birth partner and the midwife. Where a midwife remained in close proximity to the woman, she was also likely to demonstrate a positive demeanour, use a positive vocal tone and display a positive facial expression. Where a midwife displayed a neutral or negative demeanour she was more likely to use a neutral or negative vocal tone and display a negative facial expression. The SMILI also produced data that showed that different positive and negative behaviours correlated significantly with each other. Where a midwife provided more emotional support, she was more likely to provide more tangible, informational and partner support. Where a midwife displayed a neutral demeanour she was more likely to engage in negative behaviours, be inattentive and be out of the room more.

The SMILI was found to have good levels of construct validity through the identification of significant correlations between the care recorded and women's feelings expressed in the SCIB. Women rated the support they received more highly when they received higher quantities of emotional, informational, tangible and partner support and when the midwife was in the room more.

Further evidence of good construct validity was found through the identification of significant correlations between the support recorded and the observers' overall assessments of the support observed. Observers rated the support observed more highly where more emotional, informational, tangible and partner support behaviours were recorded using the SMILI and when the midwife was in the room more.

The SMILI was found to have good veridicality through the identification of significant correlations between the SMILI data, women's views and the observers' views. Though some differences in emphasis between women and observers were found, there was generally high levels of agreement between them when rating the support received or observed.

3.To explore the ability of the SMILI and outcome measures to measure the quality and quantity of midwifery support in labour in the clinical setting.

The SMILI produced a large amount of information about the quantity of midwifery intrapartum support. This included easily analysed information about the presence or absence of the midwife in the labour room. It also enabled quantities of different support and non support behaviours to be calculated. These results were grouped into related categories. Figures for each category of behaviour were calculated for each observation which provided a picture of the different proportions of the observation that each category of behaviour was seen.

Midwives in the study provided all women with one to one care during active labour, which was generally continuous rather than intermittent.

The study was successful in providing information about the quantity of different support behaviours and showed that emotional support was given more frequently than any other type of supportive, unsupportive and non-support care.

The study provided substantial information about the quality of midwifery support, identifying the generally very positive nature of the support observed. Negative behaviours were rare and positive behaviours were the norm. The study identified significant variations between the midwives observed in the quantity and quality of the support they provided, such that the support cannot be consistently described as being of high quality.

4.To undertake initial analysis of the study data to explore the ability of the study methods to identify correlations between midwifery support and clinical outcomes.

The central importance of emotional support in relation to outcomes measured was demonstrated in this study.

The first outcome, women's satisfaction with the support received, was found to have clear strong correlations with the support recorded using the SMILI. More negative behaviours and inattentiveness by the midwife were correlated with lower assessments of support by the

women. The proportion of time that the midwife was absent from the room was also strongly correlated with women's views of the support, with higher amounts of absence associated with lower assessments of support from women. More positive support behaviours, particularly emotional support and support of the birth partner, were significantly associated with more positive assessments of the support received. Multiple logistic regression analysis confirmed the Spearman's Rho correlations between women's views and the quantity of emotional support and the proportion of time that the midwife was in the room.

The second key outcome explored, type of birth, was also found to be significantly correlated with the quantity of emotional support and the proportion the midwife was in the room. The particular significance of the correlation between emotional support and type of birth was confirmed with the Mann Whitney U analysis. A logistic regression analysis was not possible with the type of birth data.

The third outcome explored, number of medical interventions, found a significant correlation between the quantity of emotional support and the number of medical interventions, with higher levels of emotional support associated with fewer medical interventions. This relationship was confirmed with a logistic regression analysis.

Evaluation of the data demonstrated that support variables were clearly associated with women and observers' assessments of intrapartum support, but that non-support elements of care such as assessment activities and medical interventions were not associated with variations in the evaluation of support.

The following chapter will discuss the results of the series of studies in more depth, identify the studies' limitations and suggest the implications of the studies for practice and further research.

CHAPTER TEN – DISCUSSION AND CONCLUSION

10.1 INTRODUCTION

The chapter which follows seeks to draw together the knowledge generated from the five studies undertaken for this research. The discussion will explore the success of the research in answering the thesis questions and the overall research questions, will identify the limitations of the research and will assess the contribution of the research to knowledge.

The studies described in the thesis followed the MRC framework for developing trials to test complex interventions (MRC 2000 and 2008). Ultimately the complex intervention to be tested in a future large scale trial is that of midwifery support in labour. However, the structure provided by the MRC framework to the studies has also ensured that the complex intervention of midwifery support may be fully explored in a large scale observational study by using the framework's structured approach to fully develop, test and pilot an intrapartum systematic observational study using a new computer based instrument.

The development of the SMILI was based on a comprehensive synthesis of the current available evidence about intrapartum support and the measurement of quality in healthcare interactions. The feasibility, usability, validity and reliability of the SMILI were tested in the series of studies.

10.2 DISCUSSION OF THE SUCCESS OF THE THESIS STUDIES IN ANSWERING THE SPECIFIC RESEARCH QUESTIONS

The secondary literature review into the methodology for the thesis studies identified the need for the development of a new systematic observation instrument to measure the quantity and quality of intrapartum support. This led to specific thesis questions which required exploration

before the overall research questions of interest identified at the end of the initial literature review could be answered.

10.2.1 Is a systematic observation study of intrapartum support feasible in the intrapartum setting in National Health Service Scotland?

The clinical testing study in four maternity units in Scotland demonstrated that an intrapartum observational study with an observer present in the labour room using a computer based systematic observation instrument was feasible and acceptable to the majority of women, birth partners and midwives approached to participate. The SMILI was found to be highly usable and acceptable to the observers.

The research demonstrates a successful intrapartum observational study. Direct observational studies of intrapartum care have been undertaken relatively infrequently in midwifery research. Discussion with midwifery researcher colleagues identified that reluctance to undertake such research appears to be due to the time consuming nature of such studies and perceived difficulties in obtaining ethical approval, access and informed consent from participants.

The type of observational research undertaken in this study using a systematic observation instrument employed by a team of trained observers has demonstrated that observational research can be less arduous and time consuming than may have been anticipated or may be the case with more ethnographic approaches to observation, where one researcher undertakes all of the observations. It may be argued that the generalisability of the research findings is strengthened as observations were undertaken by more than one observer and so reduces the impact of one person's perspective and judgments.

The development of a strong research proposal and protocol that demonstrated clear understanding of the ethical issues involved in the study enabled a smooth passage of the study through both the academic and NHS ethical approval systems with no significant amendments required. Access to potential participants in the maternity units and recruitment of participants to the study also proved to be generally unproblematic.

Feasibility issues were identified in seeking to recruit in smaller and more remote maternity units, and in future studies adequate time and resources should be allowed to enable observers to be present for long periods in less busy maternity settings to enable adequate recruitment in these settings.

In summary, the studies were successful in answering this thesis question. The studies demonstrated that a systematic observational study in the National Health Service in Scotland in the UK is feasible and acceptable to participants.

10.2.2 Can a systematic observation instrument be developed that is valid and reliable in its ability to record and measure midwifery support in labour?

The 'Supportive Midwifery in Labour Instrument' (SMILI) was tested for all of the key aspects of validity in the series of interlinked studies undertaken.

Content validity and some aspects of construct validity were tested in the first study using a card sorting exercise with a group of eleven student midwives. This exercise identified an acceptable level of content and construct validity. The exercise raised some interesting questions about the overlapping nature of the categories of support and about whether 'advocacy' should be considered as a separate category in its own right or as one element of the 'emotional support' category.

Face and content validity of the SMILI were further tested in the second study using a detailed questionnaire with an expert panel of eleven members. This study found an excellent level of content validity with all individual items of the instrument receiving at least an individual content validity index of 0.82 and an overall scale content validity index of 0.93. The majority of the panel considered that the SMILI would successfully measure both the quantity and quality of intrapartum support (81.8% and 63.6% respectively). This exercise reaffirmed the more complex task presented by seeking to measure the quality of the support rather than simply the quantity, with 36.4% of the panel considering that the SMILI would only be able to measure quality 'partially'.

The fourth study, training three volunteer observers to use the SMILI while watching labour care films, while designed to test reliability of the instrument, further tested elements of face and content validity and led to a number of changes to the operation, content and layout of the SMILI to improve its completeness and usability.

The final study enabled the SMILI to be fully tested in the clinical setting for which it was designed. Face validity of the SMILI was tested by the four observers in the clinical setting. The post observation questions with the observers identified an overall satisfaction with the functionality of the SMILI and a belief that it had enabled them to record and measure the support observed accurately. The observers felt that the programme enabled them to measure support.

The extensive nature of this study enabled further testing of the content validity, with some additions made to the content of the SMILI after the first ten observations. After these additions, no further problems or gaps were identified by observers with the content of the SMILI.

Construct validity of the instrument was tested by calculating the correlation coefficients between the quantity and quality of intrapartum support recorded and the scoring by women of the support they received using the Support and Control in Birth questionnaire. This found moderate correlation between negative behaviours of the midwife and woman's views of the support received. Moderate correlations were also found between the midwife's positive support behaviours and women's views of the support received. Statistically significant correlations were found between the level of support the midwife provided to the woman's birth partner and women's positive views. A larger sample of observations would enable further testing of the correlations between both negative and positive behaviours and women's views. It is of interest that emotional support behaviours have the strongest links with women's views, which confirms the findings of earlier studies with women which identify emotional support behaviours as the most important category of support.

Construct validity of the SMILI was further supported by the findings showing no correlation between the amount of non-support behaviours and non-supportive care including assessment and women's views of the support received. This finding brings into question the contention in a minority of qualitative studies with women that non-supportive assessment behaviours are as important or more important to women in their assessment of care as supportive elements (Manogin et al 2000). Construct validity is also demonstrated by the increased satisfaction with support correlating strongly with the amount of time the midwife was in the room with the woman.

Internal reliability of the instrument was measured using a Cronbach's alpha test of internal consistency between related variables. These tests showed a good level of consistency between related variables, though this consistency was lower between the less frequently observed negative elements.

The veridicality of the methodology was shown through the identified correlation between women's views of the support received and the observers' overall assessments of the support they had observed. For the most part, the women and midwives appeared to share their definition of the construct of support. The high level of correlation between the women's and observers' assessments further supports the validity of the systematic observational approach to measure the quantity and quality of intrapartum support.

The fourth study, testing inter and intra reliability with volunteer observers watching labour care films, showed levels of inter-rater reliability following training were moderate to strong (Kappa range correlation from .484 to .642) and intra-rater reliability was found to be strong (Kappa correlation from .682 to .776).

Testing of the inter-rater reliability of the SMILI in the clinical setting was not undertaken. This was due to the judgment that asking women and midwives to provide consent to have two observers present in the labour room would present more ethical issues in terms of being considerably more invasive of such a private experience.

In summary, the series of studies were successful in answering this specific thesis question. The SMILI was tested for key features of validity and reliability using a number of approaches and was found to demonstrate good levels of validity and reliability. However, it is recognised that the validity and reliability of any new instrument is an ongoing process, not completed in one study. Further testing of the validity and reliability of the SMILI in other settings will be required to ensure transferability of the instrument to settings outside the specific circumstances of these studies.

10.2.3 Can a systematic observation instrument measure the quantity and quality of midwifery support in labour?

The SMILI has enabled the observer to record the proportion of the observation that the midwife was present in the woman's labour room in a systematic manner. The use of a continuous timer and a simple one- click mechanism to record the movement of the midwife in and out of the room provides a great deal of information about the continuousness of the care provided by the midwife. It allows the percentage of time the midwife was in the room to be calculated very simply as a proportion of the whole observation, as well as providing information about the frequency that the midwife left the room.

The SMILI enables an observer to gather detailed information about the frequency with which a wide range of supportive and non-supportive behaviours are observed in the labour room. The individual behaviours observed were categorised for further analysis into the categories of intrapartum support identified in the literature: emotional, tangible, informational, partner and advocacy.

The SMILI contributes new information about the quality of intrapartum support provided by midwives and about the measurement of quality in the childbirth care setting. The results of the final clinical study show that women and observers shared very similar, though not identical, assessments of whether support was of a high quality or not. Women's and observers' definitions of high quality support are not linked in this study with the amount of analgesia used,

the type of birth experienced, the amount of indirect care, non supportive direct care or assessment activities carried out by the midwife. Women's assessments of the intrapartum support as being of low quality are linked to the quantities of negative behaviours of the midwife recorded using the SMILI including demonstrating a negative demeanour, negative tangible and informational behaviours. Women's assessments of the support as being of high quality are linked most significantly with the amount of emotional support, particularly rapport building, the amount of time the midwife was in the room and the midwife's positive behaviour towards the birth partner recorded using the SMILI. Observers' assessments of the quality of midwifery support also demonstrated statistically significant correlations between negative behaviours (including negative behaviour towards the birth partner and negative information provision) and a lower score. Observers' assessments reflected those of women in showing significant correlations between their scores and the amount of emotional support. Observers assessments also correlated significantly with the amount of attentiveness recorded, the amount that the midwife sought to enhance the woman's sense of control, created a positive environment, provided informational and verbal support and support for the partner. There was a significant correlation between the observer's quality score and the amount of time that the midwife was in the room.

Earlier observation instruments developed to measure intrapartum support have not measured any aspects of the quality of care. Only one of the earlier studies sought women's views about the support received during the study (Barnett 2008). The Barnett study found that the quantity of support behaviours recorded during the observation period did not correlate with women's satisfaction (Barnett 2008). This led the author of this study to question whether the construct validity of the observation instrument may have been improved through the inclusion of 'quality' elements such as the ability of the professional to provide a sense of empathy. McNiven et al and Gagnon and Waghorn also noted the lack of these indicators of quality as a limitation of their research.

In summary, the series of five studies developed a successful and feasible study design and method to record and measure the quantity and quality of midwifery support. The observational study was feasible and acceptable to participants in the clinical setting. The studies undertook initial testing of the SMILI for all aspects of validity and reliability in measuring the quantity and quality of intrapartum support in the real-time clinical setting. The SMILI was found in this series of studies to have a very good validity and a good level of reliability. High quality data was obtained using the SMILI that enabled analysis to be undertaken that provided new and detailed information about the quantity and quality of intrapartum support provided by the midwives in the study.

The quantitative methodology chosen was shown to be appropriate as it was successful in addressing the thesis questions. The central method of systematic observation followed by postnatal questionnaires and collection of clinical data enabled the collection of a large quantity of data relating to the quantity and quality of midwifery intrapartum support.

The main drawback of the methodology is the time consuming nature of such a study. It required the researcher to be present in the clinical area, to negotiate with staff to facilitate recruitment, to await the admission of suitable women to the clinical area and then to undertake the observations and follow up. However, using real time recording of observations directly onto a computer requires less data input than if the observational tool was on paper and takes less time than an instrument used to record data from a video or audio recording of events. The use of a team of observers was advantageous as it spread the work of observation between a number of people and reduced the reliance on one observer's judgments. However, training and support of the volunteer observers took considerable periods of the researcher's time.

10.3 DISCUSSION OF THE SUCCESS OF THE THESIS IN ADDRESSING THE OVERALL RESEARCH QUESTIONS

As the thesis specific questions were successfully addressed, it is possible to examine the extent to which the studies have been successful in answering the overall research questions.

10.3.1 Do NHS midwives in Scotland at this time provide continuous one to one care to women in active labour?

The clinical study was undertaken at four maternity units in Scotland, UK. The units at which observations took place were chosen in order to represent the variety of different in-patient maternity care settings available in the UK with a large urban consultant led unit providing care to all women, a large mixed urban/rural consultant led unit with an alongside midwife led unit, a small rural consultant led unit without an epidural service and a small midwife led unit. These units can be considered to be largely representative of the maternity care system in Scotland, with the exception that no home births were observed and no births in a rural stand alone midwife led unit. The settings in which observations were undertaken represent the settings in which the great majority of births take place in Scotland.

However, there are important differences between the current provision of maternity care in Scotland and in the rest of the UK. Most significantly for this study, the ratio of midwives to women in Scotland is high at an estimated one midwife for every 26-28 births, while in England the average is one midwife to 33 hospital births (Dunkley and Haider 2011). These differences will have a considerable impact on the ability of midwives in England to provide one to one continuous care of all women that they care for in active labour.

The study is therefore not able to answer this research question for the UK as a whole. However, it is considered that the clinical study makes a significant contribution to answering this research question for NHS Scotland.

The SMILI, through timing the midwife's presence and absence, enabled an assessment to be made about whether the care provided to the women may be described as 'continuous' or 'intermittent'. The Cochrane library systematic review of continuous versus intermittent support in labour does not define 'continuous' support in more detail than 'continuous presence' of the supporter (Hodnett et al 2011). This does not define whether this allows the supporter to leave the room for very brief periods to go the toilet for example, though it is assumed that such brief absences would be tolerated in this definition. The definition of continuous support employed in the largest randomised controlled trial was 'a minimum of 80% of the time' (Hodnett et al 2002a). The definitions of continuous support used in the randomised controlled trials reviewed are generally not provided other than very broad descriptions such as 'permanent presence' (Breart et al 1992). One study provided a little more detail stating that supporters in the continuous arm of the study were 'to be by the patient's bedside except for feeding and use of the toilet' (p40 Hodnett et al 2011). In another study, student midwives providing 'continuous' support were able to leave the room to attend births in other rooms (Hemminiki et al 1990). The NICE guidelines on intrapartum care stated that 'a woman in labour should not be left on her own except for short periods or at the woman's request' (p121 NICE 2007).

In the thesis clinical study one quarter of midwives (n=12) were present for at least 98% of the observation period, 57% (n=28) were present for at least 90% and only 8% (n=4) of midwives were out of the room for 20% or more of the observation. Absences from the room were generally brief. When a midwife went on a scheduled meal break another midwife always covered for her absence and remained in the room with the woman. It can therefore be concluded that in the four sites during this study continuous one to one care was provided to all women observed.

10.3.2 How does the support provided by midwives in Scottish maternity units compare to the support provided by maternity care providers in other maternity systems?

The only other systematic studies of the support behaviours of maternity care providers during labour have been undertaken in the USA and Canada.

The timing of the midwife's presence and absence in the thesis clinical study enabled the presence of the midwife to be compared to the presence of obstetric nurses in the earlier comparable studies undertaken in North America. This analysis (presented in Table 45 below) demonstrated that midwives were present in the room with the woman for a much higher proportion of the woman's labour than in the North American studies. This is the first study to demonstrate this specific contrast between a UK maternity care setting and maternity care settings in the USA and Canada.

All of the midwives in the thesis study were caring for one woman throughout the observation period. The nurses observed in the McNiven et al and Gale et al studies were also caring for one woman in active labour. The nurses observed in the Gagnon and Waghorn and Barnett studies were generally caring for two women at a time. In the Miltner study, 48% of the nurses were caring for one woman in labour and 44% were caring for two women. In the Miltner study, even when the nurses were caring for one woman in labour, they were present in the room for a study average of 72.3% of the observation (Miltner 2002), significantly lower than the study average for this study. McNiven and Gagnon and Waghorn noted that in their studies, even when the nurses were less busy and able to provide one to one care during labour, this did not increase the proportion of their time that they spent in the labour room or in providing supportive care (Gagnon and Waghorn 1996, McNiven et al 1992).

Table 45 – Comparison of presence of nurse or midwife between systematic observational studies

Author and year of study	**Percentage nurse or midwife in room**
McNiven et al 1992	Not calculated
Gagnon and Waghorn 1996	21.4%
Gale et al 2001	27.8%
Miltner 2002	58.9%
Barnett 2008	31%
Ross-Davie, Cheyne and Niven 2012	90.7 % (66.2-100%)

Interesting comparisons of the quantities of different support and non-support behaviours between the thesis study and the earlier North American studies can also be undertaken. Significant methodological differences between the studies make direct comparison of the descriptive data difficult. The five previous North American observation studies did not seek to measure the quantity of support offered to the birth partner by the maternity care professional but did measure the other four categories of support. The 'work sampling' approach used in the first three studies allowed only one behaviour to be recorded at each observation point (Gagnon and Waghorn 1996, Gale et al 2001, McNiven et al 1992,). The studies by Miltner and Barnett took a similar approach to the thesis study as the observer only recorded the care of one nurse caring for a particular woman in labour and enabled the observer to record more than one behaviour at a time. However, the Barnett study used timers to record when any behaviour was started and finished, gathering information about the length of time any behaviour was observed on a continual basis (Barnett 2008). The thesis study and the study by Miltner did not record the length of time that a behaviour was seen but undertook intermittent observations and recorded the presence of particular behaviours at those time points. The Miltner study recorded significantly fewer behaviour variables and observers gathered data at one minute intervals

(Miltner 2002). This study recorded a higher number of demeanour and behaviour variables gathered at approximately three minute intervals. It is clear that more behaviours are able to be observed and recorded in a longer observation period and so this may lead to a relative inflation in the description of the quantities of behaviours in the thesis study in comparison with the Miltner study.

However, although it is not possible to make direct comparisons in the quantity that supportive behaviours were seen in the different studies, it is possible to examine the proportions that the different categories of support were observed in relation to each other. In the McNiven et al, Gale et al, Gagnon and Waghorn and Barnett studies, informational support was the most frequently observed type of support provided by the nurses, followed by emotional support, with very low observed levels of tangible and advocacy support. In the Miltner study, as with the thesis study, the most frequently observed category of support was emotional support, followed by informational support, tangible support and with a very low level of advocacy (0.3% and 0.2% respectively).

Four of the five North American studies identified informational support as the most frequent category of support. These findings suggest a different emphasis in the care provided in the McNiven, Gale, Gagnon and Waghorn and Barnett studies compared to the thesis study, in which emotional support was observed far more frequently than informational support.

Other differences in the emphasis of care between the North American studies and the thesis study are apparent. While the Miltner study found that emotional support was the most frequent category of supportive behaviour, it is interesting to note that documentation activities took place twice as often as encouraging and reassuring the mother, with an average of 21.7 incidents of documentation in a two hour observation period compared to 11.07 incidents of encouraging and reassuring the mother. As observations were undertaken every minute in the Miltner study, this would equate to documentation occurring at 18% of observation points and encouragement at 9%. In the thesis study, documentation activities were noted to be present for

19% of the observations and verbal support was present for an average of 78.5% of observation points. Even when the verbal support figure is divided by three to allow for the shorter observation period in the Miltner study compared to the thesis study, verbal support would be recorded at 26.2% of observation periods. This suggests that verbal support was provided by midwives nearly three times as frequently in the thesis study than in the most comparable North American study. It also demonstrates that while documentation activities outweighed verbal support activities in the Miltner study, verbal support occurred substantially more frequently than documentation in the thesis study.

These comparisons, combined with the data relating to the proportion that the nurses were in the room with the women they care for, suggest that the approach to and emphasis of labour care by the obstetric nurses in the North American studies was very different from the midwives in the thesis study.

This contrast between the midwifery care observed in this study and the care recorded in the comparable studies in the USA and Canada is an important one when considering the relevance of the conclusions of the Cochrane systematic review of continuous versus intermittent support in labour (Hodnett et al 2011). This review stated that 'in hospitals worldwide, continuous support during labour has become the exception rather than the routine' (p1 Hodnett et al 2011). The findings of this thesis call into question the relevance to the UK of the assertion that professional employees lack the skills and time to offer appropriate levels of support to women in labour and that, as a result, other female supporters not employed by the institution are able to provide more effective support (Hodnett et al 2011). All of the midwives observed in this study were able to provide one to one continuous care to women in active labour as they had no other responsibilities. Most of the midwives had highly developed support skills and were motivated to provide support as a central part of their role. The variations in the quantity and quality of the support observed appeared to be related to individual motivations and styles rather than the professional role of the care provider.

10.3.3 What are the quantities of different types of support provided by NHS midwives in Scotland?

The clinical study undertaken for this thesis using the newly developed SMILI has provided significant new information about the quantities of different types of support provided by NHS midwives in Scotland.

The study has found that the quantities of positive and negative behaviours and non-support behaviours vary considerably between midwives. The study has indicated that emotional support is generally provided more frequently than any other positive, negative or non-support behaviours. The study has shown that higher quantities of emotional support are linked with the provision of higher quantities of informational, tangible and partner support. The quantities of different support behaviours were found to change through labour, with higher quantities of verbal support, attentiveness, informational and tangible support provided as labour progressed towards the birth. As labour progressed the quantities of indirect and assessment activities were found to reduce along with care for the partner.

The success of the clinical study in obtaining this information about the quantities of midwifery support in the four units in Scotland, suggest that this research question could be successfully explored in a subsequent larger study in maternity units in other parts of the UK.

10.3.4 What is the quality of support provided by NHS midwives in Scotland?

The clinical study produced significant new information about the quality of support provided by midwives in four maternity units in Scotland. The thesis employed a definition of quality of support in labour based on the theoretical frameworks of social support in labour, the literature identifying women and caregivers' definitions of high quality support, the definitions of quality in healthcare interactions in studies outside the maternity care setting and the Institute of Medicine definition of healthcare quality. The Institute of Medicine definition states that the six dimensions of healthcare quality are that it is person-centred, safe, effective, efficient, equitable and timely (p1 IOM 2001).

This led to a thesis definition of high quality intrapartum support as care which is person-centred and includes the demonstration of emotional, tangible, informational, advocacy and partner support. The midwife provides support to all women when it is needed, displays a positive attitude and remains with the woman they are caring for. If these criteria are met, the woman will describe feeling well supported and positive clinical outcomes are more likely. If the quality of the support is low, there will be an absence or low level of these behaviours demonstrated, the midwife will display a neutral or negative demeanour, will engage in negative unsupportive behaviours and will not remain with the woman continually. This will result in care that is less person-centred and safe, is ineffective, inefficient, inequitable and untimely. If these criteria are reached, the woman will assess the level of support she received as poor and clinical outcomes are likely to suffer.

Measurement of the quality of intrapartum support employing this theoretical framework calculated the frequency that key elements of the presence of the midwife in the room, any negative behaviours, emotional, tangible, informational, advocacy and partner support were displayed during the observation period. These frequency calculations were then correlated with women's perceptions of the support received and other clinical outcomes to enable an assessment of the quality of the support.

Using this definition, the study found that the quality of support was high for the majority of midwives and was assessed as being of high quality by the women receiving the care. The study did identify considerable variations in the quality of support provided by the midwives in the study.

This study is the first to seek to record the frequency of negative behaviours and demeanour in an intrapartum setting. This found that neutral and negative demeanour of the midwife correlated significantly with negative behaviours. The study found that women's assessments of the support they received were lower when more negative behaviours were observed.

The study found clear correlations between higher quantities of positive support behaviours and higher assessments of the support received by women. Correlations were also found between higher quantities of positive support behaviours and fewer medical interventions and more vaginal births.

The definition of quality in intrapartum support is, however, a complex one. No one clear picture of a midwife who is good or bad at providing support emerged through the correlation of the postnatal questionnaire results and the SMILI data. The analysis did not support a definition of high quality midwifery support that would prescribe the specific correct amounts of different positive behaviours and the absence of negative behaviours. Such a clear prescriptive definition may not be possible for such a complex intervention. However a clearer definition may be possible following subsequent larger studies.

10.3.5 What are women's perceptions of the support provided by the midwives caring for them?

The answer to this question is closely related to the question of the quality of support addressed immediately above. Women's perceptions of the support provided to them were, in this study as in other studies, generally very positive.

The results from the original study by Ford and Ayers with an online sample of 427 postnatal women within 3 years of birth (Ford, Ayers & Wright, 2009) found that the average scores were: Internal control:3.29, External control:3.27, Support:3.69 . The results of this study show considerably higher assessments of internal and external control and support than the original study, with the average internal control score 3.6, external control 4.1 and support 4.59. This is likely to be partly due to the 'halo effect' recognised as being prevalent in early postnatal studies (Simkin 1991,East and Colditz 1997, Stelmarck et al 2006), as the Ford and Ayers study was carried out over a much longer postnatal period than the 48 hours in this study.

Consideration may be given in a subsequent study to employing a more detailed longer-term postnatal questionnaire with women about the specific support they received to enhance the

ability of the study to develop an evidence-based definition of high quality support from the woman's perspective.

The findings of this study support the findings of earlier research with women about what kind of support is of particular importance to them, with the clear emphasis placed by women on the presence of the midwife and the amount of emotional support.

10.3.6 Are there any associations between the quantity and quality of the support provided by midwives and women's perceptions and other clinical outcomes?

The study was not designed to be a full-scale observational or experimental study exploring the impact of the quantity and quality of midwifery support on clinical outcomes. The study was designed to test whether the SMILI would be an effective instrument to be used in a later full-scale study.

As described above, the study has identified some correlations between the quantity and quality of the support provided and both women's views and the key clinical outcomes of type of birth and number of medical interventions.

These findings indicate that the SMILI would be an effective means of measuring the behaviours of caregivers in order to test relationships with clinical outcomes in future studies.

In summary, the thesis studies have been successful in undertaking the necessary feasibility and pilot testing of the new SMILI to ensure that future larger observational or experimental studies could fully answer the research questions posed and substantially address the current gaps in our knowledge of intrapartum support.

10.4 LIMITATIONS OF THE RESEARCH

The research undertaken for this thesis has a number of limitations.

Firstly, the study is limited in terms of its generalisability due to the limitations in the research settings and participants. All of the observations were undertaken in Scotland. The practice of midwifery in the NHS in Scotland may differ in some key respects from other parts of the UK and internationally. The great majority of the observations took place in consultant led maternity units with an epidural service. Only four observations took place outside of this context in a midwife led unit and a consultant led unit with no epidural service. None of the observations took place at home.

While the woman and midwife participants in the study provide a reasonably representative sample of the UK population in terms of risk factors, parity, age, use of pain relief, type of birth, type of midwifery training and years of experience, they do not comprise a representative sample of the UK population in terms of ethnic diversity.

A second limitation of the study may be considered to be the limitation of the focus of the research to midwives. The study did not explore the question of who is best placed to provide intrapartum support through the comparison of different possible providers of intrapartum support such as 'doulas' or the woman's chosen birth partner. This decision was made consciously to undertake a study which explored in depth what is 'normal care' in the current UK NHS, that is with midwives providing all of the intrapartum care for the majority of women, with a birth partner also present. The developed instrument would be amenable to some minor alterations to allow it to be used to record support in non-hospital settings and by non-midwife supporters.

A third potential limitation of the clinical study is the unknown impact of the presence of an observer in the labour room on the quantity and quality of the care provided. Though careful precautions were taken in this study to ensure that the observer was as unobtrusive as possible, the midwives being observed had been made aware of the overall purpose of the

research and that the observer would be recording the supportive elements of care. The effect of an observer or researcher on participants cannot be measured. It is possible that the quality of care provided by the observed midwives was on occasion of a higher level than may be expected with no observer present. However, the identification of substantial variations in the behaviours of the midwives and the presence of some negative behaviours suggest that the observers were successful in being unobtrusive and limiting their impact on the care provided.

A number of limitations in the study design should be acknowledged. The limitation of the sample population in study two to student midwives, mainly in the first year of their studies, may have limited the participants' ability to judge the content validity of the instrument fully. Secondly, testing of the inter-rater and intra-rater reliability of the instrument was limited to observation of videos and not undertaken in the clinical setting. Thirdly, accurate consent rate numbers and reasons for non-participation were not collected in the clinical study and would be required in a larger study. Finally, it may be considered that the quantitative data produced using the SMILI and postnatal questionnaire is limited in the depth with which it is able to describe the intrapartum support observed and experienced. In future studies, the use of the log to systematically gather more qualitative data and postnatal qualitative interviews with women may be considered.

A number of areas identified in the literature review have not been addressed in this thesis. The thesis studies have not explored the role played by women's expectations on their satisfaction with the support received (Green et al 1998, Hauck et al 2007), the concept of control (Larkin and Begley 2009) or the role of continuity in the quality of support (Lavender and Walkinshaw 1998, Tinkler and Quinney 1998, Lavender et al 1999). It was felt that undertaking data collection about women's expectations of the labour before the observational study would have created a very complex study which could have reduced the sample size. Data relating to women's sense of internal and external control during labour were collected using the SCIB questionnaire, however the analysis exploring the relationship between the labour care observed and women's sense of control has not been included in this thesis as it was felt to

distract from the central focus on the concept of support. These data will be further analysed and published at a later date. No exploration of the impact of continuity of carer was undertaken in this study, as none of the midwives had met the women they cared for prior to meeting them in labour.

10.5 THE CONTRIBUTION OF THE RESEARCH IN RELATION TO ESTABLISHED THEORY AND PREVIOUS RESEARCH

The development of a new valid and reliable systematic observation instrument is a key contribution to methods of investigation. The content of the instrument was based on a comprehensive review of current literature. The validity and reliability of the instrument have been tested and found to be good in the particular context of these studies. The instrument is the first systematic observation instrument of intrapartum care that seeks to measure the quality of the support observed as well as the quantity of support behaviours. The results indicating associations between the quality aspects recorded and women's views of care indicate that the SMILI has been successful in measuring key aspects of the quality of support.

The research findings confirm a number of key findings from earlier research. The theoretical framework developed from the cognitive-phenomenonological model of stress, appraisal and coping (Lazarus and Folkman 1984) suggests that women are enabled to cope with the stress of labour through the provision of positive support. The correlations found in this study between higher levels of presence of the midwife and emotional support and fewer medical interventions, operative deliveries and maternal dissatisfaction appear to affirm this theory, though a causative relationship between the variables cannot be confirmed by this non-experimental study.

Three main theoretical categories of intrapartum support have been proposed in earlier research: emotional, tangible and informational. Some research has proposed two further categories of advocacy and support of the partner. The research undertaken for this thesis has generally confirmed the theoretical categories of intrapartum support identified in previous

research. Emotional, tangible, informational and partner support were observed and recorded in all of the observations undertaken or, if they were not seen, their absence was felt by the observer. Advocacy, however, appears to sit less securely as a key category of support. Advocacy was very rarely seen, but was felt to be also very rarely necessary in the observations undertaken. A team approach to the provision of care and decision making between midwives, women, birth partners, obstetric and anaesthetic colleagues was the norm in the observations. It would be suggested from these research findings that advocacy is a sub-category of the emotional support category. Advocacy would be a very important category of support in contexts where decision-making about interventions and analgesia were made in a less collaborative way than in the research settings of this study.

The literature review identified the mechanism of action of labour support as an area that has been less extensively explored. One theory proposed is that women respond to stressful situations differently from men and that rather than having a 'fight or flight' response have a 'tend and befriend' response to stress (Taylor et al 2000). The importance of verbal support, rapport building and support of the woman's chosen partner identified in this study seem to reinforce this theory. The amount of verbal support specifically and emotional support generally was found to have a greater correlation with the type of birth than the woman's age, analgesia used and indirect care activities of the midwife. The findings of this study suggest that in order to enable normal progress and promote the likelihood of a normal birth, caregivers are wise to focus on the woman's needs for companionship and positive verbal communication.

The central importance of emotional support to women's, observers' views and outcomes is clear in this study, confirming findings of earlier research that emotional support is more important to women than informational or tangible support (Bryanton et al 1994).

The research confirms that negative behaviours by the caregiver have a significant negative impact on women's assessments of the care they received (Hodnett 2002).

Though the study is not able to make any claims about causation, the correlations found reflect the findings of the systematic reviews of randomised controlled trials that continuous support increases the rate of spontaneous vaginal birth, reduces the number of operative deliveries, reduces women's negative feelings about their care and reduces analgesia use (Hodnett et al 2011).

The research confirms that midwives value their support role as one that is central to the care of women during labour (Kennedy 2000, Miltner 2000). Midwives provided support more frequently than they carried out other types of care, with emotional support being recorded far more frequently than other direct or indirect non-support care activities, including documentation.

The importance for women of their chosen birth partner being offered support by the nurse or midwife providing care has been identified in earlier research (Szeverenyi 1989, Gungor and Beji 2007, Kainz et al 2010).The quantity of support offered to the partner in the study was the lowest of the support categories, with the exception of advocacy, with this type of support observed in only 7.5% of observation points. Women's satisfaction with the support provided to them overall in labour was found to correlate significantly with the amount of support offered to their partner. This identifies an area where women's experience of midwifery intrapartum support could be substantially improved.

Earlier studies with women have identified that where they have been left alone more in labour they also reported not being treated with respect and dignity or given adequate explanations (Healthcare Commission 2008). The thesis study supports this evidence with the finding that where the midwife spent more time out of the room this correlated with a more frequent observation of a neutral demeanour, less verbal, emotional and informational support, a higher level of inattentiveness and with the woman being less active.

10.6 CONCLUSION –

‘WE CAN ONLY BE SURE TO IMPROVE WHAT WE CAN MEASURE’ (Darzi 2008)

The research described in the thesis has made a significant contribution through the development of a robust evidence-based systematic observation instrument. A key finding of the thesis is that the developed instrument, the Supportive Midwifery in Labour Instrument (SMILI), is successful in fulfilling the task for which it was designed: to measure the quantity and quality of intrapartum support.

The research studies have demonstrated a feasible and acceptable systematic observational research study in the intrapartum setting. The completion of 105 hours of direct observation of 49 labour episodes represents the largest study of intrapartum support conducted in the United Kingdom.

The SMILI is the first instrument devised to enable an observer in a labour room to systematically record a number of key aspects of the labour episode, including the attitude, demeanour and behaviours of the woman, her birth partner and the midwife. It enables the care observed to be placed in the context of the setting in which it took place. The SMILI produces data relating to the presence and absence of the midwife from the room, the frequency of positive supportive behaviours, negative behaviours and other care activities. These data can be analysed to produce meaningful data to allow comparisons between midwives.

The study has been successful in providing new information about midwifery intrapartum support provided by NHS Scotland midwives. The midwives observed for the study provided one to one care to women in active labour, with only a small minority present in the room for less than 90% of the time. The midwives provided emotional support most frequently, followed by informational and tangible support, with partner support and advocacy seen most infrequently. Supportive activities were seen more frequently than non-supportive direct and indirect care.

The postnatal data collected in the study through postnatal questionnaires with women and clinical outcomes data enable connections to be sought between the quantities of particular behaviours seen and key outcomes, thus enabling meaningful assessments about the quality of the support to be made. Women participants appeared to value emotional support, particularly rapport building, most highly in the care they received. Significant correlations were found between the quantity and quality of midwifery support observed and clinical outcomes. The study identified that NHS midwives in Scotland at this time generally provided high quality support that was rated highly by the women they cared for. The majority of midwives provided significant quantities of emotional, tangible and informational support and demonstrated a positive and supportive attitude.

However, a minority of midwives did not provide continuous support to the women they were caring for, although they were only allocated one woman to care for. Some women did not feel well supported. Some midwives provided very little emotional support to the woman in their care, some provided no support to the woman's birth partner and some used belittling or sarcastic humour or ignored women's wishes. The support observed therefore showed significant variations which mean that it cannot be described as consistently of high quality. The identification of these variations in quality is also a strength of the research. The variations indicate the sensitivity of the SMILI to identify differences between midwives and suggest that the manner in which the observations were undertaken was unobtrusive enough to allow variations in behaviours to emerge.

10.6.1 Implications for future research and clinical practice

The research undertaken for the thesis raises a number of further questions which require exploration in future larger studies: Is the SMILI a valid and reliable observation instrument for the measurement of midwifery support elsewhere in the UK and internationally? Can the SMILI be used to measure the support provided by other care providers in other settings including obstetric nurses and doulas? Can the SMILI be used as an intervention to improve the quantity

and quality of intrapartum support by assisting observers to provide detailed, evidence based, constructive feedback to midwives about the care they provide? Would the correlations identified between the quantity and quality of support and clinical outcomes in this study be replicated in a larger experimental study? Is it possible to define 'high quality intrapartum support' as a specific set of behaviours? Would women in different settings and from different cultures assess the support provided to them differently from the women in this study? What is the impact of the partner's behaviour on the midwife's behaviours?

The methodology used and tested for feasibility in the main clinical study, using systematic observation followed by postnatal questionnaires identifying women's views and the collection of clinical outcomes data, could be used in future large scale studies in a variety of different settings.

The Supportive Midwifery in Labour Instrument has the potential to make a substantial contribution in future large scale observational or experimental studies of intrapartum support. The standardised quantitative approach to data collection will enable comparison of results at many levels: between individual practitioners, between different care providers, between institutions and between maternity care systems. The identification of associations between particular support and non-support behaviours and clinical outcomes in such large trials would contribute significantly to the development of labour support theory, the definition of high quality support and the identification of the mechanism of action of support in improving outcomes and promoting normal birth.

The SMILI has potential to be used as both a research tool and as a practice development aid. The benefits of training health professionals using evidence from the systematic measurement of care provided has been recognised and demonstrated in other non-maternity settings (Razavi et al 2002, Caris-Verhallen 2004):

'…*simply giving nurses new protocols to follow is not enough to change patterns of interaction. Education programmes should be evidence-based and pay attention to both verbal and non-*

*verbal communication in realistic situations. Good measurement tools are needed to detect inadequate and adequate communication patterns' (*p319, Caris-Verhallen 2004). The results of this study and of any larger study using the SMILI will provide good evidence about what kind of support has the most beneficial effect for evidence-based training for midwives and student midwives.

As with other systematic observation instruments such as the RIAS (Roter Interaction Analysis System, Roter and Larson 2002), the SMILI could be used to provide individual midwives with structured detailed feedback about the care that they provide. Midwives would be enabled to compare their behaviours with the quantities of those behaviours demonstrated by other midwives. The use of the SMILI as a positive practice development aid could be evaluated in a subsequent study.

Overall, the SMILI has the potential to assist midwives and other caregivers to understand more fully the role of support in improving women's experiences and the clinical outcomes of childbirth.

Final word

The research described in this thesis facilitates the measurement of the quantity and quality of midwifery support in labour. Through this measurement new knowledge about the nature and impact of support has been and will be generated. This knowledge can contribute to the improvement of the quality of support and thus to the enablement of women to have the most normal birth possible:

'It is only with careful and systematic inquiry about the nature of midwifery care that the profession can clearly define and explicate a model of excellence that can be upheld as a standard for all women' (p4 Kennedy 2000).

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12. APPENDICES

Appendix One Summary of Randomised Controlled Trials												
Principal Investigator	**Year**	**Country**	**Subjects**	**N**	**Lay/ Professional**	**Early/ Late**	**Continuous?**	**High/Low Interventions Epidural**	**Overall Effect**	**Positive Effect**	**No Effect**	**Issues Identified?**
Sosa et al	1980	Guatemala	Primips, low risk, no partners	127	Lay doulas	Early 1-2cm	Yes	Low – no epidural	Very good	LSCS 19 v 27% Oxytocin 6 v 17%, Shorter length 8.7 v 19.3 SVD 63 v 21%	None identified – psychological outcomes not measured	Hodnett excludes as states not properly randomised
Klaus et al	1986	Guatemala	Primips, Low risk, No partners	465	Lay doulas	Early 3-4cm	Yes	Low No epidurals	Very Good	LSCS 7 v 17% Oxytocin 2 v 13% Shorter length 7.7 v 15.5%	None identified – psychological outcomes not measured	
Cogan	1988	USA	Primips – high risk – premature labour	25	Lay doulas with training	Early	Yes	High	Good	Less pethidine use, shorter labour, higher apgar score	Fetal distress, oxytocin, operative delivery	Too small, different population – premature labour
Hodnett	1989	Canada	Primips, low risk, Western with partners	103	Lay labor coaches/lay midwives	Early – at home	Yes	High Epidurals 70%, synto 33%	Partial	Better psychological outcomes, Came to hospital more dilated 3.6cm v 2.2cm, More likely to have no pain relief, deliver without stirrups and have intact perineum	ARM, EFM, operative delivery Labour length More oxytocin	Type of support more significant than type of antenatal education, anxiety or commitment to unmedicated birth
Hemminki	1990	Finland	Primips and multips- could be 35 weeks,included induced women Western with partners	230	Professional – student midwives, also a small doula study	Late <8cm	No – students allowed to attend other births, a lot of resistance to the idea of providing continuous support from students and midwives	Low – no epidural	Very limited	Sub-analysis showed that for primips only 18% had a labour longer than 11 hours if supported, while 44% in control group	Induction 8-10%, LSCS, Instrumental delivery, pain relief 57 v 64%	This trial finished early due to all the problems and resistance – raised questions about quality of support when done so unwillingly

Appendix One contd Summary of Randomised Controlled Trials												
Principal Investigator	**Year**	**Country**	**Subjects**	**N**	**Lay/ Professional**	**Early/ Late**	**Continuous ?**	**High/Low Interventions Epidural**	**Overall Effect**	**Positive Effect**	**No Effect**	**Issues Identified?**
Kennell et al	1991	Houston, Texas, USA	Primips, low risk, low income, no partner	612	Lay with training, observer, then control	Early 3-4cm	Yes	High – epidural 55% in control group, oxytocin 44%	Very good	LSCS 8, 13 v 18% Forceps 8 v 26% SVD 84 v 69 v 60% Epidrual 8 v 55% Oxytocin 17 v 44% Length 7.4 v 8.4 v9.4 hours		
Hofmeyr, Nikodem and Woman	1991, 1993, 1995	South Africa	Primips	189	Lay doulas	Mid <6cm	No – only available daylight hours	Mid – high ARM rate of 71% across board No epidurals	Partial	Psychological effects most marked – lower anxiety, lower perceptions of pain, lower BP, better apgar scores, improved breastfeeding rates	LSCS 12% v 14.4% Analgesia – though was given later and less	
Breart (x3)	1992	Europe – Belgium, France and Greece	Primps, Low risk	2153	Professional – usual staff	Late <7cm	Not described	No details	Partial	In France and Belgium Operative delivery rate 30% v 35%,	In Greece operative delivery rate 27 v 29%	Very little information, brief publication, no other outcomes described, no details about usual care or the intervention
Langer Campero	1998	Mexico	Primips, low risk	724	'Lay' – but retired nurses, trained	Mid <6cm	Yes	High – epidural 88%	Limited	Shortened labour 4.56 v 5.58 hours, Increased exclusive breastfeeding 12 v 7%, higher level of control	Apgars, meconium, satisfaction, anxiety, self-esteem, epidural or LSCS (23 v 27%)	

Appendix One contd Summary of Randomised Controlled Trials												
Principal Investigator	**Year**	**Country**	**Subjects**	**N**	**Lay/ Professional**	**Early/ Late**	**Continuous ?**	**High/Low Interventions Epidural**	**Overall Effect**	**Positive Effect**	**No Effect**	**Issues Identified?**
Gagnon	1997 and 1999	Canada	Primips, low risk	413	Professional – nurses employed from outside unit staff- 30 hours training	Early <4cm	'Almost' allowed 20 mins for meals and 10 mins for breaks every 4 hours, after 10 hours handover or stayed	High epidural	Very limited	17% reduction in use of oxytocin –not statistically significant unless looked at the amount of augmentation after randomisation	Labour length, LSCS rate (13.9 v 16.2%), instrumental delivery, NICU or perineal trauma	On average 5 hours spent in unit before randomisation – 17% had epidural before randomisation and 26.3% had oxytocin before randomisation. Care before randomisation, possibility of sub-optimum support, insufficient power
Gordon	1999	USA	Primips, Partners	314	Lay doulas	Early <5cm, but some delay on admission as called in	Yes	High Epidural	Partial	Epidural 54% v 66% Positive birth experience 82.5 v 67.5% Felt coped well 46.8% v 28.3%	LSCS,forceps, oxytocin, breastfeeding, length of labour	30% excluded post-randomisation so excluded from meta analysis by Hodnett
Madi	1999	Botswana	Primips, low risk, No partners	109	Lay – female relatives	Early <6cm, accompanied to hospital	Yes	Low No epidurals	Very good	LSCS 6 v 13% SVD 91% v 71% Analgesia 53% v 73% Oxytocin 13 v 30% ARM 30 v 54% Ventouse 4 v 16%	Not identified	Normal staff ratio 1 to 4

Appendix One contd Summary of Randomised Controlled Trials												
Principal Investigator	**Year**	**Country**	**Subjects**	**N**	**Lay/ Professional**	**Early/ Late**	**Continuous ?**	**High/Low Interventions Epidural**	**Overall Effect**	**Positive Effect**	**No Effect**	**Issues Identified?**
Torres	1999	Chile	Primips, low risk	435	Lay – woman chosen by woman, trained by trial staff	Early	Yes	?Low – epidural available, no info re EFM	Partial	Oxytocin .98 SVD RR 1.02 Low apgar RR 0.2 -ve feelings RR .83 No difference in cs rate or analgesia use	Length of labour, postpartum depression	All women labouring in shared room with curtains round
Dickinson	2002	Australia	Primips, , term, Included induced women	800	Professional – ordinary midwives no additional training	Early <5cm	? No description of care given	High – 61.3% of women in the continuous support group crossed over into epidural group	Good	Increased SVD rate 6.6%, RR 1.16, Reduced instrumental delivery RR 0.87, Reduced LSCS RR 0.83, better apgars,	Satisfaction	Slightly different trial – was testing difference between continuous support and epidural, compliance with the continuous support group was only 40% and 75% with epidural group.
Hodnett	2002	Canada	Multips and primips, could have complications – 34 weeks, twins, inductionWestern partners	6915	Professional – nurses from unit staff who volunteered and received 2 days training	Late – '2nd stage not imminent'	No – no more staff deployed to enable continuous care, just offered consultancy on deploying staff effectively. 'Minimum of 80% of time'	High, Epidurals 75% Augmentation 30%	Very limited effect	Increased satisfaction	LSCS, length of labour, neonatal outcome, operative delivery, analgesia, augmentation	25% induced 6% had epidural prior to randomisation 4.9% previous LSCS 1.5 hours from admission to randomisation. Weak intervention? Previous Hodnett study showing how difficult to change amount of support given. Importance of context – need also to change culture through team approach, shared philosophy, audit

Appendix One contd Summary of Randomised Controlled Trials												
Principal Investigator	**Year**	**Country**	**Subjects**	**N**	**Lay/ Professional**	**Early/ Late**	**Continuous ?**	**High/Low Interventions Epidural**	**Overall Effect**	**Positive Effect**	**No Effect**	**Issues Identified?**
Thomassen	2003	Sweden	Primips	144	Lay - doula		Yes		Partial	Only CS rate compared		High drop out rate, study discontinued at only ¼ of planned recruitment
Campbell	2006	USA	Primips	600	Lay – family or friend chosen by woman, some training	Early – from admission	Yes	High – epidural rate 88%, oxytocin use 49%	Partial	Shorter labours 10.4 v 11.7 hours, more dilated at time of having epidural;	Epidural, LSCS rate, oxytocin use,	Whole study had lower LSCS rate than general hospital rate – a lot of women (30-40%) of women in control group brought 1-3 women companions with them – made aware by study of benefits
Bruggemann	2007	Brazil	Primips,	212	Lay - partners	Early – from admission	Yes	High – active management -admission, analgesia and amniotomy on average in less than 2 hours	Very limited	Increased satisfaction, reduced meconium	No difference in any other clinical outcome – LSCS, operative delivery, analgesia, length of labour, augmentation	Aim to show partners being present improves satisfaction and does not interfere with hospital policies such as active management.
McGrath and Kennell	2008	USA	Primips, Included induction, Middle class with partners	420	Lay doulas	Early-within 1 hour of randomisation	Yes	High Epidurals	Good	LSCS 13.4% v 25% Epidural 64% v 76% CS rate among induced women 12.5% v 58.8%	None identified	Published 20 years after research

Appendix One contd Summary of Randomised Controlled Trials												
Principal Investigator	**Year**	**Country**	**Subjects**	**N**	**Lay/ Professional**	**Early/ Late**	**Continuous ?**	**High/Low Interventions Epidural**	**Overall Effect**	**Positive Effect**	**No Effect**	**Issues Identified?**
Morhason-Bello	2009	Nigeria	Primips and Multips, Low risk, No partners in control	585	Lay – mostly husbands	Early <6cm On admission	Yes	Low No epidurals	Very good	LSCS 8.2% v 22.3% Satisfaction 63% v 32% Duration of active phase 4.7 v 5.3 hours Interval between birth and breastfeeding 16 v 60 minutes	Pain score Oxytocin 17.5% v 19.2% Non-signif Analgesia 28.8% v 30.5% non signif	Experimental group more highly educated - ?failure of randomisation
Kashanian	2010	Iran	Primips	100	Midwives	Early	Yes	Low – no epidural	Very good	LSCS RR.33 Low apgar RR .33 Synto RR .58	No length of labour, analgesia, SCBU admission or negative feelings	Experimental group in side room with midwife, control group in shared room with 5-7 other women

Appendix Two – Summary of Systematic Observation Studies of Intrapartum support

McNiven P, Hodnett E, O'Brien-Pallas L (1992) 'Supporting women in labor: a work sampling study of the activities of labor and delivery nurses' Birth, 19,1, 3-8

Design: Piloted a work sampling method to determine the proportion of time the average intrapartum nurses at a Toronto teaching hospital spends in supportive care activities.

Method:616 random observations of 18 nurses. Four day shifts – 32 hours. Every 15 minutes.

Observation tool: List of activities developed by Hodnett and Osborn as part of their 1989 RCT examining continuous support in labour, with some 'minor revisions' to make it suitable for use in direct observation.

4 dimensions of intrapartum support: emotional, informational, tangible and advocacy. Other activities divided into other activities in presence of the patient, indirect care activities out of room , all other activities and meal breaks. Mutually exclusive and exhaustive list. Observations not made about the presence of family members or other supportive persons. Method pre-tested for one 8 hour period.

Results: Total support activities 9.9%. Physical comfort 0.3%, emotional support 2.6%, instruction/information 6.6% and advocacy 0.3%. Other direct care was 38.9%, indirect care 42.5% and meal breaks 8.6%.

Gagnon A and Waghorn K (1996) 'Supportive care by maternity nurses: a work sampling study in an intrapartum unit' Birth, 23,1, 1-6

Design: Work sampling study examining how much time intrapartum unit nurses spend providing supportive care overall and during weekday and weekend shifts.Part of a larger RCT to evaluate the effect of one to one nurse labor support on outcomes – this study had found that it was not possible to ascertain the amount and type of support given through notes review and so this study instigated.

Method: Four-hour observation periods randomly selected to represent each shift and day of the week.Within each period, 8x 15 minute observation times were randomly selected. Observers located each nurse and recorded her activity. Montreal Canada, birth unit with 4000 births a year. 3 week data collection period. 3480 observations.Generally each nurse scheduled to attend 2 women in labour. Only one behaviour recorded – if one was supportive this was recorded.

Observation tool: Core list of activities developed and used in two previous studies (Hodnett and Osborn 1989 and McNiven 1992). Specific non supportive activities were added and the total list was modified to ensure that all activities were mutually exclusive and collectively exhaustive. Six broad categories:Supportive care: physical (8 items), emotional (3 items), instruction /informational support (5) and advocacy (3)Direct care (monitoring, vital signs, pericare, giving IV meds, position changing to get better EFM.)Indirect care in room – assisting with procedures, charting, postpartum care. Indirect care not in room – preparing IVs, getting equipment, giving or taking report, discussion with other staff, social discussions. Off the unit – meetings, meal breaks.

Results: Supportive care took place 6.1% of the time based on 3367 observations.50.5% of supportive care was instruction and information, advocacy 5.8%, physical comfort 26.7% and emotional support 17%.Did not vary significantly between different shifts – day or night or weekend.Those with less than 7 years experience spent 2.7% more their time offering support than those qualified for more than 7 years.Nullips received 9.2% more supportive care. With or without epidural similar amounts of supportive care.47.6% of time was 'indirect not in room' 37.1% of this time was spent reporting on condition of woman to other staff, 285 in preparing medications and 21% in documentation.

Direct care in room 10.6%. Indirect in room 4.7%. Nurses in room for 21.4% of time. 27.3% of time spent off the unit.

Gale J, Fothergill-Bourbonnais F, Chamberlain M (2001) 'Measuring nursing support during childbirth' American Journal of Maternal and Child Nursing, 26,5, 264-271

Design: Exploratory, descriptive work sampling study to determine the percentage of time nurses spend in supportive care activities.

Method: 12 nurses over 6 non-consecutive day shifts on a birthing unit of a Canadian teaching hospital. 404 observations were made. Researcher walked around unit every 9-20 minutes and noted down the activity currently engaged in by each of the nurses encountered. Activities were mutually exclusive: if two activities taking place at once, then supportive activity noted down or first activity seen if neither supportive. The staff: woman ratio throughout the study was 1:1.

Observation tool:The list of supportive nursing activities identified on the observational checklist had been developed for Mc Niven's work sampling study, 1991 and was also used by Gagnon and Waghorn 1996, based on previous qualitative research with women about what they considered the most helpful to them during labour. Activities were coded as 'supportive care (physical care for comfort purposes, emotional support, instructional/informational support and advocacy actions) or 'other' (direct care i.e. physical care for purposes of physical assessment or performance of procedures, indirect care in room, indirect care not in room and all other activities).

Results: 12.4% of time spent in supportive care,8.7% in other direct care,6.7% indirect care in room.,38.8% indirect care not in room and 33.4% all other (charting out of the room, checking the satellite fetal monitor, meal breaks and personal time and social discussion). Only 27.8% of their time was spent in contact with labouring woman. Of the supportive care observed 70% was informational/ instructional.

Miltner R (2002) 'More than support: nursing interventions provided to women in labor' JOGNN, 31,6, 753-761

Design: Descriptive, observational to describe the type and quantity of interventions provided to women in the first stage of labor. USA.

Method: 24 RNs (all of RNs employed on the unit) caring for 75 women in labor with singleton pregnancies. 75 x 2 hour episodes of care, 150 hours of observation over 4 month period. Researcher stayed in room when nurse in the room, followed her out when she left. Observations recorded every minute. Nursing activities were recorded as either one of the 23 specific nursing interventions or as 'other'. All activities were recorded, so that if two activities going on at the same time, both recorded. In 48% of episodes, the nurse was assigned only to the study patient, in 44% the nurse had two patients and in 8% the nurses had three patients.

Observation tool: Developed for the study and called the 'Intrapartum nursing observation tool'. This was divided into the categories devised in creating the 'Intrapartum care management model' developed by Miltner from a Delphi study with intrapartum nurses. These were: surveillance/assessment, care management (or indirect care interventions), informational support, emotional support or physical support. Indirect care interventions: documentation of care, procedure preparation, assisting other health care professionals, discussing care with other health care provided. Surveillance interventions: reviewing and completing admission history and physical examination, monitoring maternal vital signs, interpreting EFM, administering medication, epidural anaesthetic care, fetal resuscitation. Informational support: Info and suggestions re relaxation, pain relief, fetal status, procedures and pushing.Emotional support: remaining with mother if anxious or fearful, coaching during contractions, praising mother for her efforts, encouraging/reassuring mother. Physical support: position change for comfort, ensuring adequate urinary elimination, pelvic rocks/tilts, assisting with or encouraging ambulation.

Results: Nurses spent 58.9% of the observed time in direct or indirect care of the patient, 25.4% of time in direct or indirect care of other non study patients and 15.7% in nonpatient care activities. The mean number of total nursing interventions provided to the study patient during each 2-hour episode was 169.9. The mean number of surveillance interventions was 41.3, indirect care interventions was 49.3, supportive care interventions was 79.4.The mean number of informational support interventions was 21.8, emotional support 42.3 and physical support 15.4. The most common nursing interventions were documenting care, encouraging or reassuring the mother, interpreting EFM data, discussing care with other health care providers and assisting other health care providers. A lot less time caring for patients when assigned to more than one.

Appendix Two Contd: Summary of systematic observation studies of intrapartum support

Barnett G (2008) 'A new way to measure nursing. Computer timing of nursing time and support of laboring patients' Computers, Informatics, Nursing, 26,4,199-206

Design: Observational descriptive study to use an innovative computerized program to measure simultaneous nursing time and support activities during the first stage of active labor. A time study rather than a work sampling study: uses observation and exact measurement of the time it takes to complete a studies activity. Work sampling records the frequency of care occurrence rather than actual amount of time spent in care. This study from the point of view of the woman rather than the nurse – researcher stays in room with woman and records the care received rather than following nurse round and recording care given.

Method: US urban community hospital, 270 deliveries a year. Convenience sample of nurses and laboring women. Women nullips and multips, 37-42 weeks, in or near active first stage of labor. 17 nurses and 30 women agreed to participate. Continuous timing used when nurse entered room and when she left. Repetitive method used to record other events – the observer starts the timer at the beginning of each event of interest and stops the timer at the end. 97% received an epidural. Average observation time per patient was 170 minutes range of 30 to 240 minutes. Nurses in this study routinely cared for 2 women in labour at once. 805 cared for 2-4 patients during the observation period.

Observation tool: Used Hodnett's 4 areas of categorization of supportive care. 1. Time in room. 2.Time out of room. 3.Professional activities (assessment of mother and baby, performing or assisting with medical procedures, documenting, teaching others, communicating with other health professionals). 4. Emotional support (physical presence, verbal affirmation, reassurance, encouragement, distraction, attention, eye contact, visualisation, expressions of concern or caring, humor, social interaction, encouragement of the support person, praise). 5. Physical support (assisting with positioning, giving massage, reassuring touch, holding, promoting relaxation, promoting hygiene, giving heat or cold compresses, offering food or fluids, providing acupressure, providing hydrotherapy). 6. Instructional support (directing, coaching, giving advice, teaching, explaining, offering options) 7. Advocacy (supporting behaviours and decisions, conveying or negotiating client wishes).On/off for each of these timers. Assessment of mother and fetus was timed as both emotional support and other professional activity when the nurse made eye contact or spoke to the laboring woman.

Results:

Nurses spent 31% of the time in the room. During the time the nurses were in the room, they spent an average of 40% of their time in supportive care. 40% of this was informational, 37% emotional, physical 20% and advocacy 3%.When support is viewed from the point of time spent in active phase labour, women experience nursing support for only 13% of that phase. Other professional activities (teaching others, documenting, notifying, assessing, maintaining/applying equipment, stocking/procuring supplies, assisting other professionals) occupied 63% of the nurses' time while in the rooms.70% of the time in the room, nurses were involved in just one activity. 20% of time engaged in 2 activities.

Appendix Three: Support in labour – Operationalisation for observation

Components of Nursing Support identified in literature	Operationalisation of observable supportive behaviours	Negative/Unsupportive behaviours
Emotional		
Nursing presence (Lesser & Keane 1956 , Shields 1978, Tarkka and Paunonen 1996, Bowers 2002, Tumblin 2001, Miltner 2000,Matthews and Callister 2003)	• In room (Barnett 2008) • In room with no task being performed 'keeping company' (Gagnon 1996, McNiven 1992, Miltner 2004) • Showing undivided attention – eye contact, woman-directed gaze, leaning forward, proximity (Barnett 2008) • Demonstrates active listening (non-verbal, verbal reflecting and response to cues) (Ross-Davie)	• Out of room • Only in room when task to perform • Distracted • Ignores cues
Acceptance of attitudes, beliefs and behaviours (Lesser and Keane, Bryanton, Kintz, Tarkka and Paunonen) Caring for woman as an individual (Field 1987, Kintz 1987, Bryanton 1994, Tarkka and Paunonen 1996, Holroyd 1997, Powell- Kennedy 2000, Tumblin 2001, Abushaika 2008)	• Woman encouraged to express expectations, attitudes and beliefs (Gagnon, Gale 2001) • Discussion of birth plan – expression of support in achieving (Gagnon, Gale) • Encouragement to do whatever feels right/helpful (Ross-Davie) • Showing undivided attention – eye contact, woman-directed gaze, leaning forward, proximity (Barnett 2008) • Woman given opportunity to express expectations, attitudes and beliefs (Gagnon,Gale) • Discussion of birth plan – expression of support in achieving (Gagnon) • Explicit encouragement to do whatever feels right/helpful (Ross-Davie)	• No discussion re ideas/wishes • No discussion of birth plan • Birth plan dismissed or criticised • Criticism of behaviour • Distracted • No discussion re ideas/wishes • No discussion of birth plan • Birth plan dismissed or criticised • Criticism of behaviour
Giving woman sense of control/ level of control they want /empowering women (Watkins 1998, Lavender 1999, Powell Kennedy 2000, Matthews and Callister 2003, Bryanton 2008, Sauls 2006)	• Woman given opportunity to express expectations, attitudes and beliefs (Gagnon, Gale) • Discussion of birth plan – expression of support in achieving (Gagnon) • Explicit encouragement to do whatever feels right/helpful (Ross-Davie) • Visible attempt to carry out woman's wishes (Ross-Davie) • [Explaining, providing information (Gagnon, McNiven) • Presenting options, choices (Barnett)] – informational • Active engagement with woman during contractions – verbal and non verbal(Ross-Davie • Asking woman and partner about their views and feelings about situations (Ross-Davie) • Verbal expressions re-affirming woman's ability (Ross-Davie) •	• No discussion re ideas/wishes • No discussion of birth plan • Birth plan dismissed or criticised • Criticism of behaviour • No attempt to carry out expressed wishes • No explanations or information • Presenting decisions

Appendix 3 contd: Operationalisation of support in labour for observation

Components of Nursing Support identified in literature	Operationalisation of observable supportive behaviours	Negative/Unsupportive behaviours
Encouragement (Shields, Field, Tarkka and Paunonen, Tumblin, Matthews and Callister)	• Encouragement (Gagnon, McNiven, Miltner, Barnett) • Active engagement with woman during contractions – verbal or non verbal (Ross-Davie) • Verbal expressions re-affirming woman's ability (Ross-Davie)	• No encouragement • Ignores contractions
Conveying a sense of confidence, security and tranquility (Bowers, Field, Bryanton, Abushaika, Holroyd)	• In room with no task being performed 'keeping company' (Gagnon 1996, McNiven 1992, Miltner 2004) • Showing undivided attention – eye contact, woman-directed gaze, leaning forward, proximity (Barnett 2008) • Relaxed calm demeanour (Ross-Davie) • Soft warm voice tone (Ross-Davie) • Creating private quiet and comfortable physical environment – knocking on door, use of curtains, minimising interruptions, soft lighting, music if woman wishes (Gale 2001)	• Only in room when task to perform • Distracted • Nervous,restless demeanour • Loud, harsh or cold tone • Busy clinical environment – unmodified
Treating with respect (Bryanton, Kintz, Matthews and Callister, Abushaika)	• Actions taken to ensure privacy and modesty (knocking, use of curtains, covers, minimising interruptions, introducing all staff) (Ross-Davie) • Woman given opportunity to express expectations, attitudes and beliefs (Ross-Davie) • Discussion of birth plan – expression of support in achieving (Gagnon) • Explicit encouragement to do whatever feels right/helpful (Ross-Davie) • Visible attempt to carry out woman's wishes (Ross-Davie) • Explaining, providing information (Gagnon, McNiven) • Presenting options, choices (Barnett 2008) • Asking woman and partner about their views and feelings about situations (Ross-Davie) • Demonstrates active listening (non-verbal, verbal reflecting and response to cues) (Ross-Davie)	• No actions to ensure privacy and modesty • No discussion re ideas/wishes • No discussion of birth plan • Birth plan dismissed or criticised • Criticism of behaviour • No attempt to carry out expressed Wishes • No explanations or information • Biased or incomplete information • Presenting decisions • Distracted, cues ignored or blocked
Praise (Bowers, Bryanton, Field, Kintz, Abushaika, Miltner, Holroyd 1997)	• Praise (Gagnon, McNiven, Miltner and Barnett) • Verbal expressions re-affirming woman's ability (Ross-Davie)	• No praise, undermining efforts
Communicating a warm, positive regard (Bowers, Bryanton 1994)	• In room with no task being performed 'keeping company' (Gagnon 1996, McNiven 1992, Miltner 2004) • Showing undivided attention – eye contact, woman-directed gaze, leaning forward, proximity (Barnett 2008) • Relaxed calm demeanour (Ross-Davie)	• Only in room when task to perform • Distracted • Nervous,restless demeanour • Loud, harsh or cold tone

- **Appendix 3 contd: Operationalisation of support in labour for observation**

Components of Nursing Support identified in literature	• **Operationalisation of observable supportive behaviours**	• **Negative/Unsupportive behaviours**
<u>Establishing rapport/connection</u> (Thorsentesson 2008, Bryanton 1994, Corbett and Callister 2000)	• Introducing self (Ross-Davie) • Smiling, pleasant facial expression (Ross-Davie) • In room with no task being performed 'keeping company' (Gagnon 1996, McNiven 1992, Miltner 2004) • Soft warm voice tone (Ross-Davie) • Woman given opportunity to express expectations, attitudes and beliefs(Ross-Davie) • Discussion of birth plan – expression of support in achieving (Gagnon) • Laughter, joking, social chitchat (McNiven, Gagnon)	• No introduction to woman and partner • Cold or angry facial expression • Only in room when task to be performed • Loud, harsh or cold tone • No discussion re ideas/wishes • No discussion of birth plan, birth plan • dismissed or criticised • Negative belittling humour, sarcasm • Detached professional approach
<u>Coaching during pushing</u> (Miltner)	This described by Miltner as emotional support – but think this is more informational support.	
<u>Exploring women's expectations (Miltner)</u> <u>Assessing and meeting woman's level of need</u> (Shields 1978)	• Woman given opportunity to express expectations, attitudes and beliefs(Ross-Davie) • Discussion of birth plan – expression of support in achieving (Gagnon)	• No discussion re ideas/wishes • No discussion of birth plan • Birth plan dismissed or criticised
<u>Expressing concern, empathy and understanding</u> (Shields, Ford 2009)	• Using words, phrases and non-verbal expression to express concern and empathy ('I know', 'That's hard' 'That hurts') (Ross-Davie) • In room with no task being performed 'keeping company' (Gagnon 1996, McNiven 1992, Miltner 2004) • Showing undivided attention – eye contact, woman-directed gaze, leaning forward, proximity (Ross-Davie) • Relaxed calm demeanour(Ross-Davie) • Soft warm voice tone(Ross-Davie) • Active engagement with woman during contractions – verbal and non verbal(Ross-Davie)	• No expressions verbal or non-verbal of empathy, appears disinterested • Only in room when task to perform • Distracted • Nervous, restless demeanour • Loud, harsh or cold tone • Ignores contraction. Talks over contraction about other issues, asks questions during contraction
<u>Listening</u> (Ford 2009)	• Demonstrates active listening (non-verbal, verbal reflecting and response to cues) (Ross-Davie)	• Distracted, cues ignored or blocked

- **Appendix 3 contd: Operationalisation of support in labour for observation**

Components of Nursing Support identified in literature	• **Operationalisation of observable supportive behaviours**	• **Negative/Unsupportive behaviours**
Smiling (Tumblin, Watkins)	• Smiling, pleasant facial expression(Ross-Davie)	• Cold or angry facial expression
Talking through pain (Tumblin, Bryanton 1994) Trying to carry out woman's wishes (Bryanton 1994)	• Active engagement with woman during contractions – verbal and non verbal (Ross-Davie) • Verbal expressions re-affirming woman's ability (Ross-Davie) • Woman given opportunity to express expectations, attitudes and beliefs(Ross-Davie) • Discussion of birth plan – expression of support in achieving (Gagnon) • Explicit encouragement to do whatever feels right/helpful (Ross-Davie) • Visible attempt to carry out woman's wishes (Ross-Davie)	• Ignores contraction. Talks over contraction about other issues, asks questions during contraction • No discussion re ideas/wishes • No discussion of birth plan • Birth plan dismissed or criticised • Criticism of behaviour • No attempt to carry out expressed Wishes
Acknowledging special nature of birth for woman (Matthews and Callister 2003)	• Actions taken to ensure privacy and modesty (knocking, use of curtains, covers, minimising interruptions, introducing all staff) (Ross-Davie) • Woman given opportunity to express expectations, attitudes and beliefs (Ross-Davie) • Discussion of birth plan – expression of support in achieving (Gagnon) • Explicit encouragement to do whatever feels right/helpful (Ross-Davie) • Visible attempt to carry out woman's wishes (Ross-Davie) • Explaining, providing information (Gagnon, McNiven) • Presenting options, choices (Ross-Davie) • Asking woman and partner about their views and feelings about situations (Ross-Davie) • Demonstrates active listening (non-verbal, verbal reflecting and response to cues) (Ross-Davie) • Showing undivided attention – eye contact, woman-directed gaze, leaning forward, proximity (Ross-Davie) • Creating private quiet and comfortable physical environment – knocking on door, use of curtains, minimising interruptions, soft lighting, music if woman wishes (Ross-Davie)	• No actions to ensure privacy and modesty • No discussion re ideas/wishes • No discussion of birth plan • Birth plan dismissed or criticised • Criticism of behaviour • No attempt to carry out expressed wishes • No explanations or information • Biased or incomplete information • Presenting decisions • Distracted, cues ignored or blocked • Appears off-hand • Busy clinical environment – • unmodified

- **Appendix 3 contd: Operationalisation of support in labour for observation**

Components of Nursing Support identified in literature	**Operationalisation of observable supportive behaviours**	**Negative/Unsupportive behaviours**
<u>Being friendly, open and gentle</u> (Field, Kintz, Bowers) Attitude (Ford 2009)	• Introducing self (Ross-Davie) • Smiling, pleasant facial expression (Ross-Davie) • In room with no task being performed 'keeping company' (Gagnon 1996, McNiven 1992, Miltner 2004) • Soft warm voice tone (Ross-Davie) • Woman given opportunity to express expectations, attitudes and beliefs (Ross-Davie) • Discussion of birth plan – expression of support in achieving (Gagnon) • Laughter, joking, social chitchat (McNiven, Gagnon)	• No introduction to woman and partner • Cold or angry facial expression • Only in room when task to be performed • Loud, harsh or cold tone • No discussion re ideas/wishes • No discussion of birth plan, birth plan • dismissed or criticised • Negative belittling humour, sarcasm • Detached professional approach
<u>Having a belief in normality</u> (Powell - Kennedy 2000)	• Interventions discussed/suggested only when required according to best available evidence/clear deviation from the norm (Ross-Davie) • Caring/midwifery interventions attempted before moving on to medical interventions (Ross-Davie) • Verbal expressions re-affirming woman's ability (Ross-Davie) • Praise (Ross-Davie)	• Interventions performed without discussion or without indication • Medical interventions performed as first option doubts expressed about woman's ability • No encouragement, discouragement • No praise, criticism
<u>Verbal expression – soft tone, calm voice</u> (Adams and Bianchi, Bryanton 1994)	• Verbal expression – soft tone, calm voice (Ross-Davie)	• Loud, Harsh, cold or disinterested tone
<u>Therapeutic use of humour</u> (Adams and Bianchi 2008, Bryanton 1994)	• Positive humour (Ross-Davie)	• Belittling humour or sarcasm, no humour

- **Appendix 3 contd: Operationalisation of support in labour for observation**

Components of Nursing Support identified in literature	• **Operationalisation of observable supportive behaviours**	• **Negative/Unsupportive behaviours**
Refocusing 'take charge routine' (Adams and Bianchi, Simkin)	• Reframes woman's negative thoughts to positive(Ross-Davie) • When woman loses control helps 'bring her back' through positive assertive behaviour(Ross-Davie)	• Lacks authority/assertiveness when needed
Attempting to lessen demands on woman (Bryanton 1994)	• Actions taken to ensure privacy and modesty (knocking, use of curtains, covers, minimising interruptions, introducing all staff) (Ross-Davie) • Creating private quiet and comfortable physical environment – knocking on door, use of curtains, minimising interruptions, soft lighting, music if woman wishes (Gale 2001)	• No actions to ensure privacy and Modesty • Busy clinical environment – unmodified
Recognising when woman is anxious (Bryanton 1994)	• Demonstrates active listening (non-verbal, verbal reflecting and response to cues) (Ross-Davie) • Showing undivided attention – eye contact, woman-directed gaze, leaning forward, proximity(Ross-Davie) • Verbal expressions re-affirming woman's ability (Ross-Davie)	• Distracted, cues ignored or blocked • Appears off-hand
Behaving professionally (Bryanton 1994)	• Demonstrates technical competence(Ross-Davie) • Demonstrates ability to practice independently(Ross-Davie) • Attempts to defuse problematic situations, resolve conflict(Ross-Davie) • Uses accessible appropriate language(Ross-Davie)	• Unable to operate machinery or carry out procedures • Disorganised • Needing to call for assistance frequently • Responds emotionally to difficult situation • Uses offensive language or jargon
Physical /tangible		
Relief from pain (Lesser and Keane, Lavender, Holroyd, Bryanton 1994)	• Facilitate/Pain relief measures (running pool, applying TENS, giving entonox / diamorphine) (Ross-Davie)	• Ignores woman's request for assistance with coping with pain
Bodily care – hygiene, elimination, nutrition (Lesser and Keane, Adams and Bianchi 2008, Hodnett 2007)	• Suggests and assists with visiting toilet • Changing clothing, pads, bed linen • Offers and brings fluid and nutrition • Suggests and provides assistance with showering/bath (McNiven, Gagnon, Gale, Mitner, Barnett)	

- **Appendix 3 contd: Operationalisation of support in labour for observation**

Components of Nursing Support identified in literature	• **Operationalisation of observable supportive behaviours**	• **Negative/Unsupportive behaviours**
Monitoring mother and baby's well-being (Sauls 2006, Mackey and Lock 1989, Tumblin 2001)	• Monitors baby's well-being (McNiven, Gagnon, Gale, Mitner, Barnett) and explains findings • Monitors mother's vital signs (McNiven, Gagnon, Gale, Mitner, Barnett) and explains findings	• No regular monitoring of baby's condition • No regular monitoring of mother's condition • No description of findings after monitoring
Coaching/Assistance with breathing and relaxation (Shields, Bryanton, Kintz, Tumblin, Ford 2009, Holroyd, Watkins 1998)	• Coaching/Assistance with breathing and relaxation (McNiven, Gagnon, Gale, Mitner, Barnett)	• Ignoring contractions
Holding the woman's hand (Shields) Touch (Bryanton 1994)	• Holding the woman's hand (McNiven, Gagnon, Gale, Mitner, Barnett) • Stroking – arm, shoulder, forehead (McNiven, Gagnon, Gale, Mitner, Barnett) • Counterpressure, massage (McNiven, Gagnon, Gale, Mitner, Barnett)	• Restraining/directional touch
Technical competence (Bowers)	• Able to use machinery in room (Ross-Davie) • Carries out procedures independently(Ross-Davie)	• Requires assistance to use • Machinery in room • Requires repeated assistance
Vigilance, attention to detail (Powell Kennedy)	• Identifies problems/deviations from the norm(Ross-Davie) • Writes contemperaneous notes(Ross-Davie)	• Fails to identify problem or Take action • No writing of notes
Protecting patient's modesty (Miltner)	• Uses curtains/sheets/ positions to avoid exposure (Ross-Davie)	• Allows staff to enter room without introduction or need
Helping woman walk (Tumblin)	• Suggests and assists with changing position, walking (McNiven, Gagnon, Gale, Mitner, Barnett)	• Advises /maintains woman to remain in semi-recumbant position
Creation of a setting that meets women's needs (Powell Kennedy, Adams and Bianchi 2008)	• Creating private quiet and comfortable physical environment – knocking on door, use of curtains, minimising interruptions, soft lighting, music if woman wishes (Gale)	• Noisy, unmodified clinical environment – open door, bright lights
Intervening only when necessary (Powell Kennedy)	• Interventions discussed/suggested only when required according to best available evidence/clear deviation from the norm (Ross-Davie) • midwifery interventions attempted before medical interventions (Ross-Davie)	• Medical interventions advised/suggested without indication or discussion

- **Appendix 3 contd: Operationalisation of support in labour for observation**

Components of Nursing Support identified in literature	• **Operationalisation of observable supportive behaviours**	• **Negative/Unsupportive behaviours**
Encouragement of self-directed pushing (Sampselle 2005)	• Encouragement of self-directed pushing (Ross-Davie)	• Directed pushing
Proximity (Bertsch 1990)	• Midwife within 2 metres of woman unless required to perform task elsewhere (Ross-Davie) • Facing woman (Ross-Davie) • Positions self at woman's level (Ross-Davie)	• More than 2 metres from woman • Back to woman • Standing over woman
Informational		
Explanations (Shields, Ford, Holroyd 1997) Explaining hospital routines (Bryanton, Abushaika)	• Explains labour process • Explains hospital procedures • Ascertains level of understanding and adapts information appropriate • Explains evidence based when appropriate (McNiven, Gagnon, Gale, Mitner, Barnett)	• Use of language that will not be Understandable for woman and Partner.
Reassuring about progress (Miltner, Abushaika, Ford)	• Describes progress as positively as possible (Ross-Davie)	• Negative description of progress
Making suggestions for pain relief (Miltner, Ford)	• Provides information about ways to cope with pain (Ross-Davie) • Provides information about non-pharmacological methods as well as pharmacological (McNiven, Gagnon, Gale, Mitner, Barnett) • Provides information about actions, pros and cons of different forms of pain relief (Ross-Davie)	• Advises pharmacological pain Relief without discussing other options
Answering questions truthfully (Bryanton, Abushaika, Tumblin, Holroyd)	• Answers questions directly and honestly (Ross-Davie)	• Ignores questions • Partial answer only
Involving woman in decisions (Bryanton 2008, Lavender et al 1999)	• Provides woman and partner with evidence-based information upon which they can make decisions (Ross-Davie) • When there are decisions to be made, provides woman and partner with information and options (Ross-Davie)	• No reference to any research When helping woman and partner make a decision

- **Appendix 3 contd: Operationalisation of support in labour for observation**

Components of Nursing Support identified in literature	**Operationalisation of observable supportive behaviours**	**Negative/Unsupportive behaviours**
Carer has knowledge (Field 1987, Matthews and Callister 2003)	• Explains labour process (McNiven, Gagnon, Gale, Mitner, Barnett) • Explains hospital procedures • Ascertains level of understanding and adapts information appropriate • Explains evidence based when appropriate (Ross-Davie)	• Seems uncertain/unsure about facts
Familiarises woman with my surroundings (Bryanton 1994)	• Shows woman and partner facilities and how to use them (Ross-Davie)	• Does not orientate couple to clinical area
Advocacy		
Protecting client (Foley Minck and Kee 2002)	• Supports woman's decisions (McNiven and Gagnon)	• Ignores/undermines woman's decisions
Being the woman's voice when needed (Adams and Bianchi)	• Negotiates woman's wishes with other members of team (McNiven, Gagnon)	• Sides with 'the system' rather than advocating for the woman
Conflict resolution (Adams and Bianchi)	• Attempts to defuse problematic situations, resolve conflict(Ross-Davie)	• Reacts emotionally to difficult situation
Support for partner		
Role modelling(Hodnett 1996)	• Show partner how to help (Ross-Davie)	• Ignores partner
Offering respite and encouragement (Hodnett 1996)	• Says encouraging things to partner (Barnett 2008)	• Belittles partner
Encourages partner's involvement (Bryanton 1994)	• Praises partner's actions and how couple work together (Gale 2001)	
Supported the way partner and I worked together (Bryanton 1994)	• Praises partner's actions and how couple work together	
Provided for partner's physical needs (Bryanton 1994)	• Encourages partner to take breaks/have something to eat (Ross-Davie)	

Appendix Four: The SMILI programme

Page 1 Opening page of SMILI

Page 2 First Context Page - Unit

Page 3 Second Context Page - Woman

Page 4 Third Context Page - Midwife

Page 5 Fourth Context Page - Time

Page 6 Observation of Woman page

Page 7 Observation of Partner page

Page 8 Observation of Midwife Demeanour page

Page 9 Midwife Behaviour – Presence

Page 10 Midwife Behaviour – Verbal

Page 11 Midwife Behaviour – Advocacy

Page 12 Midwife Behaviour – Touch

Page 13 Midwife Behaviour – Physical Care

Page 14 Midwife Behaviour – Assessment

Page 15 Midwife Behaviour – Environment

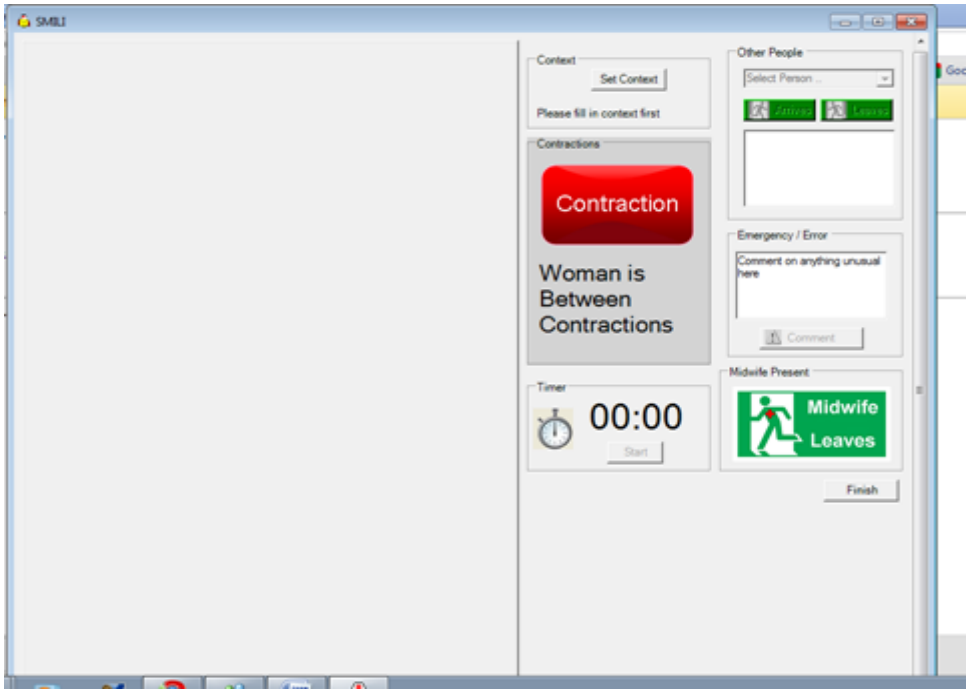
Page 16 Midwife Behaviour – Care of the partner

Page 17 Midwife Behaviour – Indirect care

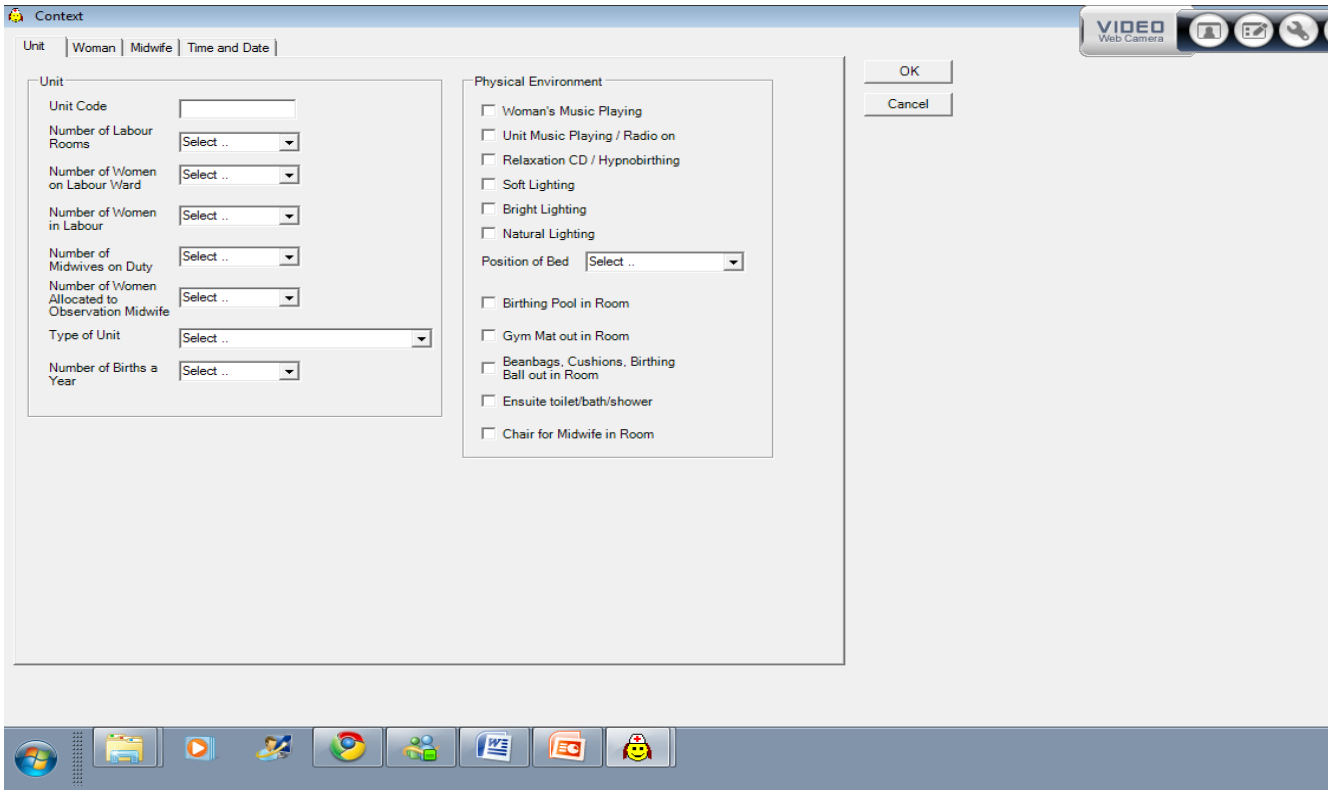
Page 18 Midwife Behaviour – Information

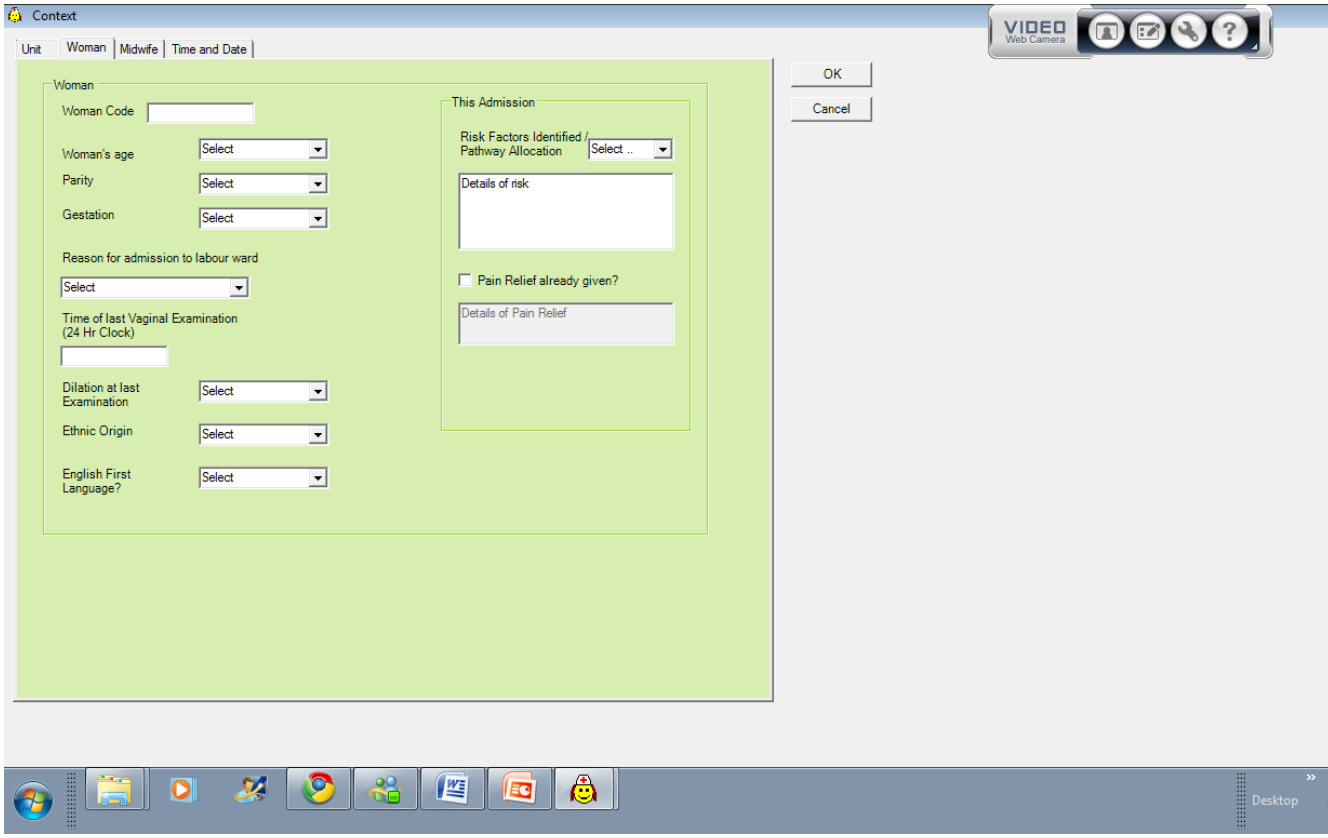
Page 19 Midwife Behaviour – Decision making

P1 SMILI opening page



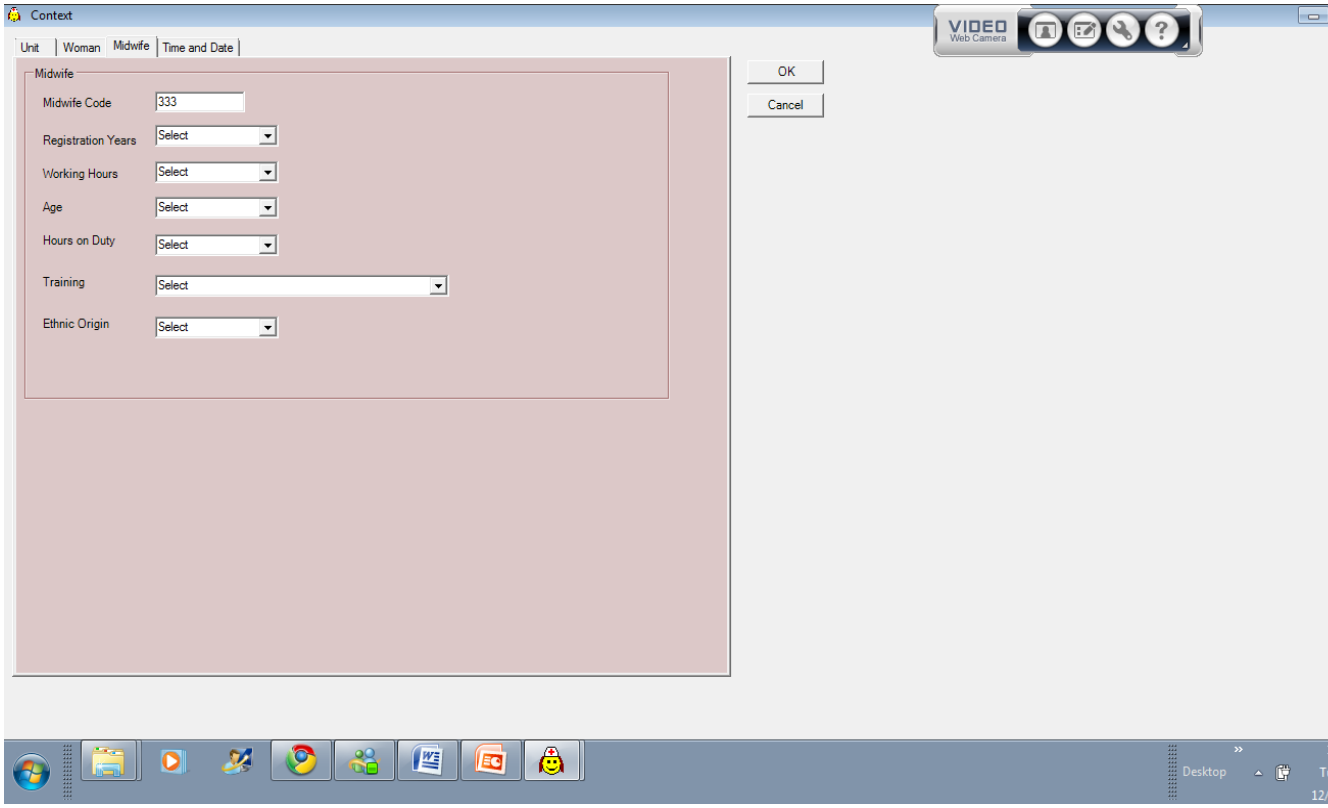
P2 SMILI -Unit
Context

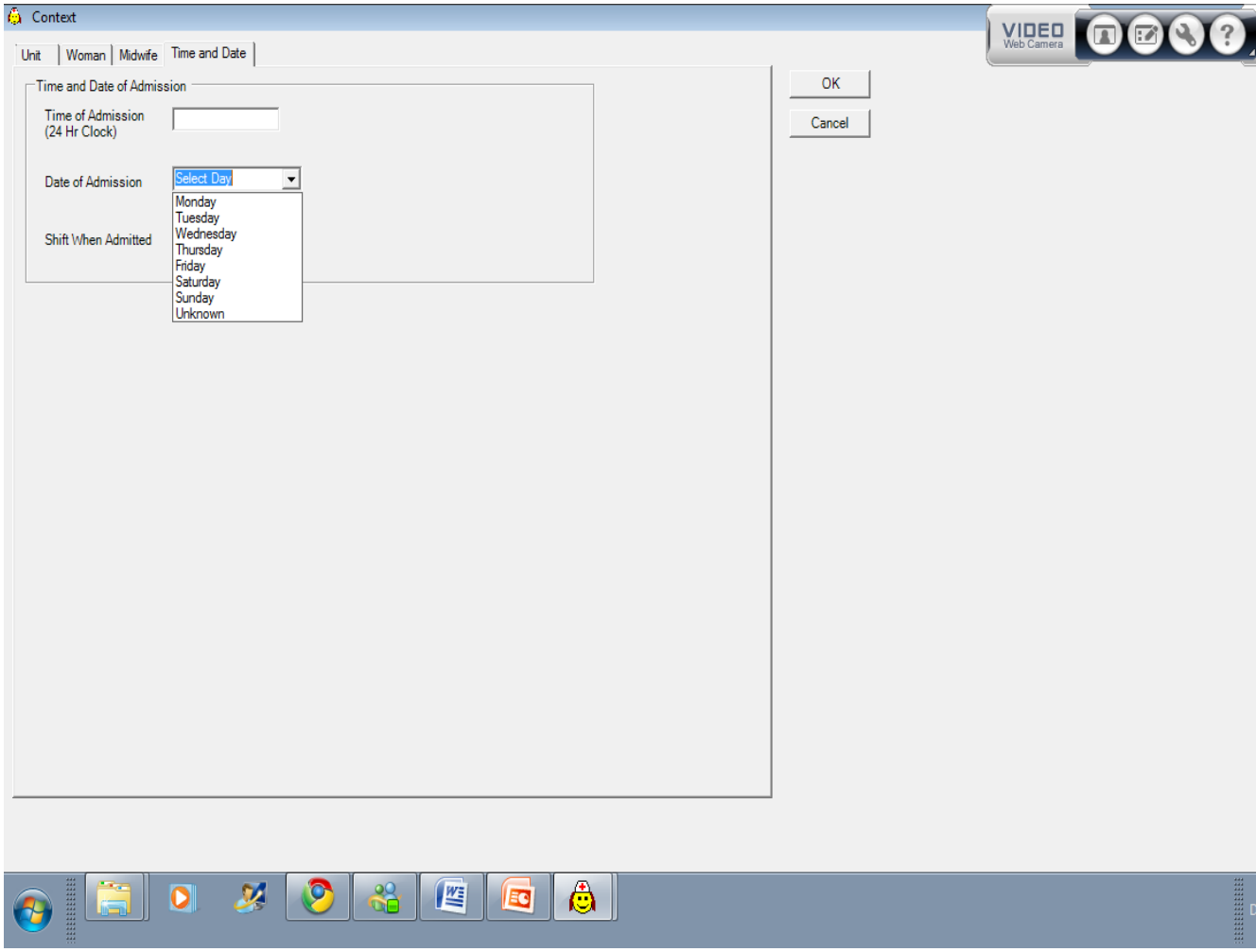




SMILI page 3 Woman context page,

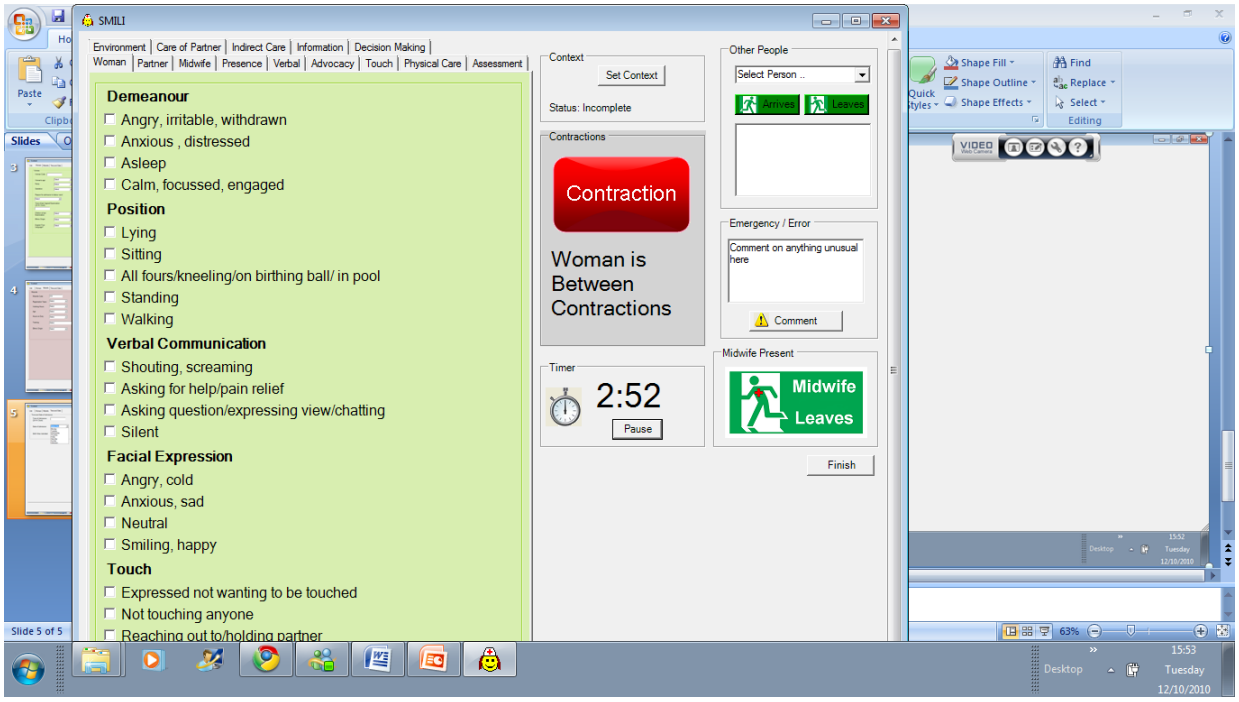
SMILI page 4 – Midwife context page, completed before observation

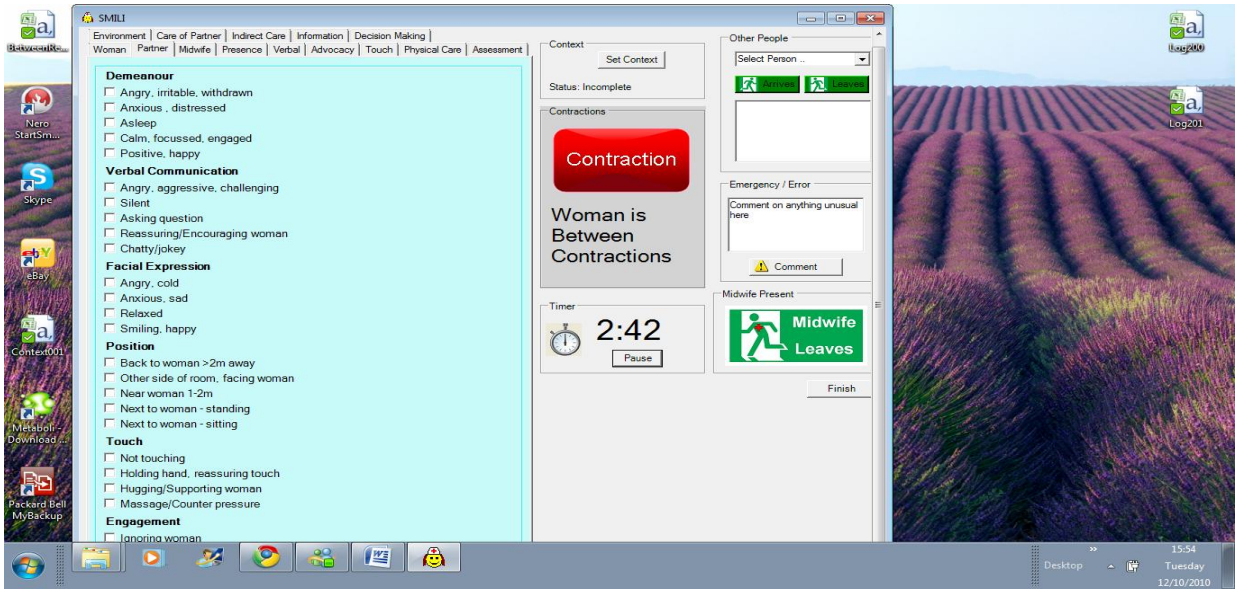




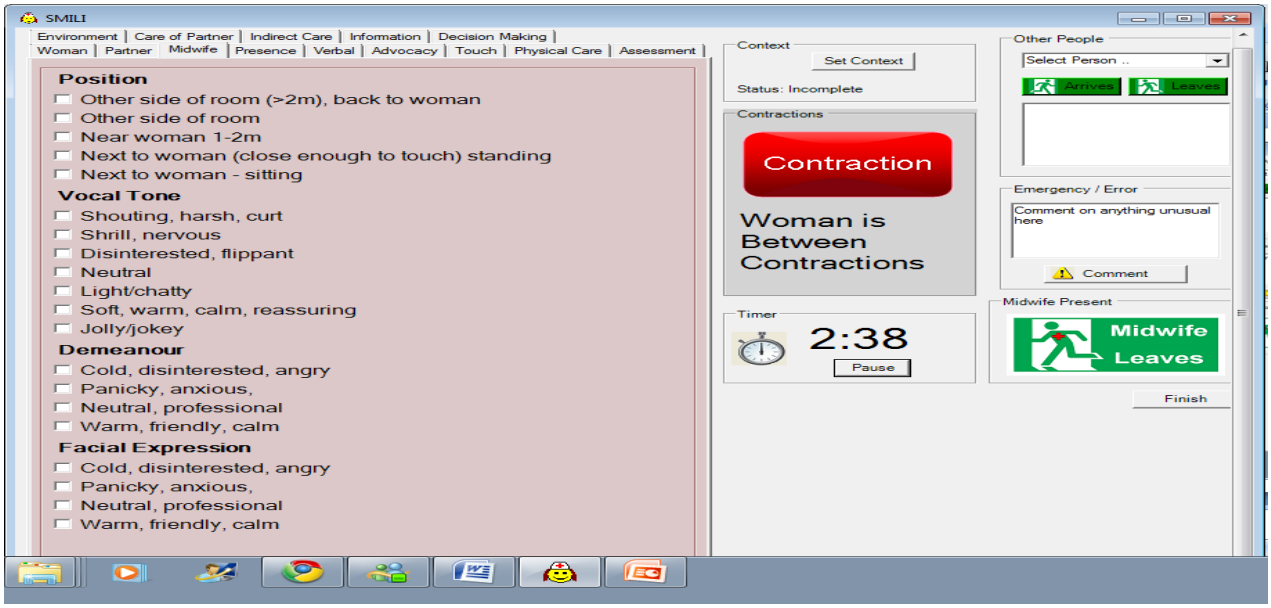
SMILI page 5 – Time context page, completed before observation

SMILI page 6 – Woman observation

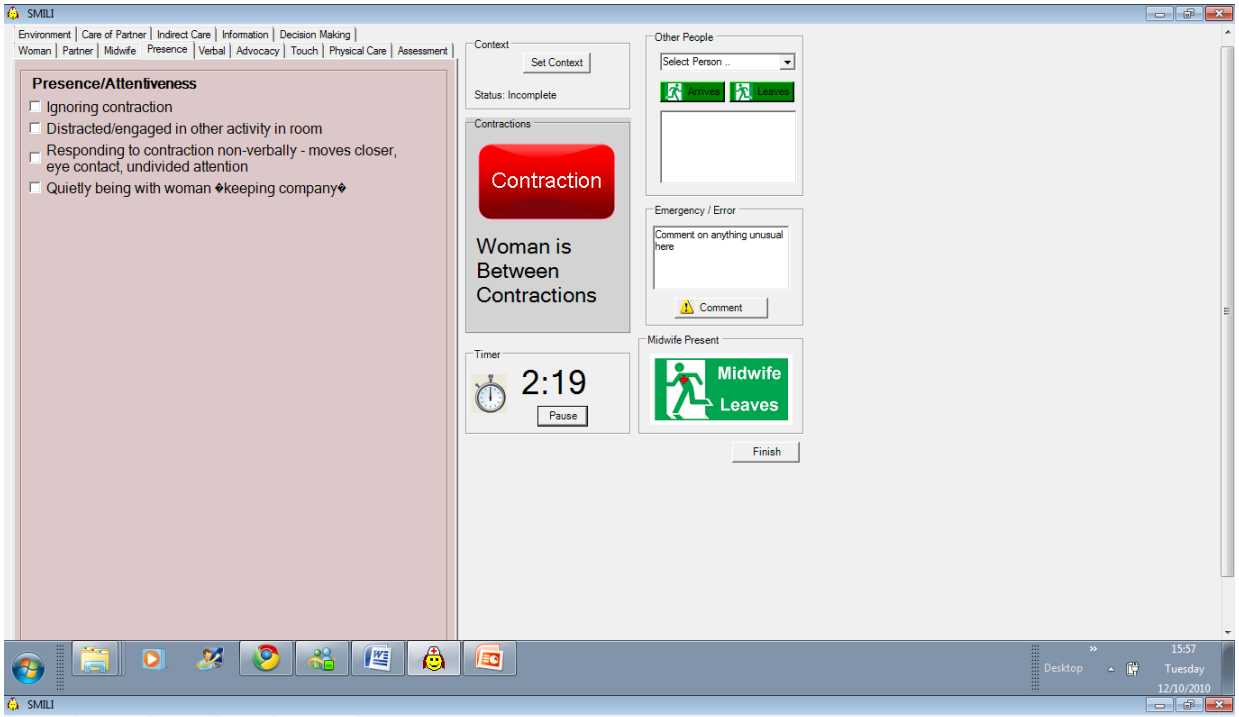




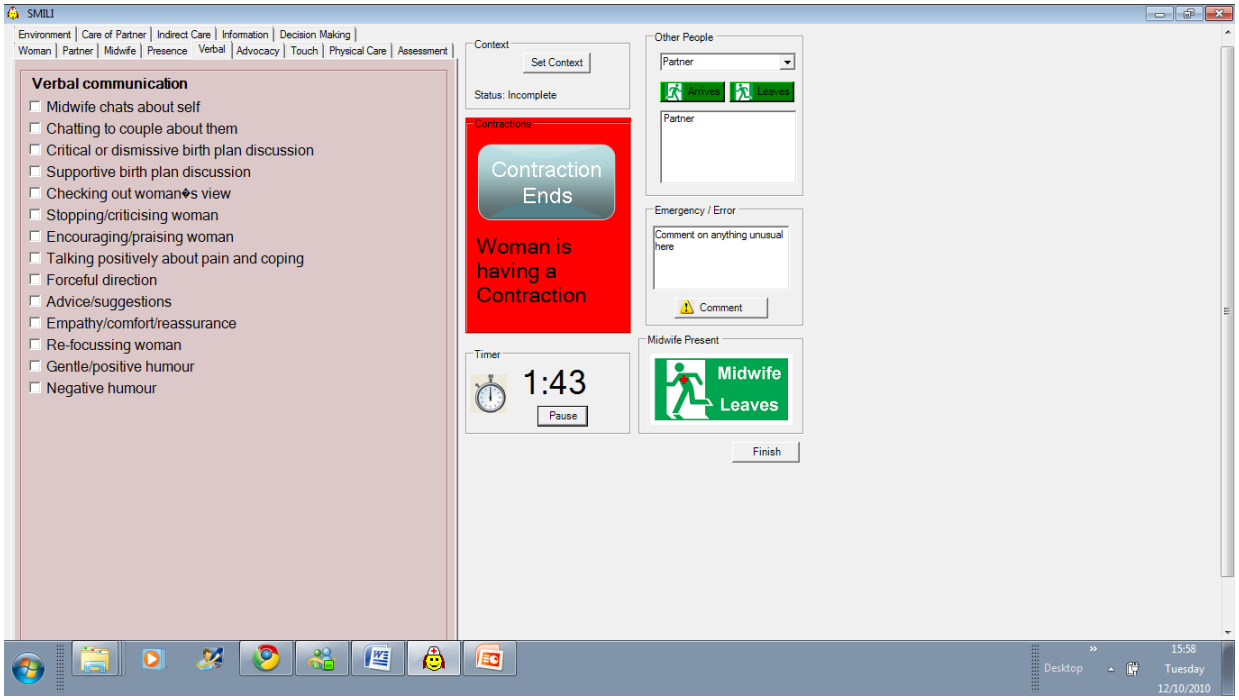
P6 Partner Observation page

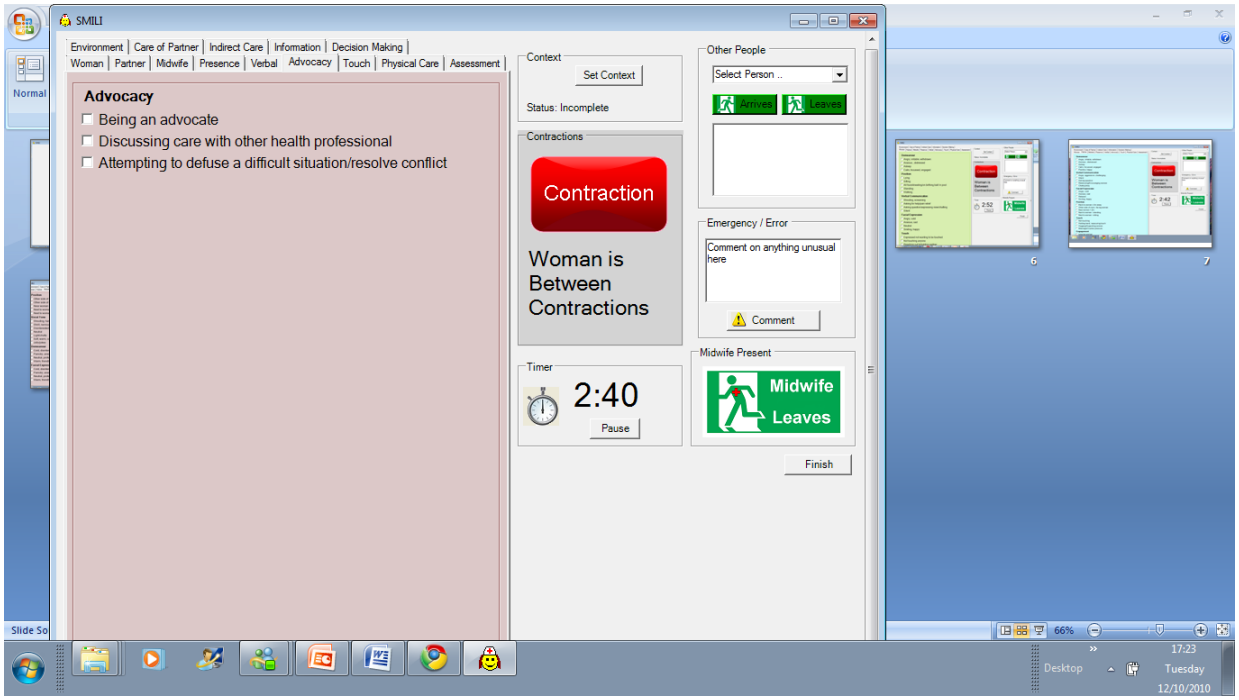


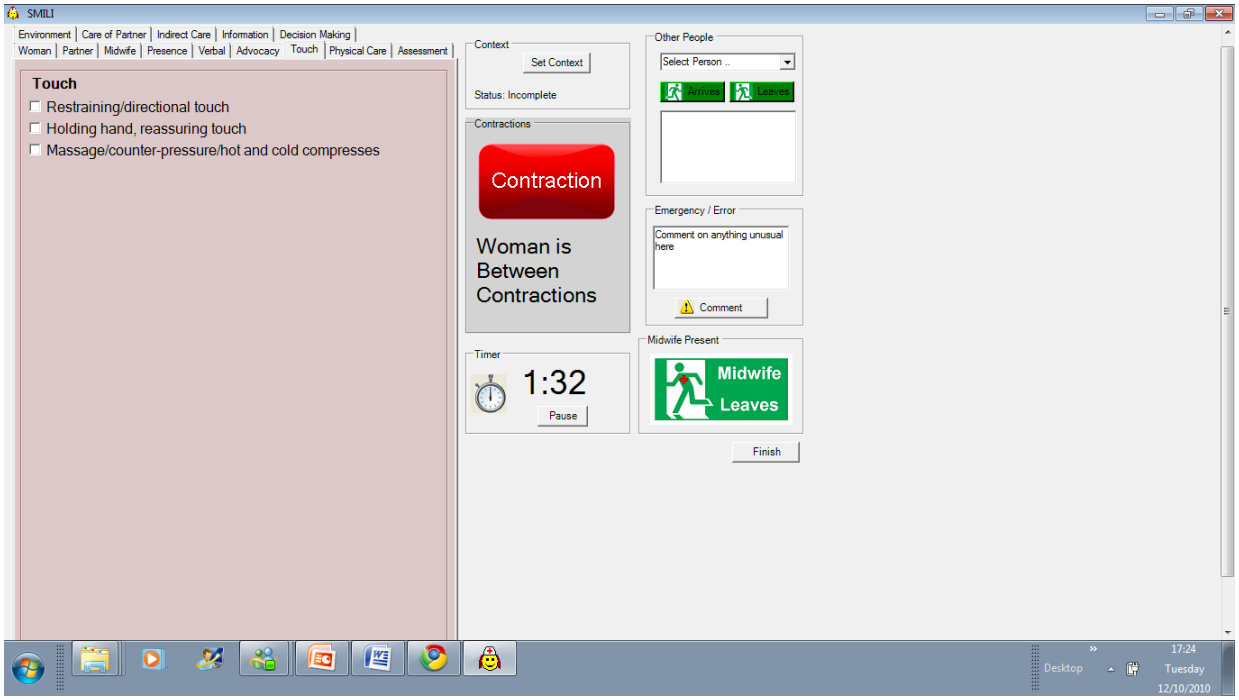
P7 Midwife Demeanour page


SMILI
Environment | Care of Partner | Indirect Care | Infomation | Decision Making
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Presence/Attentiveness
Ignoring contraction
Distracted/engaged in other activity in room
Responding to contraction non-verbally - moves closer, eye contact, undivided attention
Quietly being with woman ♦keeping company♦
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
2:19
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
Desktop
15:57
Tuesday
12/10/2010

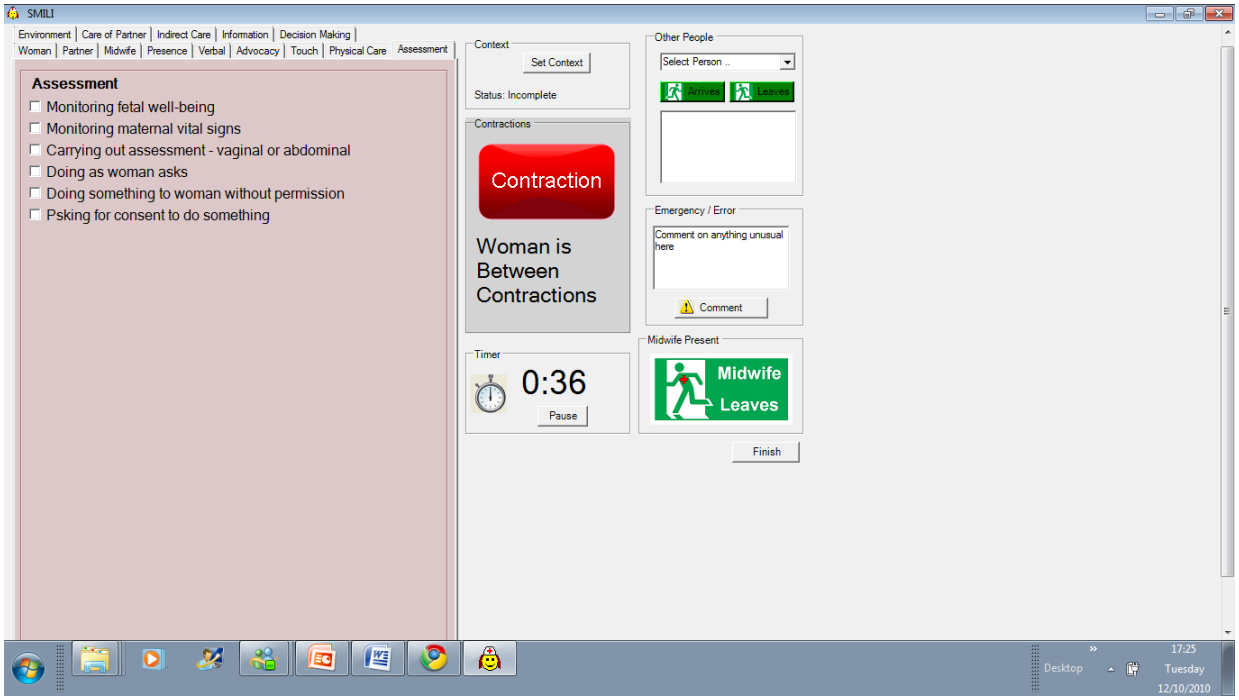

SMILI
Environment | Care of Partner | Indirect Care | Infomation | Decision Making
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Verbal communication
Talking over contraction ♦chatting♦/ giving explanation
Talking woman through contraction - coaching breathing, relaxation etc
Telling woman not to do something/criticising behaviour
Giving encouragement/ praise
Directing woman to do something quite forcefully
Expressing empathy/comfort/reassurance
Positively assertive ♦bringing woman back♦ if losing control
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
1:48
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
Desktop
15:57
Tuesday
12/10/2010

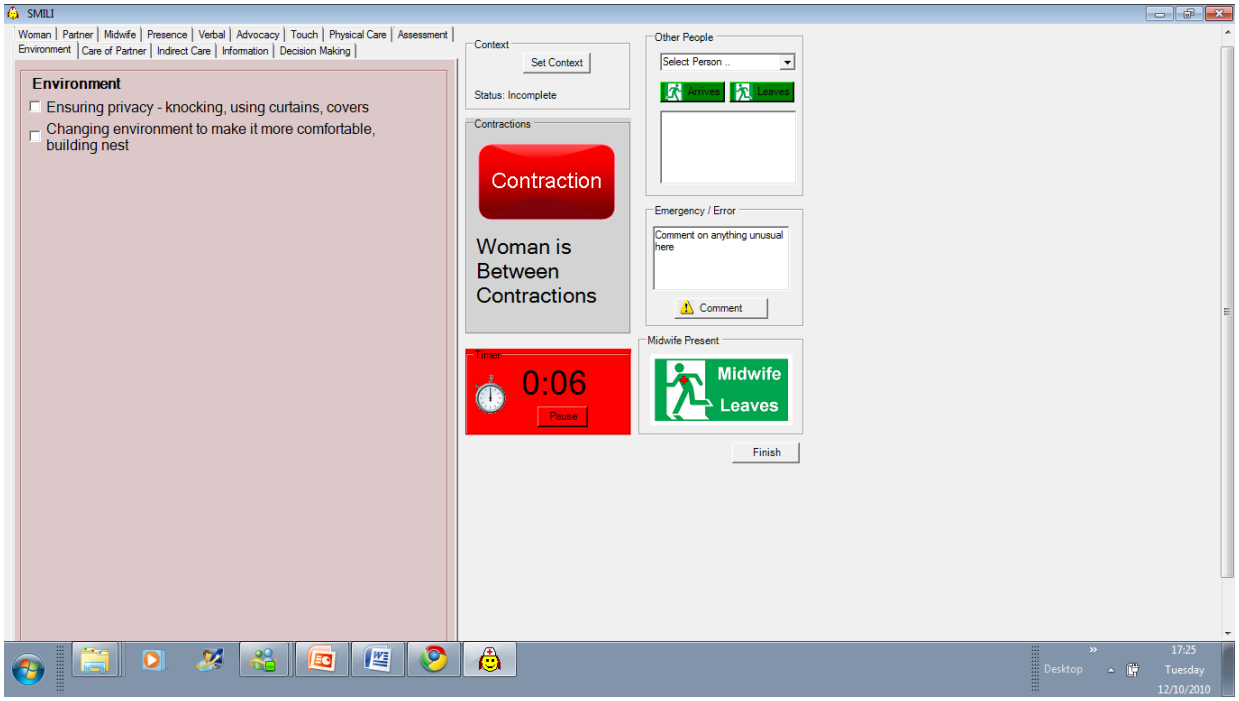

SMILI
Environment | Care of Partner | Indirect Care | Information | Decision Making |
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment |
Verbal communication
Midwife chats about self
Chatting to couple about them
Critical or dismissive birth plan discussion
Supportive birth plan discussion
Checking out woman's view
Stopping/criticising woman
Encouraging/praising woman
Talking positively about pain and coping
Forceful direction
Advice/suggestions
Empathy/comfort/reassurance
Re-focussing woman
Gentle/positive humour
Negative humour
Context
Set Context
Status: Incomplete
Contractions
Contraction Ends
Woman is having a Contraction
Timer
1:43
Pause
Other People
Partner
Arrives
Leaves
Partner
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
Desktop
15:58
Tuesday
12/10/2010

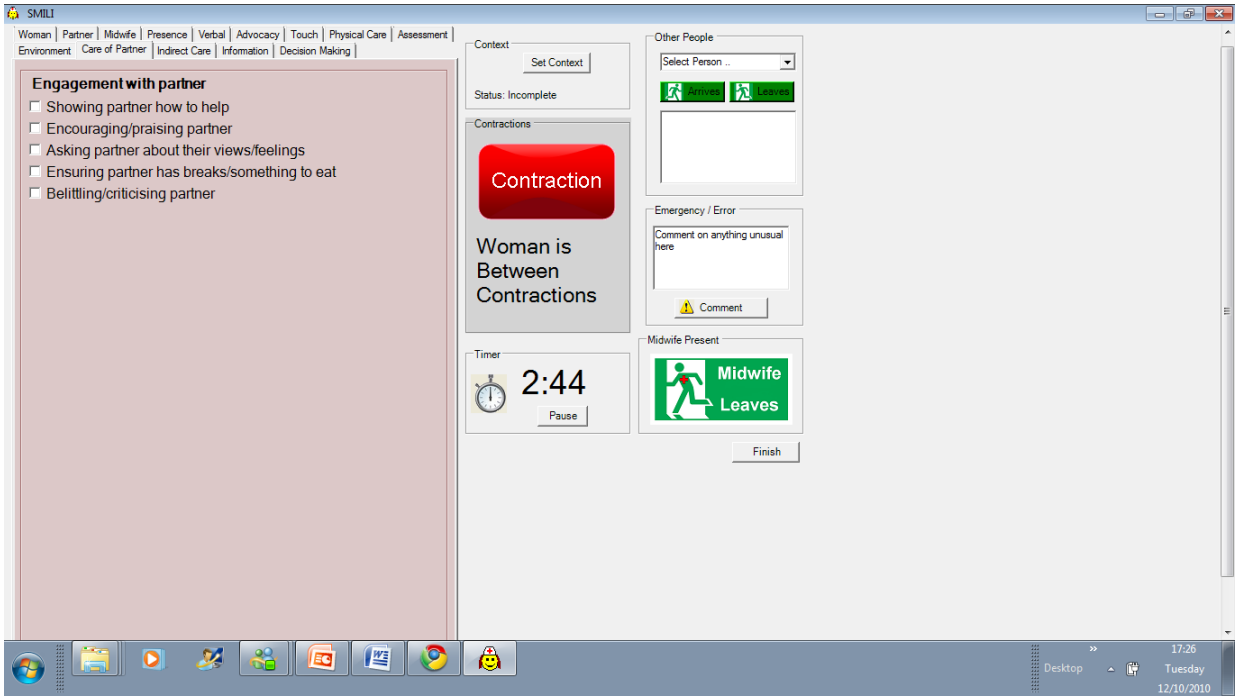

SMILI
Environment | Care of Partner | Indirect Care | Information | Decision Making |
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment |
Advocacy
Being an advocate
Discussing care with other health professional
Attempting to defuse a difficult situation/resolve conflict
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
2:40
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
Normal
Slide So
66%
Desktop
17:23
Tuesday
12/10/2010

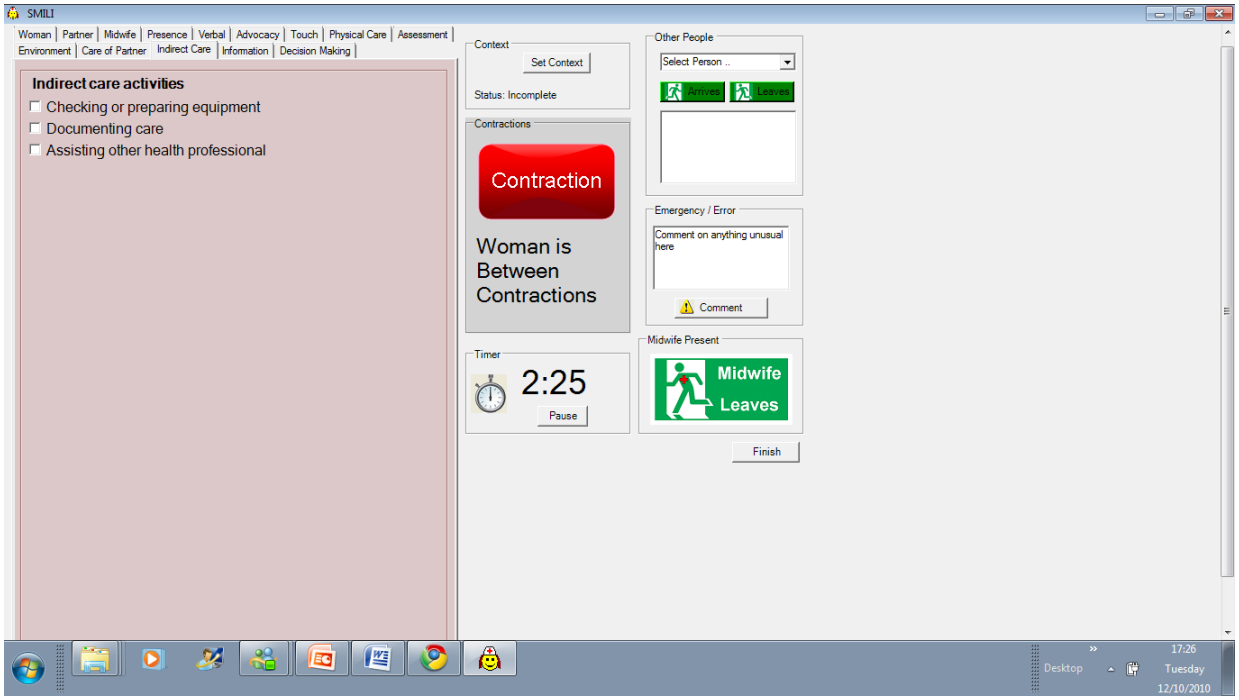

SMILI
Environment | Care of Partner | Indirect Care | Information | Decision Making
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Touch
Restraining/directional touch
Holding hand, reassuring touch
Massage/counter-pressure/hot and cold compresses
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
1:32
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
17:24
Desktop
Tuesday
12/10/2010

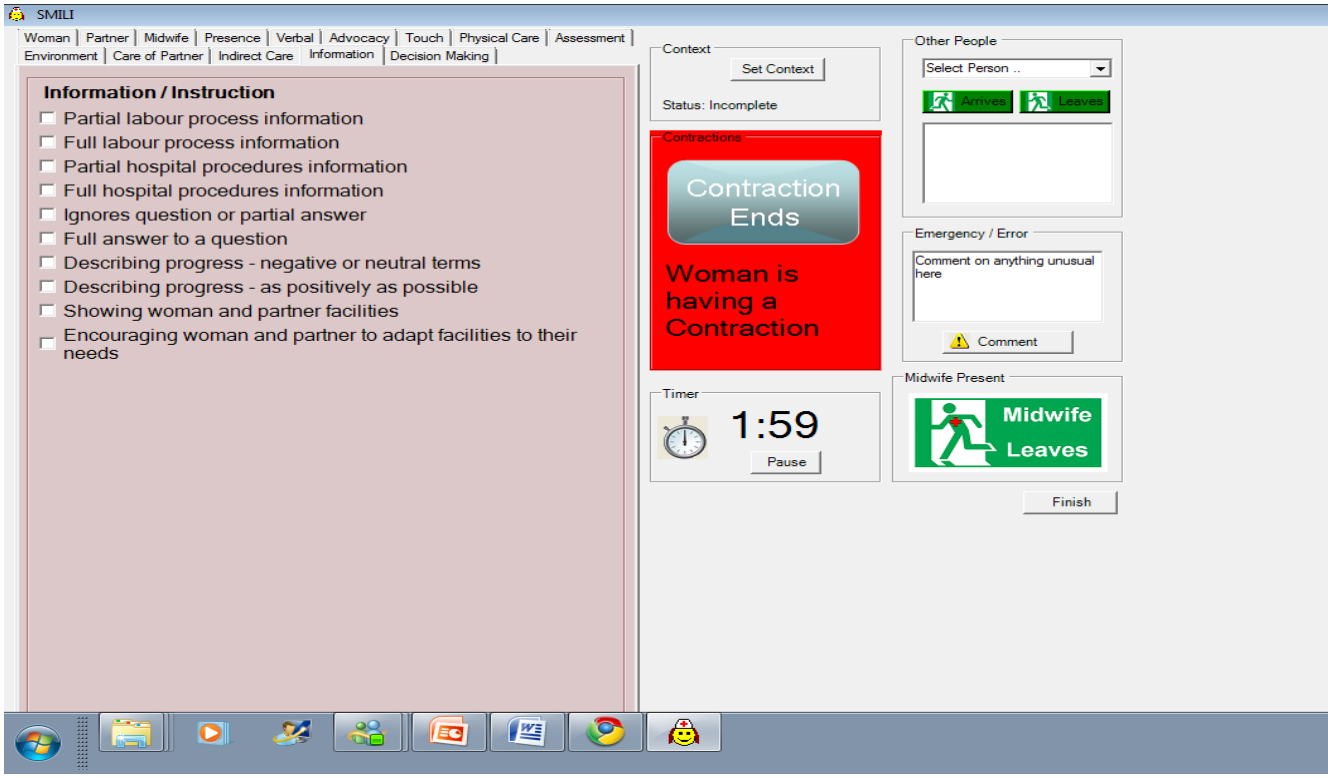

SMILI
Environment | Care of Partner | Indirect Care | Information | Decision Making
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Direct physical care
Preparing or administering pain relief
Helping woman to toilet
Changing clothes/bedding/pads
Helping with position change/mobilising
Assisting with shower or bath
Carrying out a medical intervention
Getting or giving fluid or food
Delivering baby
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
1:08
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
17:24
Desktop
Tuesday
12/10/2010

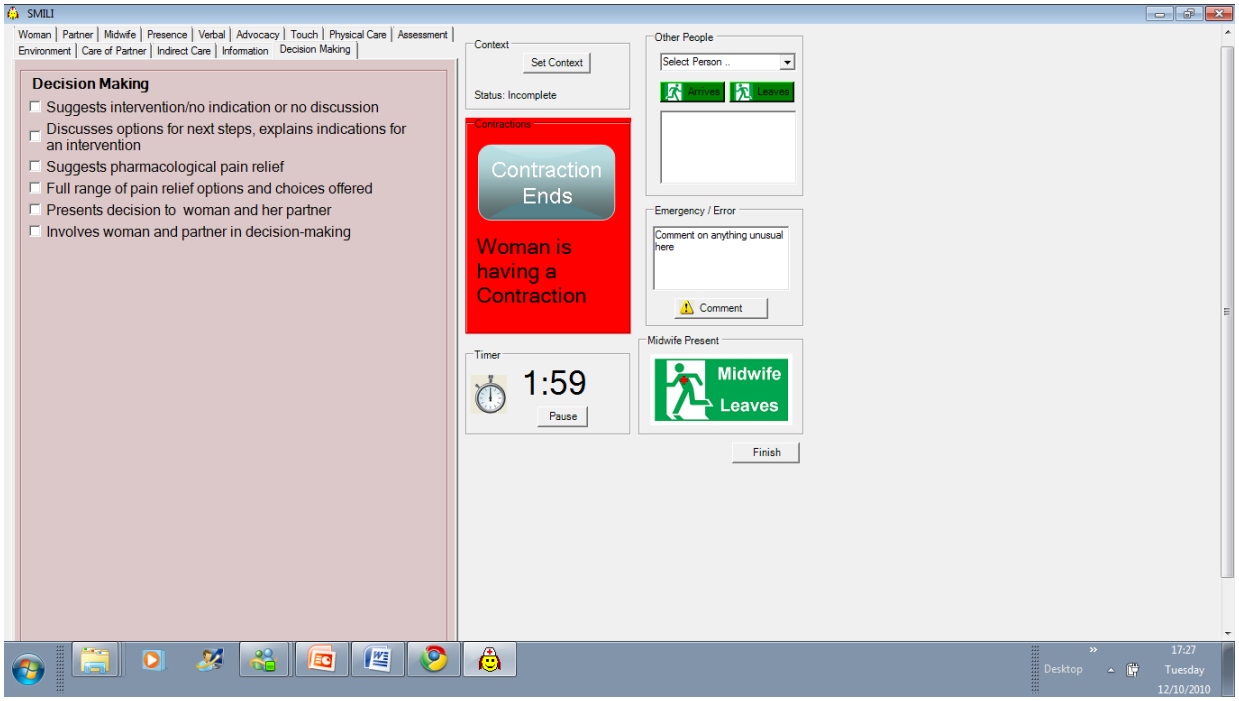

SMILI
Environment | Care of Partner | Indirect Care | Infomation | Decision Making |
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Assessment
Monitoring fetal well-being
Monitoring maternal vital signs
Carrying out assessment - vaginal or abdominal
Doing as woman asks
Doing something to woman without permission
Psking for consent to do something
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
0:36
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
Desktop
17:25
Tuesday
12/10/2010


SMILI
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Environment | Care of Partner | Indirect Care | Infomation | Decision Making |
Environment
Ensuring privacy - knocking, using curtains, covers
Changing environment to make it more comfortable, building nest
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
0:06
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
Desktop
17:25
Tuesday
12/10/2010


SMILI
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Environment | Care of Partner | Indirect Care | Information | Decision Making
Engagement with partner
Showing partner how to help
Encouraging/praising partner
Asking partner about their views/feelings
Ensuring partner has breaks/something to eat
Belittling/criticising partner
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
2:44
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
17:26
Desktop
Tuesday
12/10/2010


SMILI
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Environment | Care of Partner | Indirect Care | Information | Decision Making
Indirect care activities
Checking or preparing equipment
Documenting care
Assisting other health professional
Context
Set Context
Status: Incomplete
Contractions
Contraction
Woman is Between Contractions
Timer
2:25
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
17:26
Desktop
Tuesday
12/10/2010


SMILI
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Environment | Care of Partner | Indirect Care | Information | Decision Making
Information / Instruction
Partial labour process information
Full labour process information
Partial hospital procedures information
Full hospital procedures information
Ignores question or partial answer
Full answer to a question
Describing progress - negative or neutral terms
Describing progress - as positively as possible
Showing woman and partner facilities
Encouraging woman and partner to adapt facilities to their needs
Context
Set Context
Status: Incomplete
Contractions
Contraction Ends
Woman is having a Contraction
Timer
1:59
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish


SMILI
Woman | Partner | Midwife | Presence | Verbal | Advocacy | Touch | Physical Care | Assessment
Environment | Care of Partner | Indirect Care | Information | Decision Making
Decision Making
Suggests intervention/no indication or no discussion
Discusses options for next steps, explains indications for an intervention
Suggests pharmacological pain relief
Full range of pain relief options and choices offered
Presents decision to woman and her partner
Involves woman and partner in decision-making
Context
Set Context
Status: Incomplete
Contractions
Contraction Ends
Woman is having a Contraction
Timer
1:59
Pause
Other People
Select Person ..
Arrives
Leaves
Emergency / Error
Comment on anything unusual here
Comment
Midwife Present
Midwife Leaves
Finish
17:27
Tuesday
12/10/2010

Appendix Five – The Support and Control in Birth Instrument (SCIB)

This questionnaire asks about your experience of the labour and birth of your baby. If you had a planned caesarean, please answer the questions as best you can for how your experience was.

What kind of control did you have during labour and birth?
If a question is not relevant to your experience, please mark the box "neither".

		Agree completely	Agree slightly	Neither	Disagree slightly	Disagree completely
1	I had control over when procedures happened	5	4	3	2	1
2	I could influence which procedures were carried out	5	4	3	2	1
3	I decided whether most procedures were carried out or not	5	4	3	2	1
4	I had control over the decisions that were made	5	4	3	2	1
5	The people in the room took control	1	2	3	4	5
6	People coming in and out of the room was beyond my control	1	2	3	4	5
7	I could get up and move around as much as I wanted	5	4	3	2	1
8	I chose whether I was given information or not	5	4	3	2	1
9	I could decide when I received information	5	4	3	2	1
10	I had control over what information I was given	5	4	3	2	1
11	I felt I had control over the way my baby was finally born	5	4	3	2	1
12	The pain was too great for me to gain control over it	1	2	3	4	5
13	I was overcome by the pain	1	2	3	4	5
14	I was mentally calm	5	4	3	2	1
15	I was able to control my reactions to the pain	5	4	3	2	1
16	I was in control of my emotions	5	4	3	2	1
17	I felt my body was on a mission that I could not control	1	2	3	4	5

18	Negative feelings overwhelmed me	1	2	3	4	5
19	I gained control by working with my body	5	4	3	2	1
20	I behaved in a way not like myself	1	2	3	4	5
21	I could control the sounds I was making	5	4	3	2	1

What kind of support did you receive from healthcare staff during labour and birth?

		Agree completely	**Agree slightly**	**Neither**	**Disagree slightly**	**Disagree completely**
22	The staff helped me find energy to continue when I wanted to give up	5	4	3	2	1
23	The staff knew instinctively what I wanted or needed	5	4	3	2	1
24	The staff went out of their way to try to keep me comfortable	5	4	3	2	1
25	The staff encouraged me to try new ways of coping	5	4	3	2	1
26	The staff encouraged me not to fight against what my body was doing	5	4	3	2	1
27	The staff realized the pain I was in	5	4	3	2	1
28	I felt the staff had their own agenda	1	2	3	4	5
29	I was given time to ask questions	5	4	3	2	1
30	I felt like the staff tried to move things along for their own convenience	1	2	3	4	5
31	The staff helped me to try different positions	5	4	3	2	1
32	The staff stopped doing something if I asked them to stop	5	4	3	2	1
33	The staff dismissed things I said to them	1	2	3	4	5

Support & Control in Birth (SCIB; Ford, Ayers & Wright, 2009)

Appendix Six – Postnatal Clinical Outcomes and Global Ratings Scales form to be completed by Observer post observation

Midwife code: **Woman's code:**

Date of Observation: **Length of observation (in minutes):**

Length of first stage of labour:

Length of second stage of labour:

Analgesia/Anaesthesia used (please tick):

Breathing and relaxation ☐ Self-hypnosis ☐ Entonox ☐ Epidural ☐ ☐

Birthing pool ☐

Opiates ☐ Spinal/ General Anaesthetic

Other.....

Medical Interventions used (please tick)

Amniotomy ☐ Prostaglandin ☐ Syntocinon ☐ Episiotomy ☐

Other.....

Type of Birth

Spontaneous vaginal delivery ☐ Ventouse ☐ Forceps ☐ Emergency ☐

Caesarean

When thinking back on the whole of the observation period you have observed, please give overall ratings for the following:

1. **The quantity of midwifery support (emotional, tangible, advocacy, informational, partner support) I observed was**

0	**1**	**2**	**3**	**4**
Poor	Adequate	Good	Very good	Excellent

2. **The quality of midwifery support I observed was**

0	**1**	**2**	**3**	**4**
Poor	Adequate	Good	Very good	Excellent

3. **The SMILI helped me to record the midwifery support I observed**

0	**1**	**2**	**3**	**4**
Inadequately	Partially	Well enough	Very well	Fully

4. **Please describe any problems you experienced using the SMILI in the labour setting**

Questions for Observation midwife about being observed providing care:

1. **How did you feel about having an observer present while you were providing care?**

0	**1**	**2**	**3**	**4**
Distressed	Uncomfortable	Mildly	OK	Fine, enjoyed it
Very uncomfortable		uncomfortable		

Do you have any further comments about the observation experience….

2. **Do you think you would agree to participate in a similar study again?**

0	**1**	**2**
No	Maybe	Yes

Do you have any further comments…….

Questions for the Woman about being observed during her labour

1. **How did you feel about having an observer present while you were in labour?**

0	**1**	**2**	**3**	**4**
Distressed	Uncomfortable	Mildly	OK	Fine, enjoyed it
Very uncomfortable		uncomfortable		

Do you have any further comments about the observation experience….

3. **Do you think you would agree to participate in a similar study again?**

0	**1**	**2**
No	Maybe	Yes

Do you have any further comments…….

Appendix Seven- Written information for student midwives approached to participate in Study two

Information sheet about a research study: 'Promoting normal birth through midwifery support in labour'

Would you like to be part of a study to understand what midwives can do to provide women with the best support during labour?

This study forms part of a PhD being undertaken by midwife Mary Ross-Davie at the Nursing Midwifery and Allied Health professionals' research unit (NMAHPRU) at the University of Stirling, sponsored by the Royal College of Midwives (RCM).

- *What is the purpose of the study?*

  There has been a lot of research which indicates that continuous support during labour has a positive effect on outcomes, including increasing the normal birth rate, reducing caesarean section rates, reducing epidural use and increasing maternal satisfaction with the birth experience. There is very little research about what the content of this support should be. What should the midwife be doing to have the best impact on outcomes?

  This study aims to examine in detail what support midwives provide to women during labour and the way in which this support is offered. The way in which this will be done is through carrying out what is called a 'systematic observation' of labour care. The researcher will be present in the labour room and will use a computer based instrument to record the behaviours and demeanour of the midwife.

  The researcher is currently wishing to test whether this instrument contains all the right elements. One of the ways to do this is to see whether other people agree with the researcher's decisions about what has been included and the wording used.

- *Why am I being approached to be involved?*

  In order to test the instrument for 'validity', an important stage in the development of any new instrument, tool or questionnaire. This means to test that the instrument includes the right elements and that the behaviours to be observed are described in a way that is understandable to people other than the researcher. We have decided to approach student midwives for two reasons: as a student midwife, you have a level of knowledge about the labour process and the midwife's role that will allow you to understand the content of the instrument and secondly, student midwives in the earlier part of their training spend a considerable amount of time observing labour and the care provided by midwives and so we feel you will have understanding of how it is possible to put what you see in a labour room into words.

Appendix 7 contd

- *Do I have to participate in this study?*

  No, participation in this study is completely voluntary. Your decision about whether you wish to participate or not will not affect your studies in any way and your tutors will not be informed. If you agree to participate at this stage, you can change your mind at any time without any repercussions.

- *Who else is involved in this study?*

  For this part of the study we are asking for between five and ten student midwife volunteers. For the next stage of the study we will have a panel of ten experts in the field (midwifery researchers, experienced clinical midwives and service user representatives) who will be asked to assess the content of the instrument. We will then be asking the student midwife volunteers and this panel of experts to test using the instrument by viewing videos of labour care.

- *What will I have to do?*

  For this part of the study, you will be asked to take part in an individual 'card sorting' exercise. This will involve you sitting with the researcher and being asked to group cards with statements about things the midwife may be seen to be doing in labour (e.g. being in the room, taking a blood pressure, encouraging) and placing them with broader descriptions with which they fit (e.g. showing respect, midwifery presence).

- *How long will it take?*

  We think the exercise will take about half an hour.

- *How will my involvement and my views be recorded?*

  If you decide to participate in this study, you will be asked to complete and sign a consent form. This form will be stored in a locked cabinet in the researcher's office. It will be kept separately from the record of your answers during the card sorting exercise, so that your answers cannot be linked to you individually. Your answers in the card sorting exercise will be recorded by the researcher on a record sheet. This sheet will not have your name or personal details on it, so your answers are 'anonymised'. When describing the results of the exercise the researcher will not include details which would allow you to be identified individually.

- *Why would I want to be involved?*

  Participation in this study will hopefully be an interesting process. You may learn a little about research and the research process. You may also find it helpful to think about what are the important elements of care in labour.

  If you would like to be involved in the study, please email the researcher, Mary Ross-Davie at m.c.ross-davie@stir.ac.uk or call or text her on 07796 614 721.

Appendix Eight- Study Two: 'Promoting normal birth through midwifery support in labour' Development of a systematic observation instrument - Consent to participate

Please tick the statements that you agree with:

- I confirm that I have read and understand the information sheet dated(version ...) for the above study and have had the opportunity to ask questions. ☐
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my course being affected. ☐
- I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone. ☐
- I understand the nature and the purpose of the study. ☐
- I give permission for the information I provide to be used for research purposes (including reports, publication and presentations) with strict preservation of anonymity. ☐
- I understand that I will take part in an individual 'card sorting' exercise as part of the study and that my decisions will be recorded on a computer form by the researcher. ☐
- I understand that any information I provide will be treated in the strictest confidence. The information will be held securely for ten years and will only be available to the researcher. The information will be destroyed after this time. ☐
- I understand that no personally identifiable information will be collected and my data will be identified only by a randomly generated number. ☐
- I agree to take part in the above research study

_____ _____ _____

Participant name Date Participant signature

_____ _____ _____

Researcher name Date Researcher signature

Appendix 9 – University of Stirling Nursing and Midwifery Departmental Ethics Committee Approval letter for studies two, three and four

JP/SG

09 April 2010

Mary Ross-Davie
28 Blackford Bank
Edinburgh
Midlothian
EH9 2PR

UNIVERSITY OF STIRLING

DEPARTMENT OF
NURSING AND MIDWIFERY

Email: nursingmidwifery@stir.ac.uk
Web: www.nm.stir.ac.uk

John Paley
Chair (Acting)
Dept Ethics Research Commitee

Department of Nursing & Midwifery
University of Stirling
Stirling FK9 4LA

Tel: +44 (0) 1786 466399
Fax: +44 (0) 1786 466333
Email: j.h.paley@stir.ac.uk

Dear Mary

Promoting normality in childbirth through midwifery support

Thank you for submitting your proposal, which was discussed on 7 April 2010.

I am happy to inform you that the Committee approved the study, without reservation or qualification. My only regret is that we were unable to make this decision a month ago.

Congratulations on an excellent application, and good luck with the project itself.

Best wishes

John Paley
Chair (Acting)
Department of Nursing and Midwifery Research Ethics Committee

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Appendix Ten – Information sheet for expert panel about study three

Information sheet about a research study called: 'Promoting normal birth through midwifery support in labour'. Study Three – Validation of observation instrument

Would you like to be part of a study to understand what midwives can do to provide women with the best support during labour?

This study forms part of a PhD being undertaken by midwife Mary Ross-Davie at the Nursing Midwifery and Allied Health professionals' research unit (NMAHPRU) at the University of Stirling, sponsored by the Royal College of Midwives (RCM).

What is the purpose of the study?

There has been a lot of research which indicates that continuous support during labour has a positive effect on outcomes, including increasing the normal birth rate, reducing caesarean section rates, reducing epidural use and increasing maternal satisfaction with the birth experience. There is very little research about what the content of this support should be. What should the midwife be doing to have the best impact on outcomes?

This study aims to examine in detail what support midwives provide to women during labour and the way in which this support is offered. The way in which this will be done is through carrying out a 'systematic observation' of labour care.

What is a 'systematic observation' study?

In systematic observation, a researcher uses a 'coding sheet', event recorder, instrument or tool to record particular activities of interest. This may be done by listening to audio recordings of an event, observing videos or by recording events in real time by being present in the room with the subjects being observed. Systematic observation techniques have been used widely in research in psychology (notably in developing understanding of attachment through observing mother-baby interactions), education (in observing different teaching styles through observing and recording classroom interactions) and in health (particularly in recording Dr-patient interactions to be used in training doctors). The approach has not yet been used to record the quality and quantity of midwifery support provided to women during labour.

In this study, it is proposed that the researcher will be present in the labour room and will use a computer based instrument to record the behaviours and demeanour of the midwife.

The researcher is currently testing the instrument to assess whether it has comprehensive and understandable content and language.

Why am I being approached to be involved?

In order to test the instrument for 'validity', an important stage in the development of any new instrument, instrument or questionnaire. This means to test that the instrument includes the right elements and that the behaviours to be observed are described in a way that is understandable to people other than the researcher. When devising any new measurement instrument as part of research, it is normal good practice to work with a panel of experts in the area to be studied to form a judgement about whether the content of the instrument is valid. For this study, the researcher has decided that the panel of experts approached will need to include midwifery researchers and educationalists, experienced midwifery clinicians and service users. You have been contacted as a potential member of such as 'expert panel' through either the lead midwives and consultant midwives networks in Scotland or the service user organisations in Scotland (Maternity service liaison committees and National Childbirth Trust).

Do I have to participate in this study?

No, participation in this study is completely voluntary. If you decide you do not wish to participate, you can choose to simply not respond to this contact.

Who else is involved in this study?

A group of student midwives have been involved in an earlier stage of this validation study. For this part of the study, we are seeking to recruit an expert panel of around ten from all over Scotland to include researchers, clinicians and service users.

What will I have to do?

You will be asked to review the draft systematic observation instrument developed for this study. This draft observation instrument has been developed by the researcher following a systematic review of the literature on support in labour. You will be asked to provide your feedback on the instrument through an on-line questionnaire.

How long will it take?

We think the whole exercise will take an hour maximum.

How will my involvement and my views be recorded?

If you decide to participate in this study, you will be asked to complete and sign a consent form. This form will be stored in a locked cabinet in the researcher's office. It will be kept separately from the record of your answers to the questionnaire, so that your answers cannot be linked to you individually. Your answers in the questionnaire will be collated with the answers of other panel members by the researcher. When describing the results of the exercise the researcher will not include details which would allow you to be identified individually.

Why would I want to be involved?

We believe this is an important study in developing a more in depth understanding of the processes involved in midwifery intrapartum care and the impact of this care on outcomes. By agreeing to participate in the study, you will be assisting to ensure that the research process in developing the instrument has been systematic and rigorous and thus that the instrument itself is valid and reliable. A valid and reliable instrument to record the quantity and quality of midwifery intrapartum support will be a valuable resource for future midwifery research and practice development. Participation in this study will hopefully also be an interesting process.

If you interested in participating in this study please email Mary at m.c.ross-davie@stir.ac.uk before ..... (date)

Appendix 11- 'Promoting normal birth through midwifery support in labour' Study Three

Development of a systematic observation instrument – Expert panel - Consent to participate

Please tick the statements that you agree with:

- I confirm that I have read and understand the information sheet dated (version ...for the above study and have had the opportunity to ask questions. ☐
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without any repercussions. ☐
- I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone. ☐
- I understand the nature and the purpose of the study. ☐
- I give permission for the information I provide to be used for research purposes (including reports, publication and presentations) with strict preservation of anonymity. ☐
- I understand that I will complete an on-line questionnaire asking for my views about a draft systematic observation instrument for recording the quality and quantity of midwifery support in labour. ☐
- I understand that any information I provide will be treated in the strictest confidence. The informatio will be held securely for ten years and will only be available to the researcher. The information will be destroyed after this time. ☐
- I understand that no personally identifiable information will be collected and my data will be identified only by a randomly generated number. ☐
- I agree to take part in the above research study ☐

_____ _____ _____

Participant name Date Participant signature

_____ _____ _____

Researcher name Date Researcher signature

Appendix Twelve - Covering letter for expert panel

Iris Murdoch Building

University of Stirling

Stirling FK9 4LA

01786 466 341

1 June 2010

Dear Expert Panel Member

Please find enclosed a computer disc (or memory stick) which contains the pilot version of the newly developed SMILI (Supportive Midwifery in Labour Instrument). I have also provided you with a paper copy of the different screens of the SMILI so that you have something to refer to when you are completing the online questionnaire. I would be very grateful if you would take a look at the computer programme and then complete the online survey monkey questionnaire (link http://www.surveymonkey.com/s/5RSGXWC) to provide feedback on the relevance and clarity of the content, usability and comprehensiveness of the instrument. Please find below some more detailed background about the instrument which, I hope, will make the instrument more understandable for you.

1. **Background to content included**

   The content of the SMILI is based on a systematic review of the current available research on labour support and the measurement of quality in healthcare interactions.

   This review found that there had been only five previous studies using direct observation and recording of nursing support in the labour setting (McNiven et al 1992, Gagnon and Waghorn 1996, Gale et al 2001, Miltner 2001 and Barnett 2008). These studies, while adding to our understanding of the support provided by intrapartum nurses in the USA and Canada, did not examine midwifery support in the UK and did not seek to describe the way in which care was carried out. The instruments devised for these studies recorded the proportions of nursing time which were spent in or out of the labour room and recorded nursing behaviours into broad categories of emotional support, physical support, informational support and advocacy or in providing other non-support direct and indirect care (such as equipment preparation, maintaining intravenous fluids and medication, monitoring vital signs, monitoring the fetal heart rate). These earlier instruments did not include a number of behaviours and elements of care which are identified in the literature as being important to women: this includes behaviours that exhibit 'attitude', such as facial expression and vocal tone. A review of the large body of qualitative research with women about what they felt was important about the care provided to them in labour identifies the importance of these quality and 'attitude' aspects of care as well as simply the behaviours. It was therefore decided that rather than using an instrument devised for the previous studies, a new observation instrument was required to record not only the quantity but the quality of the support provided during labour.

   While the earlier instruments for observing labour care have not included the 'softer' aspects of care, other validated observation instruments have successfully identified and recorded these important aspects of a healthcare interaction. Instruments used to improve GP interactions with their patients (Stiles 1992, Roter and Hall 2006) have included assessment of non-verbal behaviours. There have been other studies looking at the quality of nursing care, the use of humour in health care and the measurement of empathy in healthcare interactions

(Maguire 1988, Mercer and Reynolds 2002, Fitzpatrick et al 1997, Gilloran et al 1993, Fosbinder 1994, Bottorff 1995) that have demonstrated that the assessment of these elements can be reliably measured. The next stage of the SMILI development process will be one testing the level of reliability of the instrument, with different observers viewing and recording the same episodes of care on videos and seeing whether there is an adequate level of agreement between observers.

All of the elements included in the SMILI are derived from the literature. Decisions have been made by the researcher about how broader descriptions given by women as being important to them in labour, such as 'being shown respect' or 'being given a sense of control' can actually be seen and recorded in a labour setting. So, for example, the researcher has included a number of different elements which may be considered to demonstrate showing a woman respect, these include having a pleasant facial expression, knocking on the door before entering the labour room, using curtains and covers to protect privacy, asking the woman about her feelings and views, supporting the woman's own coping strategies etc. A number of elements have also been included which, if experienced by a woman in labour, may be experienced as being shown a lack of respect, these include a curt or unfriendly demeanour, ignoring a woman's contraction, talking over a contraction, criticising a woman's behaviour etc.

2. How the SMILI will be used

The programme is designed to be used by trained observers who will observe labour care. The instrument will be pilot tested in the clinical setting from September 2010 with an observer sitting quietly in a labour room with a laptop computer. Women will have received written information about the study in pregnancy and will be asked to provide consent to participate in early labour or upon admission for induction. Midwives will also have received information about the study and will have provided consent to participate.
The instrument is not designed to be completed by the midwife providing care but by another observer not involved in providing care, though the observer will be a midwife.
Both low and higher risk women will be eligible to participate in the study. The inclusion criteria will be any woman with a singleton pregnancy presenting by the vertex at term in active labour.
The observers will generally record the care for a total of three hours (to reduce the risk of fatigue and error). One of the aims of the pilot study will be to establish whether it is possible for observers to be present for shorter periods of time and still obtain similar results.
The main focus of the study is on the first stage of labour.

3. **How to run the SMILI programme**
See the instruction sheet attached.

In tests so far, it has been possible for the researcher to complete the screens when observing a video of labour care in two minutes, but this will be further tested in the reliability testing phase. It would be possible to easily change the time allocated to the observation to three or even four minutes.
The observer is being asked to carry out an intermittent observation of behaviour – if this is every two minutes, the observer will make 30 observations in one hour, if it is every three minutes the observer will make 20 observations in one hour. This way of recording events does mean that some events will be missed compared to continuous observation, but it is the only feasible way for one observer to attempt to record so many facets of the care situation in real time.

Overall, what I hope to gain through recruiting an expert panel to review the SMILI at this stage is to assess whether you think that this instrument will measure support provided by midwives in

labour. If the majority of the panel disagree with particular elements of the SMILI, I will make appropriate amendments and then recirculate the amended version for your further consideration.
If you have any problems at all understanding how the programme works or getting the programme to work, or if you have any queries at all please do contact me either by telephone on 07796 614 721 or by email at m.c.ross-davie@stir.ac.uk.
The SMILI that you have been sent is very much a work in progress and so I would be grateful if you do not share it with others at present.
Please could you complete and sign the enclosed consent form and return to me in the envelope provided.

Please complete the online survey monkey questionnaire about the SMILI by **Wednesday 16th June 2010.**

With many thanks in advance for your time and support in participating in this research,

Yours sincerely

Mary
Mary Ross-Davie MA, BA hons, RM
PhD Student

Appendix 13 – Instructions for expert panel

The 'SMILI' - Supportive Midwifery in Labour Instrument

University of Stirling, NMAHP Research Unit, NHS Scotland; Mary Ross-Davie, BA, RM, PhD student

1. **Insert memory stick or disc**
   The memory stick will give you the option of 'run SMILI study' which you should click. The disc should just run the program automatically.
2. **Front page**
   The first thing you need to do is click on the 'context' button – which brings up the context screen.
3. **Context page**
   This allows the observer to describe how busy the labour ward is, a few details about the woman, a few details about the midwife and how the physical environment in the labour room is set up at the start of the observation.
   You need to insert a **midwife code** in order to gain access to the other screens – this is so the results can be saved and matched with individual observation midwives. Please just insert any number into the midwife code box.
   You can complete as much or as little of this screen as you want to, the results you insert will be automatically saved onto your desktop. When you have finished with the context screen, click **OK** and you will be taken to the first observation page
4. **Observation pages**
   There are two modes of observation pages. The default mode is 'between contractions'. The observer will need to click on the **'contraction'** button at the start of the observation period to identify if the woman is having a contraction. When you are looking through the SMILI please look through all the screens for both during and between a contraction. If the woman is having a contraction, different behaviours are recorded and there are a lot fewer observations to record on the 'information' page. If during the two minute observation the woman changes from being between a contraction to having a contraction, the observer can click the contraction button and the timer will reset and give the observer the 'contraction' mode screens.

   Now click the **'start'** button – this will activate a timer to count down from 2 minutes to 0. This timer will give the observer 30 seconds to complete the first screen (woman – demeanour, vocalisation,etc) and will then automatically switch to the next screen (partner – demeanour etc). After 30 seconds it will switch to the next screen (midwife – demeanour, vocal tone etc). When you are looking over the SMILI, if you want longer to consider each screen just click the **pause** button (this is the same as the start button but its name should have changed by now).
   To complete all of the midwife screens you need to click the tabs – behaviour, touch and information. In this test version it just allows 30 seconds to complete the midwife screens, but in the final instrument this will be 60-90 seconds.
5. **Midwife Present**
   The observer will click this button at any time during observations to record if the midwife leaves or enters the room. The program will record the number of seconds that the midwife is present and absent.
6. **Other people**
   This allows the observer to **record** if any other professional enters the labour room**.**
7. **Emergency/Error**
   This allows the observer to note in free text if an emergency arises or if they have made an error in recording the care.
8. When you have finished just click on the 'Finish' button.

Any data that you have recorded when testing the SMILI will be recorded onto the memory stick if you have run the SMILI from the data stick or if you have run the SMILI from a disc it will save the results onto your desk top. This will be in the form of 5 files – 'contractionres1' (or whatever number you have given as the midwife code), 'betweenres1', 'context1',log file and temp file. It would be helpful to me and Kevin (who is the computer specialist who has developed the program) if you could email me back the first four of these files as email attachments so that Kevin can assess if there are any problems with the way results are recording.
If you could send me back the data stick and disc once you have finished that would be great.

Appendix Fourteen– Information sheet about observation of videos test

Information sheet about a research study called: 'Promoting normal birth through midwifery support in labour'. Study Four – Validation and Reliability testing of observation instrument

Would you like to be part of a study to understand what midwives can do to provide women with the best support during labour?

This study forms part of a PhD being undertaken by midwife Mary Ross-Davie at the Nursing Midwifery and Allied Health professionals' research unit (NMAHPRU) at the University of Stirling, sponsored by the Royal College of Midwives (RCM).

- *What is the purpose of the study?*

  This study aims to examine in detail what support midwives provide to women during labour and the way in which this support is offered. The way in which this will be done is through carrying out a 'systematic observation' of labour care.
- *What is a 'systematic observation' study?*

  In systematic observation, a researcher uses a 'coding sheet', event recorder, instrument or tool to record particular activities of interest. This may be done by listening to audio recordings of an event, observing videos or by recording events in real time by being present in the room with the subjects being observed. Systematic observation techniques have been used widely in research in psychology (notably in developing understanding of attachment through observing mother-baby interactions), education (in observing different teaching styles through observing and recording classroom interactions) and in health (particularly in recording Dr-patient interactions to be used in training doctors). The approach has not yet been used to record the quality and quantity of midwifery support provided to women during labour.

  In this study, it is proposed that the researcher will be present in the labour room and will use a computer based instrument to record the behaviours and demeanour of the midwife.

  The researcher is currently testing the instrument to assess whether it has comprehensive and understandable content and language and whether it can reliably record the quality and quantity of midwifery support in labour.
- *Why am I being approached to be involved?*

  We are approaching student midwives and members of the expert panel who have been involved in an earlier part of this study (testing the validity of the observation instrument through a card-sorting exercise or through completing a review questionnaire). This is the next stage of the observation instrument development process to further test the validity and reliability of the instrument.
- *Do I have to participate in this study?*

  No, participation in this study is completely voluntary. If you decide you do not wish to participate, you can choose to simply not respond to this contact.
- *Who else is involved in this study?*

Appendix 14 contd

For this part of the study, we are asking for around ten volunteers from a group of student midwives, NMAHP researchers and members of an 'expert panel' of midwifery researchers, clinicians and service users.

- *What will I have to do?*

  The researcher will arrange to meet you at a mutually convenient time and location. The researcher will then show you the draft observation instrument and how it should be used. You will be given the opportunity to ask any questions you have about the research and the observation instrument. You will then be asked to watch around five short clips from commercial films which show women in labour. You will be asked to record the care you see on the films using the draft instrument.

- *How long will it take*?

  We think the whole exercise will take about one and a half hours maximum.

- *How will my involvement and my views be recorded?*

  If you decide to participate in this study, you will be asked to complete and sign a consent form. This form will be stored in a locked cabinet in the researcher's office. It will be kept separately from the record of your recorded observations, so that your answers cannot be linked to you individually. Your recorded observations will be transferred to a computer based statistical package called SPSS and the researcher will analyse the data from your and the other observers' observations. The aim of the exercise is to ensure that different observers viewing the same episode of care will have similar results using the instrument (inter-observer reliability) and that the same observer viewing one episode of care on more than one occasion will have similar results using the instrument on both occasions (intra-observer reliability). When describing the results of the exercise the researcher will not include details which would allow you to be identified individually.

- *Why would I want to be involved?*

  We believe this is an important study in developing a more in depth understanding of the processes involved in midwifery intrapartum care and the impact of this care on outcomes. By agreeing to participate in the study, you will be assisting to ensure that the research process in developing the instrument has been systematic and rigorous and thus that the instrument itself is valid and reliable. A valid and reliable instrument to record the quantity and quality of midwifery intrapartum support will be a valuable resource for future midwifery research and practice development. Participation in this study will hopefully also be an interesting process.

If you interested in participating in this study please email Mary at m.c.ross-davie@stir.ac.uk before ..... (date)

Appendix 15- 'Promoting normal birth through midwifery support in labour' Study Four- Development of a systematic observation instrument – Video observation - Consent to participate

Please tick the statements that you agree with:

- I confirm that I have read and understand the information sheet dated (version ...) for the above study and have had the opportunity to ask questions. ☐
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without any repercussions. ☐
- I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone. ☐
- I understand the nature and the purpose of the study. ☐
- I give permission for the information I provide to be used for research purposes (including reports, publication and presentations) with strict preservation of anonymity. ☐
- I understand that I will observe a number of films depicting women in labour and labour care and will record my observations using the draft systematic observation instrument, recording the quality and quantity of midwifery support in labour. ☐
- I understand that any information I provide will be treated in the strictest confidence. The informatio will be held securely for ten years and will only be available to the researcher. The information will be destroyed after this time. ☐
- I understand that no personally identifiable information will be collected and my data will be identified only by a randomly generated number. ☐
- I agree to take part in the above research study ☐

_____ _____ _____

Participant name Date Participant signature

_____ _____ _____

Researcher name Date Researcher signature

Appendix 16 – Information poster to be displayed in participating maternity units' antenatal clinics and labour ward areas

The Royal College of Midwives
The only professional organisation and trade union led by midwives for midwives

Nursing, Midwifery and Allied Health Professions Research Unit
CHIEF SCIENTIST OFFICE

The 'Promoting normal birth through Midwifery support in Labour' Study

Midwives in this maternity unit are currently taking part in a study looking at how midwives offer support to women in labour.

You may be asked when you come in during early labour if you would be willing to take part in this study. This would mean having another midwife sitting in the labour room to observe the care you are given during labour.

You can ask your midwife at your antenatal appointment for an information leaflet about this study.

You can also contact the researcher directly for more information:

Mary Ross-Davie at m.c.ross-davie@stir.ac.uk or 07796 614 721

Appendix 17 Information sheet for women and birth partners

The 'Promoting Normal birth through midwifery support in labour' study – Information Sheet

Would you like to be part of a study to understand what midwives can do to provide women with the best support during labour?

- *Who is undertaking the study?*
  This study forms part of a PhD being undertaken by midwife Mary Ross-Davie at the Nursing Midwifery and Allied Health professionals' research unit (NMAHPRU) at the University of Stirling, sponsored by the Royal College of Midwives (RCM). She is being assisted in the observations by four other midwives who are employed by NHS Scotland.

- *What is the purpose of the study?*
  There has been a lot of research which indicates that continuous support during labour has a positive effect on a number of birth outcomes, including women's satisfaction with the whole experience. There is very little research about what the content of this support should be. What should the midwife be doing to provide the best support for women in labour?
  This study aims to record in detail what support midwives provide to women during labour and the way in which this support is offered. The way in which this will be done is that the researcher (who is a midwife) will be present in the labour room and will use a small lap top computer to note down what the midwife does.

- *Why am I being approached to be involved?*
  All women booked to have their babies at the .....maternity unit during the period ..... (dates) are being given information about this research at their antenatal appointment. When you come into the unit in early labour, if everything is routine with your and the baby's well-being at that time, you may be asked by the midwife in charge of the unit if you would be happy to participate in the research that day. She would answer any questions you have about the research.

- *Do I have to take part in this study?*
  No, this study is completely voluntary. Your decision about whether you wish to take part or not will not affect the care that you receive. If you agree to take part in the study you are free to change your mind at any time with no affect on your care.

Appendix 17 contd

- *Who else is involved in this study?*
  We are hoping to get between thirty and fifty volunteer women and midwives to be involved.

- *What will I have to do?*
  You and your birth partner(s) will be given time to decide whether you wish to be involved in the study and will be asked to provide written consent to be involved. The research midwife will introduce herself to you and your birth partner and will then sit quietly in a corner of the room with you. The researcher will not get involved in conversations in the room. The research midwife will be focussing on the care that the midwife provides and will be recording this on the laptop computer using a specially designed form. The research midwife will also record how you are during the labour and what your birth partner is doing to support you. She will not be involved in providing any care, unless an emergency arises. The record made is a written record and does not involve any filming or audio recording. After the birth, the research midwife will ask if the researcher can visit you to ask you about how you felt about the research midwife being in the room during your labour and to complete a short questionnaire about how you felt you were supported during your labour.

- *How long will it take?*
  The researcher will ask to be present from the time you give consent to be involved in the study for the next three hours of your labour. You and your birth partner are free to ask the research midwife to leave the room at any time. The questionnaire and conversation with the researcher after the birth will not take longer than ten minutes in total.

- *How will my involvement and my views be recorded?*
  If you decide to take part in this study, you will be asked to complete and sign a consent form. This form will be stored in a locked cabinet in the researcher's office. It will be kept separately from the record of the labour care, so that the description of your labour care cannot be linked to you individually. The record of your care will not have your name or personal details on it, so the record is 'anonymised'. When describing the care observed the researcher will not include details which would allow you to be identified individually. After your baby is born, the researcher will ask you to complete a short questionnaire which asks you about you felt about the support you received during your labour.
  You will be provided with a copy of a summary of the completed research if you would like it.

- *Why would I want to be involved?*
  Taking part in this study will hopefully be an interesting and positive experience. By participating you will be assisting with some research that will add to our knowledge of what midwives can do to make birth as positive experience as possible.

  If you would like to be involved in the study or have any further questions, you can email the researcher, Mary Ross-Davie, at m.c.ross-davie@stir.ac.uk or call or text her on 07796 614 721.

Appendix 18 - Study of the Supportive Midwifery in labour Instrument - Consent to participate (woman)

Please initial the statements that you agree with: **Initial box**

- I confirm that I have read and understand the information sheet dated (version …) for the above study and have had the opportunity to ask questions. ☐
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my care being affected. ☐
- I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone. ☐
- I understand the nature and the purpose of the study. ☐
- I give permission for the observation record to be used for research purposes (including reports, publication and presentations) with strict preservation of anonymity. ☐
- I understand that a midwife researcher will be present in the room with me during my labour. The researcher will note down using a laptop computer the care that is offered during my labour. ☐
- I understand that the midwife researcher will note down how I am and how my birth partner is during the labour. ☐
- I understand that after the birth the researcher will visit me to ask me about how I felt about having an observer in the room during the labour and to answer any questions I have about the research. ☐
- I understand that the midwife researcher will give me a questionnaire after the birth to complete before I go home about how I feel I was supported by my midwife during my labour. ☐
- I understand that the midwife researcher will look at my labour notes after the birth to note down the outcomes of my labour – how long my labour was, the type of birth and how I and the baby are after the birth. ☐
- I understand that the observation record, questionnaire and birth outcomes record will be treated in the strictest confidence. The information will be held securely for ten years and will only be available to the researcher. The information will be destroyed after this time. ☐
- I understand that no personally identifiable information will be recorded on the observation record, questionnaire or birth outcomes record and my data will be identified only by a randomly generated number. ☐
- I agree to take part in the above research study ☐

_____	_____	_____
Participant name	Date	Participant signature
_____	_____	_____
Researcher name	Date	Researcher signature

Appendix 19 - Pilot study of the Supportive Midwifery in labour instrument- Consent to participate (birth partner)

Please initial the statements that you agree with: **Initial box**

- I confirm that I have read and understand the information sheet dated (version …) for the above study and have had the opportunity to ask questions. ☐
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my partner's care being affected. ☐
- I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone. ☐
- I understand the nature and the purpose of the study. ☐
- I give permission for the observation record to be used for research purposes (including reports, publication and presentations) with strict preservation of anonymity. ☐
- I understand that a midwife researcher will be present in the room with me during my partner's labour. The researcher will note down using a laptop computer the care that is offered during the labour. ☐
- I understand that the midwife researcher will note down how I am and how my partner is during the labour. ☐
- I understand that the observation record will be treated in the strictest confidence. The information will be held securely for ten years and will only be available to the researcher. The information will be destroyed after this time. ☐
- I understand that no personally identifiable information will be recorded on the observation record, questionnaire or birth outcomes record and my data will be identified only by a randomly generated number. ☐
- I agree to take part in the above research study ☐

Participant name	Date	Participant signature
Researcher name	Date	Researcher signature

Appendix 20 – Information for midwives carrying out consent procedure with women

Only women who are not distressed should be approached to discuss participation in the study. Please go through the following steps:

1. First ensure that the woman and her birth partner(s) have had the opportunity to read the information leaflet.
2. Ask the woman and her partner if they have any questions about the research having read the leaflet. If they ask you something that you are not sure what the answer is, please simply contact the researcher present on labour ward to ask them to advise you.
3. Explain that the study has as its aim to study the support that women are offered by their midwife during labour. There has not been any study to try to describe in detail what makes up good quality support.
4. If the woman and her partner agree to take part in the study this would involve having a researcher, who is a trained midwife, present in the room with them for three hours. The researcher will use a laptop computer to note down the midwife's actions and behaviour and general notes on what is happening in the room.
5. The woman, partner or midwife can ask the researcher to leave at any time.
6. The researcher will not be involved in providing care and will not join in conversations.
7. The computer record will not contain the woman or the midwife's name or individually identifying details.
8. After the three hours is completed, the researcher will leave the room. After the baby is born, the researcher will ask to meet with the woman again to answer any questions and to ask her to complete a short questionnaire about how well she felt she was supported in labour. This should only take about 10 minutes in total.
9. Ask the woman and her birth partner to read through the consent forms, tick the appropriate boxes and sign and date the forms (there is a separate form for each of them).
10. Please then let the researcher know that the consent procedure has been completed and return the consent form to her.

Many thanks for taking time to assist with this research study. Mary Ross-Davie, Midwife and PhD student, 07796 614 721. M.c.ross-davie@stir.ac.uk.

Appendix 21- Written information for midwives approached to participate in Study – Leaflet

Would you like to be part of a study to understand what midwives can do to provide women with the best support during labour?

This study forms part of a PhD being undertaken by midwife Mary Ross-Davie at the Nursing Midwifery and Allied Health professionals' research unit (NMAHPRU) at the University of Stirling, sponsored by the Royal College of Midwives (RCM).

- *What is the purpose of the study?*
  There has been a lot of research which indicates that continuous support during labour has a positive effect on a number of birth outcomes, including women's satisfaction with the whole experience. There is very little research about what the content of this support should be. What should the midwife be doing to provide the best support for women in labour?
  This study aims to examine whether the newly developed 'SMILI' or 'Supportive Midwifery in Labour Instrument' can effectively record what support midwives provide to women during labour and the way in which this support is offered. The way in which this will be done is through carrying out what is called a 'systematic observation' of labour care. The researcher (who is a midwife) will be present in the labour room and will use a small lap top computer to record what the midwife does.

- *Why am I being approached to be involved?*
  The head of midwifery of your maternity unit has agreed to this study. We have successfully gained ethical approval for this study from the University of Stirling nursing and midwifery departmental ethics committee and from the .....NHS ethics committee and local Research and Development department.
  We are providing information about this pilot study to all midwives regularly providing intrapartum care at the .....maternity unit. We are looking for between eight and thirteen volunteer midwives. We hope to observe between eight and thirteen episodes of labour care for this feasibility and pilot study at this maternity unit.

- *Do I have to participate in this study?*
  No, participation in this study is completely voluntary. Your decision about whether you wish to participate or not will not affect your employment in any way. Neither your line manager nor supervisor will be advised whether you volunteer or not. If you agree to participate in the study you are free to change your mind at any time without any repercussions.

- *Who else is involved in this study?*
  We are looking for between eight and thirteen midwives and the women they are caring for in labour to be involved at this unit. A further twenty to forty midwife/woman pairs at three other comparison maternity units are also being recruited.

- *What will I have to do?*
  If you decide to volunteer to be involved, you can contact the midwife researcher to discuss the research in more detail or ask any questions you may have. On pre-arranged dates the observation midwives will attend the maternity unit at the beginning of an ordinary working shift. At this point, they will ask all of the midwives on duty if they are willing to participate in the research. They will then ask any volunteers to provide written consent to participate. The midwife researcher will take a few demographic details from you about how long you have been a midwife etc. The midwife in charge of the unit will approach any women on the maternity unit at the time

who meet our inclusion criteria (woman in early active labour, suitable for midwife-led care) to seek their consent to participate in the study.

Once you and the woman you are caring for have both agreed to participate, the researcher will introduce herself to the woman and her partner. The midwife researcher will then sit quietly in a corner of the room for the next three hours of the labour in which you provide care. The observer will be recording the main elements of the care provided by the midwife on the laptop computer using a specially designed form. The observer will also record how the woman is during the labour and what the birth partner is doing to support the woman. The record made is a written record and does not involve any filming or audio recording.

We ask you to provide care to the woman and her partner as you would do in the course of your ordinary work.

The observer will not be recording the technical competence of the midwife in carrying out assessment procedures. The focus of the research is on the support offered to the woman during her labour.

As the observer is a midwife, she is bound by the professional code of conduct and so would have to take action if she observed care that she felt presented a risk to the well-being of the mother and baby. If the observer felt that the care she was observing was unsafe she would ask to speak to you outside the room and would inform senior staff as appropriate.

However, the observer will only take such action if the care is deemed to be unsafe. She will not be informing any senior staff, your line manager or supervisor about the care she has observed.

- *How long will it take?*

  The observer will ask to be present from the time the woman has given consent to be involved in the study for three hours unless the midwife caring for her changes during that time. You, the woman and the birth partner are free to ask the observer to leave the room at any time. The researcher will then ask to speak with you for around 5 minutes following the birth to ask your views about the experience of having an observer present during the labour.

- *How will my involvement and my views be recorded?*

  If you decide to participate in this study, you will be asked to complete and sign a consent form. This form will be stored in a locked cabinet in the researcher's office. It will be kept separately from the record of the labour care, so that the description of the labour care cannot be linked to you individually. The record of your care will not have your name or personal details on it, so the record is 'anonymised'. When describing the care observed the researcher will not include details which would allow you to be identified individually.

  You will be provided with a copy of the summary of the completed research.

- *Why would I want to be involved?*

  Participation in this study will hopefully be an interesting and positive experience. By participating you will be assisting with some research that will add to our knowledge of what midwives can do to make birth as positive experience as possible.

  If you would like to be involved in the study or have any further questions, you can email the researcher, Mary Ross-Davie, at m.c.ross-davie@stir.ac.uk or call or text her on 07796 614 721.

Appendix 22- Pilot study of the 'Supportive Midwifery in Labour Instrument' - Consent to participate (midwife)

Please initial the statements that you agree with: **Initial box**

- I confirm that I have read and understand the information sheet dated (version …) for the above study and have had the opportunity to ask questions. ☐
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without any repercussions. ☐
- I understand that this form will be kept separately from any other information that I provide and will be stored in a locked drawer for the researcher's use only and will not be shared with anyone. ☐

  I understand the nature and the purpose of the study. ☐
- I give permission for the observation record to be used for research purposes (including reports, publication and presentations) with strict preservation of anonymity. ☐
- I understand that a midwife researcher will be present in the room while I provide care to a woman during her labour. The researcher will note down using a laptop computer the care that is offered during the labour. ☐
- I understand that the researcher will ask to meet with me after the baby has been born to ascertain my views about being observed during the labour. ☐
- I understand that the observation record will be treated in the strictest confidence. The information will be held securely for ten years and will only be available to the researcher. The information will be destroyed after this time. ☐
- I understand that no personally identifiable information will be collected and my data will be identified only by a randomly generated number. ☐
- I agree to take part in the above research study ☐

Participant name	Date	Participant signature
Researcher name	Date	Researcher signature

Appendix 23 – Letter from Stirling University Ethics Committee

JP/SG

UNIVERSITY OF STIRLING

08 July 2010

DEPARTMENT OF
NURSING AND MIDWIFERY

Email: nursingmidwifery@stir.ac.uk
Web: www.nm.stir.ac.uk

John Paley
Chair (Acting)
Dept Ethics Research Commitee

Department of Nursing & Midwifery
University of Stirling
Stirling FK9 4LA

Tel: +44 (0) 1786 466399
Fax: +44 (0) 1786 466333
Email: j.h.paley@stir.ac.uk

Mary Ross-Davie
28 Blackford Bank
Edinburgh
Midlothian
EH9 2PR

Dear Mary

Promoting normality in childbirth through midwifery support

Thank you for submitting your proposal, which was discussed on 7 July 2010. We are grateful that you were able to attend the meeting, and I am delighted to report the proposal was approved, subject to a number of minor amendments, as well as the following qualification:

Today's meeting was non-quorate. However, the Committee decided to review the submitted proposals in order not to delay applicants' progress unduly. Any decisions taken today will need to be ratified by the next quorate meeting of DREC (presumably in September).

The minor amendments should be completed, and notified to me. I will then take Chair's action to confirm ethical approval. The following list is in page number order.

[3] It might be helpful if the postnatal questionnaire and field journal could be mentioned at an earlier point. It might also be an idea to keep the terminology consistent (journal or diary) so as to avoid any possible confusion.

[6] A brief mention of exclusion criteria could be made here, given the reference to inclusion criteria.

[6] At some point, 'early labour' should be operationally defined.

[7] It would be useful if you could incorporate into the account of data collection something specific about the presence of a birth partner, and the consequences for observation. Our query about the partner being included in the SMILI was answered effectively at the meeting (I would be grateful if you could append the final version of SIMLI to your response)/

[23] The third bullet point says 'if everything is straightforward'. This might be a little disconcerting. The Committee suggested 'routine' as an alternative to 'straightforward'.

[25] It was suggested that consideration be given to separate consent forms, and/or that you could provide a brief justification of having just the one.

[27] The second bullet point says that the head of midwifery and clinical director have agreed to participate. This is perhaps ambiguous, and it might be better to say 'have agreed to the study'. This is also the first mention of the clinical director, and it was suggested that some reference be at an appropriate point earlier in the text.

[28] The information sheet says the researcher will ask to be present until the baby is born. The main text specifies three hours, maximum. The discrepancy should be clarified.

[30] An independent contact should also be identified (independent, that is to say, of the research team).

As you will see, these are minor details. The Committee's overwhelming response to the proposal was that it was exceptionally well thought out, thorough, and fluently written. We would like to congratulate you on an exemplary document.

Yours sincerely

John Paley
Chair (Acting)
Department of Nursing and Midwifery Research Ethics Committee

Appendix 24 – NHS Ethics Approval

NHS Fife NHS Forth Valley NHS Tayside

East of Scotland Research Ethics Service

Tayside Committee on Medical Research Ethics B
Research Ethics Office
Tayside Academic Health Sciences Centre
Ninewells Hospital & Medical School
Residency Block, Level 3
George Pirie Way
Dundee
DD1 9SY

Ms Mary Clare Ross-Davie
PhD student
Iris Murdoch Building
University of Stirling
STIRLING
FK9 4LA

Date: 22 September 2010
Your Ref:
Our Ref: LR/**10/S1402/54**
Enquiries to: Mrs Lorraine Reilly
Extension: Ninewells extension 40099
Direct Line: 01382 740099
Email: Lorraine.reilly@nhs.net

Dear Ms Ross-Davie

Full title of study: **A study to test the feasibility, validity and reliability of the 'Supportive Midwifery in Labour Instrument' or 'SMILI' in the intrapartum care setting.**

REC reference number: **10/S1402/54**

The Research Ethics Committee reviewed the above application at the meeting held on 10 September 2010. Thank you for attending to discuss the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The following points require to be addressed by letter and submission of revised documentation where requested. **Please note that there is no requirement to amend your application form.**

1. Regarding the application form:
   - P3 of the application form has a different named academic supervisor to the signed declaration page – please clarify.
2. Regarding the Participant Information Sheet (PIS):
   - Please adapt and insert an appropriate introductory paragraph as below:

POSITIVE ABOUT DISABLED PEOPLE

clarified that all the participants would be given a letter of introduction and a copy of the Participant Information Sheet at the antenatal clinic.

- You clarified that the feedback from midwifes regarding an observer being present was very supportive as sometimes they have students in the room and are used to having additional people present in the room.

- You also clarified that the observer would only be observing for three hours but you would look to see if they could reduce that further.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Investigator CV		25 August 2010
Protocol	1.0	25 August 2010
REC application		25 August 2010
Covering Letter		26 August 2010
Letter from Sponsor		26 August 2010
Advertisement	1.0	25 August 2010
Participant Information Sheet: Pregnant Women	1.0	25 August 2010
Participant Information Sheet: Midwives	1.0	25 August 2010
Participant Consent Form: Woman	1.0	25 August 2010
Participant Consent Form: Birth partner	1.0	25 August 2010
Participant Consent Form: Midwife	1.0	25 August 2010
Questionnaire: SCIB	1.0	25 August 2010

Questionnaire: Postnatal Clinical Outcomes	1.0	25 August 2010
Evidence of insurance or indemnity		26 August 2010

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/S1402/54	**Please quote this number on all correspondence**

Yours sincerely

Mrs Sandra Forbes
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments
"After ethical review – guidance for researchers

Copy to: Dr Helen Cheyne, University of Stirling
Ms Carol Johnston, Stirling University
NHS Grampian R&D office

Appendix 25 – R & D approval for four sites

Research & Development
R&D Management Office
1st Floor, Tennent Institute
Western Infirmary
GLASGOW G11 6NT

NHS Greater Gla and Cly

Our Ref: MB/LR
Enquiries to: Dr Michael Barber
Direct Line: 0141 211 8548
e-mail: Michael.Barber@ggc.scot.nhs.uk

14th Oct 2010

Ms Mary Clare Ross-Davie
NMAHPRU
Iris Murdoch Building
University of Stirling
Stirling
FK9 4LA

R&D Management Approval

Dear Ms Ross-Davie

R&D Reference: GN10MW371
REC Ref: 10/S1402/54
Chief Investigator: Ms Mary Ross-Davie
Project Title: A study to test the feasibility, validity and reliability of the 'Supportive Midwifery in Labour Instrument' or 'SMILI' in the intrapartum care setting
Protocol Ref: V1.0 dated 25/08/10

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Management Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a quarterly basis
   b. Any change of staff named on the original SSI form
   c. Any amendments – Substantial or Non Substantial
   d. Notification of Trial/study end including final recruitment figures
   e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Dr Michael Barber
Research Co-ordinator

Cc: NRSPCC, R&D Office, Aberdeen

Research and Development Support Unit
Ground Floor
Dumfries and Galloway Royal Infirmary
Bankend Road
Dumfries
DG1 4AP

NHS
Dumfries
& Galloway

Fife and Forth Valley Research Ethics Committee B
Research Ethics Office
Residency Block
Level 2
Ninewells Hospital and Medical School
Dundee
DD1 9SY

Our Ref: 10/DGY/040

Date 8th October 2010

Your reference 10/S1402/54

A study to test the feasibility, validity and realiability of the "Supportive Midwifery in Labour Instrument" or SMILI in the interpartum care setting.

To whom it may concern

Please be advised that this study received a favourable site specific review by R&D in NHS Dumfries and Galloway on 8th October 2010with Karen King, Consultant Midwife named as the local PI for this site.

Sincerely

Dr Gwen Baxter
Research scientist and R&D Manager

Cc
Karen King
CI

Copies of Research Governance Framework document available via the website www.sehd.scot.nhs.uk/cso and then use the publications link.

Ms Mary Clare Ross-Davie
NHS Borders
NMAHP Research Unit
Iris Murdoch Building
University of Stirling
Stirling
FK9 4LA

R&D Department
Corporate Services Building
Monklands Hospital
Monkscourt Avenue
AIRDRIE
ML6 0JS

Date 08/10/2010
Enquiries to Lorraine Windsor,
R&D Facilitator
Direct Line 01236 712459
Email Lorraine.Windsor@lanarkshire.scot.nhs.uk

Dear Ms Ross-Davie

PROJECT TITLE: A study to test the feasibility, validity and reliability of the 'Supportive Midwifery in Labour Instrument' or 'SMILI' in the intrapartum care setting

R&D ID NUMBER: L10051

NRS ID NUMBER: NRS10/ GY08

I am writing to you as Chief Investigator of the above study to advise that R&D Management approval has been granted for the conduct of your study within NHS Lanarkshire as detailed below:

NAME	TITLE	ROLE	NHSL SITE TO WHICH APPROVAL APPLIES
Ms Maureen Mc Sherry	Consultant Midwife	Principal Investigator	Wishaw General Hospital

For the study to be carried out you are subject to the conditions outlined overleaf:

Cont/...

Conditions

- You are required to comply with Good Clinical Practice, Ethics Guidelines, Health & Safety Act 1999 and the Data Protection Act 1998.

- The research is carried out in accordance with the Scottish Executive's Research Governance Framework for Health and Community Care (copy available via the Chief Scientist Office website: http://www.show.scot.nhs.uk/cso/ or the Research & Development Intranet site: http://firstport/sites/randd/default.aspx.

- You must ensure that all confidential information is maintained in secure storage. You are further obligated under this agreement to report to the NHS Lanarkshire Data Protection Office and the Research & Development Office infringements, either by accident or otherwise, which constitutes a breach of confidentiality.

- Clinical trial agreements (if applicable), or any other agreements in relation to the study, have been signed off by all relevant signatories.

- You must contact the R&D Department if/when the project is subject to any minor or substantial amendments so that these can be appropriately assessed, and approved, where necessary.

- You notify the R&D Department if any additional researchers become involved in the project within NHS Lanarkshire.

- You notify the R&D Department when you have completed your research, or if you decide to terminate it prematurely.

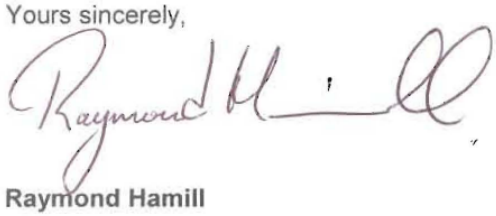
- You must send brief annual reports followed by a final report and summary to the R&D office in hard copy and electronic formats as well as any publications.

- If the research involves any investigators who are not employed by NHS Lanarkshire, but who will be dealing with NHS Lanarkshire patients, there may be a requirement for an SCRO check and occupational health assessment. If this is the case then please contact the R&D Department to make arrangements for this to be undertaken and an honorary contract issued.

Cont/...

I trust these conditions are acceptable to you.

Yours sincerely,



Raymond Hamill
Research & Development Manager

cc.

NAME	TITLE	CONTACT ADDRESS	ROLE
Ms Maureen Mc Sherry	Consultant Midwife	Wishaw General Hospital	Principal Investigator
Carol Johnstone	Business Development Manager	University of Stirling	Sponsor Contact
Dr Helen Cheyne	Director of NMAHP Research Unit	University of Stirling	Academic Supervisor

c.c – (email)
nhsg.nrscc@nhs.net

Healthcare Quality, Governance and Standards Unit
Research, Development & Evaluation Office
58 Lister Street
Crosshouse Hospital
Kilmarnock
KA2 0BB

NHS Ayrshire & Arran

Tel: (01563) 825856
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Geraldine Butcher
Consultant Midwife
Ayrshire Maternity Unit
Crosshouse Hospital
Kilmarnock
KA2 0BE

Date: 2 November 2010
Your Ref:
Our Ref: CAW/KLB/NM R&D 2010AA065

Enquiries to: Karen Bell
Extension: 25850
Direct Line: 01563 825850
Email: Karen.bell@aaaht.scot.nhs.uk

Dear Mrs Butcher

A study to test the feasibility, validity and reliability of the 'Supportive Midwifery in Labour Instrument' or 'SMILI' in the intrapartum care setting

I confirm that NHS Ayrshire and Arran have reviewed the undernoted documents and grant R&D Management approval for the above study.

Approved documents:

Document	Version	Date
R&D Form	Version 3.0	25/08/10 signed
SSI Form	Version 3.0	29/10/10 signed
Information Sheet for Midwives	Version 2.0	28/09/10
Information Sheet for Women & Birth Supporters	Version 2.0	28/09/10
Consent Form for Birth Partners	Version 2.0	28/09/10
Consent Form for Women	Version 2.0	28/09/10
Consent to Participate – Midwife	Version 1.1	01/09/10
Poster	Version 1.0	25/08/10
Questionnaire - Post-Natal Outcome	Version 1.0	25/08/10
Questionnaire - Validated	Version 1.0	25/08/10

The terms of approval state that the investigator authorised to undertake this study within NHS Ayrshire & Arran is: -

- Geraldine Butcher, NHS Ayrshire and Arran

With no additional investigators.

If any other member of the research team requires access to NHS Ayrshire and Arran premises or patients please inform the department as soon as possible so that we can issue the necessary paperwork.

The sponsors for this study are University of Stirling.

This approval letter is valid until 2 October 2011.

PLEASE NOTE: the laptop and memory stick(s) which will be used for this study should not be connected to NHS Ayrshire & Arran computers or to the network. If this should become necessary please contact the IT department for further guidance.

Appendix 26 - Example Log

No.of seconds	Log Notes
16	Partner Arrives
436	Partner Leaves
974	midwife showed partner how to make tea, got someone to make woman toast
989	encouraged woman to eat toast and put tea where she could reach it
996	Midwife Leaves
1011	midwife asks if its ok if she goes to check urine
1020	woman sitting eating toast
1060	Midwife Returns
1124	Partner Arrives
1382	midwife mentions that they have discussed birth plan earlier
1939	setting up entonox and explaining how to use
1973	checks if OK to leave to get a jug of water
2029	Midwife Leaves
2074	midwife gave woman entonox but said you don't have to use it, you decide. Is it Ok if I leave you in (partner's) capable hands?
2110	woman and partner chatting to each other
2136	Midwife Returns
2204	Midwife Leaves
2213	Midwife Returns
2254	brings water for all including me
2270	midwife turns down lights
2331	Partner Leaves
2428	silence
2693	midwife suggests trying to get up and wander around, woman does this
2697	Partner Arrives
2711	Midwife Leaves
2761	woman goes to toilet
2790	woman just starting to use entonox
2842	feels dizzy after entonox so lies down
2911	Midwife Returns
2967	Midwife Leaves

No.of seconds	Log Notes
3056	Midwife Returns
3257	Other Midwife Arrives
3438	going to pause now as main midwife going on break
3667	Other Midwife Leaves
3675	Parent Arrives
4202	mother chatting and joking with woman and partner
4321	Midwife Leaves
4367	woman asked partner to get her a drink - midwife goes to look to see if they have lucozade
4376	Partner Leaves
4405	Midwife Returns
4693	Partner Arrives
4770	partner back with a newspaper and reading it
4840	Midwife Leaves
4887	Midwife Returns
5135	lots of silence, midwife writing baby labels and reading notes
5161	woman very calm and in control though, lying on bed with eyes closed
5360	Senior Midwife Arrives
5543	Senior Midwife Leaves
5583	mother asks 'will you be delivering' midwife 'I hope so'
5608	the woman then says 'no, that's me' midwife laughs, pats her leg and says 'that's right good answer'
5755	Parent Leaves
5902	just relax in between
6129	Feel lots of pressure?
6456	midwife encouraging woman to go to toilet, woman not keen
6653	Partner says he is going to make phone call - midwife says no don't go but shows him where to make quick call nearer by
7142	Partner Leaves
7150	Parent Arrives
7659	Parent Leaves
8513	midwife saying she will keep her hand there to feel for a bag of waters during a contraction

Appendix 27 – Quantity of non-support behaviours for all observations

Midwife number	Non-Support Direct Care	Assessment	Indirect Care
1	4	21.5	26.5
2	6.5	26.5	27.5
3	0	35	48.5
4	0	21.9	31.6
5	4.5	41.3	45.5
6	1.1	23.7	60.0
8	1.2	26.2	56.3
9	8.1	43.2	99.9
10	0	18.1	14.3
11	0	22.5	27.5
12	0	7.3	39.9
13	0	26.6	29.9
14	0	26.7	29.4
16	3.1	17.5	14.05
17	4.2	15.7	14.2
18	1.4	19.6	24.1
19	0	23.4	40.4
20	3.1	37.5	48.3
21	8	24	88
22	2.1	25.3	89
23	3	9	28.35
24	0.8	73.2	32.4
25	1.4	16.8	18.5
26	6	6	59
27	1.2	72.4	13.9
28	0	33.2	18.7
29	2.3	15.8	26.2
30	4.1	38.7	55.1

Midwife number	Non-Support Direct Care	Assessment	Indirect Care
31	0	27.7	14.6
32	0	38.0	43.6
33	0	29.1	35.6
34	0	35.6	24.6
35	8.3	13.1	19.2
36	4.5	16.7	46.4
37	1.4	20.8	25.2
38	1.5	14.5	15.2
39	0	17.5	34.0
40	5.7	15.4	19.5
41	7.1	33.2	59.4
43	7.3	45	61.9
44	13.4	23.7	34.7
45	7.6	5	74.1
46	0	38.2	61.3
47	1.9	17.4	22.4
48	1.1	38.6	49.6
49	1.85	49.5	44.3
50	5.75	29.6	70.9
51	0	33.5	35.3
53	3.45	23.7	20.8
Average	**2.9**	**27.7**	**40.4**

Appendix 28 - Results of the Support and Control in Birth Questionnaire, 42 complete

Midwife Code	Internal Control (range 1-5)	External control (range 1-5)	Support (range 1-5)
2	4.3	4.1	5
4	4.5	4.5	5
5	1.6	1.3	1.1
6	4.4	4.8	4.8
8	4.9	4.8	4.7
9	incomplete	3.1	incomplete
10	2.6	4.2	5
11	2.6	4.2	4.7
12	4.7	4.9	5
13	3.1	4.6	4.3
14	4.9	4.6	4.9
16	3	3.8	4.8
17	1.7	3.5	3.6
20	4.7	4.7	4.8
21	4.5	3.9	5
22	3.1	4	4.8
23	incomplete	3.4	4.9
24	1.7	3.5	5
25	incomplete	4.9	4
26	incomplete	4	4
27	3.1	3.3	5
28	3.6	4.9	5
29	4.8	4	5
30	4.4	4.3	5
31	4.6	4.8	5
32	3	4.2	4
33	3	4.2	4
35	4.3	4.1	4.6
36	1.7	3.5	4.2
37	2.3	4.2	4.6
38	3.7	5	5
39	4	4.5	4.5
40	2.1	3.5	3.5
41	3.8	4.2	4.7
42	3.1	4.1	4.6
43	4.2	4.1	4.9
44	4.2	4.1	4.8
46	3	4	5
48	4.6	3.9	4.2
49	3.9	4	4.7
50	4.2	4.3	5
51	3.9	4	4.9
53	5	5	5

Appendix 29 - Quantity of sub-categories of emotional support across all observations.

Midwife number	Positive Demeanour	Attentiveness	Verbal Support	Rapport Building	Enhancing woman's sense of control	Creating a positive environment
1	84.9	48.3	115.5	36.5	35	6
2	133.1	55.9	145.5	101	24	19
3	74.5	66.7	54	40	8	4
4	68.25	59.6	17.3	42.65	35.65	0
5	35.1	42.8	0	8.6	12.35	0
6	87.4	38.6	65.85	19.2	25.45	6.65
8	137.0	99.8	115.65	72.05	58.9	1.25
9	232	77	16.2	62.1	59.4	13.5
10	140.7	151.9	242.7	49.85	21.8	1.65
11	154.3	163.9	172.2	7.5	20	0
12	206.6	80.1	59.0	63.2	66.0	1.45
13	128.1	81.9	76.5	14.8	43.98	3.3
14	121.14	177.7	91.35	23.35	38.25	1.3
16	158.2	124.3	229.5	21.15	34.2	8.45
17	131.25	89.05	114.8	22.7	11.4	2.8
18	91.5	81.6	154.6	1.45	40.7	1.5
19	110	119.2	117.1	20.4	17.5	2.9
20	87.3	67.2	92.4	16.95	36.25	5.9
21	213.2	48	8	68	32	8
22	230	75	16.9	33.9	21.2	0
23	104.1	48.1	87.3	26.1	24.0	0
24	139.0	161.9	104.6	11.6	69.7	16.4
25	114.5	92.5	96.0	30.15	45.1	6.1
26	124.1	28.9	76.35	24.5	34	6
27	171	163.7	170.55	32.15	61.55	30.75
28	136.2	108.1	18.35	77.8	8.8	2
29	136.8	79.5	57.35	32.65	16.75	0.8
30	272.3	53.1	12.2	89.7	24.46	0
31	163.2	101.2	74.8	16.6	22.15	4.8

Midwife number	Positive Demeanour	Attentiveness	Verbal Support	Rapport Building	Enhancing woman's sense of control	Creating a positive environment
32	75.1	58.1	24.9	8.4	19.1	1
33	131.3	106.0	29.7	11.35	8.8	1.25
34	139.05	103	59.5	11.05	15	0
35	254	127.2	142.7	13.85	22.65	0
36	179.9	79.5	55.2	20.75	25.75	1.45
37	225.3	56.3	3.8	92.25	23.8	0
38	220.8	83.5	137.2	11.75	24.4	3.1
39	238.2	106.1	47.6	50.45	26.35	3.65
40	192.8	54.8	61.45	2.3	25	0
41	297.3	103.3	16.5	57	35.2	6.9
43	172.6	58.3	46.25	43.75	26.1	1.2
44	144.0	128.3	39.25	12.15	26.4	6.25
45	243.9	75.8	28	23	51	2.5
46	227.2	92.8	15.2	122.9	38.3	0
47	207.9	80.5	22.85	51.8	31.95	0
48	143.3	56.8	35.6	50	20.15	0
49	255.4	158.2	49.7	22.1	25.05	0.9
50	181.4	44.8	33.3	55.2	17.7	0
51	182.8	158.5	58.1	18	10	0
53	210	161.65	71.7	22.75	37.8	2.5
Average	163.4	95.5	78.6	36.0	31.8	3.7

Appendix 30 - Associations between non-support elements and women's and observers' views

Associations between maternity unit and years of qualification and women and observer's assessments

	Spearman's rho	SCIB Support	Global rating of quantity	Global rating of quality
Maternity unit	Correlation P value	.066 .678	-.178 .247	-.171 .272
Registration years	Correlation P value	.249 .211	.082 .655	.098 .595

Non-support elements of care and woman's SCIB results and observer's overall quality score

	Spearman's rho	Woman's assessment SCIB Support	Observer's global rating of quality
Care Pathway	Correlation P value	.122 .433	.116 .224
Parity	Correlation P value	-.049 .760	-.034 .413
Analgesia	Correlation P value	-.064 .686	-.028 .432
Medical Intervention	Correlation P value	-.222 .157	-.451* .012
Type of birth	Correlation P value	-.106 .502	-.178 .133
Indirect care	Correlation P value	-.088 .581	-.077 .315
Non-support direct care	Correlation P value	-.111 .485	-.090 .285
Assessment	Correlation P value	.130 .411	-.071 .327