

# Managing Prolonged Labour Using Different Partogram Action Lines: Obstetric Outcome and Maternal Satisfaction

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## Author's Role

Prior to commencing this study, the author worked as a clinical midwife but was particularly interested and involved with evidence based care. During a working party which was formulated to implement a partogram, several inconsistencies were highlighted regarding labour management. This led to the Clinical Director, Mr. S. Walkinshaw applying for a Trust Research Fellow grant. The application was successful and the author became the Trust Research Fellow for a two year period to explore the area of prolonged labour and partogram use. At the time of the grant submission the area of study had been discussed but the design had not been finalised. The authors role was to design and co-ordinate a study which would explore prolonged labour in relation to the hospital's current labour management.

The author formulated a trial protocol, gained ethical approval, developed a tool to measure maternal views, presented the protocol to midwives and obstetricians, recruited the participants, managed the data, carried out the data analysis and disseminated the findings.

Mr. S. Walkinshaw continued to be involved in the study as Clinical Director, Consultant obstetrician and Director of studies. As Clinical Director, Mr. Walkinshaw offered support and advice on protocol adherence and the practicalities of co-ordinating a study on a busy delivery suite. Being a Consultant obstetrician enabled a different perspective from the authors to be aired through regular discussions.

Mr. Z. Alferevic is a well established and credible trialist and although he played a less active role in the study co-ordination, his expertise was invaluable. Mr. Alferevic reviewed copies of the trial protocol prior to commencement, discussed design issues with the author and advised on data management.

Mr. A. Wallymahmed and Mr. S. Fear gave ongoing statistical support to the author. Prior to commencing this study, the author's data analysis experience was minimal. Through working with Mr. Wallymahmed and Mr. Fear, the author was able to gain experience in data analysis, sample size calculations and questionnaire validation.

Mrs. I. Walton, in addition to being a PhD Supervisor, was particularly involved in the analysis and dissemination of the qualitative data.

It is evident that the expertise gained from the various sources mentioned has allowed the author to complete an academic piece of work. Importantly, this work is of benefit to the Trust in terms of managing the labours of women.



## Abstract

**Background:** There are many controversies surrounding intrapartum care. In particular, the identification and management of prolonged labour stand out as areas where many questions remain unanswered. Many hospitals now use a partogram to assist them in the detection of prolonged labour by allowing midwives and obstetricians to record labour progress in a graphical manner. However, this tool and its components have not been adequately evaluated. One component, the action line, which is positioned on the partogram to trigger intervention when labour becomes prolonged, was introduced with no formal assessment on a Caucasian population. The debate surrounding its appropriateness continues in the 1990's with no consensus on exactly where this line should be placed.

**Objective:** To assess the effect of 3 different partogram action lines on the rate of caesarean section and the level of maternal satisfaction.

**Design:** Prospective randomised clinical trial.

**Setting:** Regional teaching hospital in North West of England

**Participants:** Nine hundred and twenty eight primigravid women with uncomplicated pregnancies who presented in spontaneous labour at term

**Interventions:** Consented women were randomised so as to have their progress of labour recorded on a partogram with an action line 2, 3 or 4 hours to the right of the

alert line. If the progress reached the action line, a diagnosis of prolonged labour was made. Prolonged labour was managed according to the standard ward protocol which included amniotomy in the presence of intact membranes and a syntocinon infusion.

**Main outcome measures:** Primary - Caesarean section and maternal satisfaction, Secondary - Need for augmentation, duration of labour, analgesia, cord blood gas analysis, postpartum haemorrhage, number of vaginal examinations, Apgar score and admission to special care baby unit.

**Results:** Caesarean section rate was the lowest when labour was managed using a partogram with a 4 hour action line. The difference between the 3 and 4 hour partogram was statistically significant (OR 1.8, 95% CI 1.1-3.2) but the difference between 2 and 4 hours was not (OR 1.4, 95% CI 0.8-2.4). The women in the 2 hour arm were more satisfied with their labour when compared to the women in the 3hour ( $p<0.0001$ ) and 4 hour ( $p<0.0001$ ) arm.

**Conclusion:** The data suggest that women prefer “active” management of labour. It is possible that partograms which favour earlier intervention are associated with higher caesarean section rate. As the evidence on which to base the choice of partograms remains inconclusive further research is required.

## GLOSSARY

<b>Amniotomy (ARM)</b>	The surgical rupture of the fetal membranes to augment/induce labour.
<b>Antepartum</b>	Before labour
<b>Apgar Score</b>	A method of assessing the baby's condition by observing five vital signs: respiratory effort, heart rate, colour, muscle tone and response to stimuli.
<b>Augmentation of labour</b>	Stimulation of a labour that began spontaneously, usually by intravenous oxytocin.
<b>Auscultation</b>	Listening to the fetal heartbeat with a hand held device.
<b>Cardiotocography (CTG)</b>	Electronic fetal monitoring
<b>Cephalic presentation</b>	The fetus presents head down; its position is described by the location of the back of the fetal skull (occiput) with respect to the mother.
<b>Cephalopelvic disproportion (CPD)</b>	The measurements of the fetal head and/or mothers pelvis do not facilitate a normal vaginal delivery.
<b>Cervicograph (Cervicogram)</b>	A tool used for recording cervical dilatation
<b>Dystocia</b>	A term used to describe slow labour progress
<b>Episiotomy</b>	A surgical incision into the perineal body to enlarge the vaginal opening for childbirth
<b>Fetal blood sampling (FBS)</b>	When fetal hypoxia is suspected in labour, the fetal pH is estimated. Using an endoscope, blood is taken from the fetal scalp for the estimation of blood gases and acidity.
<b>Fetal scalp electrode (FSE)</b>	A device placed on the fetal scalp to record fetal heart rate
<b>Full dilatation</b>	When the cervix has been completely drawn up into the lower uterine segment and can no longer be felt on vaginal

	examination
<b>Gravid</b>	Pregnant
<b>Halo effect</b>	A feeling of euphoria often experienced following the delivery of a normal healthy baby
<b>Hypertonus</b>	A term used to describe either a very prolonged uterine contraction or contractions which occur more frequently than 5 in every 10 min period.
<b>Hyperstimulation</b>	The over stimulation of the uterus (usually associated with oxytocin use)
<b>Intrapartum</b>	During labour
<b>Intrauterine pressure catheter (IUPC)</b>	A device placed inside the uterus to directly monitor uterine pressure and therefore give a more accurate recording of contraction strength
<b>Laceration, perineal</b>	
1 <sup>st</sup> degree	Into the skin
2 <sup>nd</sup> degree	Into the underlying muscle
3 <sup>rd</sup> degree	Includes laceration involving anal sphincter and/or rectum
<b>Liquor</b>	The fluid in which the fetus floats. Amniotic fluid.
<b>Meconium</b>	The first intestinal discharges of a fetus/newly born child.
<b>Multipara</b>	A woman who has had two or more children
<b>Multigravida</b>	A pregnant woman who has had more than one pregnancy
<b>Nullipara</b>	A woman who has never given birth to a child
<b>Oxytocin</b>	A pituitary hormone which stimulates uterine contractions. Synthetically prepared to induce/augment labour.
<b>Passenger</b>	The fetus
<b>Passages</b>	Pelvis, uterus, cervix and vagina
<b>Powers</b>	Contractions
<b>Perineum</b>	The pyramid shaped area extending from the fourchette to the anal canal. It is roughly triangular in shape and is composed of connective tissue, muscle and fat. It gives attachment to the muscles of the pelvic floor.

<b>Partogram (partograph)</b>	A tool used to record intrapartum observations
<b>Placenta praevia</b>	Low lying placenta (into lower uterine segment)
<b>Postpartum</b>	After the birth
<b>Preterm</b>	Birth prior to 37 weeks gestation
<b>Primipara</b>	A woman who has given birth to her first child
<b>Primigravida</b>	A woman who is pregnant for the first time
<b>Station</b>	The location of the presenting fetal part with respect to the plane of the ischial spines of the mother's pelvis
<b>Syntocinon</b>	A synthetically prepared hormone used to induce/augment labour.
<b>Syntometrine</b>	A drug containing 0.5mg ergometrine and 5 units of syntocinon. Used to hasten separation of the placenta and diminish blood loss.
<b>Ventouse</b>	A suction apparatus used to expedite delivery.

# PART 1

## INTRODUCTION

# **Chapter 1**

## **Introduction**

The purpose of this chapter is to provide a brief overview of the thesis. A general background to the area of research and a rationale for the investigation is outlined. A summary of the main findings and their implications is provided followed by directions for further research in the area.

### **1.1. Background**

The partogram is considered a valuable tool in the improvement of maternity services by allowing midwives and obstetricians to display intrapartum details in a pictorial manner. A number of common partogram designs follow the work of Philpott (1972), and most incorporate an action line (Philpott & Castle 1972a). An action line allows unambiguous diagnosis of prolonged labour enabling the timing of intervention to be based on the rate of cervical dilatation. It is conventionally placed a number of hours to the right of another line, the alert line (Philpott 1972), which describes the rate of cervical dilatation of the slowest 10% of primigravidae (Philpott & Castle 1972b).

The timing of intrapartum interventions which may correct prolonged labour and include amniotomy, intravenous hydration, analgesia, oxytocic infusion and operative delivery (Walkinshaw 1994), has not been subjected to rigorous evaluation. The Dublin group (O'Driscoll, Foley & MacDonald 1984), have proposed that an active management package which relies on early identification of prolonged labour with early correction by oxytocin reduces the caesarean section rate. Despite inclusion of all the components of the National Maternity Hospital protocol for active

management of labour, a more recent randomised study of 1934 nulliparous women (Frigoletto, Lieberman, Lang, Cohen, Barss, Ringer & Datta 1995) failed to provide evidence that such a protocol reduces the caesarean section rate. Most other studies of various forms of early intervention have shown reductions in duration of labour but not in caesarean section outcome (Thornton & Lilford 1994).

Philpott and Castle (1972a), who were the first to provide specific guidelines on the timing of intervention for prolonged labour, recommended an action line 4 hours to the right of the alert line. This recommendation was to enable adequate time to transfer women from peripheral units to a central unit when labour became prolonged. This design has only recently been adequately evaluated when the World Health Organisation carried out a large multicentre trial of 35484 women in south east Asia (World Health Organisation 1994). They achieved caesarean section rates of 10% in primigravidae in labour and have therefore recommended the widespread use of a partogram with a 4 hour action line.

However, as the evidence to support either a 2 or 4 hour action line was inconclusive in 1992, a consensus was reached among senior medical and midwifery staff at the Liverpool Women's Hospital that the partogram in Liverpool would contain a 3 hour action line. This adaptation to the WHO partogram has been used by others (Dujardin, De Scampheleire, Sene & Ndiaye 1992) who believe that partograms have not been sufficiently evaluated. One limitation of previous studies has been the failure to examine the individual components of the partogram. Yet, recent evidence suggests that the appearance of the partogram can directly influence obstetric outcomes (Tay & Yong 1996).



A neglected aspect of the debate over timing of intrapartum intervention is the view of women themselves. Both early and late interventions may have many unwanted sequelae - limitation of maternal mobility, increased use of epidural analgesia, increased incidence of fetal heart rate abnormalities, uterine hypertonus and caesarean section. Unfortunately, no information is available on women's views of the relative merits of these differing approaches.

### **1.2. Aims of the present study**

The area of investigation which was explored in the thesis was prolonged labour. In particular this area was explored in relation to the timing of intervention. The major aim of the study was to assess the effect of different timing of intervention on clinical and psychological outcomes. To this end a randomised controlled trial was designed in which women were allocated to have their labour managed with the assistance of one of three partograms. The partograms which were used contained action lines which were placed at different intervals from the alert line- 2hour, 3hour or 4hour. These lines were used as a guide to the appropriate timing of intervention to accelerate labour.

The first aim of the study was to assess the effect on the mode of delivery of managing labour using partograms with action lines drawn at 2, 3 or 4 hours to the right of the alert line. Quantitative methods were used to prospectively measure and record appropriate information following each woman's delivery.

The second aim was to assess the effect on maternal satisfaction of managing labour using partograms with action lines drawn at 2, 3 or 4 hours to the right of the alert

line. A thorough search of the literature highlighted the lack of empirical evidence in this area. Women's views have rarely been assessed within a randomised controlled trial. To complement the obstetric data, women were administered a specifically designed questionnaire to ascertain their views on their labour experience. Both structured and open questions were used to provide a comprehensive understanding of women's feelings. This data was examined in relation to the allocated partogram, previous literature and intrapartum outcomes.

The third aim was to assess the effect on intrapartum outcomes of managing labour using partograms with action lines drawn at 2, 3 or 4 hours to the right of the alert line. Previous studies have reported differences in outcomes dependant on the timing of intervention, for example, duration of labour (Thornton & Lilford 1994; Frigoletto et al.1995). This study therefore examined intrapartum factors in relation to the different partogram action lines used.

A further aim was to assess the effect on neonatal outcomes of managing labour using partograms with action lines drawn at 2, 3 or 4 hours to the right of the alert line. There is some evidence that differences in neonatal outcome may result from different approaches to the management of labour augmentation (Walss Rodriguez, Gudino Ruiz & Tapia Rodriguez 1987; Fraser 1992).

To add another dimension to the research, midwives' views of the partogram and related management were also assessed. Although there have been some evaluations of partogram use in relation to clinical and maternal outcomes, there has been no adequate assessment of the views of the practitioners who use the tool when

monitoring labour. This study explored the views of midwives, using specifically designed questionnaires comprising of open and closed questions. The data were analysed using descriptive and qualitative methods.

Within this study, the amalgamation of data from the different sources, as outlined above, was imperative to provide an overall account of the effects of the different timings of intervention. The ultimate study aim was therefore to interpret and disseminate the findings in an attempt to change clinical practice.

### **1.3. Structure of the thesis**

Part one of the thesis presents the theoretical and empirical background to the study. Chapter two outlines the origins of research into prolonged labour. In particular, this chapter examines the research literature relating to the assessment and management of prolonged labour. This chapter concentrates on the obstetric outcomes associated with labour. Chapter three examines the literature surrounding maternal views. Finally, there is a summary and integration of these two research areas in chapter four. This chapter also briefly outlines the present study into the timing of intervention.

Part two focuses on the methodology of the study. Chapter five outlines the research origin by exploring the methodological choice from a philosophical perspective, emphasising the importance of a combined methodological approach. This chapter continues by addressing the ethical considerations of the study. This chapter explores the ethical issues surrounding maternity ‘patients’ as well as issues surrounding the randomised controlled trial. Chapter six is devoted to the methodological considerations that were addressed in the design of the study. A thorough evaluation

of the randomised controlled trial is included in this chapter. Chapter seven describes the method employed in the study. Chapter eight concentrates on the method of evaluating the midwives views. Chapter nine describes the data analyses of the study.

Part three includes the study findings in relation to the main research questions. Chapter ten reports the findings of the baseline and demographic data. The results showed that the three trial arms were in fact comparable. The data also provided evidence that the findings were generalisable.

Chapter eleven begins to present the findings which attempt to answer to the first part of the primary research question - *Are there differences in the caesarean section rate and level of maternal satisfaction when managing labouring primigravid women using a 2hour, 3hour or 4 hour action line?* This chapter devotes itself to the intrapartum and obstetric outcomes. The intrapartum details showed that when compared to the 4 hour arm, more women in the 2 hour arm crossed the partogram action line and therefore received more interventions to augment labour (OR 1.6, 95% CI 1.1-2.2). This offered reassurance that, in the main, there was adherence to the research protocol. The study does show differences in caesarean section rates in the three arms - 2 hours 11.1% (CI 8% - 15.2%), 3 hours 14.2% (CI 10.6% - 18.8%), 4 hours 8.3% (CI 5.6% - 12.2%) as shown in table 3. However, only when the 3 and 4 hour arms were compared did the difference reach statistical significance (OR 1.8, 95% CI 1.1-3.2). All other secondary outcomes showed no significant differences between the three trial arms. The 3 hour partogram offered no clear benefits in terms of clinical outcome.

Chapter twelve presents the findings which relate to the second aspect of the primary research question - maternal satisfaction. This chapter presents the results from the preliminary analysis carried out during questionnaire development, as well as the study results. The 2 hour partogram has obvious benefits in terms of psychological outcome. Women allocated to the 2 hour arm were more satisfied with their labour experience despite receiving more intervention. These findings support earlier randomised studies (Hodnett, Hannah & Weston 1997; Blanche, Lavender, Alfrevic & Walkinshaw 1998) which found that pregnant women in high risk situations preferred active management. The 3 hour partogram offers no clear benefit in terms of psychological outcome.

Chapter thirteen presents the findings from the exploration of the midwives' views. The findings suggest that midwives believe the partogram can be a beneficial aid to managing a woman's care in labour, however it is often too prescriptive, denies midwifery autonomy and detracts from individualised care. The midwives also believed that certain components of the partogram (i.e. latent phase, alert line, action line and observations) need further investigation.

A discussion of the findings, their standing in relation to the current literature and their implications can be found in part four. Important methodological issues identified in the present study are raised here. The findings of the study have clear implications for labouring women. Further studies are required, however, to determine whether the caesarean section rate is higher in the two hour arm. Additionally, an in-depth exploration of maternal views is needed. It is acknowledged that the study focused mainly on caesarean section and maternal satisfaction. It may

be that other outcomes are affected by the positioning of the partogram (for example blood loss.). Future studies should attempt to address this issue.

## **Chapter 2**

### **Prolonged Labour: Theory, definition, management and implications**

#### **2.1. Introduction**

From time immemorial women have helped each other in childbirth and midwives have been recorded as the main care-givers (Donnison 1977). In the ancient world, childbirth was regarded as a female “mystery” of which generally women had the understanding and knowledge to attend pregnant women. This knowledge and understanding has increased dramatically over the years alongside that of obstetricians. However, despite the many advances in obstetrics and midwifery, many mysteries remain unsolved. Moreover, as stated by Olah and Gee (1996),

*“Unfortunately, we have spent the last 25 years managing labour without knowing what we do”* (p. 103)

In the 1970’s following the Peel report (1970) maternity care was centralised in large obstetric units with a corresponding increase in obstetric intervention in pregnancy and childbirth. A classic example of this was the rise in the induction rate (Cartwright 1979) which increased from 15% of all labours in 1965 to 41% in 1974. These interventionist policies appeared to be supported by favourable trends in perinatal mortality and therefore were not greatly challenged. Recently, however, a combination of staff awareness and consumer challenges has led health professionals to revisit areas of obstetrics and midwifery and to re-evaluate current practices.

The following study addresses issues surrounding prolonged labour, an area of obstetrics and midwifery which remains clouded by uncertainties. Before these problems can be addressed, it is first necessary to define labour. A universal definition of labour is that it is the process by which the fetus and placenta are expelled from the uterus (Taylor & Bush 1978; Sweet 1988). Obstetricians and midwives divide labour into three stages. The first stage being from the onset of regular painful contractions accompanied by effacement of the cervix and dilatation of the os to full dilatation of the cervical os; the second stage being from full dilatation of the cervical os until the birth of the baby and the third stage is from the birth of the baby until complete expulsion of the placenta and membranes. Some would argue that the first stage can be divided into a latent phase and an active phase (Friedman 1978, World Health Organisation 1988, Gee & Glynn 1997). The latent phase is the time period between the time the cervix is not dilated until it is 3cm and the active phase is from cervical dilatation of 3cm and onwards. These definitions are greatly simplified and in fact provide limited assistance when related to clinical practice.

The following literature review will highlight the complexities of labour and the controversies of labour management with particular reference to the prolonged first stage of labour. Three main areas will be explored in the first section, namely, the definition and recognition of prolonged labour, the evolution of the partogram and the management of prolonged labour. The subsequent section will then focus on the psychological aspects related to prolonged labour and its management.



## 2.2. Diagnosis of Labour

The importance of correct diagnosis of labour cannot be emphasised sufficiently as misdiagnosis may lead to an incorrect diagnosis of dysfunctional labour and unnecessary intervention (O'Driscoll et al. 1984). Although recognised as an arbitrary starting point, the most useful and frequently used marker of the onset of labour is the time of admission when the woman is admitted in labour (Crowther, Enkin, Kierse & Brown 1989). However, it is well reported that many women who admit themselves to hospital in labour are not considered to be in labour by the staff (O'Driscoll, Stronge & Minogue 1973; Bonovich 1990). This suggests that a more objective measure of labour diagnosis may be required.

While maternity professionals recognise the importance of *passenger*, *passages* and *powers* as contributors to labour progress (Gee & Glynn 1997), there appears to be some consensus that the rate of cervical dilatation is the most precise measure (Friedman 1967; Hendricks, Brenner & Kraus 1970; Philpott & Castle 1972; Studd 1973; Duignan, Studd & Hughes 1975). However, the way this information is utilised is not clear cut.

One aspect of labour which remains poorly understood is the latent phase. There is a lack of evidence from controlled trials to guide practitioners on the significance of this phase and the best policy for care of women at this time. Some consider it to be the end of pre-labour (Hendricks et al. 1970), while others believe it to be a true entity (Koontz & Bishop 1982). The mean length of the latent phase was found by Friedman to be 6.4 hours in primigravidae (Friedman 1955) and 4.8 hours in multigravidae (Friedman & Sachtleben 1961). The mean rate, however, is of little clinical

significance because variations appear to be great between individual women. Friedman (1955) believed a latent phase of 20 hours for primigravidae should be considered prolonged. Cardozo, Gibb, Studd Vasant and Cooper (1982) considered an interval greater than six hours to indicate prolongation and the World Health Organization (1994) suggested an interval of greater than 8 hours. Furthermore there are those who do not believe in the existence of a latent phase at all. O'Driscoll, Meagher and Boylan (1993), suggest that terms such as *labour not established* or *latent labour* 'serve only as stratagems to relieve the doctor or midwife of the onus of having to make a decision,' p36. The philosophy of the National Maternity Hospital labour ward, where O'Driscoll worked, is that a woman is either in labour or she is not.

One of the commonest problems in labour management is differentiating between a prolonged latent phase and false labour (Crowther et al. 1989). Several physiological changes occur prior to commencement of the active phase which may contribute to incorrect diagnoses of labour. Prior to cervical effacement the cervix undergoes a process of 'ripening' which is known to be promoted by oestrogens and prostaglandins (Gee & Glynn 1997). During this period, a gel composed of glycoproteins, which normally binds the collagen fibres of the cervix, changes composition thus changing the cervical state (Osmers, Rath, Pflanz, Kuhn & Stuhlsatz 1993). This process can be recognised clinically by using semi-objective means, e.g. Bishop score (cervical consistency, dilatation, length, position within the pelvis and station of the presenting part). Incorrect diagnosis can lead to unnecessary intervention and/or maternal distress. If women are only admitted to the delivery suite when labour has been confirmed, as practised in the National Maternity hospital, then

perhaps they are less likely to be misdiagnosed. Many midwives would support this view, recommending that during the latent phase women are best left in their own environment (Flint 1986).

If a latent phase is not acknowledged, an objective measure of labour diagnosis must be made. In a study by Hogston and Noble (1993), labour was confirmed by vaginal examination when the cervix was fully effaced and 1cm dilated. It may be that by refusing to acknowledge a latent phase, an incorrect diagnosis of labour was made leading to labours progressing beyond 12 hours. According to Olah, Gee and Brown (1993) the presence of muscle fibres in the cervix during the latent phase, may in fact constrict the cervical canal, resulting in a poor response to oxytocin and the generation of high intrauterine pressures and fetal distress. Diagnosis of labour is very subjective, and because of this little evidence has been provided from randomised trials.

### **2.3. Labour Progress**

Labour is initiated, and progress maintained, by the contractions of the uterus (Crowther et al. 1989). Confirmation of progress, however, is determined by the identification of increasing cervical dilatation and cervical effacement. Recent evidence suggests that the cervix plays an important part in the progress of labour and the generation of intrauterine pressure (Olah et al. 1993). Normal labour has been arbitrarily defined as when a baby is born within a period of 12 hours, via the natural passage, through the efforts of the mother, and when no harm befalls either party as a result of the experience (O'Driscoll & Meagher 1980). Yet, a more useful definition is the rate of progress of cervical dilatation (usually expressed in centimetres per hour)

(Crowther et al. 1989). Correction of prolonged labour is therefore dependant on regular cervical assessment. However, this measure, although generally accepted, may not be precise and there are no reported trials of either inter-observer or intra-observer reproducibility. Furthermore, midwifery experience has highlighted the variations in estimations of cervical dilatation from different practitioners.

Failure of the cervix to respond to uterine contractions may be interpreted as a failure to progress, where in fact, as Porreco (1990) points out, it may be that the obstetricians and midwives have failed, by not waiting for adequate cervical effacement and dilatation of the cervix before diagnosing labour. Certainly, Cardozo et al. (1982) reported an increased caesarean section rate in primigravid women whom they accelerated during a prolonged latent phase of labour.

There is also no clear guidance from the literature regarding the most accurate time to perform the vaginal examination. Friedman (1954) measured cervical dilatation at the peak of the contraction. Whereas Richardson, Sutherland and Allen (1978) reported that the cervix was maximally dilated 15 seconds after the peak of each contraction. As there is insufficient evidence to guide practitioners, then perhaps signs of increasing maternal discomfort should be the factor determining examination time (Crowther et al. 1989).

Another important issue is the frequency of performing vaginal examinations. Like many other issues surrounding labour management, a consensus has not yet been reached. Philpott and Castle (1972b) advised 4 hourly assessments, and if delay was detected, two-hourly. O'Driscoll et al. (1993) and Duignan (1985) recommend that

progress is assessed one hour after admission to the labour ward then one to two hourly thereafter. Although, conventionally a minimum of 2 hours is required to diagnose arrest of cervical dilatation (Cohen & Brennan 1995), there are those who believe that one hour is sufficient (Bottoms, Sokal & Rosen 1981; Friedman & Neff, 1987), particularly if the examinations have been performed by the same practitioner. Studd, Cardozo and Gibb (1982) advised three hourly assessments; and Cardozo and Studd (1985) recommended three to four hourly examinations. A survey of English labour ward policies by Garcia, Garforth and Ayers (1985) found that 70 percent of units had policies on cervical assessment, 36% of which had a fixed routine and 34% had a more flexible approach. In the units with a fixed policy, over half had a four-hourly policy, 15% had an 'at least four-hourly policy' and 5% had a 'not greater than four-hourly policy'. These variations highlight the inconsistencies in labour management.

A further area of debate is the acceptable rate of cervical dilatation. The mean rate found by Friedman (1955) was 1.2 cm per hour. Philpott and Castle (1972a), however, suggested that a rate of 1 cm per hour was a better cut-off to distinguish between normal and abnormal progress. This rate of 1cm per hour was also accepted by Beazley and Kurjak (1972), O'Driscoll et al. (1973), Cowan, Middelkoop and Philpott (1982a,b) and Gibb, Arulkumaran, Lun and Ratnam (1984). However, this was disputed by a Canadian national consensus conference which suggested that 0.75cm per hour was more appropriate (National Consensus Conference on Aspects of Caesarean section Planning Committee 1985). However it must be remembered that these definitions are population dependant.

## **2.4. Defining prolonged Labour**

Abnormally prolonged labour and its effects are important contributors to maternal and perinatal mortality and morbidity world wide (Llewelyn-Jones 1986). Obstructed and prolonged labour comprise one of the five major causes of maternal mortality and morbidity in developing countries (Mahler 1987; World Health Organisation 1991). The number of maternal deaths due to obstructed labour and/or rupture of the uterus varies between 4% and 70% of all maternal deaths, amounting to a maternal mortality rate as high as 410/100,000 live births (WHO 1994b). The literature suggests that in many countries maternal mortality due to these causes is almost as severe in the 1990's as it was 30 years ago. In addition, significant maternal morbidity is associated with prolonged labour, since both postpartum haemorrhage and infection are less common in women with short labours. Maternal mortality has been largely due to ruptured uterus or puerperal infection and perinatal mortality has been mainly due to asphyxia. Maternal morbidity has resulted from maternal distress due to exhaustion and ketosis and perinatal morbidity from fetal distress and traumatic delivery (Llewelyn-Jones 1986). Early detection of abnormal progress of labour and prevention of prolonged labour to minimise adverse effects is therefore imperative. Abnormal labour has three main causes: inefficient uterine action, occipitoposterior position and cephalopelvic disproportion (O'Driscoll et al. 1993). Trends have shown that caesarean section rates are rising and the greatest increase can be attributed to failure to progress in labour (Kiwanuka & Moore 1987; Neuhoﬀ, Burke & Pureco 1989; Schiffrin & Cowan 1989). However, before the problems of preventing and managing prolonged labour can be addressed, it is first important to highlight the difficulties of defining exactly what constitutes an abnormal labour.

As pointed out by Downe (1994), midwives and obstetricians can all agree that a major degree of placenta praevia or a clear cephalopelvic disproportion should be classified as abnormal. However, there is little consensus concerning the labouring primigravida who has made slow but steady progress for 20 hours in the absence of maternal or fetal distress. The definition of normality is vague, with a resulting variation in hospital guidelines. Many studies have described the duration and velocity of labour in various groups of women (Friedman 1955; Hendricks et al. 1970; O'Driscoll, Jackson & Gallagher 1970; Philpott & Castle 1972a; Beazley & Kurjak 1972; Studd 1973; Duignan et al. 1975; Melmed & Evans 1976; Sokol, Stojkov, Chik & Rosen 1977; Cardozo et al. 1982; Gibb, Studd, Magos & Cooper 1982; Hunter, Enkin, Sargeant, Wilkinson & Togueu 1983; Klein, Lloyd, Redman, Bull & Turnbull 1983; Tuck, Cardozo, Studd & Gibb 1983). These descriptions range from Duignan et al. (1975) who describe the duration of labour for a primigravidae being 5.6 hours to Friedman (1955) suggesting that 13.3 hours is more appropriate. Yet this data lacks clinical relevance as direct comparisons are difficult due to variations in study eligibility criteria. A more recent definition of prolonged labour provided by the World Health Organisation for primiparous women was a labour lasting more than 18 hours (WHO 1994). In the National Maternity Hospital in Dublin, the definition of a prolonged labour has been steadily and systematically reduced from 48 hour to 12 hours (O'Driscoll et al. 1993). In the struggle to balance early diagnosis and correction of prolonged labour with the use of unnecessary intervention, no consensus has yet been reached amongst midwives and obstetricians to provide a definition of normality.

Visual presentation itself may influence decision making, with alterations in the slope and scale of labour progress effecting alterations in clinical judgement (Cartmill & Thornton 1992). Although this study was based on hypothetical decisions made by doctors, it does identify an important point. If labours visually appear longer, then it is understandable that professionals may wish to intervene sooner. This hypothesis has yet to be tested in a randomised controlled trial.

It must also be considered that individualised care may not allow for a rigid policy. As pointed out by Gee and Glynn (1997) the normal rate of progress for one woman may not be normal for another. Any hospital policy must therefore account for such variations.

## **2.5. Demographic Variables Affecting Labour Progress**

Another important consideration in maternity care is the identification of women who may be at an increased risk of developing prolonged labour. A study by Calkins and Irvine (1930) began addressing this issue in a study of 1250 consecutive labours in the University of Virginia Hospital looking at both primiparous and multiparous women. They found no evidence to support previous beliefs that factors such as age, height, weight, length of conjugata vera, size of the baby and duration of pregnancy have an effect on the length of the first stage of labour. Although mean scores do not enter into the analysis of this data, the unknown number of exclusions of abnormally long labours makes the accuracy of the results difficult to assess. Nor do the authors explain how they defined an abnormally long labour.



Similarly, both primigravid and multigravid women were included in the study carried out by Hendricks et al. (1970) yet the rate of cervical dilatation showed little variation. This was later confirmed by Duignan et al. (1975) in a prospective study of 3217 consecutive labours in women with a singleton pregnancy. This study, in which the partogram (Philpott 1972) and labour stencil (Studd 1973) were used, also revealed no significant differences in the progress of normal labour in the different racial groups. It thus provided practitioners with some evidence to suggest that these tools may have universal benefits. However, further studies are required to support this hypothesis. Studies of mixed groups, show statistically significant differences in length of labour and in the incidence of abnormal labour in different racial groups (Tuck et al. 1983).

## **2.6. Evolution of the partogram**

Identification of deviations from normal labour has been a topic for debate for many years, therefore it was not surprising that a simple, inexpensive tool to aid obstetricians and midwives was welcomed by many. The partograph (or partogram) provided health professionals with a continuous pictorial overview of the labour and allowed early identification and diagnosis of the pathological labour (Hall & Krins 1981).

The first obstetrician to provide a realistic tool for the study of individual labours was Emanuel Friedman (1954). In his study of 100 primigravidae at term, cervical dilatation was determined by frequent rectal examinations. For reproducibility, the examination was performed at the peak of the contraction and for uniformity, measurements were recorded in centimetres. A simple, but effective chart was

devised whereby square graph paper was used, with 10 divisions representing the cervical dilatation. The measurements were recorded and joined to the previous measurement in a straight line. The slope of each line was determined in terms of centimetres of dilatation per hour. The curves obtained by this simple technique were all similar in shape and resembled a sigmoid curve. Friedman's explanation divided the first stage of labour into two parts - firstly, the latent phase which extends over 8-10 hours and up to 3cms dilatation, secondly, the active phase, characterised by acceleration from 3-10 cm at the end of which is a decelerative phase. The major criticism of the development of this curve was the fact that no exclusions were made for malpresentations, malposition or multiple pregnancies. Similarly, inclusions incorporated women receiving oxytocin infusions, caudal analgesia and/or operative delivery. However, although the Friedman's labour curve is a crude version of the one used by many midwives and obstetricians today, it did recognise the fact that labour is sensitive to interference, prolonged with heavy sedation and shortened with stimulation. These have remained important factors when managing labouring women.

A randomised study of 434 women in Mexico (Walss et al.1987) reinforces the benefits of the Friedman partogram. In this study, women were randomised to either a Friedman partogram or a non-graphical descriptive chart. The results showed that there were more operative deliveries in the descriptive group and more babies with low Apgar scores at 5 minutes. The conclusions drawn from this study were that the Friedman partogram has not only diagnostic and prognostic value but that it also influences the management of women in labour.

The efforts of Friedman have been acknowledged by obstetricians world wide (Hendricks et al. 1970; Hall & Krins 1981; Burgess 1986; Holmergan 1993). However, although Hendricks gives credit to Friedman for developing and popularising “graphicostatistical analysis” of labour, he and his associates question part of his work. Their study of 303 women suggested that there is no deceleration phase at the end of the first stage of labour. They also did not support Friedman’s belief that the cervicograph should commence at 0cm, as their study demonstrated that the cervix progressively dilates from 36 weeks gestation. This latter point was later supported by Studd (1973) who demonstrated that it was more appropriate to relate expected progress to the first admission examination.

Philpott’s (1972) partograph developed from the original cervicograph of Friedman’s, providing a practical tool for recording intrapartum details. This was in an attempt to utilise midwives and assistants extensively in a hospital in Zimbabwe (then Rhodesia) where doctors were in short supply.

To advance Friedman’s (1967) partograph, an *alert line* was placed on the cervicograph. This innovation was introduced following the results of a prospective study of 624 consecutive women (Philpott & Castle 1972). Unlike Friedman, Philpott and Castle had a more focused eligibility criteria for their study. Women were only included in the study if the cervix was already 3cm. dilated on admission.

The alert line, unlike that of Friedman’s was straight not curved. The line was a modification of the mean rate of cervical dilatation of the slowest 10% of primigravid women in the active phase of labour and progressed at a rate of 1cm per hour. The

alert line joined points representing 1cm. dilatation at zero time (admission) and full dilatation (10 cm.). Should a woman's cervical dilatation progress slowly and cross this *alert line*, then arrangements were made to transfer her from a peripheral unit to a central unit where prolonged labour could be managed more effectively.

Although the authors claimed that the alert line could have universal application in the management of primigravidae, their own description of such a specific sample raises some questions. Firstly, they acknowledged that the rate of progress during the phase of maximum slope of 100 consecutive normal African primigravidae was half that of American patients. This they attribute to a high prevalence of mild cephalopelvic disproportion among their 'normal patients.' Secondly, the mean rate of cervical dilatation of 1 cm per hour was slower than Friedman's statistical limit of 1.2 cm per hour. Thirdly, their patients tended to arrive at hospital later than those previously reported (Hendrick et al. 1970). Finally, although the alert line appeared to separate efficient from inefficient labour, as reflected by the rate of cervical dilatation, this was not a randomised trial and therefore the findings should be accepted with caution.

The next stage in the development of the partogram by Philpott and Castle (1972a) was the introduction of an *action line* drawn four hours to the right of the alert line. This line was developed on the premise that correction of primary inefficient uterine action would lead to a vaginal delivery. To evaluate the action line a prospective study was carried out which concluded that the action line allowed 50% of patients whose cervicograph crossed the alert line to avoid being given oxytocin stimulation. It also showed a lowered incidence of prolonged labour and a reduction in caesarean sections. However, the reliability of this study can be questioned as although it is a

‘prospective clinical study of 624 patients’, many of the findings are based on comparisons of women who delivered in the department in 1966. Furthermore, the actual number of women who crossed the action line was only 68, chance findings can therefore not be completely excluded.

John Studd became an enthusiastic advocate of the partograph following his visit to Rhodesia. Although initially its application was for women in Central Africa, by the Autumn of 1972 it was being used in Birmingham (Studd & Philpott 1972). Studd introduced the partogram to obstetricians throughout Britain using the platform of the Blair Bell Research Society to disseminate information on this new innovation. By 1973 half of the teaching hospitals in the United Kingdom were using the partogram despite no formal evaluation of its use on a British population and although the partogram itself was accepted, the suitability of the action line was questioned by practitioners. Studd (1973) offered two answers to this questioning. Firstly, previous data was based on an African population and so racial differences may have influenced the diagnosis and management of prolonged labour. Secondly, the position of the action line was believed to be too far to the right and so optimum time for oxytocin stimulation was passed. In the face of these criticisms Studd decided to find the mean rate of cervical dilatation in normal labour for a British population. The sample actually included 4000 women of various racial groups, but the preliminary study reported on data from only 176 Caucasian nulliparous and 264 Caucasian multiparous. Studd devised and introduced a stencil to aid in the correct plotting of progress on the partogram. Five stencils were used which represented five progress slopes on the partogram. The choice of slope was dependent on the cervical dilatation on admission. Studd concluded that the partogram could aid in the recognition of

prolonged labour. Based on his observations, Studd decided that intervention, for women not reaching the expected rate of progress, should occur two hours earlier than had previously been reported (Philpott & Castle 1972b). Studd is acknowledged for pioneering the partogram in Britain, however his retrospective study is flawed mainly due to the fact that he included many women who were admitted to the study before the cervix was 3 cm dilated. By his own definition of labour, these women were in the latent phase and should have been excluded.

Beazley and Kurjak (1972) who were strong believers of the benefits of the partogram, suggested that the need to accelerate labour could only be confidently judged when the course of normal labour was available for comparison. They, (unlike Friedman 1954), described a method of plotting a partogram which did not require a precise diagnosis of the onset of labour. In their retrospective study of 1000 consecutive deliveries, the results of vaginal examinations were plotted for 460 primigravidae and 276 multigravidae and a normal distribution was obtained. A prospective study containing a sample of fifty primigravidae and forty five multigravidae was then used to validate the tool.

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What is surprising perhaps, is that the use of the partogram itself has only recently been rigorously evaluated (WHO 1994). The WHO partogram is an adaptation of the one formulated and described by Philpott and Castle (1972a,b). To test whether the use of the WHO partograph improves labour management and reduces maternal and fetal morbidity and mortality, a prospective study of 35,484 women was carried out. The study lasted fifteen months and involved four pairs of tertiary level hospitals in South East Asia. During the first five months all the hospitals collected data about

delivery. For the next five months the WHO partograph was introduced into one of each hospital pair. For the last five months the partograph was introduced into the remaining four hospitals. The protocol for management of labour included; - no intervention in latent phase until after 8 hours, amniotomy in the active phase, augmentation, caesarean section or observation to be considered if the action line was reached. The introduction of this package was accompanied by 'several days' of intensive teaching of the midwifery and the medical staff. The outcomes which showed significant improvement when the partogram was used were: fewer prolonged labours (>18 hr), fewer augmented labours and less postpartum sepsis.

In order to avoid the pitfalls of a historical control design, hospitals were randomly allocated to implement the partograph in phases. However this method also had its pitfalls. The authors state that it was not possible to randomise the individual to either conventional or to partograph care. There is only one reliable way of testing whether an intervention improves outcome and that is with a randomised controlled trial. The research method used in that study had several ways in which the results could have been biased and lays the results open to doubt.

To test whether the partograph was the cause of change in outcome between the hospitals studied, the introduction of the partogram should have been the only variable which was changed. In this study, the introduction of the partogram was accompanied by several days intensive teaching of midwifery and medical staff with the help of a WHO consultant in each centre. It was also introduced with a protocol which specified, among other things, that the women's membranes were ruptured in

the active phase of labour. Either, or both of these latter changes could have led to the change in outcomes, e.g. fewer augmented labours.

Even if the results could be relied upon, one could question how applicable they are in other settings, i.e. other than in tertiary level hospitals in South East Asia. The authors stated that the WHO trial showed beyond doubt that the partograph should be used on all women in labour (WHO 1994). How can the reader know what the effect would be of the introduction of a partograph in, for example, an Indian health centre with no facilities for caesarean section, an African hospital without adequate supplies (for example, intravenous giving sets) or a British hospital where care is given by highly trained midwives? The results of the study do not offer adequate support to allow the partograph to be recommended for use for all women.

The WHO press release claimed that the use of the partograph reduced the caesarean section rate - in fact, the paper showed that this was not a significant result. Only reductions in prolonged labour, augmented labours and postpartum sepsis reached statistical significance. The authors report that the proportion of labours requiring oxytocic augmentation was reduced by 54% - from 20.7% to 9.1%. It is difficult to come to any conclusion except that the previous rate of augmentation was unnecessarily high. This interpretation is supported by the authors' observation that the improvements were 'most marked in normal women.' In which case the partograph was simply correcting a poor standard of care, rather than making childbirth safer per se.



It must be understood that the majority of trials of partography have taken place in hospital settings where most maternal deaths occur among women admitted with severe complications and often neglected labour (Lennox & Kwast 1995). No trial to date (even the WHO trial) has demonstrated that the partograph does reduce maternal mortality. However, in a Western culture where mortality is low, physical and psychological morbidity are perhaps the most appropriate markers of success. The partogram as a whole needs to be evaluated further as do the individual components of its makeup.

## **2.7. Management of prolonged labour**

In most parts of the western world, caesarean section rates have been steadily rising without evidence of a reduction in perinatal mortality and morbidity. Both consumers (Audit Commission 1997) and practitioners (Henderson 1996) have voiced concerns about the increase in maternal morbidity and this has led to the quest for a management package which will offer low caesarean section rates coupled with positive outcomes for mother and baby.

O'Driscoll et al. (1973) seemed to have discovered the perfect solution to prolonged labour by introducing an Active Management Package which maintained a low caesarean section rate envied by many. Caesarean section rates of 5-7% led to world wide interest in what has been known as *The Dublin Approach*. This active management package has become synonymous with early use of amniotomy and syntocinon to achieve a rate of cervical dilatation of at least 1cm/hr. The protocol also

depends on accurate diagnosis of labour, a constant support person, the recognition of a latent and active phase in the second stage of labour and peer reviewed audits.

Criticism of this management stem primarily from the disbelief that such a package can improve clinical care. Francome, Savage, Churchill and Lewinson (1993), noted that when this package was introduced, prolonged labour affected only 5.1% of women. So it should be acknowledged that the National Maternity has only maintained its standards rather than improved them. Furthermore, there may also be other reasons to account for the low caesarean section rate. For example the National Maternity Hospital avoided many of the innovations seen in most obstetric units during the 1970's and 1980's (Henderson 1996). The reduced rate of intervention involved low rates of induction which may also have contributed to the avoidance of rising caesarean section rates. Similarly, the limited use of electronic fetal monitoring may have avoided escalating instrumental delivery rates. Barrett, Jarvis, Macdonald, Buchan, Tyrrell and Lilford (1990) concluded that 30% of caesarean sections performed for fetal distress were probably unnecessary. A further explanation is the fact that peer review has been in place in the National Maternity Hospital for about 30 years ( Boylan, personal communication) which is considered to be a key factor in ensuring that caesarean section rates remain constant. Urquhart, Grieve and Geals (1987) discovered that the actual process of carrying out an audit of their own unit's caesarean section rates resulted in a drop in the rate from 15.8% to 11.6%.

The active management package also places a large emphasis on a high level of support during labour, a factor which has been shown in other studies to be associated with shorter labours, higher rates of normal vaginal delivery and a reduction in the

analgesia used (Sosa, Kennell, Klaus, Robertson & Urrutia 1980; Klaus, Kennell, Robertson & Sosa 1986). Klaus speculated that increased levels of adrenaline are associated with anxiety and prolonged duration of labour. Therefore, social support may lessen anxiety, reducing adrenaline concentrations and thus shortening labour. These Guatemalan studies could be criticised, however, due to the unrepresentative study samples. Potentially high levels of anxiety, prior to the commencement of the study, in poorly educated mothers, attending an overcrowded hospital and in the absence of any traditional support may not be considered a 'normal' population. Women labouring in these conditions were more likely to have gained benefit from any form of social support (Nolan 1995). Further, more representative studies have, however, shown both the short term (Kennell, Klaus, McGrath, Robertson & Hinkley 1991) and long term benefits (Hofmeyr, Nikodem, Wolman, Chalmers & Kierner 1991) of constant companionship in labour. A systematic review of the effects of support in labour also suggested substantial benefits (Hodnett 1995). This meta-analysis of 10 randomised trials including 3336 women, supports the fact that companionship in labour can be effective in reducing both analgesia requirements and the incidence of operative deliveries, and improves fetal outcome.

O'Driscoll and Foley (1983) suggested that other units could reduce their caesarean section rates by using a similar 'active management package'. However, subsequently, Leveno, Cunningham and Pritchard (1985) advised caution in trying to imitate such management, predicting a potential increase in the incidence of intrapartum deaths and neonatal seizures. Their conclusion was reached from a comparison of statistics between Parkland Hospital, Dallas and the National Maternity hospital, Dublin. However, although the nurses in Dallas collected their data prospectively, they were

analysed against retrospective data retrieved from the National Maternity Hospital. Additionally, as acknowledged by the authors, it was perhaps unfair to compare the two units, as the populations, in terms of demographic details, were not actually comparable.

The O'Driscoll protocol has received some support from Turner, Webb and Gordon (1986) and Turner, Brassil and Gordon (1988) based on research carried out at Northwick Park Hospital in London. Turner et al. (1988) analysed the outcomes for primigravidae delivered in the first full year of active management implementation and concluded that this new policy increased the number of spontaneous deliveries. In addition to the obvious problem that this was not a randomised controlled trial, this descriptive study is flawed, the main problem being the fact that there were several changes in labour management during the same time period. A reduction in induction rates, the more conservative approach to the second stage of labour and the use of fetal blood sampling may all have affected obstetric outcome. Additionally, Turner et al. (1988) reported that the introduction of the active management package did not in fact increase the use of syntocinon in the unit studied. This suggests that some other factor/factors may have accounted for the findings.

Further support for the active management package came from Akoury, Brodie, Caddick, McLaughlin and Pugh (1988), following the completion of an observational study of nulliparous women. In this study an active management policy was carried out on 552 consecutive women who had presented at term in spontaneous labour. The outcomes from these women were then compared to a control group of 533 similar women delivered in the preceding year. The findings showed that the caesarean

section rate fell from 13% to 4.3% ( $p<0.0005$ ) and the number of labours lasting longer than 12 hours also fell, from 20% to 7% ( $p<0.005$ ). These favourable outcomes did not appear to be at the expense of an increase in fetal morbidity or mortality.

## **2.8. Early versus late intervention**

As briefly mentioned earlier, the active management package has become synonymous with the early use of amniotomy and when labour deviates from 1cm/hour, the administration of intravenous oxytocin. This management protocol has received huge interest amongst obstetricians who have attempted to objectively assess potential benefits in terms of obstetric outcome and caesarean section rate. What is interesting, and should be remembered, is the fact that some units have reported lower caesarean section rates than in Dublin by adopting a minimalist approach to labour (Van Alten, Eskes & Treffers 1989; Rockenschaub 1990).

A number of studies from the 1970's onwards have examined elements of active management to determine which of these may affect outcomes such as the caesarean section rate and duration of labour. These studies have focused primarily on early versus late intervention, recognising the potential importance of the timing of obstetric procedures. It is the early use of amniotomy and administration of oxytocin when prolonged labour is diagnosed which has attracted most interest and led to a series of clinical trials.

There have been eight randomised trials of reasonable methodological quality (Wetrich 1970; Stewart, Kennedy & Calder 1982; Franks 1990; Barrett, Savage,

Phillips & Lilford 1992; Fraser, Sauve, Parboosingh, Fung, Sokol & Persaud 1991; Fraser, Marcoux, Moutquin, Christen, Armson & Verreault 1992; Fraser, Marcoux, Moutquin & Christen 1993; Garite, Porto, Carlson, Rumney & Reimbold 1993; UK Amniotomy Group 1994) which have assessed the effect of early versus late amniotomy. Two of these trials (Fraser et al. 1993; UK Amniotomy Group 1994) were multi-centred with over 2000 participants from the United Kingdom and Canada. In these multi-centred trials an attempt was made to reduce bias by analysing by intention to treat, however, compliance with the conservative management policy was poor. A stricter conservative policy may have resulted in different findings. All trials showed some decrease in the duration of labour in the group randomised to amniotomy, with primigravidae showing the greatest reduction. However, meta-analysis of 6 of these trials (Thornton & Lilford 1994) showed little effect on either maternal or fetal outcomes. One study (Fraser 1992) did show a reduction in the number of babies with an Apgar score of less than seven at five minutes in the amniotomy group. However, the clinical relevance of this finding is uncertain.

Early use of oxytocin compared with delayed use has been examined in a number of other trials. Some of the trials (Read, Miller & Paul 1981; Hemminiki, Saarikosi, Lenck & Hennksson 1985; Bidgood & Steer 1987) reported that the membranes were artificially ruptured if intact prior to randomisation. In a further study, (Hunter 1991) amniotomy was performed immediately following randomisation. In two of the studies ambulation was an integral component of the policy for the control group (Read et al. 1981; Hemminki et al. 1985) whereas there was no prescriptive intervention in the other two (Bidgood & Steer 1987; Hunter 1991). In only one trial did the oxytocin appear to reduce the duration of labour (Bidgood & Steer 1987). In this trial the

participants were semi-recumbent. There were no significant differences in any other outcomes, including mode of delivery. The only statistically significant findings when these trials were systematically reviewed and combined for meta-analyses were an increased incidence of pain and hyperstimulation in the early oxytocin group (Fraser 1992). As in the amniotomy trials, there were problems of compliance in the control groups with a large percentage of women assigned to this group receiving oxytocin (between 25 and 75%).

One study (Cardozo 1990) attempted to compare the administration of oxytocin with saline for women in prolonged labour in a randomised controlled trial of 759 women. The findings suggested that syntocinon was superior to saline in improving the rate of cervical dilatation ( $p < 0.001$ ) and therefore the authors concluded that early recognition and treatment would improve maternal and fetal outcome. This study was methodologically flawed. The authors used a crossover design as they did not consider it ethical to carry out a double blind trial and as such the potential for bias was great. In fact 68 women who were allocated to the saline arm received syntocinon as the initial solution.

The first review of randomised controlled trials assessing two components of active management was conducted by Kierse (1989). This review examined four trials which compared early amniotomy and syntocinon use with conservative management of prolonged labour (Read et al. 1981; Hemminki et al. 1985; Cohen, O'Brien, Lewis & Knuppel 1987; Bidgood & Steer 1987a,b). None of the four trials reported a reduction in the rate of caesarean section among the actively managed group. These

trials were limited by small numbers of participants and there were difficulties maintaining the control groups.

Fraser (1992) reviewed a further two studies. Breart, Garel and Milka-Cabanne (1992) found no significant differences in caesarean section rates between those in the active management arm and those in the control. However, Lopez-Zeno, Peaceman, Adashek and Socal (1992) did find a significant difference, with the actively managed group having a significantly lower rate of caesarean section. In this trial, a similar number of women in both trial arms received oxytocin, although higher doses were given in the experimental arm. This suggests that perhaps this trial actually compared two different protocols of active management as opposed to active versus conservative management. This trial might be criticised for the potential introduction of bias, which was created by the management of all study women in the same labour ward with the same personnel. The trial could also be criticised for not excluding women with pre-existing medical conditions. This might account for the comparatively high rate of caesarean section in the control group (14%).

Clinical trials to test the active management approach are few. Meta-analysis of the randomised clinical trials on specific components of active management (Thornton & Lilford 1994), show that oxytocin augmentation does not improve caesarean section rates, operative vaginal delivery rates or neonatal outcome. However, as pointed out by Olah and Gee (1996), oxytocin does increase hyperstimulation and the amount of pain experienced by the woman. Amniotomy, although showing a minimal reduction in labour duration, does not appear to affect perinatal outcome or operative delivery rates (Barrett et al. 1992; Fraser et al. 1993; UK Amniotomy Group 1994).



Randomised studies to evaluate the efficacy of the whole package of active management are extremely rare. One study which did appear to assess all aspects of the active management package was that carried out by Frigoletto et al. (1995). This study was probably the first to provide enough evidence to forcefully challenge the management as outlined by the Dublin group. Frigoletto randomly assigned 1934 nulliparous low risk women to either an active management group or usual-care group, before thirty weeks gestation. The components of active management were identical to those outlined by O'Driscoll et al. (1993): customised childbirth classes; strict criteria for labour diagnosis; standardised labour management (which included early amniotomy and treatment with high dose oxytocin); and one to one nursing support. Women with full-term, uncomplicated pregnancies who presented in spontaneous labour (the protocol-eligible subgroup), who had been assigned to the active management group were admitted to a separate unit.

Despite the 'active management package', no differences were found between groups in the rate of caesarean section, either among all women or in the protocol-eligible subgroup. However the median duration of labour was shorter in the protocol-eligible subgroup by 2.7 hours and the rate of maternal fever was lower (7% versus 11%,  $p=0.007$ ). There were three times as many women whose labour lasted more than 12 hours in the usual care group than in the active management group (26% versus 9%,  $p<0.001$ ). From this study one may conclude that active management of labour may not reduce caesarean section rates but it may be associated with some outcomes which may be considered as favourable. Frigoletto et al. (1995) do acknowledge the possibility of the Hawthorne effect (Roethlisberger & Dickenson, 1939) contributing to their findings. That is, because they were focused on caesarean section rates, the

overall caesarean section rate was reduced. They did evaluate this potential effect retrospectively and found no differences in mode of delivery and oxytocin use between the usual care group who were protocol-eligible and all low risk women who delivered their first baby during the six months preceding trial commencement. The conclusion from Frigoletto et al. (1995) was that their data does not provide adequate justification for the universal recommendation of active management of labour. Their study contributes to the many controversial debates surrounding labour management.

## **2.9. Management of Labour in the Study Hospital**

The study hospital has used a partogram for many years based on that adapted by Beazley and Kurjak (1972). This was revised in 1994 following the publication of the findings of the World Health Organisation study (WHO 1994). One of the main changes to the previous chart was the introduction of an action line but the positioning of this line was open for debate. The literature, as previously discussed, offered no clear guidance, so a compromise was reached. It was decided amongst midwives and obstetricians that the study hospital partogram would include an action line placed three hours from the alert line. This meant that it was somewhere between that recommended by O'Driscoll et al. (1973) and that recommended by the World Health Organisation (WHO 1994). This adaptation to the WHO partogram has been used by others (Dujardin et al. 1992) who believe that partograms have not been sufficiently evaluated.

The study hospital acknowledges the existence of a latent phase and like Studd (1973) defines active labour when the cervix is three centimetres dilated. Four hourly vaginal

examinations are performed as suggested by the World Health Organisation (WHO 1994).

Like Hendricks et al. (1970) and Studd (1973), at the study hospital, the expected rate of progress is determined from the first admission examination. The acceptable rate of progress from there on, if the woman is in labour, is one centimetre an hour. This rate conforms to what is generally accepted by obstetricians (Philpott 1972; Beazley & Kurjak 1972; O'Driscoll et al. 1973; Cowan et al. 1982a,b; Gibb et al. 1984). Once a woman's cervical dilatation progress has crossed the action line an amniotomy is performed and a syntocinon infusion is commenced until regular uterine contractions are maintained.

## **2.10. Summary**

The literature highlights the confusion and inconsistencies which surround the management of women diagnosed as being in prolonged labour. It also highlights the lack of evidence on which to provide a definition of prolonged labour. It appears that labour management may be derived from two philosophies - one which promotes conservative management and the other which promotes a more active approach. The diagnosis of prolonged labour and subsequent timing of intervention may therefore be considered crucial factors in determining intrapartum outcomes. The partogram plays a pivotal role in diagnosing prolonged labour and as such has become an integral part of labour management in many units. Yet, interventions triggered by the use of a partogram include amniotomy, hydration, analgesia, oxytocic infusion and operative delivery all of which have their potential drawbacks. There remains considerable

controversy over the relative efficacy of these partogram triggered interventions (Thornton & Lilford 1994; Walkinshaw 1994), and there is no clear guidance from randomised trials.

Most studies have focused on caesarean section rates as the primary outcome measure when assessing the active management package or its components. However, recently caesarean section rates have been rising, to around 10% in Dublin (National Maternity Hospital Annual Report 1996), and to around 14% for groups using a four hour action line (Fraser et al. 1993). The caesarean section rate is an important obstetric outcome, however in most studies psychological outcomes have been completely overlooked.

A major limitation of the literature that has been discussed so far in this chapter, is the lack of emphasis on the mother's wishes. What research has been carried out suggests that women prefer conservative management (Fraser 1993). However, most studies only paid lip service to the women's views and others neglected them altogether. The involvement of women's views appeared to be a low priority for O'Driscoll and Studd (1973). Studd writes that:

*"The suggestions by O'Driscoll that obstetricians should become active conductors of labour rather than passive observers is well taken."* (p.455)

Yet as pointed out by Walkinshaw (1994) maternal satisfaction is an important outcome measure particularly with regard to interventions in labour. The following chapter will discuss such views with particular reference to the labour experience.

## **Chapter 3**

### **Prolonged labour in relation to Maternal views**

#### **3.1. Introduction**

Many women enter labour expecting a positive and personally rewarding experience (Brucker & MacMullen 1987). Some women will have these expectations confirmed by the reality of their experience but unfortunately others will not (Stolte 1987). This may be due to unanticipated factors such as obstetric intervention (Brown & Lumley 1994), or to unrealistic expectations (Szczepinska 1995). Childbirth has recently been described as a gamble, being a “lottery in which there will, sadly, be losers” (Szczepinska 1995). Yet, ideally the odds should be stacked in favour of both a safe and fulfilling experience.

The shift from home to hospital births following the Peel report (1970) led to a philosophy of childbirth that only recognised labour as being normal in retrospect. This resulted in a medical paradigm being adopted in most areas of maternity care, whereby childbirth was viewed as a ‘pathological’ as opposed to a ‘physiological event’ (Davis 1994).

In the 1980’s, a series of influential reports from the House of Commons Social Services Committee focused almost exclusively on the issues which surround perinatal and infant mortality (House of Commons Social Services Committee 1980,1984,1989). However, in 1992, a different approach was adopted by the report of an all party select committee chaired by MP Nicholas Winterton (Department of Health 1992). This report expressed concern about hospitalisation of ‘normal’ healthy

women and the unnecessary use of routine intervention. It strongly supported the need to assess women's views on childbirth issues and contained a vision of a maternity service which offered both safety and satisfaction. One of the recommendations in this report has been more recently addressed in the Department of Health report, Changing Childbirth (Department of Health 1993). This report offers guidance for health professionals in an attempt to improve the service offered to women and their families, giving more choice to consumers.

Midwives and obstetricians strive for a healthy mother and baby and it could be argued that if neither are at risk, then the woman should be the only person who decides whether or not intervention is required. Most papers fail to acknowledge the views of women. Those who have contributed greatly to our knowledge of prolonged labour, for example, have failed to seek or respect maternal opinions. As commented by Crowther et al. (1989).

*"The rate of progress must be considered in the context of the woman's total well being, rather than simply as a physical phenomenon.... Slow progress should alert one to the possibility of abnormal labour but should not automatically result in intervention."* (p843)

It may be argued that once labour has become dysfunctional then some of that control slips away from the women and into the hands of the care giver. However, as there remains much debate as to how obstetricians and midwives manage dysfunctional labour, it is hardly surprising that even less conclusive evidence is available to inform us of the views/feelings of the women. In their eagerness to discover the most

appropriate treatment for prolonged labour, many obstetricians have tended to neglect the important outcome of maternal satisfaction. But, if health professionals are to view women holistically then they need to explore both the physical and psychological aspects which contribute to the overall experience of labour.

The most neglected aspect of the debate over timing of intervention is the view of women themselves. In the WHO study (WHO 1994), 14% of primigravidae required intravenous oxytocin. Rates of 35 to 40 % are not uncommon using active management regimens (O'Driscoll et al. 1984; Turner, Fox & Gordon 1987; Hunter 1993). Such interventions have many unwanted sequelae - limitation of mobility, increased use of epidural analgesia, increased incidence of electronic fetal heart rate abnormalities, uterine hypertonus and uterine rupture. Yet, no information is available on women's views of the relative merits of these differing approaches. Walsh (1994) points out that the alert and action lines of the partogram can assist in the prediction of abnormal labour. However, it is only a relative indication that labour may be abnormal and should be viewed in the light of other maternal and fetal parameters.

In the current climate of woman centred care, it is no longer acceptable to carry out a study without eliciting the views of the women themselves. The following review of the literature will address this issue by discussing the factors which contribute to a 'satisfied' experience of childbirth.

### 3.2. Defining satisfaction

*Satisfaction* is a word that health professionals frequently use in an attempt to provide a measure in which services can be judged. In maternity care, maternal views are frequently explored in an attempt to establish whether particular services or management lead to a *satisfied* or *dissatisfied* consumer.

The dictionary definition of satisfaction is ‘fulfilment of obligation’ (Coulson, Carr, Hutchinson & Eagle 1981). However, in relation to childbirth it is not quite as easy to provide an adequate definition. It has been suggested that satisfaction is “A feeling of well-being resulting from the care the individual receives” (Field 1985). However, the difficulties of defining and measuring satisfaction have been widely reported (Locker & Dunt 1978; Oakley 1983; Lomas, Dore, Enkin & Mitchell 1987; Shearer 1987; Bramadat & Dreiger 1993), with little consensus about the best way forward. The complexities of childbirth and the individuality of each woman’s experience makes it extremely difficult to confidently measure such an ill defined outcome. As stated by Lumley (1985),

*“satisfaction with birth is a complex, subtle and constantly changing collage of memories, reflections, beliefs, reactions and convictions, ‘remembered’ by a series of active and even creative processes.” (p144)*

During labour a woman experiences a cocktail of emotions ranging from the pain and distress of the first and second stage of labour to the happiness and relief felt following the delivery of a healthy baby (Waldenstrom, Borg, Olsson, Skold & Wall 1996). A further problem is requesting that women rate their satisfaction with care



when they may believe that the alternative management provided a greater risk to either themselves or their baby (Shearer 1994).

Even women themselves have been shown to find difficulty in verbalising what is meant by 'satisfaction'. A small qualitative study of nine postnatal women found satisfaction described as "just a warm feeling" or "I'm happy" and dissatisfaction as a "negative feeling" or "just not feeling comfortable with it" (Bramadat & Driedger 1993). These descriptions are consistent with the theory that satisfaction is a positive response to an event. ( Linder-Pelz 1982a & Linder-Pelz 1982b).

It must be remembered that what is considered to be a marker of success to the woman does not always relate to that of the health professional. Achievement and satisfaction with childbirth is often viewed by the professional in terms of perinatal and maternal morbidity and mortality rates. However, by using these markers in isolation many obstetricians and midwives fail to 'understand the sense of disappointment that some women experience following delivery, even when the outcome is a healthy baby' p32 (Churchill 1995).

Each woman will measure her experience of labour differently and therefore it is important that planned individualised care is not neglected. However, many themes have emerged from the literature which suggest that they affect the way in which women perceive their labour. Some variables are repeatedly reported as being major contributors to satisfaction with the experience of birth. Pain (Slade, MacPherson, Hume & Maresh 1993) experience of control (Kitzinger 1975; Brewin & Bradley, 1982; Green, Coupland & Kitzinger 1990), interventions (Cartwright 1977; Morgan,

Bulpitt, Clifton & Lewis 1982; Cranley, Hedahl & Pegg 1983), duration of labour (Mackey 1995) and support (Chalmers & Wolman 1993) have been frequently associated with the level of satisfaction. These themes will now be addressed under the following headings -

♦ **Intervention**

♦ **Control**

♦ **Pain**

♦ **Duration of labour**

♦ **Overall experience**

### **3.3. Intervention**

Having discussed the potential pros and cons of intervention on clinical outcomes in the previous chapter, the emotional effects will now be addressed.

*“Allowing childbirth to proceed as nature intended....some will be successful, some will be damaged and some may die in the process ” (p163).*

This statement by Lorna Muirhead, the president of the RCM during her address at the RCM annual conference (Duff 1997), clearly highlights her views on the importance of intervention in some labours. Few would disagree with the fact that interventions can sometimes save lives (Churchill 1995). Furthermore, most health professionals would agree that medical intervention has a place in midwifery but only when a labour becomes abnormal and either the mother or baby becomes at risk (Hayward & Chalmers 1990). Yet, the difficulties of defining an abnormal labour have

already been highlighted in the previous chapter. There are many issues that surround the use of intervention which have been shown to affect both the physical and psychological outcomes of labour (Oakley 1980). It is generally believed that the longer a woman labours in the hospital, the more medical intervention she will receive (Stumpf 1993). This is often referred to as the 'snowball effect' - one intervention leading to another.

One of the earliest researchers to adequately assess maternal views in association with intervention was Cartwright (1979) during a study of induction of labour. Cartwright reported that there was a small increase in depression for those women whose labours were induced. The results of this study also showed that some women indicated a number of reasons why induction may be a favourable option. Women who responded in this way believed induction to be convenient as it brought about a welcome end to a long awaited event. This highlights the fact that for some women intervention can be seen as positive.

A postal survey which yielded 1508 replies from ten areas in England (Jacoby 1987) concluded that women's views about the management of their labours were clearly related to the procedures they experienced. It appears from the literature that there may be a direct relationship between obstetric intervention and maternal satisfaction with those women receiving more intervention being the most dissatisfied. Correlations have been found between technological intervention in childbirth and feelings of dissatisfaction, to the extent that it can lead to depression in the post natal period (Ehrenreich 1979).

Brown and Lumley (1994), reached a similar conclusion in their study of 790 Australian women, finding a higher score of dissatisfaction when related to obstetric intervention ( $p=0.015$ ). The responses to their postal questionnaire showed that in both primiparous and multiparous women, dissatisfaction was associated with induction, augmentation, epidural, forceps and episiotomy. Although this survey offers an overview of maternal feelings, like many other studies it fails to address the issue of measuring the effect of any one particular variable on specific groups of women. Additionally, all women who had given birth during one particular week were questioned, with few exclusions. This meant that the sample included women who had elective intervention making it difficult to assess whether routine unnecessary intervention had caused the dissatisfaction or whether it was intervention in general. Also, in this study, lack of information was associated with a fourfold to six-fold increase in dissatisfaction which may account for the dissatisfaction with intervention, especially if the respondents failed to understand the rationale for the particular interventions.

Hutton (1994), found that women wanted midwives to believe in their ability to give birth without intervention. Unfortunately, in the reporting of this study of 18 focus groups, no information is provided concerning the demographics of the sample, the number of women who had referred to intervention or the timing of the discussions. Although women may, in fact, want the support of midwives to gain more 'natural' labours, it is difficult to make this assumption based on the reported findings of this study.

An interesting view is held by Ehrenreich and English (1979) who accuse health professionals of adopting an interventionist approach to gain job satisfaction. This view is disturbing, as it suggests that the satisfaction of the medical profession is gained at the expense of the woman's experience.

### **3.4. Control in labour**

Control has been described as a primary need for all individuals and a particularly important element for women in labour (Hodnett & Simmons-Tropea 1987).

As reported by Flint (1991),

*“To take on this very powerful and demanding role it is obvious that a woman needs to be brimming over with self confidence, she needs to feel strong both physically and emotionally, she needs to feel in control of the situation.” (p S20).*

Many authors have addressed the issue of control in labour with similar findings. In a study of the influence of expectations on satisfaction, the results showed that control was the most important variable for a satisfying childbirth experience (Humenick & Bugen 1981). Similarly in an exploratory study of 50 women's views about what contributed to a positive birth experience, 39 said that personal control was important (Butani & Hodnett 1980). In a further study (Davenport-Slack & Boylan 1974), a woman's desire to participate in decision making was also associated with a positive experience of labour.

More recently, the concept of control has been investigated further and many meanings are reported (Green et al. 1990). Yet consensus suggests that it is more commonly associated with an act on a person and it has a direct influence on maternal

satisfaction. Yet as pointed out by Flint (1991) it is up to health professionals to create an environment conducive to a woman being able to feel in control. Flint believes that the environment should be one in which the room should be homely and private, the midwife should be known and the woman should be in charge. Those women feeling 'in control' have been shown to have a more positive experience of childbirth.

It is widely reported that some women feel that they have lost control of their bodies at the time of giving birth (Ehrenreich & English 1979). Some argue that this loss of control is due to the disempowerment of women who strive for normality yet are faced with the medicalisation of childbirth (Oakley 1980; Kitzinger 1980; Graham & Oakley 1981).

### **3.5. Pain Relief in labour**

In the antenatal period fear of pain in labour may be common for many women (Lowe 1996). However, the woman's ability to cope with the pain is more likely to affect her level of satisfaction than the perceived painfulness of labour (Humenick & Bugen, 1981; Simkin 1991; Brarnadet & Driedger 1993).

A survey of 295 women in Sweden (Waldenstrom et al. 1996) found that although labour was usually perceived as very painful, women's attitudes towards the pain were not completely negative, with 28% of women questioned viewing it in a positive light. Their study showed that a positive birth experience does not preclude pain and distress and concluded that both negative and positive feelings can coexist. Caution should be used in reading this study because all the women were questioned

in hospital one day after delivery when the *halo effect* would predominate. Also, a fixed scale questionnaire was used which have been shown to elicit fewer negative responses than open ended questions (Lumley 1985; Shearer 1987)

Despite the limitations of this survey, these findings are consistent with the earlier findings of Salmon, Drew and Miller (1990) who found that pain and distress are independent of the positive feelings of fulfilment and achievement.

Another qualitative study (Hutton 1994) found that pain was not the most frequently reported “worst memory”. In this study of 18 groups of recent users of maternity services, only 5 groups discussed the pain of labour as a bad memory. However, although the author states that the discussions were respondent led, it is unclear as to whether each group was facilitated by the same person which makes it difficult to confirm the generalizability of these findings. The groups were organised by a pressure group, the National Childbirth Trust, and as no demographic information is supplied to the reader, the groups cannot be assumed to be representative.

### **3.6. Duration of Labour**

As discussed in the previous chapter, prolonged labour often leads to various interventions, some of which may lead to dissatisfaction. Women’s experiences of the duration of labour have not adequately been explored. One study that involved interviews with 50 women within 48 hours of giving birth found that 29 mothers perceived their labour to have passed quickly, while 14 felt it had passed slowly (Butani & Hodnett 1980). A study by Beck (1983) which explored 60 women’s

temporal experiences of labour, using the verbal estimation method, found that women overestimated time intervals which suggests that time was 'dragging for them.' The problem with both these studies is that only quantitative methods were used which made the findings superficial. A later study by Beck (1994) using a phenomenological approach provided an in-depth account of 7 women's experiences. Beck found that while absorbed in labour, time seemed endless, but at the same time women were amazed at how quickly time had passed. Interestingly, women's expectations of the anticipated duration of labour influenced their temporal experiences, as did their experience of pain. Women welcomed progress reports of labour to assist in the passing of time and found support and companionship as key contributors to this passage of time.

A study conducted by Brown and Lumley (1994), found that a first stage lasting longer than 12 hours was associated with dissatisfaction among multiparous, but not in primiparous women. This could be due to the expectation of a shorter labour by the multiparous women.

The physical and emotional exhaustion of a long labour, especially when accompanied by technical and/or operative intervention can lead to dissatisfaction and to long term grieving (Churchill 1995). The implications of a prolonged labour are therefore vitally important.



### **3.7. Overall labour experience**

In the majority of studies which report on overall level of satisfaction, a higher proportion of women are satisfied than are not. However, some would argue that the male-dominated frame of reference still threatens the extent to which women in labour can fulfil their hopes and expectations (Churchill 1995). This suggests that the measures used to assess overall satisfaction may produce invalid results.

There are several possible reasons why high overall satisfaction levels have been found in exploratory studies of maternal views despite the dissatisfaction reported in relation to different variables. It could be as previously mentioned that the structured format of a questionnaire makes it more difficult for women to respond negatively (Lumley 1985; Shearer 1987). It could also be that many of the women were questioned after the event so that they had time to consider the benefits of a good outcome as opposed to the actual labour and delivery (Jacoby 1987). Riley (1977) argues that women may not 'mind' greatly about what has happened to them, especially in their relief and pleasure at having produced an intact child. Support for this theory comes from Jacoby's study as she found that mothers of babies who were not well enough to go home with them were less likely to say that their labours were managed as they liked.

It could actually be that health professionals meet the needs of the women in their care and that although there are negative elements to childbirth it does not detract from an overall positive experience. It has been suggested that previous research, being largely feminist, is unrepresentative and ignores the fact that most women are satisfied with the care they receive (Enkin 1988). In a randomised, cross cultural

study of 221 women both positive and negative feelings were expressed by the women being interviewed (Chalmers & Meyer 1994).

Some authors argue that a woman's overall experience is related to her previous expectations (Szczepinska 1995). As a consequence, some studies have adopted an expectation - fulfilment approach (Pascoe 1986; Kerssens 1994). Although the expectation-fulfilment model has been recently criticized (Avis 1995), there is also evidence to suggest that satisfaction does relate to the level of expectations (Linder-Pelz a,b, 1982; Green et al. 1990; Bramadat & Driedger 1993). One particular study (Driedger 1991), highlighted the fact that women interpreted satisfaction as an evaluative response resulting from the interaction of the event with their expectations: "I had fulfilled what I wanted".

### **3.8. Summary**

All the themes previously discussed (pain, control, intervention, duration of labour, overall experience) may be interrelated, adding to the complexities of childbirth but the extent to which each variable contributes to the woman's emotional well being is not clear from the evidence.

Most of the studies reported have used survey methods to assess the views of a chosen sample of maternity users. Women have been chosen by random allocation (Jacoby 1987) or by giving birth during a specified period of time (Waldenstrom et al. 1996). However, although these studies provide the reader with a broad overview of women's experiences of childbirth, they fail to identify and compare the views of different groups of women on specific aspects of care.

In the studies reported, none have provided a clear definition of *intervention*. Hospitals vary considerably, and what is routine in one may be unacceptable in another. There may be differences between women's views of routine interventions perceived as unnecessary and those of interventions that they perceive as being essential for them and their baby. It must also be considered that there may be medical reasons why some women do not receive the management of their choice (Jacoby 1987). Those women who have intrapartum interventions or operative procedures may feel dissatisfied but equally relieved at the outcome of a healthy baby. The dissatisfaction may be with either their labour management or with themselves.

It is well documented that women should be given choices in labour (Department of Health 1993; Audit Commission 1997). To allow these choices it is equally important to provide unbiased information. Professionals have to listen to what the women say without preconceived judgements interfering with their decisions. Lack of agreement may make this difficult. The second report of the Maternity Services Advisory Committee (1984) states that,

*“there is considerable concern among some women about what they consider to be unnecessary intervention in childbirth”* p 13

Unless considered retrospectively, the definition of parameters for *unnecessary intervention* is not that easy. Studies that have looked at women's preferences and made comparisons with the actual event have failed to acknowledge the realities of childbirth. As pointed out by Szczepinska (1995), ‘expect perfection and events are bound to fall short and cause disappointment.’ Some midwives may be guilty of lacking the courage to provide realistic expectations for pregnant women thereby

reinforcing the disappointment when abnormalities of labour occur. As pointed out by Muirhead “who would *choose* forceps, haemorrhage, a 3<sup>rd</sup> degree tear or eclampsia” (Duff 1997), but the reality is that these things happen.

Jacoby (1987) concludes that ‘on the whole’ women do not want interventionist labours. However there may in fact be those who do. If individualised care is to be provided then women should not be viewed as a homogenous group. Women’s preferences for and against intervention should be considered by midwives and obstetricians who should acknowledge that intervention may be acceptable or indeed preferable in certain situations.

Prolonged labour may create a situation whereby some women might choose early intervention. However, the evidence to refute or support this claim remains limited, due to a lack of randomised controlled trials in this area. In particular, the literature is void of trials which have included the measurement of women’s views.

This present study aims to assess women’s views on obstetric intervention with particular emphasis on the timing of intervention in prolonged labour. This study recognises at the outset the difficulties of measuring satisfaction, but, if a holistic approach is to be achieved maternal views must be explored.

## **Chapter 4**

### **Overall Summary and Study Rationale**

Despite the wealth of literature addressing the problems surrounding prolonged labour, there is little conclusive evidence on which to base practice. As there is no firm evidence to suggest the appropriate way to diagnose normal or prolonged labour, it is perhaps not surprising that inconsistencies remain in the management of labour. The timing of intervention, in particular, has not been subjected to rigorous examination, resulting in differing models of intrapartum care. Furthermore, many studies have examined the whole ‘package’ of labour care, thereby making it difficult to assess which individual variable has actually affected the outcomes.

The Dublin group (O’Driscoll et al. 1984; Turner et al. 1987) have proposed an active management package which relies on early identification of prolonged labour with early correction by oxytocin administration. Their philosophy requires intervention when labour progress deviates 1 to 2 hours from the alert line. Impressively low operative delivery rates have been achieved but at the expense of high obstetric intervention rates. It could be said that an active management package assumes that labour is abnormal until proven normal and some would argue that,

*“every first pregnancy is a trial of labour as the unknown balance between the powers, passages and passenger of the birth process are being tried out for the first time”* p24 (Holmgren 1993).

Cardozo & Studd (1985) triggered intervention at 2 hours and achieved a caesarean section rate of 8.7% for primigravidae. The WHO partogram sets its action line 4 hours to the right, and caesarean section rates of 10% are achievable in primigravidae in labour (WHO 1994).

These authors make the assumption that caesarean section rates are the most important outcome. However, as stated by Axten (1995),

*“Obstetricians’ assumptions that labour should progress within a medical framework detract from the uniqueness of each woman’s labour.” P19.*

Childbirth is a universal phenomenon but the idiosyncrasies of each labour may make it inappropriate to evaluate individual outcomes (for example, caesarean section rate) as markers of achievement. Some would argue that although active management of labour has its benefits it should not be used “before nature has been given a chance” (Axten 1995). Yet, there are no clear guidelines as to how long obstetricians and midwives should allow nature to proceed unaided. It has been suggested that the timing of intervention is vital to a woman’s sense of fulfilment (Stumpf 1993), intervention often being offered as a ‘solution’ before there has been a ‘problem’.

According to Dr John Lawson (1989), then vice president of the Royal College of Obstetricians and Gynaecologists the partogram is the most important advance in modern obstetric care in the past 20 years. The partogram can be an important tool to assist in decision making but incorrectly utilised it may become “a rigid dictator, leading doctors to insist on action, rather than assessment” (Robinson 1995)

It would be difficult to disagree that the partogram has shown some clear benefits in obstetrics and midwifery but, this tool should not have been introduced *per se*, before a proper evaluation was undertaken of its effectiveness. Cartmill and Thornton (1992), suggest that the visual aspects of the partogram may influence a practitioner's decision making. It is therefore vitally important that the characteristics of the chart are accurately displayed. The position of the action line may have a direct influence on maternity outcomes but this matter has never been adequately addressed.

Lack of evidence on which to base practice was highlighted during local debate over labour ward guidelines in Liverpool in 1994. When compiling a new partogram, the action line was drawn three hours to the right of the alert line as a compromise between literature supporting both two and four hours. This alerted midwives and obstetricians to the fact that there is insufficient evidence on which to base clinical practice. Thus, the issue of timing of obstetric intervention during spontaneous labour needed to be urgently addressed, including eliciting women's views. This study aims to provide unique evidence to allow clearer and more accurate intrapartum guidelines to be produced.

## **PART 2: METHODOLOGY**



## **Chapter 5**

### **Considerations in the design of the study**

#### **5.1. Introduction**

As discussed in the previous chapter, most randomised controlled trials have failed to adequately assess both the physical and the psychological outcomes when examining the area of prolonged labour. This present study attempts to rectify this by basing the study design on a more holistic framework. Although experimental methods are predominantly used in this study, a postpositivist approach (discussed later in this chapter) has been adopted because the views of the participants are considered of equal importance to the main clinical outcome.

An examination of the current literature coupled with the inconsistencies in labour management led to the following research questions.

Primary research question:

*Are there differences in the caesarean section rate and level of maternal satisfaction when managing labouring primigravid women using a 2hour, 3hour or 4 hour action line?*

Secondary research question:

*Are there differences in intrapartum and neonatal outcomes when managing labouring primigravid women using a 2hour, 3hour or 4 hour action line?*

## **5.2. Methodological Choice from a Philosophical Perspective**

Many researchers who have investigated intrapartum problems, have adopted a positivist approach, using only quantitative methods in an attempt to provide more 'respectable', hard data. Yet as pointed out by Guba (1990) when referring to the basic belief of positivism, the ultimate aim of science is to predict and control natural phenomena. However, the fact that the sample is very much subject centred makes it difficult and inappropriate to predict or control those under investigation. It is well recognised that the implicit adoption of tenets of science, based in a positivistic paradigm, gives rise to conflicts with humanistic philosophy (Playle 1995). The approach to this study, therefore, aimed to 'humanise' the research by exploring and giving equal precedence to both 'soft' and 'hard' outcomes.

The underpinning philosophy for this study is reflected by several dichotomies, for example, applied rather than pure research and policy rather than theoretical research. This study is distanced from the laboratory setting of pure research, by being a pragmatic clinical study which aims to have findings generalisable to future practice. In addition, client contributions are welcomed; this is believed to favour the utilisation of the research outcomes to practice (Heller 1986). The involvement of the participants throughout all stages of planning and conducting the research assisted in the development of a positive relationship between researcher and user. This consumer involvement is being stressed increasingly in NHS practice (Dodds et al. 1996).

Rossi (1980) noted that policy research is not only of value when determining policy but is also of interest to more than one academic discipline. This study fulfils this

criterion, being applicable to both obstetrics and midwifery, and the ultimate goal is to review and possibly change hospital policy for the benefit of those whom it serves. Although it is anticipated that the research findings will generate theory, progress will only be made once the findings are applied to the natural setting as a whole (Trist 1976).

The postpositivist approach adopted for this study recognises the need for “as many sources of data investigators, theories and methods as possible” (Guba 1990), as it is believed that a combination of methods will allow a more comprehensive view of the field of study, i.e. prolonged labour. As comparisons were to be made between three treatment groups (i.e. 2,3 and 4 hour partogram) an experimental method was believed to be the only accurate method of identifying ‘real’ differences in study outcomes. However, it is recognised that only an approximation of the truth can ever be achieved. Postpositivists argue that ‘there is no Archimedean point or absolute foundation for knowledge, they accept a nonfoundationalist epistemology’ (Guba 1990). This does not mean that research standards are lowered, but this approach does make a distinction between what is believed to be true and what really is true. Objectivity remains the ideal, yet truth is characterised in this approach in terms of ‘some form of correspondence with reality’ (Trigg 1985). The beliefs of the researcher, the clinicians and the trial participants will contribute to the realism of the study outcomes.

The randomised controlled trial has been increasingly promoted over the last 30 years as the major evaluative tool within medicine. At the same time, feminists have increasingly criticised the ways in which the construction of what counts as

'knowledge' omits women's perspectives and experiences (Oakley 1990). The postpositivist approach, aims for objectivity yet recognises the external influences which contribute to the outcomes being measured. It is recognised that even the most carefully designed experiment still takes place in a social context (Couchman & Dawson 1990). In this present study, midwives are required to interact with their colleagues, the women in their care, the setting and the tools of their profession. This interaction may have an important bearing on the study and is thus acknowledged from the outset.

This being a pragmatic study must acknowledge outcomes from different perspectives, both physical and psychological, therefore triangulation was considered essential. Methodologically, postpositivism lays emphasis on the importance of triangulation (Denzin 1978) which stems partly from the disbelief that the findings from one source alone can be relied upon (Guba 1990). As such, the postpositivist would recommend that most inquiries should base their findings on a multiple approach. Triangulation may assist in strengthening the research findings by aiding in obtaining complementary findings (Morse 1991). In this current study three important aspects of the labour were considered, i.e. obstetric outcomes, maternal experiences and midwives' views. All three perspectives contributed to providing an insight into the overall labour experience.

Some researchers, who believe the epistemological stance should direct the research question, debate the rationale of combining paradigms and using both quantitative and qualitative research methods in the same study (Kuhn 1972). However, others see

the advantages of using a research strategy that integrates them (Reason & Rowan 1981; Reason 1988; Brannen 1992).

Burrell and Morgan (1979) argue that as the research philosophies are contradictory to each other they can not be reconciled in one study. It has also been suggested that difficulties may arise when using different methods in terms of the investment of time (Robson 1993), the elimination of bias (Fielding and Fielding 1986) and the overlapping of concepts uncovered during data analysis (Brewer & Hunter 1989). However, in this present study it was felt that the advantages of being able to incorporate qualitative and quantitative techniques outweighed any potential disadvantages. Furthermore, the aforementioned problems did not appear to be relevant to the present study, or, could be overcome.

There have been powerful pragmatic arguments put forward in favour of a combined methodological approach (Silverman 1985; Bryman 1988), many social scientists now believing that a single methodological approach may lead to superficial findings. The emphasis on wholeness means a rejection of fragmented and theoretical knowledge that is separated from experience and clinical practice. This present study was intended to produce findings which could be viewed in the context of the clinical and social environment, not as isolated dependent and independent variables which are usually associated with experimental research. As pointed out by Martin (1990) research on people is different from research in the natural sciences. As such, a combination of qualitative and quantitative methods can be advantageous by ensuring that the results reflect a deeper understanding of individual views and an appreciation of the women's overall agenda. In this present study a restricted approach has been

rejected in favour of *methodological eclecticism* (Cormack 1991), i.e. the freedom to choose different methods to provide a more comprehensive view of the field of study. A combined approach which recognises both quantitative and qualitative methods of data collection was therefore used to provide a holistic picture on which to base practice.

A quantitative approach was used to provide evidence of the effect of the partogram action line on obstetric outcomes. This provided measurable data from which comparisons could be made. The qualitative approach provided information about women's perceptions of their labour experience. This ensured that more in depth data was provided, making the overall study findings comprehensive, meaningful and applicable to clinical practice .

### **5.3. Ethical considerations**

The theory, deontology, is the main influence in the moral philosophy associated with midwifery. This theory is associated with Immanuel Kant (1724-1804) and is based around moral duty (Clarke 1995). Kant believed that individuals should always be respected and should not be used by others for personal gain. The Code of Professional Conduct (UKCC 1992), is grounded in deontology as it clearly states its major principle to be 'the primacy of the patient'. The respect for colleagues is also highlighted, with emphasis on prevention of abuse by others. This should be achieved in the clinical midwifery field as well as when conducting research in this area.

All respondents were seen and treated as individuals throughout the research process, by consideration of their physical, emotional and social well being. It is well recognised that a woman in labour feels intensely vulnerable (Robinson 1997) and research can heighten the anxiety by placing women in a position whereby they have to consent for an unborn child as well as themselves. Additionally, the woman may be suffering from pain and may be experiencing the side effects of analgesia. Despite the ethical issues previously mentioned, results from a multi-centred trial exploring early versus late artificial rupture of the membranes in primigravidae, revealed that five of the centres did not give women any information about the trial until they were in labour (UK Amniotomy Group 1994). This was regarded as unacceptable by the present researcher. In this present study, a major consideration was the provision of suitable, accurate information, administered at an appropriate time. The research design was one in which informed choice was emphasised. In addition to written information, the trial participants were given an opportunity to discuss the trial at length with a research midwife. Women were not encouraged to make a decision at this point, instead they were given from 20 weeks gestation until the time of delivery to make a decision. This enabled women to feel comfortable about *refusing* to participate (Robinson 1995).

Clarke (1995), stated that “practice does not take place in a moral vacuum” p224, and that “midwives carry personal and professional moral responsibility for their practice, and the effect it has on others”p224. Midwifery as a profession is faced with many ethical dilemmas which may be heightened when conducting research.

The view of experimental research as inherently unethical is central to the feminist critique (Birke 1986; Spallone & Steinberg 1987). The three main issues leading to this ideology being, the denial of choice, the degree of practitioner uncertainty and lack of informed consent (Oakley 1990). These issues will be highlighted in the following paragraphs.

As stated by Dawson (1986), "Randomised controlled trials were originally used in agriculture, and their application to man...raises practical difficulties and moral dilemmas." Experimental research with people, therefore poses ethical problems (Robson 1993) as subjects are explicitly manipulated. Research viewed as leading to prediction gives the possibility of control over what people do, which has an obvious moral dimension.

The ethics of a randomised controlled trial are heightened as both the clinical researcher and the respondents must believe that there is enough uncertainty about the treatment to warrant participation. As pointed out by Zelen (1979) many investigators decline to participate in a trial as they believe that the 'patient-physician relation' is compromised by the acknowledgement of uncertainty.

The American Nurses' Association (1975) recognises the moral issues in research and claims that it is necessary that the dignity, human rights and welfare of the subjects be considered and protected adequately according to the ethical principles of the profession. Clarke and Robinson (1989) support this belief saying that care, consent and confidentiality are central to the moral concerns and rights of the patients involved in health service research. It was therefore necessary for the proposed



research to be presented to both the university and Trust ethics committees prior to commencement (appendix 1).

Prior to the commencement of the study it was necessary to decide whether any woman known to have a history of mental disorder was to be exempted from the study. Also whether any woman unable to communicate effectively, i.e. with learning difficulties or limited comprehension of the English language should be excluded. These exclusions were believed to be important as it would have been questionable as to whether or not an informed consent could be obtained. According to the British Sociological Association (1991), informed consent implies a responsibility to explain as fully as possible, and in terms meaningful to participants, what the research is about, who is undertaking it and financing it, why it is being undertaken and how it is to be disseminated. Consideration was also given to the fact that a woman carrying an abnormal fetus, whose baby was ward of court or whose baby was for adoption should be excluded. It was felt that to have included such women might have caused them unnecessary emotional distress.

It was recognised that the respondent has the right to refuse to participate at any stage of the research process and this was clearly stated in the information sheet and verbally. As the management for women in prolonged labour is uncertain, it may actually have been unethical **not** to approach eligible women.

Confidentiality was assured and written consent was requested from each respondent. The respondents were informed that anything they would write on the questionnaire would remain anonymous. They were also informed that the presentation of the data

would not include their names or any other means of identification. On presentation of the open responses, pseudonyms would be used when appropriate. As highlighted by Punch (1986) settings and respondents should not be identifiable in print and they should not suffer harm or embarrassment as a consequence of the research.

## **Chapter 6**

### **Methodological Considerations**

In order to answer the research question, a randomised controlled clinical trial was designed using both quantitative and qualitative methods of data collection in an attempt to view the data from different perspectives. In planning the study design, there were several methodological considerations which needed to be addressed. These considerations, which will be discussed in the present chapter, centre around prospective studies, experimental design, randomisation, bias, validity and reliability and instruments for data collection.

#### **6.1. Design**

Careful study design is the foundation of quality clinical research (Noller and Melton 1985) and so careful considerations had to be made at the planning stage of the study. As suggested by Sacket (1986) there are only a handful of ways to do a study properly but a thousand ways to do it wrongly.

##### ***6.1.1. Clinical Trial***

From the outset a clinical trial was proposed. The indication for conducting a clinical trial is that there is uncertainty about the effectiveness of a proposed intervention (Lowe 1993). In this present study, the uncertainty surrounding the appropriate management for women in prolonged labour was evident from the literature as well as from daily clinical practice. Practitioner support, which was essential in order to run the study efficiently, was forthcoming. This was perhaps because the midwives and obstetricians had long awaited the answer to this question. As stated by Lowe (1993)

‘A stance of uncertain neutrality has to be the norm for participating clinicians.’ In the present study, the current management, i.e. 3hour partogram, was a compromise between an ‘aggressive’ and ‘conservative’ approach, therefore, to some extent, neutrality already prevailed.

A pragmatic design leads to analysis by ‘intention to treat’, which means that once a woman is randomised to a treatment arm, the data is analysed as if she received the intervention, whether it occurred or not. It has been recommended that all clinical trials be analysed on an intention to treat basis (Campbell & Machin 1993), as it offers a closer comparison to the ‘real clinical world’. Explanatory studies, on the other hand, require a more tightly controlled situation which does not allow for naturally occurring clinical disruptions/problems. In the present study, in order to be able to generalise the findings into practice, a pragmatic design was considered imperative, and therefore results were analysed on an ‘intention to treat’ basis.

Altman (1991) classified clinical research in the following three ways:

1. observational or experimental;
2. prospective or retrospective;
3. longitudinal or cross sectional.

These aspect will be discussed in detail to provide the rationale for the emerging study design.

### ***6.1.2. Experimental Design***

Observational studies can take different forms, often to investigate the possible associations between various factors and the development of a particular disease or condition. In fact many areas of maternity care lend themselves to an approach that does not involve a randomised trial, for example, the effects of alcohol consumption on pregnancy. Two main types of observational study that are used to investigate causal factors are the case controlled study and the cohort study.

The main advantage of the case controlled study is that it is relatively simple, quick and cheap. However, this design is disadvantaged in relation to the possible biases in the comparison of cases and controls. The selection of appropriate controls and cases in addition to the reliance on retrospective and recall information make this approach susceptible to bias.

The cohort study is a valuable approach to following a group of individuals over a period of time (Breslow & Day 1987). But this design also has its difficulties. These studies can take a long time, tend to be expensive and are unsuitable for studying rare outcomes. A further difficulty with cohort studies is the loss to follow-up. This loss can contribute to a considerable risk of bias and can weaken the analysis. Even with a relatively short follow up period there will be losses for various reasons, some of which might be related to the aim of the research. In a study of 6219 pregnant women in New Haven (Martin & Bracken 1987) the main analysis was reduced to only 3858 following the birth of the babies of the pregnant women initially identified. This study provides an example of the potential degree of loss to follow up. Surveillance bias

may also be introduced in cohort studies as high risk groups may be investigated more rigorously than others.

A further study alternative is the crossover design whereby the same group of patients are given all treatments of interest in sequence. Randomisation is used to determine the order in which the treatments are used. This design has many potential problems which relate to withdrawal, carry-over of treatment and *period effect* (Woods, Williams & Tavel 1989). This method was unsuitable for this present study mainly because crossover studies cannot be used for conditions which can be cured. The nature of this present trial meant that the woman could receive only one of the treatments at one given time period.

According to Altman (1991) if it is possible, both ethically and logistically, then an experiment involving randomisation is the preferred choice of study design. After considering all design aspects an unrelated subject design was considered the only appropriate form of experimentation for this present study. This design has the potential disadvantage of identifying different characteristics amongst the respondents affecting the results (Hicks 1996). However, the advantages of being able to compare groups of respondents during the same time period outweighs any potential errors. As discussed in the previous chapter, there is evidence (WHO 1994) of methodological inadequacies in non randomised controlled trials which have explored the same topic.

### **6.1.3. Randomisation**

There are various methods of treatment allocation using random and non random approaches. However, the use of non-random controls in clinical trials lessens the

credibility of the results. One alternative to random allocation is systematic allocation whereby treatments are allocated according to, for example, the hospital number or time of arrival. This method is open to abuse as the allocation can be altered by anyone with access to the procedure, resulting in a biased allocation. The use of non-random concurrent controls also has its limitations. This method leads to problems of interpretation, because it is usually very difficult to establish that the groups are comparable, for example, when the groups are taken from patients at different hospitals.

The use of historical controls is also seriously flawed as the researcher can never eliminate the possible biases due to factors that may have changed over time. Sacks et al. (1983) demonstrated this point by comparing trials of the same therapies in which historical or randomised controls were used. He found a consistent tendency for historically controlled trials to yield the most optimistic findings.

The most acceptable method of treatment allocation was therefore randomisation. The aim of a randomised experiment is to compare two or more intervention groups by some valid measurable outcomes whilst at the same time ensuring that these groups are comparable in respect of any conceivable influences on outcome (Lowe 1993). In this present study 3 groups of similar women were being compared, the valid primary measurement outcomes being, the rate of caesarean section and maternal satisfaction score. Randomisation was important to the success of this study to safeguard against bias and to provide the basis on which to perform appropriate statistical tests (Altman 1982) from which inferences could be made.

#### ***6.1.4. Prospective Studies***

A prospective as opposed to retrospective study was considered vitally important to provide some control over the collection of appropriate data (Lowe 1993). Decisions regarding data can be made at the outset of a prospective study, ensuring that relevant information is gathered. Retrospective studies suffer from what has become known as the post hoc fallacy - 'after this, therefore caused by this' (Oyster, Hanten & Llorens 1987) but in retrospective studies temporal sequence does not necessarily imply causation. Retrospective studies may also be criticised because of historical changes which may influence any differences measured. Another problem of retrospective studies is that the effect of the interaction of variables cannot be accurately measured. This means that the researcher interpreting the data can introduce bias by ignoring or emphasising certain relationships which he or she considers to be relevant. Further problems include incompleteness of information and possibilities of inaccuracy in recalled information (Altman 1991).

Prospective studies are methodologically stronger than retrospective studies, because the existence of a comparison group strengthens the case for the possible causative effect of the independent variable, in this case, the position of the partogram action line.

Having decided that a prospective approach was the most acceptable for this study, it must be acknowledged that in planning the study, the current management protocol, and that of other maternity units, was viewed retrospectively which enabled the generation of the hypothesis. Randomised controlled trials should not be carried out unless there is some evidence to justify further study.



### ***6.1.5. Longitudinal versus cross-sectional studies***

A longitudinal study is one which monitors an individual over time, whereas cross-sectional studies observe an individual only once. Observational studies may be longitudinal or cross-sectional whereas experiments are usually longitudinal (Campbell & Machin 1993). Like most clinical trials, this present study is longitudinal because the main focus of interest was the effect of the treatment. In this study the intervention commenced at one time point and the effect on the outcomes (caesarean section and maternal satisfaction) was evident at a later time period. Although cross-sectional designs are appropriate for descriptive research, particularly prevalence studies, compared with longitudinal designs a greater number of biases are probable.

## **6.2. Bias**

### ***6.2.1. Prevention of Selection Bias***

Because of selection bias non-randomised trials can supply falsely optimistic (Doll & Peto 1980) or even wrong (Ederer 1977) reports of new treatment. The main purpose of randomisation was to safeguard against selection bias by making the selection maximally unpredictable (Gore & Altman 1982). If the study was to have any impact on clinical management, it was imperative that a representative sample be obtained. The appropriate way of ensuring this was by randomisation. Non experimental designs run the risk of having groups which differ in important characteristics. In quantitative research the sample should be representative of some larger population to which it is hoped to generalise the research findings. So, to achieve external validity simple random sampling was used whereby women were randomly allocated to one of the trial arms by the aid of a table of random numbers. To prevent a large discrepancy

between the number of women allocated to each trial arm, randomisation took place in batches of 120. This method gave each person an equal chance of being included in the sample and also made all possible combinations of persons for a particular sample size equally likely (Robson 1993).

### ***6.2.2. Prevention of accidental bias***

Randomisation is also important to insure in the long term against accidental bias between groups in respect of some important patient variable. This study uses an independent samples design and thus had the potential for variation created from participant variables (Coolican 1994).

Although it was important that the women in each group were equal in terms of both demographic and intrapartum data, it was not believed necessary to use stratified randomisation as the sample size was large enough to confidently reject the possibility of imbalances (Lowe 1993). Altman (1984) states that randomisation protects against substantial accidental bias if the sample size is 200 or more. Variables which could potentially affect the study outcome were checked across the three trial arms. Postcodes were also collected from all women and related to the Under Privileged Area score (Jarman 1997) in an attempt to identify any unforeseen geographical biases. The Under Privileged Area score (Jarman 1983) was established following the report of the joint Department of Health and Social Security and General Medical Services Committee Working Party on Underdoctored Areas (1980). These reports suggested a need to identify those areas where the difficulties were greatest so that services could be improved. From a study of 180 random general practitioners, written evidence was analysed which generated 21 categories thought to be related to

social characteristics of the population. Thirteen of these categories were social factors and eight were related to service provision. A consensus was then reached to include only 10 of the social factors in the final scoring: children under 5, unemployment, poor housing, ethnic minorities, single parent households, elderly living alone, overcrowding, lower social classes, highly mobile people and non-married couple families. These factors were tested and validated in four different parts of England and Wales.

### ***6.2.3. Prevention of Experimenter bias***

In all research involving human respondents the researcher can influence the study outcome unintentionally through interaction with either the data or the subjects. This source of error, which has been described as *experimenter bias effect* (Hicks 1996), had to be considered when designing this study. The best way to prevent this is to make the study double blind (Campbell & Machin 1993), in which neither the woman or the researcher is aware of the treatment allocation. However, the nature of this study meant that it was not possible to blind either the woman, clinician or researcher. To have blinded the clinician would have made it impossible to manage the labour. To have blinded the woman would have denied her the information that may have influenced her labour decisions, for example, use of analgesia. To be able to make choices in labour a woman deserves a full account of her progress and needs to know what her future management may be. A labouring woman must be given as much information as she desires (Kirkham 1989). From the researcher's point of view this study aimed to neutralise, as far as possible, potential bias and so the researcher was not involved in the care of any of the trial participants. It is recognised that total objectivity is difficult to achieve and may be virtually impossible (Guba 1990). Having

anticipated the potential problem of bias from clinicians, midwives were questioned about partogram use prior to the dissemination of the study findings. If the midwives had shown a preference for one particular trial arm this could have directly influenced the women's views.

## **6.3. Eligibility**

### ***6.3.1. Study Inclusions***

There is some evidence from earlier trials to suggest that labour progress is not determined by parity (Calkins & Irvine 1930; Hendricks et al. 1970). However, although complications are less common in multiparous women, their management is strongly influenced by the care and outcomes of their previous pregnancies (Middle & MacFarlane 1995). As such, primigravid women only were included in the trial.

Women were included in the trial if the fetus presented with a cephalic presentation only. A woman carrying a malpresented fetus would be at a greater risk of obstetric intervention which would make interpretation of the findings difficult. It has been suggested that different partograms should be used to manage women who present in labour with known complications (Juntunen & Kirkinen 1994).

Women had to be at 37 weeks gestation of pregnancy or more to participate in the trial. Complications can occur due to fetal prematurity which could cause skewing of the results if they are not excluded. Midwifery experience highlighted that women who present in pre term labour, may not follow the 'normal' pattern of labour progress. It is very rare, for example, for these women to require augmentation of labour.

Women were randomised following confirmation of spontaneous labour. This was assessed by digital vaginal examination. The research protocol requested that women be randomised only when the cervix was effaced and 3 centimetres dilated and accompanied by regular painful uterine contractions. This was to prevent women being entered into the study too early and receiving intervention which was not required. It also encouraged the standardisation of entry thereby, minimising both selection bias and accidental bias.

### ***6.3.2. Study Exclusions***

Women were excluded from entering the trial if their labour required induction. An induced labour requires immediate intervention and carries an increased risk of caesarean section (Cardozo 1993). This would therefore affect the study outcomes. Women with diabetes or with a multiple pregnancy were also excluded, to further restrict an inappropriate high risk sample being obtained, on which inferences about the general population will be made (Altman 1991).

### **6.4. Study Setting**

The hospital was chosen because it is a regional unit and therefore consists of a mixed clientele of various ethnic groups and social classes. This hospital has over 6,000 deliveries per annum, providing a large target population from which an adequate sample could be obtained. Being employed by the Trust made the unit accessible, convenient and familiar to the researcher. Having already networked with the obstetric and midwifery staff provided the researcher with the confidence that co-

operation and support would be forthcoming, both of which were imperative to the success of the study.

### **6.5. Participant Recruitment**

It was believed to be important that women received the information prior to discussing the trial, to allow them adequate time to absorb the information. The quality of information given to pregnant women has been previously questioned (Kirkham 1989). It was therefore imperative that eligible women had several opportunities to discuss the study.

Due to limitations on resources and practical problems of availability, it was not possible for all eligible women to meet with the research midwife to discuss the trial. This group (n=331) of women received the information sheet at the booking clinic and then were approached for consent on delivery suite after discussion with the attending midwife. For these women, it was important that they were approached as early as possible, to enable them to absorb the information prior to the onset of uterine contractions and analgesia. In these circumstances, the midwife would use her own personal judgement as to whether it was appropriate to reintroduce the study and obtain consent. The participation rate for this group of women was 31% which was a great deal lower than the rate for women approached at twenty weeks gestation.

For the sake of all the women, it was important not to allow trial enthusiasm to lead to unintentional pressure being placed on the women. Robinson (1995) provides an example of a doctor who found refusal to participate in a trial “frightfully inconvenient”. This doctor seemed to believe that the words ‘inform’ and ‘consent’

automatically went together. In this study women were not encouraged to make a decision at the time of discussing the trial, however, 92% of them did. This may have been due to the fact that they had received written information several weeks earlier and therefore had already discussed the study with their team midwife, community midwife or GP. Some women had also used the contact number on the bottom of the information sheet to inquire further about the study.

### **6.6. Method of randomisation**

Following confirmation of eligibility, randomisation was carried out by the delivery suite midwives who were unaware of the randomisation sequence. The sealed opaque envelope method of randomisation was chosen as it was one with which the midwives were familiar and it had the advantage of being inexpensive and easily utilised. It is acknowledged, however, that this method has the potential for interference with the randomisation sequence (Gore & Altman 1982) If a clinician decided to open the envelope prematurely or discard what she considered to be an unfavourable treatment then the randomisation process would fail. In this study, the clinicians were eager to answer the long debated question and therefore it was considered unlikely that tampering occurred. Central randomisation via a 24 hour telephone service would have safeguarded against randomisation interference, but, lack of resources made this method impossible. It is unusual for telephone randomisation to be carried out in a single centred trial.

### **6.7. Outcomes**

It was anticipated that many outcomes would be measured, however this being a randomised clinical trial it was important to decide in advance which measures were

of major interest as multiple testing reduces statistical power. Although it is recommended that the focus of attention should be on only one outcome measure (Altman 1991; Campbell & Machin 1993), in this present study two outcomes were given equal precedence. These were maternal satisfaction and caesarean section as these are the factors that are likely to influence clinical change (see previous chapter). Although it is acknowledged that many factors contribute to the labour experience, for the purpose of this study, other outcomes were considered of secondary importance. Secondary outcome data are collected in clinical trials for two main reasons. Firstly, they confirm that the treatment groups are comparable with regard to certain interventions, such as episiotomy. Secondly, they confirm that favourable primary outcomes are not achieved at the expense of any other outcomes. Interesting findings among the secondary outcomes should be interpreted with caution: As suggested by Altman (1991), they should be viewed as ideas for further research not as definitive results.

## **6.8. Sample size**

As there was little available evidence to allow precise sample size calculations, a large pilot study was needed to assess feasibility of a definitive trial on this subject. To prevent wrong conclusions being drawn from the findings, it was necessary to safeguard against a type I error. The conventional significance level of 5% (Hicks 1996) was used for this study.

To calculate an appropriate sample size it was necessary to consider what differences between treatments would be clinically valuable. To have a high chance of detecting a statistically significant, worthwhile effect and to prevent against a type II error the



power of the study had to be large enough (Altman 1991). Although a greater power requires a larger sample size, the power for this study had to be sufficiently high to be clinically important.

#### ***6.8.1. Sample size for Caesarean Section Outcome***

The sample size of 300 per group was chosen to enable detection of differences as large as 5% in caesarean section rate between groups with 80% power and to give 95% confidence intervals of approximately  $\pm 3.5\%$  assuming an observed caesarean section rate of 10% under then current standard treatment.

#### ***6.8.2. Sample Size for Maternal Satisfaction Outcome***

A sample size of 200 per group was sufficiently large to detect differences in the satisfaction score of  $<1$  with the  $> 95\%$  power. Based on the pilot phase, the mean and standard deviation of satisfaction scores was 21.5 (5.4) and it was decided that a difference in the satisfaction score of less than 1 was unlikely to be of any clinical significance and this was therefore an adequate sample size. Based on previous hospital delivery data and recruitment rates from previous trials 600 women were expected to be randomised into the study in one year.

The large sample provided more robust data and allowed the findings to become more generalisable. Generally speaking conclusions from a large trial are considered more reliable than conclusions from a small one (Anderson 1990)

## **6.9. Instrument effects**

The actual instruments used to collect dependent measures may serve as a source of bias (Oyster et al. 1987). Acceptable data can only be collected with reliable instruments that have been proven to be valid. The questionnaire, used to assess maternal satisfaction, in the present study, had the potential to introduce bias and therefore had to be rigorously evaluated (discussed later in this chapter).

## **6.10. Deviations**

In all clinical trials non compliance and missing data can be expected and therefore must be anticipated. In designing the study it was recognised that, by virtue of their non participation (overall study) or not replying (questionnaires), the non responders might be different from the responders. As much information, as resources allowed, was collected on all women approached to participate in the trial and on those who failed to complete the questionnaire. This meant that information about the population could be contrasted with that of the sample.

Missing data were minimised by the careful organisation of data collection and recording. Midwives were trained in management of the study in order to maximise adherence to the study protocol. This was further reinforced at regular staff updates where the need for accurate data recording was emphasised.

## **6.11. Instruments for data collection**

Without high quality data collection methods, researchers must always question the accuracy and robustness of their conclusions (Polit & Hungler 1991). Methods of data collection are therefore an integral part of any research design. For the demographic

and intrapartum data, a structured approach was adopted and pre specified information criteria, based on the clinical outcomes, had already been established (appendix 2). This approach lends itself to data which are easily quantified and require no subjective judgement by the researcher. So, wherever possible, data was retrieved from the hospital computer system and cross referenced with case records. It is recognised, however, that this approach to data collection had the potential disadvantage of inaccurate and/or incomplete data, as the researcher had to rely upon others to input the information. Data checks were made periodically in order to minimise errors by cross referencing the research data with individual case records and information supplied in the delivery register.

Unlike the demographic and intrapartum data, the maternal satisfaction data was obtained from the women themselves. The instrument chosen to assess maternal satisfaction was a specifically designed questionnaire (appendix 3). Although other methods were considered for the study they were rejected for various reasons. It was felt that focus group interviews might provide a large amount of data, but the sample size would make this impractical. Similarly, interviews would provide quality data but the size of the sample would provide vast quantities of unmanageable data. Although observational methods have the advantage of directness, making it possible to study behaviour as it occurs, it could be considered as an invasion of privacy. Furthermore, such methods are also very costly in time.

One advantage of questionnaires is that they are widely used in the health service and generally well accepted by both staff and clients. In fact, it has been argued that the questionnaire is the best tool that social scientists possess for generating useable

knowledge (Lindholm & Cohen 1979). Also, in comparison with other methods, using questionnaires enabled a relatively large sample of women to be questioned quickly and cheaply, yet producing a good volume of data.

As women were questioned as part of a randomised trial, the instrument had to be able to establish the strengths of the relationship between variables. However, because the sample is very much subject centred and questions of a personal nature were to be asked, a qualitative element to the instrument was believed to be equally important. To have relied solely on a positivistic approach, using quantitative methods, would have neglected the social and cultural construction of the variables which were being compared (Silverman 1993). As argued by Kirk and Miller (1986), attitudes, opinions and feelings do not simply attach to the inside of people's heads. Therefore, to have asked women about their labour without allowing them the freedom to express their opinions and feelings would have been insensitive and would have limited the depth of the data. A combined approach to data collection was therefore adopted for this study, using structured questions followed by an open-ended one.

#### ***6.11.1. Development of the questionnaire***

The questionnaire was specifically designed for the study as previous tools when piloted were either unacceptable to the respondents or did not measure the desired areas of childbirth. Tools piloted included the Labour Agency Scale - LAS (Hodnett & Simmons-Tropea 1987) and Labor and Delivery Satisfaction Index - LADSI (Lomas et al. 1987). In addition, questionnaires which included visual analogue scales, Likert agreement type scales and pain scales were piloted. The main criticism of the tools piloted was their poor usability. Women commented that they were too long and

did not allow for question clarification or freedom of expression. In particular the women commented that they disliked the visual analogue scales as they found it difficult to equate a point on a line with a feeling or opinion. In addition they were not focused on the areas being explored, namely pain, labour duration, control and perception of overall experience.

As childbirth can be considered a major life event, an expectation-fulfilment model (Noyes, Levy, Chase & Udry 1974) was used whereby the women were asked to respond to whether or not their expectations had been met. Expectations of an event constitute a major factor in the level of satisfaction when that event takes place (Szczepinska 1995).

Four main themes were explored through the questionnaire - control, pain, duration of labour and overall experience. These themes were generated through midwifery experience which included information derived from informal conversations with various groups of women and literature (see previous chapter). Two supporting questions were also included asking whether the women would take part in the study again if time suddenly went backwards and how they would feel if the care practice in the group they were allocated to became normal practice. These two questions have been successfully used in previous randomised controlled trials (for example, Hodnett, Hannah & Weston 1997).

A deliberate decision was made not just to search solely for an overall “satisfaction score” as it has been widely reported that overall ratings tend to underestimate the extent of dissatisfaction with particular aspects of care (Shearer 1983; Strasser &

Davies 1991; Shearer 1987; Bramadat & Driedger 1993). An important part of the questionnaire was to also identify the individual variables within the process that affected satisfaction in each trial arm as well as an indication of the level of satisfaction.

The questionnaire consisted of 6 structured questions followed by an open ended question (appendix 3). This allowed some organisation of the data yet also gave respondents the opportunity to express their own opinions. If the questionnaire had been completely structured it would have had the potential disadvantage of not tapping women's individual views. Using a quantitative methodology format may not be completely appropriate in order to study what is in essence a qualitative concept (Phillips 1995). On the other hand, a questionnaire consisting solely of open questions would have made it difficult to test the hypothesis as comparable data would be difficult to achieve.

Content validity was achieved by asking primigravid women in the ante-natal and post natal period "What worries you most about labour?" The responses to this question were consistent and included areas of pain, duration of labour and ability to remain in control. The literature supports these themes (Davenport-Slack & Boylan 1974; Green et al. 1990; Mackey 1995; Lowe 1996).

The six structured questions were in the form of a five point category rating scale. A rating scale was used as personal opinions were required and the differences between groups of women could be calculated. By using the *graded alternative question type* (Couchman & Dawson 1990), respondents could select a negative or positive

response, depending on their feelings. However, being aware of the potential problem of respondents automatically ticking, for example, all the positive responses, the available options were not placed in ordered columns.

#### **6.11.2. *Piloting the questionnaire***

In an attempt to ensure that the questionnaire was both workable and acceptable to the respondents and to colleagues, a pilot study was carried out. As the questionnaire was specifically designed for the study and had not already been validated, a preliminary study was necessary to ensure the instrument was appropriate for obtaining the required data. Participants for the pilot study were selected from the target population.

#### **6.11.3. *Construct validity***

Construct validity was achieved when questionnaires were administered to 20 women following delivery of their first baby. The *known groups technique* was used whereby “groups that are expected to differ on the critical attribute because of some known characteristic are administered the instrument” (Polit & Hungler 1993). Half the questionnaires were administered to women following an uncomplicated labour with a normal delivery and the other half were administered to women following an emergency caesarean section. Previous studies have discovered that women in the immediate postnatal period following emergency caesarean section have negative responses (Marut & Mercer 1979; Trowell 1982; Cranley et al.1983; Kirchmeiser 1985). As anticipated, more positive responses were made by the first group of women. In the first group the mean scores were 4.2, 4.0, 4.1, 4.1, 3.9 and 4.2, whereas the second groups mean scores were lower 3.3, 3.2, 3, 3.1,3.1, and 2.8. If

this had not been the case the validity of the instrument would have been questioned. Prior to administration, the questionnaire was viewed by a statistician as well as a consumer group representative.

#### **6.11.4. *Questionnaire Usability***

Each respondent in the pilot phase was visited individually to ascertain their views of the questionnaire. It was discovered that the questionnaire design did not appear to cause any problems for the respondents. All appropriate questions were answered and there was no evidence of respondents misunderstanding any part of the questionnaire. The format was one that allowed adequate space for additional comments and it was noted that the women did actually use this space constructively. Administration of the questionnaire ran smoothly with no respondent refusing to complete the questionnaire. The staff working in the postnatal areas during the pilot study felt that the research did not hinder their working routine in any way.

Thus following piloting the questionnaire was considered to be an appropriate tool to examine the views of the women in the study and was therefore administered to all trial participants.

#### **6.11.5. Questionnaire administration**

All questionnaires were administered by the research midwife herself in an attempt to add consistency to the procedure. Being a midwife led to initial concerns about placing the respondent in a vulnerable position. This matter was addressed by Cormack (1991) who noted that difficulties may arise from role conflict when the researcher is also a care provider. This issue was overcome as casual clothes were



worn as opposed to a uniform and during the study, no time was spent working directly in the clinical area. As the study progressed, it became evident that the women perceived research and clinical staff differently. Comments such as, “can I ask you a question because I don’t want to ask a midwife?” and “Will you collect my questionnaire rather than a midwife?” support this theory. Also, during the antenatal period a relationship had been developed with many of the women which enabled them to speak openly and freely.

Conclusive evidence was not found to suggest the best time to administer the questionnaires so they were administered to all participating women on their second postnatal day. This enabled women who had a difficult labour/delivery to have recovered, yet reduced the risk of memory failure. It also enabled women to complete the questionnaire prior to the onset of any “baby blues” and reduced the risk of their responses being influenced by external influences such as their family, friends or home environment. The women were encouraged to complete their questionnaire prior to discharge to ensure a good response rate. The response rate was 86.5% which may have been because the area being explored was of particular interest to the respondent. As Sommer (1991) points out “a questionnaire is of little use with the respondents who are ... uninterested in the topic.” p150

The questionnaires were returned by any method chosen by the individuals in an attempt to reassure them that their responses were confidential. Most women handed their questionnaire to a member of staff, some placed it in a sealed envelope and left it at the main reception desk at the time of discharge and some requested that it be

collected from them by myself. A few women chose to take the questionnaire home and returned it by post.

## **6.12. Reliability**

### **6.12.1. Factor analysis**

In order to identify which questionnaire variables could be combined as unified concepts, a factor analysis was performed. The first stage of the Factor analysis was *factor extraction*, whereby clusters of related variables could be seen within a matrix of factors. The most widely used method (Polit & Hungler 1991), called *principal components*, was used in this study.

The second stage of the Factor analysis involved factor rotation, which enhanced the interpretability of the factors by aligning the variables more clearly with a particular factor. The factor loadings shown in the matrix were then examined to identify the underlying concepts and to assess the factor scores.

### **6.12.2. Cronbach Alpha**

The 6 questionnaire items (control, experience, length, pain, practice and repeat) were entered to establish the reliability and internal consistency using Cronbach Alpha (Cronbach 1984). This internal-consistency method was used as opposed to the test-retest reliability method to prevent resistance as well as a practice effect (Oppenheim 1992). The reliability coefficients would provide an important indicator of the quality of the instrument. Although there is no standard for what an acceptable reliability coefficient should be, it has been suggested (Polit & Hungler 1991) that for group comparisons, 0.70 or even 0.60 would be sufficient. As important clinical decisions were to be made on the basis of the questionnaire findings, an acceptable coefficient

for this study was pre specified as  $> 0.70$ . This would mean that more than 70% of the variability in obtained scores would represent true individual differences and less than 30% of the variability would reflect random extraneous fluctuations.

### **6.13. Analysis**

#### **6.13.1. *Quantitative analysis***

The process of analysis was performed on the basis that the data was generated from a randomised controlled trial. An important reason for using random sampling was that statistical methods of analysis are based on what is expected to happen in random samples from populations with specified characteristics (Altman 1991). Statistical tests are also carried out in randomised trials on the premise that each individual had an equal chance of receiving any of the treatments being investigated (Gore & Altman 1982). The analysis therefore relies on the comparability and generalisability of the women in the three trial arms.

Sappsford and Abbott (1992) stated that the initial step in data analysis is to organise the data in a form which will produce appropriate results. In order to achieve such results several steps were carried out. Prior to any statistical analysis all appropriate, quantifiable data was tested for normality of distribution using the Shapiro-Wilk W test. The null hypothesis of this test is that the sample is taken from a normal distribution, thus a significance level of 0.05 rejects the supposition of normality. Use of parametric methods for variables for which W is significant is therefore not recommended (Buchan 1994). Many authors agree that this is the most reliable quantification of normality for small to medium sample sizes (Canover 1980; Shapiro & Wilk 1965; Finney 1971). In most instances, throughout this study, tests have been

performed in accordance with the normality of the data. When this has not been the case, an explanation has been provided.

#### **6.13.2. *Qualitative analysis***

The qualitative findings were pivotal to this study. Researchers from a positivist paradigm often see qualitative research as having a subsidiary role, saying that data is analysed simply to support the quantitative findings (Coolican 1994). In this study the researcher rejects that view, seeing the qualitative data as meaningful in its own right. However, because of the potential introduction of bias during the analysis of the open responses one had to adhere to the guidance of Patton (1980). Patton believes that the main principle of qualitative analysis is that causal relationships and theoretical statements be clearly emergent from and grounded in the phenomena studied. To this end, the theory should emerge from the data; it is not imposed on the data.

#### **6.14. *Summary***

Desirable features of a controlled clinical trial are a clearly defined hypothesis or research question, a double blind assessment of patients, a sufficiently large sample size, a minimum of patient withdrawal or non compliance, an identical management policy and adequate resources and administration (Lowe 1993). Additionally, the study must be deemed to be morally and ethically acceptable by all involved. In an attempt to minimise potential methodological problems all these issues have been addressed.

This chapter has highlighted some of the methodological issues surrounding the design of the study. Wherever possible these have been addressed within the design.

Where this has not been possible, potential difficulties, which may influence the results, have been discussed and are emphasised in the following chapter.

## **Chapter 7**

### **Method**

#### **7.1. Design**

A clinical, randomised controlled design was employed in which eligible women were allocated to one of three treatment arms.

#### **7.2. Setting**

The study was carried out in an inner city maternity hospital. Permission to undertake the study was secured from the Local Research Ethics Committee (appendix 1) appropriate midwifery managers, the clinical director and the consultant obstetricians (appendix 4)

#### **7.3. Sample**

<b>Inclusion</b>	<b>Exclusions</b>
Primigravidae	Multiple pregnancy
Cephalic presentation	Diabetes
≥37 weeks gestation	Known fetal abnormality
Singleton pregnancy	Known psychiatric condition
Spontaneous labour	Non English speaker
	Known learning disability
	Woman whose baby is for adoption

#### 7.4. Outcome Measures

<b>Primary Outcomes</b>	Caesarean Section Rate (Overall) Maternal Satisfaction Score
<b>Secondary Outcomes <i>Labour</i></b>	Action line reached or crossed Amniotomy Use of Syntocinon infusion Presence of meconium Use of intrauterine pressure catheter Continuous electronic monitoring Intermittent electronic auscultation Auscultation only Fetal scalp electrode applied Fetal blood sampling in 1 <sup>st</sup> stage of labour Abnormal fetal blood sampling requiring delivery in 1 <sup>st</sup> stage of labour Fetal blood sampling in 2 <sup>nd</sup> stage of labour Abnormal Fetal blood sampling in 2 <sup>nd</sup> stage requiring delivery Epidural Number of vaginal examinations after randomisation Randomisation to delivery interval (minutes)
<b>Secondary Outcomes <i>Delivery</i></b>	Spontaneous vaginal delivery Instrumental delivery for delay Instrumental delivery for distress Caesarean section for delay in 1 <sup>st</sup> stage Caesarean section for delay in 2 <sup>nd</sup> stage Caesarean section for distress in 1 <sup>st</sup> stage Caesarean section for distress in 2 <sup>nd</sup> stage
<b>Secondary Outcomes <i>3<sup>rd</sup> Stage</i></b>	Episiotomy 3 <sup>rd</sup> degree tear Syntometrine Any additional oxytocic drug Retained placenta Post Partum Haemorrhage (> 500mls) Need for blood transfusion
<b>Secondary Outcomes <i>Neonatal</i></b>	Birth weight Apgar score at 5 minutes Admission to Special Care Baby Unit Cord pH, Cord Base Deficit
<b>Secondary Outcomes <i>Maternal</i></b>	Fulfilment of expectations (Control, Pain, Length of labour, overall experience). Maternal views

## **7.5. Recruitment**

Information leaflets (appendix 5 ) were given to primigravidae at the booking visit. At the 20 week ultrasound visit eligible women were asked by the ultrasonographer whether they would be willing to spend time discussing the research. Most women (99%+) agreed to this and therefore many women spent time with the research midwife, discussing the trial.

Women who did not meet with the research midwife at the 20 week ultrasound scan were approached for consent on delivery suite after discussion with the attending midwife. For these women, it was important that they were approached as early as possible, to enable them to absorb information prior to the onset of uterine contractions and analgesia thought significant enough to interfere with judgement. In these circumstances, the midwife would use her own personal judgement as to whether it was appropriate to re introduce the study and obtain consent.

In this study women were not encouraged to make a decision at the time of discussing the trial, however, 92% of them did. This may have been a consequence of having received the written information several weeks earlier and therefore an opportunity to discuss the study with their team midwife, community midwife or GP. Some women had also used the contact number on the bottom of the information sheet to inquire further about the study.

For those women who decided to take part, two consent forms were signed (appendix 6) and the demographic data was recorded. At this point the hand held notes were flagged with an identifying sticker to aid appropriate follow up. Those women who



were undecided were encouraged to contact the researcher when a decision had been made. All women were given a contact number so that queries could be quickly addressed. All consenting women were informed that they could withdraw from the study at any time without affecting their future care.

## **7.6. Randomisation**

Following confirmation of eligibility, randomisation was carried out by the delivery suite midwives using the sealed opaque envelope method. The midwives were unaware of the randomisation sequence. The actual partograms were placed in the randomisation envelopes to enable the process to run smoothly and to ensure the allocated partogram was actually used. Monthly checks were made to ensure that the randomisation procedure was being carried out accurately. These checks were performed by ensuring that all envelopes were accounted for and that they followed the sequential order. Regular comparisons of trial arm allocations with the master copy of the randomisation schedule were also made.

## **7.7. Trial arms**

- partogram containing 2 hour action line (Appendix 7)
- partogram containing 3 hour action line (Appendix 8)
- partogram containing 4 hour action line (Appendix 9)

## **7.8. Management**

Eligible women were randomised to the trial once established labour had been confirmed by digital examination. Labour was confirmed if a) the cervix was effaced, b) the cervix was at least 3cms dilated, and c) regular uterine contractions at least every 5 minutes lasting a minimum of 20 seconds were present.

The labour management of randomised women was unaffected if labour followed the expected rate of progress, but, if cervical dilatation crossed the allocated action line then a clinical assessment was made and delivery suite guidelines for the management of prolonged labour were followed (appendix 10). Where augmentation was required, this involved giving an oxytocin infusion alone when membranes were ruptured, or amniotomy followed by an oxytocin infusion when the membranes were intact. The oxytocin infusion rate commenced at 2Mu/min and was doubled every 30 minutes until effective regular uterine contractions were achieved, the maximum rate of oxytocin being 32Mu/min. Women with an oxytocin infusion or with an epidural analgesia in situ had continuous external fetal monitoring. Fetal blood sampling was carried out when fetal heart abnormalities were detected. Caesarean sections were performed for a blood pH of less than 7.2 and a base deficit of more than 8. When a fetal blood sample could not be obtained, the decision to perform a caesarean section, based on a cardiotocograph abnormality alone, was made by a senior obstetrician. The fetal monitoring guidelines were based on the criteria outlined by Hon (1975). All women in the first 12 months of the study were administered a questionnaire on the second postnatal day by the research midwife.

### **7.9. Data Input**

Data was entered onto an Excel spreadsheet, being compatible with both Arcus and SPSS. Data were double entered by an independent person (secretary) prior to analysis in an attempt to minimise the number of errors. The data were inputted on a separate data sheet on the computer then compared with the original, four rows at a time. This laborious, but necessary task, identified only thirty six errors, which were reviewed and altered accordingly.

## **Chapter 8**

### **Method of Evaluating Midwives' views**

#### **8.1. Design**

A small descriptive study was carried out during the main trial to elicit the views of the midwives. The main importance of this part of the study was to be able to study whether there was a midwifery bias towards any particular partogram.

#### **8.2. Sample**

All midwives who had worked on the delivery suite during the trial period were approached to participate. These midwives had used all three partograms.

#### **8.3. Recruitment**

All eligible midwives were approached by the researcher prior to the dissemination of the overall study findings. The midwives were informed that participation was on a voluntary basis and that their answers would remain anonymous. Verbal consent was obtained. The same ethical considerations, as those previously discussed in relation to the women, applied.

#### **8.4. Data collection**

The focus of this investigation was the midwives' views on partograms. No previous tool was available to explore this particular area therefore, a specifically designed questionnaire was developed (appendix 11). Questionnaires were used as opposed to interviews because the researcher-midwife relationship may have influenced the responses. Midwives were asked about their general feelings towards written

guidelines in an attempt to explore their views towards prescribed instructions. It was believed that this may have directly influenced their views of partogram use. These general questions were followed by specific questions which explored the different aspects of the partogram. The midwives were asked to answer a closed question and then provide the rationale for that response.

The questionnaires were administered to the midwives personally by the researcher and collected via a post box which was left in the clinical area. The numerical data was input onto a spread sheet for descriptive analysis. The open responses were in the format of supporting statements and were grouped into categories to supply the rationale for the responses given. General themes which developed from the data were also reported.

### **8.5. Conclusion**

Having carefully designed the study it was necessary to use appropriate methods of analysis to obtain meaningful findings. The following chapter will identify and discuss the various methods of analysis used in this study.

## **Chapter 9**

### **Analysis**

#### **9.1. The quantifiable data**

The quantifiable data were analysed using a combination of two statistical packages, namely Arcus and SPSS (version 6.0). Statistical advice was sought throughout all stages of analysis. Data from the sub group and the overall sample were analysed in the same way and so will not be independently referred to in this chapter. Analysis of the data derived from the two opposing paradigms is to be discussed in this current chapter.

#### **9.2. Demographic and Intrapartum Data**

For the nominal data, whereby the analysis involved comparisons of proportions, odds ratios and 95% confidence intervals were calculated. The confidence level of 95% is the conventional choice as only 5% of the time would the confidence interval not include the true population value (Altman 1991). Fishers exact test (Gart's method) was used to construct exact confidence limits for the odds ratio of the fourfold tables (Thomas 1971). The Fishers exact test was used for 2 X 2 tables being more accurate than the more often used Chi-squared test. There was no need to use the fourfold chi square test when Arcus provided an exact test which can cope with reasonably large numbers (Buchan 1994).

A one way anova and unpaired t test was used to compare the difference in means between the groups. The Kruskal Wallis and Mann-Whitney U test was used to compare the difference in medians between the groups.

### **9.3. Maternal Satisfaction Data**

#### **9.3.1. Quantifiable responses**

In an attempt to organise the data from the outset, the questionnaire responses were numerically pre coded. The coded responses were then input onto a database alongside the demographic and intrapartum information. Although the data was ordinal, the sample size made it appropriate to perform a one-way anova to determine whether differences existed between the groups (Hicks 1996). The Scheffe' multiple range test (Hicks 1996) was then carried out to establish specific differences between the groups. This test has been considered the most superior multiple range test (McNemar 1963) as it can be applied to unequal numbers of subjects in each trial arm. Also, the Scheffe test, being conservative, would reduce the possibility of a type one error in a relatively large sample. Although the Scheffe is a post hoc test, a significant level of 0.05 is generally considered acceptable by statisticians ( Fear, personal communication). Multiple significance testing gives a high probability of finding a significant difference just by chance (Altman 1991).

#### **9.3.2. Open responses**

The qualitative data were analysed using the more lengthy, manual process of forming categories and generating themes to make sense of and understand the open responses supplied by the women. The purpose of data analysis being to impose some order on a large body of information so that some general conclusions could be reached (Polit & Hungler 1993). Several stages were therefore carried out to ensure an accurate interpretation of the findings, because “.....generally speaking, the data in

their raw form do not speak for themselves. The messages stay hidden and need careful teasing out.” (Robson 1993, p380)

The first stage of analysis was to become familiar with the data. To do this, the questionnaires were read several times in an attempt to obtain an overall impression of the data. Identification of common characteristics was then carried out, and, for ease of interpretation these were put under category headings. The categories were identified from comments made by the women themselves rather than created by the researcher on speculative grounds.

In the next stage, a method of analysis proposed by Norris (1981) was used, whereby the data was systematically indexed to facilitate the development of themes and conceptual frameworks from the most frequently recurring topics. The numerical value obtained from counting occurrences was unimportant in its own right. What was important was to be able to categorise the occurrences in order to analyse and compare the various meanings produced within each category.

The practicalities of this process were overcome by using a word processing package (Microsoft Word, version 7) to cut and paste the responses, making them interchangeable between category headings. Different coloured highlighters were used to mark the different topics within the text prior to being cut apart. This technique is relatively quick and cost effective although it does tend to rely on the judgement of the analyst (Stewart & Shamdasani 1990). The data was viewed by two researchers who independently generated categories from the responses. Using more than one analyst provided an opportunity to assess the reliability of the coding with respect to



major themes and issues. One of the researchers was not involved in the project in any way. The categories were then collated and individually discussed until a consensus was reached.

The examination of common themes raised by the women in relation to the research hypothesis and previous literature was pivotal to the analysis. It was believed that a sufficient amount of quotable data should be presented to illuminate and support the results provided. Therefore, when appropriate the actual words of the women were included in the findings (following chapter).

#### **9.4. Conclusion**

The analysis of study data incorporated both qualitative and quantitative methods, thereby enhancing the quality of the findings. The following chapter will present these findings.

## **PART 3: RESULTS**

## Chapter 10

### Baseline Data and Group Comparability

#### 10.1. Introduction

The study took place between January 1996 and August 1997 in a single obstetric unit with 10,189 deliveries during this period. Of these total deliveries, 3717 were to primigravid women. Out of 1633 eligible women at term, 429 declined participation, 171 were never approached, 98 consented women were not randomised and 3 consented women withdrew prior to randomisation. This left a total of 932 randomised women. However, 4 randomised women could not be traced due to the inaccurate recording of demographic details. This meant that data was collected on a total of 928 women. Only 10% of eligible women were never approached to consider participating in the trial (Figure 10.1).

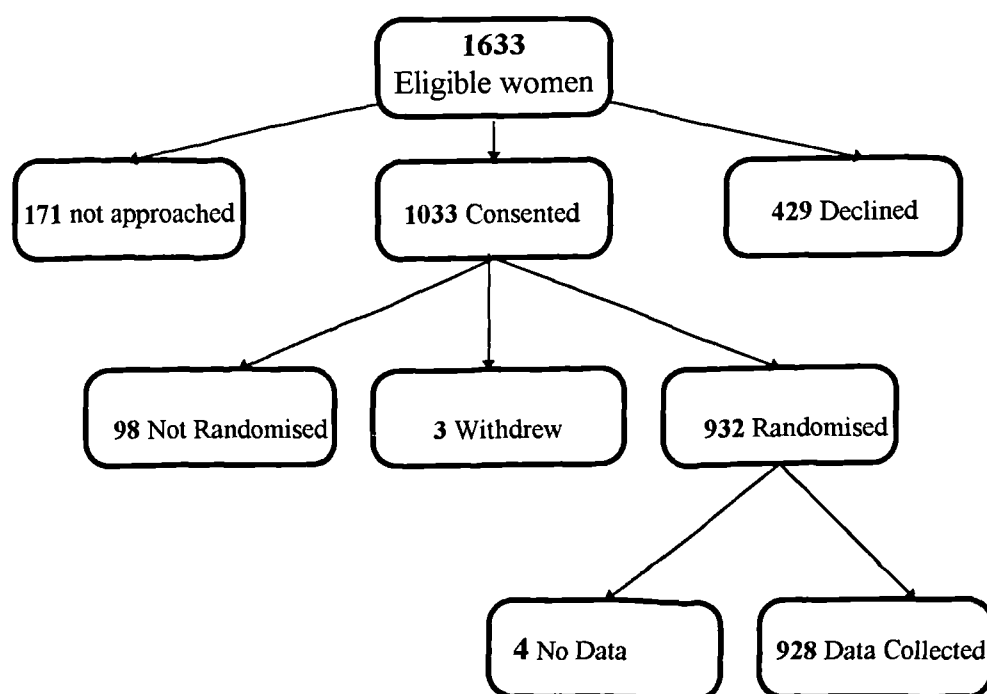


Figure 10.1. Schema indicating sample population

## **10.2. Group Comparability**

Demographic and obstetric data for all eligible women can be seen in Table 10.1. The demographic details and cervical state at randomisation for the overall sample can be seen in Table 10.2. As there was no difference with respect to maternal age, gestational age, cervical dilatation, cervical effacement or presence of membranes it can be confirmed that the randomisation process was successful. The demographic information in terms of maternal age, gestation, cervical dilation, cervical effacement, and condition of membranes showed no significant differences among the trial arms. The demographic details and cervical state at randomisation for those women whose level of satisfaction was assessed is given in Table 10.3. Data for non responders can be seen in Table 10.4. These findings are similar to those for the responders.

Data for women who had been approached to participate in the trial but declined were not identified from all those eligible. As consent was not obtained from these women it was considered unethical to retrieve information concerning their labour. The Royal College of Nursing (1992) clearly state that the prior consent of patients must be obtained if records are to be used for research purposes.

The Under Privileged Area scores (UPA) can be seen in Tables 10.5-10.6. The mean UPA score for the target population was 23.8 with a standard deviation of 10.5. The scores for the sample population are similar to the target population. There were no significant differences between the trial arms in either the overall sample or the sub group. The mean UPA score for the geographical areas covered by the study hospital was 24.3 (SD 11.5). This score suggests that the sample was representative.

**Table 10.1. Target population**

		n=1633
<b>Demographics</b>	Maternal Age, mean (SD)	25.5 (5.7)
	Gestational Age, mean (SD)	282.1 (8.2)
<b>Obstetric</b>	Caesarean section	147 (9%)
	epidural rate	457 (28%)

**Table 10.2. Baseline information - overall sample**

	2hrs N=315	3hrs N=302	4hrs N=310	2hrs vs. 3hrs Odds Ratios ( 95% CI) or p value	3hrs vs. 4hrs Odds Ratios ( 95% CI) or p value	2hrs vs. 4hrs Odds Ratios ( 95% CI) or p value
Maternal age**	25.1(5.1)	24.8 (5.4)	25 (5.1)	df=2,925	F= 0.4	p=0.7*
Gestation **	280.2 (7.9)	279.7(8.2)	280.2(8.1)	df=2,925	F= 1.3	p=0.3*
Cervix 3-10 cm	256	243	241	1.1(0.7-1.6)	1.2 (0.8-1.8)	1.2 (0.8-1.9)
Cervix effaced	270	245	259	1.4 (0.9-2.2)	1.2 (0.8-1.8)	1.2 (0.7-1.9)
Membranes intact	196	203	197	1.1 (0.8-1.6)	1.2 (0.8-1.7)	1.1 (0.8-1.5)

\*One Way ANOVA

\*\*Mean (SD)

**Table 10.3. Baseline information - Sub group: Maternal Satisfaction**

	<b>2HOUR</b> n=179	<b>3HOUR</b> n=169	<b>4HOUR</b> n=171	<b>2hrs vs. 3hrs</b>	<b>3hrs vs. 4hrs</b>	<b>2hrs vs. 4hrs</b>
					<b>Odds Ratios</b> <b>95% CI or P</b>	<b>value</b>
maternal age*	25.1 (5.1)	25 (5.3)	24.8 (4.8)	F=0.42	df = 2, 612	p=0.65**
gestation*	281.4 (8.2)	280.9 (8.5)	281.5 (9.1)	F=0.73	df = 2, 612	p=0.48**
Cervix <3cm	28 (16%)	32 (19%)	37 (22%)	0.8 (0.4-1.4)	0.8 (0.5-1.5)	0.7 (0.4-1.2)
Cervix 3-10 cm	151 (84%)	137 (81%)	134 (78%)	1.3 (0.7-2.3)	1.2 (0.7-2.1)	1.5 (0.8-2.7)
Cervix effaced	149 (83%)	139 (82%)	146 (85%)	1.1 (0.6-1.9)	0.8 (0.4-1.5)	0.9 (0.5-1.6)
Membranes intact	113(63%)	119 (70%)	112 (65%)	0.7 (0.4-1.2)	1.3 (0.8-2.0)	0.9 (0.6-1.4)

\* Mean (SD)

\*\* One way ANOVA

**Table 10.4. Non Responders versus Responders**

	<b>Non Responders n= 96</b>	<b>Responders n=519</b>
Age, Mean (SD)	24.6 (5.3)	24.9 (5.1)
Gestation, Mean (SD)	280.1 (8.2)	281.3 (8.6)
Cervix $\geq$ 3cm at randomisation, n (%)	72 (75%)	445 (85.7%)
Randomisation - Delivery interval, Mean (SD)	536.8 (322.3)	535.7 (276)
Epidural rate, n (%)	34 (35.4%)	167 (32.2%)
Spontaneous vaginal delivery rate, n (%)	62 (64.6%)	341 (65.7%)



**Table 10.5. Under Privileged Area scores (UPA): Overall sample versus responders**

Sample vs. Responders	
Overall sample, Mean (SD)	23.3 ( 11.6)
Responders Mean (SD)	22.9 (11.4)
p = 0.6*	

\*unpaired t-test

**Table 10.6. Under Privileged Area scores (UPA): Comparison of trial arms**

	2hour n =315	3hour n =302	4hour n =311	2 vs. 3	3 vs. 4 p value**	2 vs. 4
Sample population mean (SD)	22.4 (11.3)	24.05 (11.7)	23.4 (11.9)	0.08	0.5	0.3
Responders mean (SD)	21.9 (11.9)	23.04 (10.8)	23.9 (11.2)	0.3	0.5	0.1

\*\*Unpaired t-test

## Summary

The previous tables (10.1.-10.6.) provide evidence that the three trial arms were comparable with regard to demographic data. They also confirm that the sub group was similar to the overall sample and that the overall sample was similar to the target population. The study findings can therefore be interpreted in the knowledge that they are generalisable.

## **Chapter 11**

### **Intrapartum/obstetric outcomes**

#### **11.1. Overall Sample findings**

The overall intrapartum details can be seen in table 11.1. This table shows that when compared to the 4 hour arm, using Fishers Exact test, more women in the 2 hour arm crossed the partogram action line and therefore received more interventions to augment labour (OR 1.6, 95% CI 1.1-2.2).

As can be seen in table 11.1. the women in the 2 hour arm received significantly more action line triggered intervention than those in the 4 hour arm (OR 1.7, 95 % CI 1.3-2.4, P=0.0006 Fisher's exact test). The intervention may have been amniotomy, amniotomy and syntocinon or syntocinon alone. This offers reassurance that the research protocol was adhered to. When the different interventions were analysed separately, no significant differences were found. This was due to the fact that some women received an amniotomy prior to their progress crossing the action line, for example, if there were signs of fetal distress or if the woman was approaching the second stage of labour. Similarly, some women received syntocinon prior to their progress crossing the action line due to a clinical indication to do so.

Table 11.2. shows the delivery outcomes for the sample. The study does show differences in caesarean section rates in the three arms - 2hours 11.1%, 3hours 14.2%, 4hours 8.3% as shown in Table 11.2. However, only when the 3 and 4 hour arms were compared did the difference reach statistical significance (OR 1.8, 95% CI 1.1-3.2, P= 0.03 Fisher's exact test). As a consequence of the number of caesarean

sections, there was also a significant difference in the overall number of vaginal deliveries between the 3 and 4 hour arms (OR 0.5, 95% CI 0.3-3.2,  $P = 0.03$ , Fisher's exact test). When the vaginal deliveries were separated into spontaneous and instrumental, no significant differences were found.

An important secondary outcome in this study was the randomisation to delivery interval as one would expect this to differ between the three trial arms according to the timing of intervention. However when the medians were compared using Kruskal Wallis there were no significant differences between the trial arms ( $df=2$ ,  $t=0.2$ ,  $P=0.9$ ).

As shown in table 11.3., the neonatal outcomes showed no significant differences between the three trial arms. Similarly, the 3<sup>rd</sup> stage of labour outcomes and the postnatal outcomes ( Table 11.4.) showed no significant differences.

In addition to the pre specified analyses, several post hoc analyses were carried out in light of the previous findings (Tables 11.5-11.7.). Table 11.5. showed that there was no statistically significant differences in the number of women whose progress crossed the action line between those who were randomised before or after 3cm dilatation. When the three trial arms were compared, there were more women in the 2 hour arm who were randomised at 3cm or more whose progress crossed the action line than in the 4 hour arm ( $p=0.006$ ).

When the randomisation to delivery interval was compared between those who did and did not receive an epidural, it was found that there was a statistically significant increase in duration for those women with an epidural in situ ( $p=0.0004$ ).

**Table 11.1. Intrapartum Outcomes: Overall sample**

	2 hours n=315	3 hours n=302	4 hours n=311	2 hrs vs. 3 hrs	3 hrs vs. 4 hrs	2 hrs vs. 4 hrs
Randomisation -delivery* (min)	516 (330-737)	532.5 (332.5-739.3)	517 (302-734)	- 7 (-52, 36)	17 (-28, 60)	10 (-35, 54)
Action line crossed	163 (51.7%)	124 (41%)	118 (38.1%)	<b>1.5 (1.2-2.1)</b>	1.1 (0.8-1.6)	<b>1.7 (1.3-2.4)</b>
Action taken **	146 (46%)	119 (39%)	110 (35.5%)	1.3 (0.9-1.9)	1.2 (0.8-1.7)	<b>1.6 (1.1-2.2)</b>
Amniotomy only	120 (38%)	122 (40.4%)	121 (39%)	0.9 (0.6-1.3)	1.1 (0.8-1.5)	1.0 (0.7-1.4)
Syntocinon used	144 (45.7%)	136 (45%)	129 (41.6%)	1.0 (0.7-1.4)	1.1 (0.8-1.6)	1.2 (0.9-1.6)
Epidural	120 (38%)	99 (32.8%)	101 (32.6%)	(0.9-1.8)	1.0 (0.7-1.4)	1.3 (1.8-0.9)
Vaginal examination*	4 (3-6)	4 (3-6)	4 (3-6)	-----	-----	-----
Meconium	38 (12.1%)	40 (13.2%)	31 (10%)	0.9 (0.5-1.5)	1.4 (0.8-2.4)	1.2 (0.7-2.1)
IUPC <sup>‡</sup>	1	1	1	-----	-----	-----
Continuous external fetal heart rate monitoring	168 (53.3%)	156 (51.7%)	161 (51.8%)	1.1 (0.8-1.5)	1.0 (0.7-1.4)	1.1 (0.8-1.5)
Intermittent monitoring	60 (19%)	59 (19.5%)	70 (22.5%)	1.0 (0.7-1.6)	0.8 (0.6-1.3)	0.8 (0.5-1.2)
Auscultation	3	2	2	-----	-----	-----
Continuous internal fetal heart rate monitoring	83 (26.3%)	85 (28.1%)	78 (25.1%)	0.9 (0.6-1.3)	1.2 (0.8-1.7)	1.1 (0.7-1.6)
Fbs <sup>‡‡</sup> - normal 1 <sup>st</sup> stage	10 (3.2%)	12 (4%)	7 (2.3%)	0.8 (0.3-2.0)	1.8 (0.6-5.5)	1.4 (0.5-4.5)
Fbs. - normal 2 <sup>nd</sup> stage	0	1	0	-----	-----	-----
Fbs. - abnormal 1 <sup>st</sup> stage	5	1	2	-----	-----	-----
Fbs. - abnormal 2 <sup>nd</sup> stage	5	2	2	-----	-----	-----

\* Intrauterine Pressure Catheter \*\* Fetal blood sampling

Results are expressed odds ratios (95%CI) or difference in medians (95%CI). \* Median and Interquartile range

\*\* Action taken when action line crossed (amniotomy alone, syntocinon alone or amniotomy and syntocinon).

**Table 11.2. Delivery Outcomes - overall sample**

	<b>2 hours n=315</b>	<b>3 hours n=302</b>	<b>4 hours n=311</b>	<b>2 hrs vs. 3hrs</b>	<b>3 hrs vs. 4 hrs</b>	<b>2 hrs vs. 4 hrs</b>
<b>Caesarean section</b>	35 (11.1%)	43 (14.2%)	26 (8.4%)	0.8 (0.5-1.2)	<b>1.8 (1.1-3.2)</b>	1.4 (0.8-2.4)
Caesarean section (Fetal distress)	12 (3.8%)	12 (3.9%)	7 (2.3%)	1.0 (0.4-2.4)	1.8 (0.6-5.5)	1.7 (0.6-5.2)
Caesarean section - (Failure to progress)	23 (7.3%)	31 (10.3%)	19 (6.1%)	0.7 (0.4-1.3)	1.8 (0.9-3.4)	1.2 (0.6-2.4)
<b>Vaginal Delivery</b>	280 (88.9%)	259 (85.8%)	285 (91.6%)	0.8 (0.5-1.2)	<b>0.5 (0.3-0.9)</b>	0.7 (0.4-1.3)
Spontaneous Vaginal	214 (67.9%)	191 (63.2%)	212 (68.2%)	1.2 (0.8-1.7)	0.8 (0.6-1.1)	1.0 (0.7-1.4)
Instrumental Vaginal	66 (20.9%)	68 (22.5%)	73 (23.5%)	0.9 (0.6-1.4)	0.9 (0.6-1.4)	0.9 (0.6-1.3)

Results are expressed odds ratios (95%CI)

Table 11.3. Neonatal Outcomes-overall sample

	2hrs n=315	3hrs n=302	4hrs n=311	2hrs vs. 3hrs	3hrs vs. 4hrs	2hrs vs. 4hrs
Cord Ph*	7.3 (0.07)	7.3 (0.07)	7.3 (0.07)	-----	-----	-----
Apgar <7 at 5min	6 (1.9%)	4 (1.3%)	5 (1.6%)	3.9 (0.4-191.2)	0.5 (0.009-9.9)	2.0 (0.3-22.0)
SCBU Admission	4 (1.3%)	1 (0.3%)	2 (0.6%)	3.9 (191.2-0.4)	2.0 (115.7-0.1)	2.0 (22.0-0.3)
Birth Weight*	3425.6 (460.1)	3400.6 (478.4)	3362.5 (450.4)	F=1.47	df = 2, 925	P=0.23**
Base Deficit*	5.2 (3.0)	5.1 (2.7)	5.3 (3.1)	F=0.4	df = 2, 733	P= 0.7**

Results are expressed odds ratios (95%CI) or comparison of means (One way ANOVA)\*\*.  
Mean (SD)

**Table 11.4. 3<sup>rd</sup> stage/postnatal outcomes - Overall sample**

	2hrs n=315	3hrs n=302	4hrs n=311	2hrs vs. 3hrs	3hrs vs. 4hrs	2hrs vs. 4hrs
Blood loss >500mls	39 (12.4%)	39 (12.9%)	30 (9.6%)	1.0 (0.6-1.6)	1.4 (0.8-2.4)	1.3 (0.8-2.3)
Transfusion	5	6	4	0.8 (0.2-3.2)	1.6 (0.4-7.6)	1.2 (0.3-6.3)
Retained placenta	9	7	8	0.8 (0.3-2.5)	0.9 (0.3-2.9)	0.9 (0.3-2.7)
Intact perineum	112 (35.6%)	99 (32.8%)	99 (31.8%)	1.1 (0.8-1.6)	1.0 (0.7-1.5)	1.2 (0.8-1.7)
1 <sup>st</sup> degree tear	25 (7.9%)	27 (8.9%)	28 (9%)	0.9 (0.5-1.6)	1.0 (0.5-1.7)	0.9 (0.5-1.6)
2 <sup>nd</sup> degree tear	75 (23.8%)	66 (21.9%)	74 (23.8%)	0.9 (0.6-1.3)	0.9 (0.6-1.3)	1.0 (0.7-1.5)
3 <sup>rd</sup> degree tear	3	4	5	0.7 (0.1-4.3)	0.8 (0.2-3.9)	1.7 (0.3-11.0)
Episiotomy	95 (30.2%)	101 (33.4%)	99 (31.8%)	0.9 (0.6-1.2)	1.1 (0.8-1.5)	0.9 (0.6-1.3)
Episiotomy + tear	4	3	4	1.3 (0.2-8.9)	1.3 (0.2-8.9)	1.0 (0.2-5.3)
Episiotomy +3 <sup>rd</sup> degree tear	1	2	0	-----	-----	-----
No oxytocics	3	4	5	0.7 (0.1-4.3)	1.2 (0.3-6.2)	0.6 (0.1-3.1)
Syntometrine	251 (79.7%)	224 (74.2%)	250 (80.4%)	1.4 (0.9-2.0)	0.7 (0.5-1.0)	1.0 (0.6-1.4)
Additional drugs	25 (7.9%)	32 (10.6%)	30 (9.6%)	0.7 (0.4-1.3)	1.1 (0.6-1.9)	0.8 (0.4-1.5)

No statistically significant differences using Fisher's exact test

## Tables 11.5.-11.7. Post hoc intrapartum analyses

**Table 11.5. Overall number of women whose cervixes were at least 3cm dilated at randomisation and crossed the action line compared with those women with cervixes less than 3cm dilated**

	≥ 3cm	< 3cm	≥ 3cm vs. < 3cm
	n=740	n=188	Fishers exact test
			OR (95%CI)
Number of women			
who crossed the	324 (43.8%)	81 (48.8%)	1.0 (0.7-1.4)
action line			P = 0.9

**Table 11.6. The number of women in each trial arm who were randomised when the cervix was 3 cm dilated or more, whose labour progress crossed the action line**

	2hrs n=315	3hrs n=302	4hrs n=311	2 vs. 3	3 vs. 4 OR (95% CI)	2 vs. 4
Number of	128	103	93	1.3	1.2	1.6
women (%)	(40.6%)	(34.1%)	(29.9%)	(0.9-1.9)	(0.9-1.7)	(1.1-2.3)
				p = 0.1	p = 0.3	p = 0.006
Fishers Exact test						



**Table 11.7. Randomisation to delivery interval - comparing women with and without an epidural**

	Epidural n=320	No epidural n=608	Epidural vs. No epidural
Randomisation-Delivery Interval	584.4 (275.7)	518 (275.3)	df=926, t=3.5 p=0.0004

## 11.2. Sub Group Results

The intrapartum details for the sub group, i.e. those who were administered a questionnaire, can be seen in Table 11.8. which are similar to the intrapartum data as a whole (table 11.1.).

Similarly, in the sub group (table 11.1) there were more labours that crossed the action line in the 2 hour arm (n=90, 50%) than the 4 hour arm (n=64, 37%). However, in the sub group, when the trial arms were compared, using Fishers exact test, there were no significant differences. In this group (tables 11.1) the women in the 2 hour arm received significantly more action line triggered intervention than those in the 4 hour arm ( OR 1.7, 95% CI 1.1-2.7, P=0.02 Fisher's exact test).

Table 11.9. shows the delivery outcomes for the sub group. As can be seen the differences in caesarean section rate did not reach statistical significance.

As previously mentioned, an important secondary outcome in this study was the randomisation to delivery interval. However, like in the overall sample, when the medians were compared using Kruskal Wallis there were no significant differences between the trial arms in the sub group (df=2, t=0.2, P=0.9).

As shown in tables 11.10. and 11.11., the neonatal, 3<sup>rd</sup> stage of labour and postnatal outcomes showed no significant differences between the three arms.

**Table 11.8. Intrapartum Outcomes - Sub group**

	2hour, n=179	3hour, n=169	4hour, n=171	2 vs. 3 hr	3 vs. 4 hr	2 vs. 4 hr
Action line crossed	90(50%)	73 (43%)	64 (37%)	1.3 (0.9-2.1)	1.3 (0.8-2.0)	1.5 (0.9-2.4)
Action line triggered intervention**	83 (46%)	66 (39%)	57 (33%)	1.3 (0.9-2.1)	1.3 (0.8-2.0)	1.7 (1.1-2.7)
Randomisation-Delivery interval, minutes, *	501.5 (321-730)	552 (326-726)	508 (310-777)	-12 (-71,48)	-5 (-64,55)	-12 (-72,48)
Epidural	69 (39%)	48 (28%)	50 (29%)	1.6 (0.9-2.5)	1.0 (0.6-1.6)	1.5 (0.9-2.4)
Vaginal examinations*	4 (3-5)	4 (3-6)	4 (3-6)	-----	-----	-----
Amniotomy only	66 (36.9%)	68 (40.2%)	60 (35.1%)	0.9 (0.6-1.4)	1.2 (0.8-2.0)	1.1 (0.7-1.7)
Syntocinon used	82 (45.8%)	74 (43.8%)	75 (43.9%)	1.1 (0.7-1.7)	1.0 (0.6-1.6)	1.1 (0.7-1.7)
Meconium	29 (16.2%)	25 (14.8%)	25 (14.6%)	1.1 (0.6-2.1)	1.0 (0.5-1.9)	1.1 (0.6-2.1)
IUPC*	1	0	1	-----	-----	-----
Continuous external fetal heart rate monitoring	96 (53.6%)	83 (49.1%)	77 (45%)	1.2 (0.8-1.9)	1.2 (0.8-1.8)	1.4 (0.9-2.2)
Intermittent monitoring	33 (18.4%)	34 (20.1%)	42 (24.6%)	0.9 (0.5-1.6)	0.8 (0.4-1.3)	0.7 (0.4-1.2)
Auscultation	1	1	0	-----	-----	-----
Continuous internal fetal heart rate monitoring	49 (27.4%)	51 (30.2%)	52 (30.4%)	0.9 (0.5-1.4)	1.0 (0.6-1.6)	0.9 (0.5-1.4)
Fbs <sup>##</sup> - normal 1 <sup>st</sup> stage	2	4	3	-----	-----	-----
Fbs. - normal 2 <sup>nd</sup> stage	0	1	0	-----	-----	-----
Fbs. - abnormal 1 <sup>st</sup> stage	3	0	2	-----	-----	-----
Fbs. - abnormal 2 <sup>nd</sup> stage	4	2	1	-----	-----	-----

\* Intrauterine Pressure Catheter <sup>##</sup> Fetal blood sampling

Results are expressed odds ratios (95%CI) or difference in medians (95%CI). \* Median and Interquartile range

\*\* Action taken when action line crossed (amniotomy alone, syntocinon alone or amniotomy and syntocinon).

**Table 11.9. Delivery Outcome - sub group**

	2hour n=179	3hour n=169	4hour n=171	2 vs. 3 hr	3 vs. 4 hr	2 vs. 4 hr
					OR (95% CI)	
<b>Vaginal Delivery</b>	158 (88.3%)	145 (85.8%)	155 (90.6%)	0.8 (0.4-1.6)	1.6 (0.8-3.4)	1.3 (0.6-2.7)
Spontaneous Vaginal delivery	116 (65%)	111 (65%)	114 (67%)	1.0 (0.6-1.6)	1.1 (0.7-1.7)	1.1 (0.7-1.7)
Instrumental delivery	42 (23%)	34 (20%)	41 (24%)	1.2 (0.7-2.1)	0.8 (0.5-1.4)	1.0 (0.6-1.6)
<b>Caesarean section (overall)</b>	21 (12%)	24 (14%)	16 (9%)	0.8 (0.4-1.6)	1.6 (0.8-3.4)	1.3 (0.6-2.7)
Caesarean section (failure to progress)	12 (7%)	18 (11%)	13 (8%)	0.6 (0.3-1.4)	1.4 (0.6-3.3)	0.9 (0.4-2.1)
Caesarean section (fetal distress)	9 (5%)	6 (3%)	3 (1%)	1.4 (0.4-5.0)	2.1 (0.4-12.9)	3.0 (0.7-17.3)

No statistically significant findings using Fisher's exact test

**Table 11.10. Neonatal Outcomes - Sub group**

	2hrs	3hrs	4hrs	2hrs vs. 3hrs	3hrs vs. 4hrs	2hrs vs. 4hrs
	n=179	n=169	n=171			
Cord pH*	7.3 (0.07)	7.3 (0.07)	7.3 (0.07)	-----	-----	-----
Apgar <7 at 5min	4	2	4	-----	-----	-----
SCBU Admission	2	1	1	-----	-----	-----
Birth Weight*	3448.2 (464.6)	3374.9 (453.9)	3364.8 (470.9)	F=1.7	df = 2, 516	P=0.2
Base Deficit *	5.3 (2.7)	5.1 (2.7)	5.5 (3.3)	F=0.5	df = 2, 379	P=0.06

Results are expressed as a comparison of means (One way ANOVA)\*\*.

\* Mean (SD)

**Table 11.11. 3<sup>rd</sup> stage/postnatal outcomes: sub group**

	2hrs n=179	3hrs n=169	4hrs n=171	2hrs vs. 3hrs	3hrs vs. 4hrs	2hrs vs. 4hrs
					OR (95% CI)	
Blood loss >500mls	25 (14%)	19 (11.2%)	16 (9.4%)	1.3 (0.6-2.6)	1.2 (0.6-2.7)	1.6 (0.8-3.3)
Transfusion	4 (2.2%)	6 (3.6%)	3 (1.8%)	0.6 (0.1-2.7)	2.1 (0.4-12.9)	1.3 (0.2-8.9)
Retained placenta	8 (4.5%)	5 (3%)	7 (4.1%)	1.5 (0.4-6.1)	0.7 (0.2-2.7)	1.1 (0.3-3.3)
Intact perineum	64 (35.8%)	56 (33.2%)	51 (29.8%)	1.1 (0.7-1.8)	1.2 (0.7-1.9)	1.3 (0.8-2.1)
1 <sup>st</sup> degree tear	16 (8.9%)	19 (11.2%)	17 (9.9%)	0.8 (0.4-1.7)	1.1 (0.5-2.4)	0.9 (0.4-1.9)
2 <sup>nd</sup> degree tear	38 (21.2%)	37 (21.9%)	43 (25.1%)	1.0 (0.6-1.7)	0.8 (0.5-1.4)	0.8 (0.5-1.4)
3 <sup>rd</sup> degree tear	2 (1.1%)	2 (1.2%)	2 (1.2%)	-----	-----	-----
Episiotomy	55 (30.7%)	52 (30.8%)	57 (33.3%)	1.0 (0.6-1.6)	0.9 (0.5-1.4)	0.9 (0.6-1.4)
Episiotomy + tear	3 (1.7%)	1 (0.6%)	1 (0.6%)	-----	-----	-----
Episiotomy +3 <sup>rd</sup> degree tear	1 (0.6%)	2 (1.2%)	0	-----	-----	-----
No oxytocics	0	3 (1.8%)	1 (0.6%)	-----	-----	-----
Syntometrine	142 (79.3%)	130 (76.9%)	140 (81.9%)	1.2 (0.7-2.0)	0.7 (0.4-1.3)	0.8 (0.5-1.5)
Syntocinon IV or IM	20 (11.2%)	23 (13.6%)	14 (8.2%)	0.9 (0.4-1.7)	1.7 (0.8-3.6)	1.4 (0.7-3.1)
Additional oxytocic drugs	17 (9.5%)	13 (7.7%)	16 (9.4%)	1.3 (0.6-2.9)	0.8 (0.3-1.9)	1.0 (0.5-2.2)
No statistically significant differences using Fisher's exact test						

## **Chapter 12**

### **Maternal Satisfaction Data**

#### **12.1. Questionnaire Reliability**

To identify which questionnaire variables could be combined as unified concepts (see table 12.3), a factor analysis using Principal Component Analysis with varimax rotation (Hicks 1996) was performed by entering the six items (control, length of labor, pain, experience, repeat, practice). The items all loaded on one factor (Table 12.1.), which suggests that the questionnaire was unidimensional; that is, all factors related to satisfaction with the labor experience.

**Table 12.1. Factor Matrix**

<b>Factor Matrix:</b>	<b>Factor 1</b>	<b>Factor 2</b>
Control	.74056	-.18489
Experience	.67439	-.27764
Length	.68899	-.34124
Pain	.74499	-.39115
Practice	.67716	.62992
Repeat	.68519	.61897

After data were collected for 519 women, the internal consistency of the six questions was examined by calculating correlations between each item using Pearson's correlation coefficient (Table 12.2.). When a positive correlation ( $p < 0.001$ ) was discovered among all six items (control, experience, length of labor, pain, practice, repeat), they were then entered to establish the reliability and internal

consistency using Cronbach's alpha; alpha was 0.82, which suggests that the questionnaire had internal consistency.

**Table 12.2. Pearsons correlation**

	<b>Control</b>	<b>Experience</b>	<b>Length</b>	<b>Pain</b>	<b>Practice</b>	<b>Repeat</b>
<b>Control</b>	-----	-----	-----	-----	-----	-----
<b>Experience</b>	0.4112	-----	-----	-----	-----	-----
<b>Length</b>	0.4036	0.4179	-----	-----	-----	-----
<b>Pain</b>	0.5581	0.4638	0.5158	-----	-----	-----
<b>Practice</b>	0.3574	0.2615	0.2633	0.2877	-----	-----
<b>Repeat</b>	0.3427	0.3032	0.2812	0.2620	0.7149	-----

**P < 0.001 (all variables)**



## **12.2. Questionnaire Response**

The questionnaire response rate was 86.5 percent ( $n=519$ ), with fairly equal numbers of women responding in each trial arm (2 hr 89%, 3 hr 80%, 4 hr 84%). A minimal number (see table 12.3.) of women, evenly distributed across the three trial arms, responded that they did not know what to expect in answer to questions on some items (control: 12.3%, length: 6.2%, pain: 7.7% and experience: 5.8%). This response was difficult to code because it could be interpreted as a positive, negative, or neutral response. These data were not considered to be part of the rating scale and therefore were not included in this analysis. Omitting this option altogether may have forced some women to respond in a way that did not truly reflect their feelings.

## **14.3. Questionnaire Findings**

The satisfaction data is presented in categorical form in Table 12.3. This table demonstrates the frequency of responses to each question. As can be seen in Table 12.4., a one-way ANOVA was calculated on the satisfaction data, significant results for all variables were obtained ( $p<0.001$ ), and comparisons were therefore performed using the Scheffé multiple range test (Tables 12.5. - 12.10.). In the overall satisfaction score (Table 12.11) the Scheffé test showed that women in the 2-hour arm were significantly more satisfied than those in either the 3-hour or 4- hour arms ( $p=0.0001$ ). In all six questions a post hoc Scheffé test at  $p<0.05$  showed a significant difference between 2 and 4 hours. With respect to the items of control, pain, and practice, the post hoc Scheffé test at  $p < 0.05$  showed a significant difference between 2 and 3 hours, and with respect to the item of repeat, a significant difference was found between 3 and 4 hours (Tables 12.5. - 12.10).

**Table 12.3. Categorical Data**

	<b>2HOUR n=179</b>	<b>3HOUR n=169</b>	<b>4HOUR n=171</b>
<b><u>Control</u></b>			
I did not know what to expect	22 (12.2%)	20 (11.8%)	27 (15.8%)
Much worse/somewhat worse than expected	35 (19.4%)	66 (39.1%)	75 (43.9%)
About what I expected	44 (24.4%)	41 (24.2%)	34 (19.9%)
Somewhat/much better than expected	77 (43.3%)	42 (24.9%)	35 (20.5%)
Missing data	1 (0.6%)	0	0
<b><u>Length</u></b>			
I did not know what to expect	8 (4.4%)	9 (5.4%)	16 (9.4%)
Much longer/somewhat longer than I expected	55 (30.6%)	65 (38.7%)	95 (55.6%)
About what I expected	63 (35%)	47 (28%)	29 (17%)
Somewhat shorter/much shorter than I expected	53 (29.4%)	47 (28%)	31 (18.1%)
Missing data	1 (0.6%)	0	0
<b><u>Pain</u></b>			
I did not know what to expect	11 (6.1)	14 (8.3%)	12 (7%)
Much worse/somewhat worse than I expected	51 (28.3%)	61 (36.3%)	101 (59.1%)
About what I expected	51 (28.3%)	52 (40%)	34 (19.9%)
Somewhat better/much better than expected	65 (36.1%)	41 (24.4%)	24 (14%)
Missing data	2 (1.1%)	0	0
<b><u>Experience</u></b>			
I did not know what to expect	11 (6.1%)	10 (6%)	12 (7.1%)
Much worse/somewhat worse than I expected	52 (28.9%)	61 (36.3%)	82 (48.2%)
About what I expected	48 (46.7%)	46 (27%)	37 (21.8%)
Somewhat better/much better than expected	68 (37.7%)	51 (30.4%)	39 (22.9%)
Missing data	1 (0.6%)	0	1 (0.6%)
<b><u>Taking part in the study again</u></b>			
Definitely/probably not	14 (7.8%)	23 (13.7%)	46 (26.9%)
I'm not sure	30 (16.7%)	28 (16.7%)	26 (15.2%)
Probably/definitely yes	136 (75.6%)	117 (69.6%)	99 (57.9%)
Missing data	0	0	0
<b><u>Study group becoming normal practice</u></b>			
Very/slightly disappointed	13 (7.2%)	28 (16.7%)	60 (35.1%)
Not sure	51 (28.3%)	50 (29.8%)	51 (29.8%)
Fairly/very pleased	114 (63.3%)	85 (50.6%)	57 (33.3%)
Missing data	2 (1.1%)	5 (3%)	3 (1.8%)

**Table 12.4. Maternal Satisfaction variables**

Questions 1-4 scale = 2-6, questions 5 and 6 scale =1-5						
		<b>2 HOUR</b>	<b>3 HOUR</b>	<b>4 HOUR</b>	<b>F (df)</b>	<b>P</b>
Q1	MEAN	4.45	3.57	3.27	28.01	<0.0001
<b>Control</b>	St.Dev.	1.26	1.29	1.27	(2,468)	
Q2	MEAN	3.96	3.50	3.10	14.44	<0.0001
<b>Length</b>	St.Dev.	1.19	1.37	1.33	(2,510)	
Q3	MEAN	4.11	3.43	3.11	21.22	<0.0001
<b>Pain</b>	St.Dev.	1.27	1.34	1.15	(2,504)	
Q4	MEAN	4.23	3.61	3.37	15.7	<0.0001
<b>Experience</b>	St.Dev.	1.3	1.3	1.25	(2,501)	
Q5	MEAN	3.94	3.5	3.2	13.75	<0.0001
<b>Repeat</b>	St.Dev.	0.99	1.1	1.3	(2,537)	
Q6	MEAN	3.88	3.17	2.82	28.66	<0.0001
<b>Practice</b>	St.Dev.	1.15	1.5	1.52	(2,531)	

As can be seen in table 12.4., a one way anova showed significant differences for each of the six questionnaire items. It was therefore necessary to perform a multiple range test to explore these differences further. In all six questions, Post Hoc Scheffe test at  $p < 0.05$  shows a significant difference between 2 hours and 4 hours (Tables 12.5. - 12.10). In questions 1, 3, and 6 Post Hoc Scheffe test at  $p < 0.05$  shows a significant difference between 2 hours & 3 hours and in question 5, a significant difference was found between 3 hours & 4 hours.

**Table 12.5. Scheffe Multiple Comparison - Control**

	Mean	Significant contrast	P value
<b>2 vs. 3</b>	4.45 - 3.57	L/SE (L) = 5.37	0.03
<b>2 vs. 4</b>	4.45 - 3.27	L/SE (L) = 7.19	0.02
<b>3 vs. 4</b>	3.57 - 3.27	L/SE (L) = 1.83	0.26

Critical value for contrasts = 2.46

**Table 12.6. Scheffe Multiple Comparison - Length**

	Mean	Significant contrast	P value
<b>2 vs. 3</b>	3.96 - 3.5	L/SE (L) = 2.9	0.11
<b>2 vs. 4</b>	3.96 - 3.10	L/SE (L) = 5.37	0.03
<b>3 vs. 4</b>	3.5 - 3.10	L/SE (L) = 2.47	0.15

Critical value for contrasts = 2.45

**Table 12.7. Scheffe Multiple Comparison - Pain**

	Mean	Significant contrast	P value
<b>2 vs. 3</b>	4.11 - 3.43	L/SE (L) = 4.34	0.05
<b>2 vs. 4</b>	4.11 - 3.11	L/SE (L) = 6.38	0.02
<b>3 vs. 4</b>	3.43 - 3.11	L/SE (L) = 2.04	0.21

Critical value for contrasts = 2.46

**Table 12.8. Scheffe Multiple Comparison - Overall experience**

	Mean	Significant contrast	P value
<b>2 vs. 3</b>	4.23 - 3.61	L/SE (L) = 3.90	0.06
<b>2 vs. 4</b>	4.23 - 3.37	L/SE (L) = 5.44	0.03
<b>3 vs. 4</b>	3.61 - 3.37	L/SE (L) = 1.54	0.34

Critical value for contrasts = 2.45

**Table 12.9. Scheffe Multiple Comparison - Repeat**

	Mean	Significant contrast	P value
<b>2 vs. 3</b>	3.94 - 3.51	L/SE (L) = 3.18	0.09
<b>2 vs. 4</b>	3.94 - 3.23	L/SE (L) = 5.20	0.03
<b>3 vs. 4</b>	3.51 - 3.23	L/SE (L) = 2.02	0.22

Critical value for contrasts = 2.46

**Table 12.10. Scheffe Multiple Comparison - Practice**

	Mean	Significant contrast	P value
<b>2 vs. 3</b>	3.88 - 3.17	L/SE (L) = 4.94	0.04
<b>2 vs. 4</b>	3.88 - 2.8	L/SE (L) = 7.44	0.02
<b>3 vs. 4</b>	3.17 - 2.8	L/SE (L) = 2.49	0.15

Critical value for contrasts = 2.45

**Table 12.11. Overall Satisfaction score**

	<b>2 hours</b>	<b>3 hours</b>	<b>4 hours</b>	<b>2 vs. 3</b>	<b>3 vs. 4</b>	<b>2 vs. 4</b>
<b>Mean</b>	23.5	21.4	19.3	<0.0001	< 0.064	<0.0001
<b>(SD)</b>	(5.9)	(6.1)	(5.6)			

Post hoc Scheffe test

## 12.4. Post Hoc Analyses

The pre specified data analyses generated further questions which were explored through the following post hoc analyses (Tables 12.12 - 12.16.). One important question was whether women who had not received any intervention at all were more satisfied than those who had. Table 12.12. shows that women were more satisfied if they did not receive any intervention ( $p < 0.0001$ ). Similarly, those women who had a normal delivery but received intrapartum intervention were less satisfied ( $p < 0.0001$ ) than those who did not receive intrapartum intervention (Table 12.13.).

When the two extreme trial arms (2 and 4 hour) were compared (Table 12.14), women who had no intrapartum intervention and a normal delivery had a higher mean score in the 2 hour group. However these findings were not statistically significant. There was a statistically significant difference ( $p < 0.0001$ ) between the trial arms when women who had received intrapartum intervention and had an instrumental delivery were compared (Table 12.15.). The women in the 2 hour arm were more satisfied. Similarly, women who had received intrapartum intervention and had a normal delivery were more satisfied in the 2 hour arm (Table 12.16.).

**Table 12.12. Satisfaction: women who received no intrapartum intervention and had a normal delivery compared with women who received intervention and/or had an instrumental delivery**

	Normal labour and delivery (A) n=157	Intervention and/or instrumental delivery (B) n=362	A vs. B unpaired t test
Satisfaction scores			
mean (SD)	23.8 (5.1)	20.4 (5.2)	df=517, t=6.8 p<0.0001

**Table 12.13. Satisfaction: women who did not receive any intrapartum intervention and had a normal delivery compared with women who received intervention and had a normal delivery**

	No intervention and normal delivery (A) n=157	Intrapartum intervention and normal delivery (B) n=184	A vs. B unpaired t test
Satisfaction scores			
mean (SD)	23.8 (5.1)	20.9 (5.1)	df=339, t=5.3 p<0.0001



**Table 12.14. Satisfaction: women without intrapartum intervention who had a normal delivery**

	2 Hours n=54	4 Hours n=54	2 vs. 4 unpaired t test
Satisfaction scores			
mean (SD)	24.9 (5.2)	23.6 (4.3)	df=106, t=1.4 p=0.2

**Table 12.15. Satisfaction: women with intrapartum intervention who had an instrumental delivery**

	2 Hours n=126	4 Hours n=117	2 vs. 4 unpaired t test
Satisfaction scores			
mean (SD)	22.7 (5.1)	17.8 (4.3)	df=241, t=8 p<0.0001

**Table 12.16. Satisfaction: women with intrapartum intervention who had a normal delivery**

	2 Hours n=66	4 Hours n=61	2 vs. 4 unpaired t test
Satisfaction scores			
mean (SD)	22.9 (4.9)	18.6 (5)	df=125, t=5.0 p<0.0001

### **12.5. Open Response Findings**

Of the 519 (86%) women who returned the questionnaire, 412 (79%) expressed their views in a narrative way. A similar number of women in each trial arm responded (2hr-142, 3hr-132, 4hr-138). The responses of women were consistent, with agreement about aspects which they considered important contributors to a positive labour experience. There were many more positive comments (n=647) than negative ones (n=415). However, the women's responses did not appear to relate to whether or not they had received intervention or to which trial arm they were allocated to. Unless indicated, the findings therefore represent the views of the group as a whole.

Although the data was in the format of direct quotes from the women, it was believed useful to quantify the data by summarising the frequency of responses in terms of both negative and positive comments. This provided a general overview of the women's thoughts and feelings. The following charts (figures 12.1 and 12.2) identify the themes generated from these most frequently occurring responses. Some women wrote about both positive and negative aspects identifying that they were satisfied with part of their experience but not with others. Additionally, some women wrote about positive aspects which were not fulfilled.

The main intrapartum themes which emerged from the analysis were support, information, intervention, decision making, control, and pain relief (intrapartum and postnatal). Additionally, many women commented on their experience of participating in a trial.

### 12.5.1. Positive responses

As can be seen from figure 12.1. There were many factors which contributed to a positive birth experience. However, although the themes have been illustrated separately many of the themes do in fact overlap. This is demonstrated by the quotes supplied by the respondents (illustrated later in this chapter).

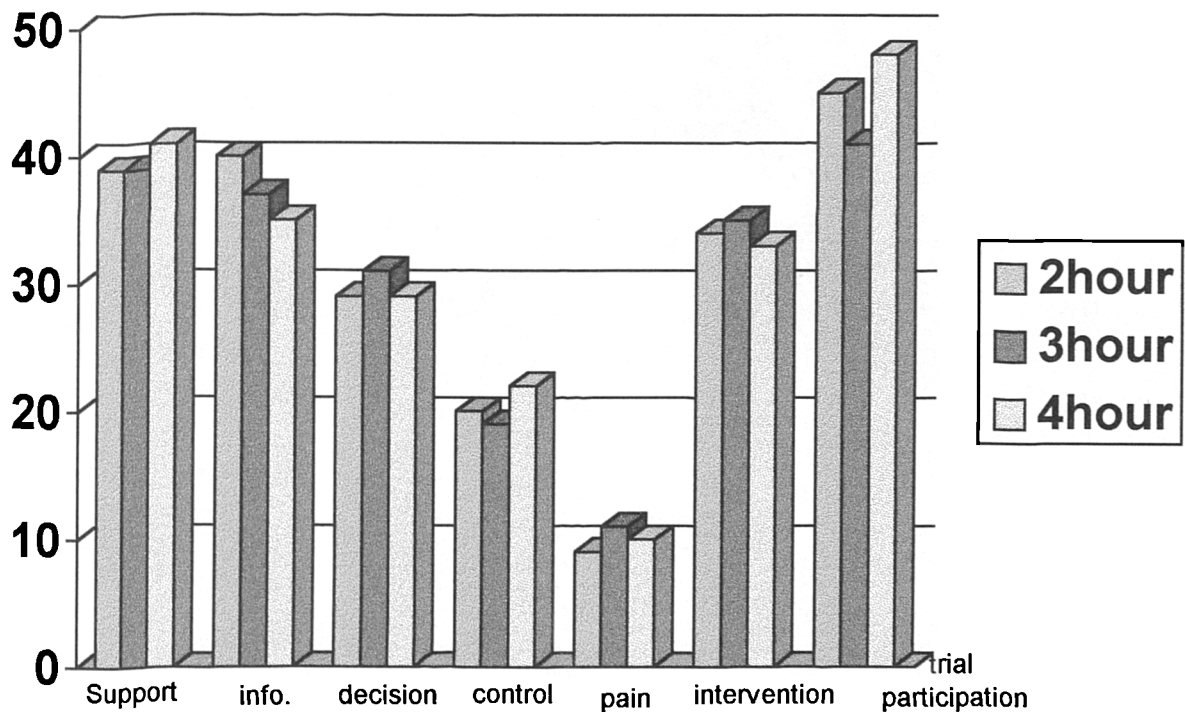


Figure 12.1. Number of positive responses

*Support* = Number of women who wrote that they had received appropriate support from either midwife or partner

*Info.* = Number of women who wrote that they had received appropriate intrapartum information

*Decision* = Number of women who believed they were actively involved in decision making

*Control* = Number of women who wrote that they felt in control during labour.

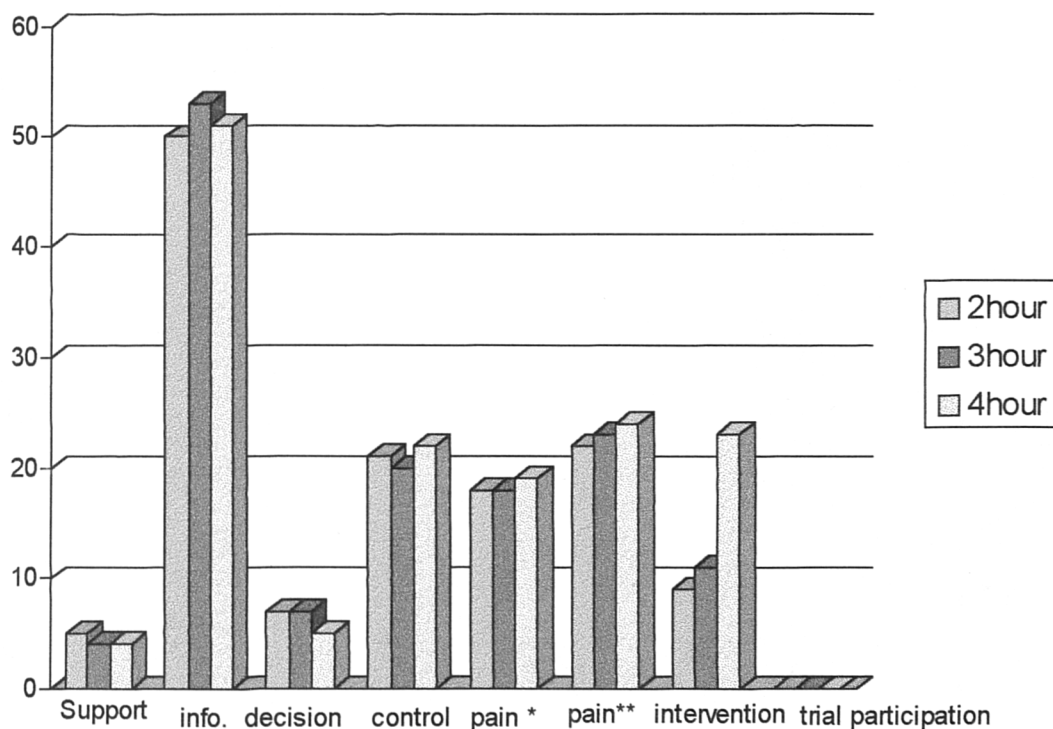
*Pain* = Number of women who wrote that they received appropriate pain relief during labour.

*Intervention* = Number of women who wrote positively about the intervention that they had received.

*Trial participation* = Number of women who wrote positively about being in a trial.

### 12.5.2. Negative Responses

Similar themes were identified from the negative responses as the positive ones. However, as can be seen from figure 12.2. none of the women wrote negatively about being a trial participant and some women wrote negatively about postnatal pain.



**Figure 12.2. Number of negative responses**

*Support* = Number of women who wrote that they did not receive appropriate support from the midwife.

*Info.* = Number of women who wrote that they did not receive appropriate information (this was either in the ante, intrapartum or postnatal period)

*Decision* = Number of women who believed they were unable to be actively involved in decision making

*Control* = Number of women who wrote that they did not feel in control during labour.

*Pain\** = Number of women who wrote that they did not receive appropriate pain relief during labour.

*Pain\*\** = number of women who wrote that they received inadequate pain relief in the postnatal period.

*Intervention* = Number of women who wrote negatively about intervention (either because it was considered to be unnecessary or because it was required sooner)

*Trial participation* = No women wrote negatively about trial participation

## Support

The responses showed clearly that women in each trial arm agreed that one of the most important aspects of their labour was support. Both the support of the midwives and that of a partner/friend were considered crucial to a fulfilling experience. All women in the study had a partner, friend or family member present throughout the labour which the women perceived as beneficial. One woman articulated the views of 119 (28.9 %) women by saying that,

*“I felt that the care I received throughout a long labour was appropriate and I felt I was treated excellently by all I came in contact with. These were the factors that were most significant to my well being throughout the birth rather than the protocols regarding clinical intervention.”*

Thirty two (7.8%) women reminisced about previous maternity care as told to them by older relatives, being reassured that advancements have been made for the benefit of women:

*“My mum said it (the birth) was a nightmare in her day..... My dad wasn't allowed in and my mum said she felt so alone. I am so glad that things have changed because I don't think I could have coped if I'd of been alone...”*

Partners and family members supported the women in various ways, for example one woman reported that:

*“My boyfriend was great because he was really nervous before I went into labour but he ended up getting really involved and he even cut the cord. I was so proud of him and it made it all so special.”*

However, 78 (18.9%) of women said that their partners wanted to “just be there in the labour room” which was perceived as equally special.

## **Control**

The concept of ‘control’ has been investigated and many meanings are reported (Green et al 1990). However, the researcher did not attempt to provide a definition of control as it was more important to identify women who used this term and explore what it meant to them. The women talked about both self control and external control.

Being in control was seen as a positive aspect of labour, with 124 (30%) women stating that it was necessary to maintain personal “dignity during labour.”

*“I was pleased that I felt I had a lot of control during labour. If I had lost control I would have felt really embarrassed. I thought I might let myself down by screaming or swearing but I’m glad to say I never ”*

Although 61 (14.8%) women acknowledged that they had maintained control during the intrapartum period, they also stressed the difficulty of achieving this aim.

*“Childbirth is really difficult and it is very hard to stay in control even when all is normal. My labour was normal but I still found it extremely difficult to remain calm and listen to the midwife and make decisions.”*

Unfortunately, not all women felt they were in control. One woman suggested that the control was taken away from her:

*"I did not feel in control - the hospital are in control. A lot of the time, probably due to pain relief I felt I did not know exactly what was going on. There seemed to be a lot of people milling around, but nobody actually explaining everything that was going on."*

However, women defined control in many ways identifying that their expectations played a role in whether or not their anticipated experience was fulfilled.

The views of one woman were echoed by many when she wrote about the importance of knowing that the staff were in control:

*"I felt at all times that the midwives and doctors were in control of the situation, which was reassuring as I was high risk. My progress was slow, the baby had had his bowels open (meconium) and the heart trace was dipping but everyone knew exactly what to do so I was pleased with the way things went."*

### **Decision making**

108 ( 26%) women acknowledged the fact that they wanted to participate in decision making. However the desired degree of involvement differed greatly between individuals. One woman's account of her second stage of labour difficulties shows clearly the importance of involving women when important decisions are to be made:

*"When I was not getting anywhere pushing, the doctor asked if I wanted help. I was pleased that I was asked and that it was not forced on me. I feel that it was my decision."*

In the above quote, the respondent had underlined the word 'asked' in her attempt to emphasise the importance of her own contribution to her labour management.

Participation in decision making can only occur if effective communication between woman and midwife is achieved. One woman was clearly denied the opportunity to make a decision regarding her pain relief:

*"The midwife did not have enough time for me. I knew that the right pain relief was important and I said I had an open mind, but she interpreted that as an immediate request for diamorphine - I was given it so quickly as it was more convenient for the midwife."*

Of the 108 women who acknowledged the fact that they wanted to participate in decision making, 89 (82%) commented on the importance of both them and their partners being involved in deciding on various aspects of care. The main decisions women wanted to make were - who should be present at the delivery, method of pain relief and position at delivery.

### **Information**

One hundred and fifty four ( 37.4%) women felt unprepared for labour which they attributed to either lack of information or their own unrealistic expectations. Some women considered themselves to blame for this lack of information:

*"I wish I had more information antenatally, I didn't really know what to expect regarding pain and delivery etc. I also wish I'd practised the breathing exercises more frequently as during the labour I found it hard to breath properly. I'll know next time!"*



A few women attributed their lack of information to the insensitivity of the staff:

*"I felt that the reasoning for my being left so long was not explained properly."*

The most distressing account was one from a woman who had been in labour for 16 hours which resulted in an assisted delivery:

*"The actual birth of my child had to be assisted by having an episiotomy and forceps delivery which was not explained beforehand and no pain killing injection given. The actual delivery has left me feeling quite traumatised for the moment. I understand my baby was in distress and the course of action had to be taken, I just feel it could have been carried out more sympathetically."*

One area which 60 (14.6 %) women felt unprepared for was the second stage of labour, commenting that they "didn't expect it to be so difficult" and they "did not know how to push."

Those women who felt prepared, responded more positively than those who did not. Similarly, those who believed they had required adequate and accurate information throughout their labour were less likely to view their labour negatively:

*"They (midwives) explained everything that was happening which was great because when they explained things I felt a lot calmer."*

Receipt of information was perceived by 112 women (27.2%) as being a contributor to the sense of control:

*“The midwife explained what was going on as I was in labour and this meant I felt I was in control.”*

Many women commented on the lack of information they received following the delivery of their baby. Although the women were questioned on the second post natal day they were already seeking answers to questions regarding their intrapartum experience. Of the 87( 21%) women who commented about postnatal information a consensus was reached which acknowledged that postnatal support was lacking:

*“Someone should talk to you after you have had your baby because although my midwife was very good when I was in labour I would have liked to have asked her about what went on. My labour went fine, I think, because I had a normal delivery but it would have just been nice to have talked to the midwife about the labour.”*

### **Intrapartum Pain**

Eighty five women (20.6%) mentioned pain or pain relief, highlighting its importance as a contributor to intrapartum well being. There did not appear to be any differences between women randomised to the different trial arms. Fifty five women across the 3 trial arms, commented that their chosen method of pain relief was ineffective whilst 30 women believed their pain to have been managed in an appropriate way to meet their individual needs.

Although some women said that the pain was “unbearable” or “a lot worse than expected” , there were others who believed that the pain was “not so bad” or “a lot better than expected”

Women in the study had various methods of pain relief for their individual needs. While some women commented that they were “very happy to be able to manage with very little pain relief” there were others who “wanted everything for the pain”. The following accounts of two women’s chosen pain relief demonstrates their individuality:

*“I enjoyed being in the pool. The warm water helped with the pain and helped me to be more mobile. The aromatherapy was enjoyable. It helped build a more relaxed atmosphere and made me feel in control.”*

*“The epidural was extremely effective. I would definitely recommend it to other women. Being pain free meant I could sleep which meant my labour seemed shorter and I wasn’t too tired to push the baby out.”*

### **Postnatal pain**

In addition to comments regarding intrapartum pain, sixty nine women (16.7%) commented on the pain they felt in the postnatal period. Only 3 of the women who commented had delivered their baby by caesarean section. It was interesting to note that 52 of the women who had commented on postnatal pain had received an epidural during labour.

Approximately half of the comments made regarding pain referred to perineal discomfort,

*“The stitches are so painful. I feel like I am about to burst underneath. I am in agony especially when I try to walk”*

These women generally acknowledged that there were methods of relieving this pain,

*“The pain of my stitches was a bit better after having tablets but my mum brought me a rubber ring which helped a lot”*

However, 60 women commented on ‘afterpains’ and it became obvious from the comments that for the majority of the women these pains were totally unexpected.

One woman wrote:

*“I couldn’t believe the cramps I had in my stomach after the baby was born it was almost as bad as giving birth. Nobody told me I would get afterpains I wish I had known so I would have been more prepared.”*

Another said:

*After you have had your baby and you’ve been stitched up you think it’s all over but NO, along comes the afterpains. I have heard people talk about them but I didn’t think they would be as bad.”*

Unlike the perineal pain, it appeared that women believed that there were no methods of relieving afterpains. One woman highlighted this point when she wrote:

*“It (afterpains) is just part of the whole process. There is nothing really you can do about it. You just have to get on with it and hope that they don’t last too long. The midwife said it was normal but didn’t really do anything.”*

## Intervention

Probably the most interesting theme generated was intervention. The fact that these women were taking part in a study assessing intervention may have heightened their awareness of intervention, thereby influencing the generation of this theme. However, most women did not perceive intervention as a negative aspect of labour, instead 102 (24.8%) women saw it as a positive contributor to their experience when abnormal labour patterns developed. Women felt reassured when allocated to the 2 hour action line, knowing that intervention would occur promptly if indicated:

*“Although no intervention was needed I was happy to know that after 2 hours I would be helped along rather than left.”*

Surprisingly only one woman believed that she had unnecessary intervention, however, 41 (10%) women believed that they either waited too long for intervention or did not feel they were given the intervention they required:

*“I think earlier intervention (if needed) would be more welcome, as it offers the patient more reassurance and choice.”*

*“I didn't seem to be making any progress and would not have liked to go much longer without assistance.”*

The number of women in the 4 hour arm who said that they waited too long for intervention was double that of those in the other two trial arms (table 12.17.).

**Table 12.17. Women who wrote that they waited too long for intervention**

	2 hour n=138	3 hour n=132	4 hour n=142	2 vs. 3	3 vs. 4 Fishers exact test	2 vs. 4
Number of women who wrote that they waited too long for intervention	8	10	23	p=0.6	p=0.03	p=0.004

*"After 5cms I was pleased to be checked (vaginal examination). After the length of time it was taking I was very glad when the registrar said I could have the drip. From the time that the drip was put up to the birth, I could not believe how quickly it went, I wish I'd of had it earlier"*

A minority of women (n=2) suggested that intervention should be used with caution, identifying the negative aspects of its use:

*"The point to make is that intervening earlier may just tip the balance and may cause more problems when perhaps the idea is to make it easier. Unnecessary intervention in my opinion only adds to the load that a woman has to cope with. Labour in itself is very demanding and personally I was glad that I required no intervention."*

### **Trial Participation**

It was encouraging to note that 134 (32%) women acknowledged the need for research, recognising the positive effects on maternity care.

*"I think the study is good as it keeps up with new ideas of improving things for childbirth"*

It was evident that women accept and welcome research into maternity care, being aware of the benefits to themselves and their families:

*"I think it is very important to do studies about childbirth and how new mothers cope with the birth of their baby so they improve techniques to make mother, fathers and babies more confident in this emotional experience."*

Another said:

*"As long as the protocols are based on sound medical clinical evidence then I would be happy with whatever was adopted as the hospital policy."*

It was welcoming to read some women saying "I was pleasantly surprised when I was approached about the PALS study," and, " Thanks so much for telling me about the PALS." Women apparently did not feel coerced into participating in the trial , instead they felt that they were given an additional choice:

*"When I was approached about the study I was very pleased because improvements can only be made if people like me take part. I did not feel that I had to take part because I went home to think about it. I was allowed to choose whether I wanted to take part which made me think very hard about the study."*

## **Summary**

The open responses concentrated on seven main areas, namely, support, information, intervention, decision making, control, pain relief and trial participation. Although the themes have been presented separately, it appears from the comments made that they inter relate. Viewed holistically, the evidence from the women suggests that a failing

in one aspect can directly influence another. A good example of this is the woman who said that because the midwife explained 'what was going on' she felt *in control*. These open responses complement the intrapartum and structured questionnaire data, allowing a clearer picture of events to emerge.



## **Chapter 13**

### **Midwives' Views**

As discussed previously (methodology chapter) it was necessary to assess the midwives' views on the use of the partogram and its components. The main reason for measuring midwives's views was to confirm that they were not biasing the women's expectations. A midwife who appeared dissatisfied with the allocated partogram had the potential to relay this dissatisfaction to the women in her care. It was therefore important to be certain that the women's responses reflected their own feelings and not those influenced by the midwife. Of the 86 midwives questioned, 71 (82.6%) responded, their characteristics can be seen in Table 13.1. The midwives views of the partogram differed as can be seen in table 13.2. This offered reassurance that the midwives had no strong preference towards any particular partogram.

However, interestingly, when the midwives preferences were compared according to the number of years qualified as a midwife, statistically significant differences were shown (Table 13.3.). There were more midwives that had been qualified for more than ten years who preferred the 2 hour partogram than those qualified for 5 years or less ( $p= 0.04$ , Fisher's exact test) or than those qualified for 5 to 10 years ( $p=0.04$ , Fisher's exact test). Similarly, there were significantly more midwives in the group qualified for 5 years or less who showed a preference for the 4 hour partogram (5-10 years  $p= 0.03$ , > 10 years  $p<0.0001$  using Fisher's exact test). These findings suggest that the longer a midwife is qualified, the more likely she is to prefer early intervention. On the other hand, the more recently qualified midwives show a preference for the more conservative approach.

**Table 13.1. Midwives Baseline Details**

		Responses (N=71)
<b>Years qualified</b>	<1	2 (2.8%)
	1-5	12 (16.9%)
	6-10	18 (25.4%)
	11-15	19 (26.8%)
	>15	20 (28.2%)
<b>Midwifery grade</b>	E	47 (66.2%)
	F	6 (8.5%)
	G	18 (25.4%)
<b>Used partogram without action line</b>	No	14 (19.7%)
	Yes	57 (80.3%)
<b>Are written guidelines necessary</b>	No	0
	Yes	71 (100%)

**Table 13.2. Midwives views of partogram**

		Responses (N=71)
<b>Is a Partogram necessary?</b>	No	2 (2.8%)
	Yes	69 (97.2%)
<b>Is an action line necessary?</b>	No	9 (12.7%)
	Yes	62 (87.3%)
<b>Which position of the action line is most beneficial to woman?</b>	2hr	19 (27%)
	3hr	26 (36%)
	4hr	19 (27%)
	undecided	7 (10%)
<b>Is a latent phase necessary on partogram?</b>	No	48 (67.6%)
	Yes	20 (28.2%)
	missing data	3 (4.2%)
<b>Partogram choice for spontaneous labouring primigravida</b>	No partogram	2 (2.8%)
	Partogram without alert or action line	9 (12.7%)
	Partogram with alert line only	22 (31%)
	Partogram with alert and action line	38 (53.5%)

**Table 13.3. Choice of partogram in relation to years qualified**

	≤ 5 years qualified (A) n=14	6-10 years qualified (B) n=18	> 10 years qualified (C) n=39*	A vs. B	B vs. C OR (95% CI)**	A vs. C
<b>2 hours</b>	<b>1</b>	<b>2</b>	<b>16</b>	0.6 (0.01-13.3)	0.2 (0.02-0.9) p=0.04	0.1 (0.002-0.9) p=0.04
<b>3 hours</b>	<b>2</b>	<b>10</b>	<b>14</b>	0.1 (0.01-0.9) p=0.04	2.2 (0.6-8.1)	0.3 (0.03-1.7)
<b>4 hours</b>	<b>10</b>	<b>6</b>	<b>2</b>	7.3 (1.2-53.4) p=0.03	9.3 (1.4-100.6) p=0.02	67.8 (8.0-768.4) p=<0.0001

\* NB 7 midwives in this group were undecided

\*\*Fishers exact test

### 13.1. Generated themes

Several themes were clearly identified from the most frequently recurring responses, the main ones of which have been illustrated in the table below (13.4.).

**Table 13.4. Generated themes**

Themes	Examples
Lack of midwife autonomy/ Restrictive practice	“Sometimes you become too focused on the partogram and forget about your clinical skills” “It is difficult to manage a case when the guidelines are so strict” “Sometimes you know that a woman does not require intervention but because she has crossed the action line you have to start syntocinon”
Educational benefits	“The partogram is great for teaching students” “The partogram is a great aid, especially when you have new members of staff”
Practical advantages	“The partogram is easy to use and allows you to know quickly how a woman’s labour is progressing.” “It prevents you from having to make lots of detailed notes”
Individualised care	“ It is difficult to treat each woman as an individual when her care is guided by a chart” “Although I like the partogram I use it only in conjunction with other observations, eg. Fetal and maternal”

These themes can also be clearly identified throughout the rationale given by the midwives for their closed responses.

### 13.2. Rationale for midwives responses

#### *Are written guidelines necessary?*

All of the midwives questioned believed that guidelines were necessary. In particular they suggested that they helped the midwife to care for the mother and baby. One midwife said:

*“Guidelines are necessary to ensure well-being of both mother and baby during labour. Also gives all women equal care and all midwives a point of reference for that care.”*

However, the midwives also stated that guidelines should not be too prescriptive.

*“Guidelines should be exactly that - Guidelines. They should not be seen as protocols. There should be room for individual interpretation.”*

Another said:

*“... they should not be rigid, but used as guidelines, with provision for individualised care to be given and woman's choice where practical.”*

Although the midwives said they thought that guidelines were necessary, 24 (33.8%) of the respondents said that they should only be used for complicated labours:

*“We have many different types of labouring mothers. Guidelines for normal labours - NO. But for other difficult and complex issues - YES.”*

The main advantages of guidelines appeared to be their educational value as they were thought to be *‘excellent for newly qualified and inexperienced staff’*. Yet the

midwives stated that guidelines were only useful if they were '*regularly updated*' and '*based on evidence*'.

### ***Is a Partogram necessary?***

Most of the midwives (97.2%) thought that the partogram was a necessary tool for labour. In particular, the midwives recognised the benefits of being able '*to see at a glance what is happening*'. They suggested that the partogram reduces duplication of records and also allows 'handovers' to be completed efficiently.

Several of the midwives stated the long term benefits of the partogram:

*"The WHO stipulates that a plan of action should be used for labouring women (partogram) to avoid maternal morbidity and perinatal mortality. The use of a partogram is a tool to aid the action taken to prevent obstructed labour and reduces the risks of prolonged labour and LUSCS."*

They also acknowledged the fact that the partogram was '*useful for teaching purposes*'

The two midwives who said that the partogram was not necessary, believed that sometimes they are misused. One midwife gave two examples of how they can be misused:

*"If they are misused (1) plotted incorrectly, (2) plotted correctly but if progress abnormal this continues to be plotted (even using second graph!) without appropriate action being taken. In these two cases they are of little use."*

The midwives who believed that the partogram is necessary also had some reservations. One midwife summed up the views of others in the following quote:

*“Using this to determine action or intervention should be taken in accordance with other factors, i.e. maternal wishes, fetal condition, maternal condition, amount of analgesia...it should not be too rigid as to exclude other ways of management.”*

### ***Is an action line necessary?***

The reasons for the 62 midwives believing that the action line was necessary were similar to those in the previous question. They said that it *‘helps managing the labour’* and you can *‘diagnose prolonged labour at a glance’*. One midwife also stated that *‘it is useful as a point of discussion between midwife, patient and doctor’*.

However, she continues by saying:

*“In some circumstances it may be more beneficial to discuss management at this point and be more flexible e.g. ROM followed by an hour for observation and hopefully progress before syntocinon starts..”*

Those that did not think an action line was necessary shared the rational for their responses:

*“I feel it takes away autonomy and individual clinical decisions. The carer should be alerted if progress is not along alert line, but treatment and intervention necessary would vary from individual to individual. Maternal preference should also be of paramount importance.”*

A further point made was:



*“ With the action line, only dilatation is taken into consideration when often there is significant progress re. thinning of cervix or descent of head without dilatation.”*

***Which position of the action line is most beneficial to women?***

This question was important to the main study because bias from the midwives may have influenced the maternal satisfaction findings. The midwives were split with regard to their preferred position of the action line - 2hr (19/27%), 3hr (26/36%), 4hr (19/27%) and undecided (7/10%).

It appeared from the responses to this question that the midwives beliefs were dichotomised. Those who supported the 2 hour action line were receptive to early intervention, whereas those who supported the 4 hour action line appeared to be anti-intervention. Those who supported the 3 hour action line believed that this was ‘*a compromise between the other two*’.

An example which highlights the beliefs of those who supported the two hour line is:

*“Action should be taken early when the body is not tired and hopefully will respond better. May reduce the risk of PPH.”*

Another midwife said:

*“With efficient uterine action the cervix will dilate well over a 2 hour period. If uterine action is insufficient waiting 3 or 4 hours only prolongs labour by which time the woman is tired and disheartened, the uterus itself becomes more and more insufficient. Unnecessary risk of operative delivery and a risk of PPH and other postnatal problems.”*

The midwives who preferred the 4 hour action line had an opposing view. They believed that *'waiting may prevent unnecessary intervention.'*

The midwives who chose the 4 hour action line shared the same views:

*"I feel that given the time most primigravid women will progress before intervention is necessary"*

*"I feel sometimes we intervene too soon and that often we do not allow labour to progress "normally" as if their progress is not the text book 1cm/hour, we want to interfere. I feel that many women would do much better if 'allowed' a little bit more time to progress "normally"*

The largest group of midwives were those who supported the 3 hour partogram (36%). This was the partogram which was currently in use in the study hospital. The midwives who preferred this action line, did so because they believed *'the two hour is too short- leads to unnecessary intervention and the four hour is too long.'*

One midwife expanded on this rationale:

*"2 hour causes increased intervention and does not give physiological labour much of a chance. 4 hour may delay intervention too long causing an increased risk due to delay - caesarean section, post partum haemorrhage etc."*

### ***Is a latent phase necessary on partogram?***

Most of the midwives (67.6%) did not believe that a defined latent phase on the cervicograph was necessary. Again the midwives wrote about individualised care, suggesting that defining a normal latent phase is of little clinical value.

*“Latent phase appears to last from days to hours and is difficult to define as it is all down to individual coping mechanisms, pain threshold, definition of “painful”, “regular” etc.”*

However, those who disagreed and believed the latent phase was necessary thought that *‘it prevents women from getting augmented too early.’* Without a latent phase *‘there is an increased risk of intervention.’*

### ***Partogram choice for spontaneous labouring primigravidae***

Two of the midwives questioned said that they would choose ‘no partogram’ for an uncomplicated labouring woman. Yet, the majority (53.5%) chose the partogram with alert and action line. This was the partogram that the midwives were most familiar with. As one midwife said:

*“This answer is biased as I have no experience of using a partogram without an action line therefore cannot make a comparison”*

However the majority of midwives (80.3%) had used different types of partogram. The reasons for choosing a partogram with an action line were consistent and centred around the detection of abnormalities:

*“Whilst I would always consider the uncomplicated client as likely to remain like that, and do not want to pathologise her, I like to have boundaries. As*

*competent or confident as I may be I may handover to someone less experienced and the unforeseen does happen. It particularly helps in CPD."*

Some midwives found it difficult to decide which was the most appropriate partogram format when weighing up all the pros and cons:

*"I think it helps having the alert and action line from the midwives point of view. Although it does not take into account the individual and takes choice away from the woman (i.e. early or late intervention). From a risk management litigation perspective it may be useful defining practice in this way, although it is a very restrictive practice and more obstetrically led rather than midwifery led. For a normal uncomplicated labourer - really it is not research based to impose time limits."*

The midwives who chose either a partogram without lines or with an alert line only gave the same rationale for their response. They believed that these *partograms* 'allowed midwives to make their own judgement' and could 'take into consideration other factors.'

One midwife who chose a partogram with an alert line only stated:

*"I feel that the action line should only be a guide and that nothing should be definite as each individual situation has different needs depending on clinical situation and maternal preference. Some women would request intervention if progress were 1 hour slower, some do not wish for intervention and would prefer to wait at least 4 hours. As long as they are fully informed it should be their choice as to when intervention occurs."*

This was echoed by a midwife who chose no lines and wrote:

*"I agree with the action line to prevent prolonged labour but I feel that each woman should be treated individually considering all the facts."*

## **Summary**

The findings from the midwives questionnaires highlighted several major issues. It appears that the majority of midwives do perceive the partogram as being necessary. However, the midwives also expressed their frustrations at being guided so rigidly by a tool that was perceived to be inflexible to the needs of the individual woman. There was no preference towards any particular partogram action line which to some extent reflects the uncertainty already discussed in the literature review. The midwives were aware of the uncertainties surrounding the individual components of the partogram which may have led to some of them stating that women's preferences should predominate.

## **PART 4: DISCUSSION**

## **Chapter 14**

### **Final Discussion**

#### **14.1. Introduction**

At the study outset it was acknowledged that the partogram was often considered a necessary tool in the management of labour. Although many aspects of this chart do require further investigation, health professionals today would find it difficult to dispute the benefits of the partogram, particularly in developing countries. Having managed labours using partograms with and without an action line, it is apparent that women are often more likely to receive appropriate care when the midwife and obstetrician are given additional guidance. This has been confirmed when carrying out local intrapartum audits. At the time when the partogram was introduced, a system of clearly defined guidelines to assist in the transfer of women from a periphery unit to a central unit (Philpott & Castle 1972) was clearly a great breakthrough in terms of mortality and morbidity. However, although the partogram has been heralded as the most important advance in modern obstetric care in the past 20 years (Safe Motherhood 1990), questions remain as to its effectiveness in developed countries. The inconsistencies surrounding prolonged labour have been well reported (Olah & Gee 1996) and are too vast to be tackled in a single study. Therefore, this study assessed one important component of the active management package. The timing of intervention, as guided by the action line, is an area of maternity care which has not previously been adequately assessed.

This chapter will discuss the major issues which were highlighted through conducting this study. The first section (14.2.) includes a critical analysis of the study

methodology. By reflecting on the original study design, philosophical, ethical and methodological issues will be addressed. Limitations of the study and practical problems encountered will be discussed.

The following section (14.3.) will include a detailed interpretation of the study findings. The results showed that women in the 2 hour arm were more satisfied with their labour experience than those in the 3 and 4 hour arm. However, the women in the 4 hour arm had the lowest caesarean section rate. A statistically significant difference was found when compared to the 3 hour arm. These main findings will be discussed in relation to the secondary findings and the previous literature.

A further section (14.4.) discusses the implications of the research findings for future practice. This section commences by discussing the practice implications for the study hospital, then continues by addressing the wider agenda.

The final section (14.5.) explores the potential for further research. This present study has highlighted many uncertainties in labour management and generated a number of further research questions.

## **14.2. Methodological Issues**

### ***14.2.1. Methodological choice from a philosophical perspective***

The majority of previous studies which have assessed aspects of active management of labour have adopted a positivist approach using only quantitative methods. Those trials which have influenced the debate surrounding the management of prolonged



labour (for example, Frigoletto et al. 1995) and the use of different partograms (for example, Tay & Yong 1996) have neglected one of the most important aspects of maternity care, i.e. maternal views. This current study has begun to redress the balance by giving equal precedence to the more qualitative issues. It is interesting to note that some of the more recent ongoing trials are in fact including maternal views as an integral part of the trial design (for example, Term Breech - A randomized controlled trial of planned caesarean section or planned vaginal birth for term breech, Oracle - The overview of the role of antibiotics in curtailing labour and early delivery, Amnioinfusion Trial - A multicentre randomized controlled trial of amnioinfusion for the presence of meconium in labour). This may be due to the growing number of midwives who have become involved in perinatal trials, coupled with the general awareness that women should be 'partners' in the research process (Kenyon 1997). This current study was designed on the premise that the women were involved in all stages of the research process. Firstly, through consumer group representatives, women viewed and amended the information sheet prior to the study's commencement. They also advised on the amount of verbal information that was required in order to make an informed decision. Some women participated in piloting the questionnaires and advised on the most suitable method of returning completed ones. Others took part in the actual study which for some meant a change in labour management, and for many meant completing a questionnaire. Additionally, women disseminated study information to friends and relatives, which to some extent contributed to the healthy recruitment rate. Some women telephoned the researcher to request trial participation having discussed the trial with a previous participant. Many researchers appear to pay lip service to consumer input, yet the success of this current study can be attributed to the ongoing participation of the women. However,

what made this current study unique was the fact that maternal satisfaction was considered important enough to be a primary outcome measure (discussed in more detail later). Therefore a dual approach to the research question, proved to be effective. The trial findings would have been limited if a single methodological approach had been used.

Although postpositivism encourages a realistic inquiry, which may in fact include qualitative issues, this paradigm continues to be characterized as a modified version of positivism (Guba 1990). Critics of the postpositivist paradigm would therefore argue that research which is generated from this paradigm continue to be dominated by a science-orientated approach (Perkins 1992) . It has also been proposed that medical staff in particular, find it difficult to accept findings that stem from research which does not fall within the norms and conventions of a positivistic stance (Webb 1984). Even authors who acknowledge the important contribution of qualitative research in evidence based medicine highlight the unequal social relationships of health research (Popay & Williams 1998). It may be that the power and influence afforded to different disciplines and types of knowledge has been inhibiting the integration of research methods. When designing this present study the difficulties of integrating qualitative data were considered. However, although the postpositivist approach has its limitations, it was deemed to be the most appropriate paradigm for the trial design. Being a randomised controlled trial meant that some order was necessary to be able to make inferences from the data. Furthermore, as discussed later, the qualitative findings did in fact influence changes to practice. These changes were accepted by all members of the multidisciplinary team which suggests that clinicians may be becoming more accepting of research which stems from 'alternative paradigms'.

This postpositivistic approach adopted acknowledged the importance of external variables such as previous expectations, cultural factors and social influences. However, although the study did explore some social aspects such as the Under Privileged Area score, a comprehensive exploration of individual circumstances was not deemed feasible due to the large sample size.

#### ***14.2.2. Ethical Considerations***

Prior to commencing this study it was envisaged that the researcher would discuss the trial with all eligible women prior to consent. This was ambitious, and in fact proved not to be feasible given the volume of women and the limitation of time and resources. Therefore, although most of the eligible women (82 %) discussed the trial with the researcher at 20 weeks gestation, unfortunately some women did not. This meant that a small group of women consented to participate whilst on the delivery suite (n=126). This was not an ideal situation because although these women had received an information sheet prior to labour, one could argue that they may not have had sufficient time to discuss their options. As stated by the General Medical Council (1998), the researcher should 'allow them ('patients') sufficient time to reflect on the implications of participating in the study' (p19). Incidentally, all women who participated in the study were literate. Women with learning difficulties were identified from their case records and excluded from the study. This approach conformed to the Charter laid down by the National Childbirth Trust and Association for Improvements in the Maternity Services (1997), in that written information was given at a time that allowed women to 'learn about randomised controlled trials and the research issues involved, and consider the physical and emotional implications of possible effects for them'(p2). This information was given to the woman to keep, and

a contact number was included. Several women did in fact telephone the researcher to discuss issues or to arrange a convenient time to meet. Furthermore, it was believed that the midwives were capable of assessing whether or not it was appropriate to obtain consent from a labouring woman. Women verbally consent to treatments and interventions throughout labour and should be equally free to choose whether they wish to take part in a trial or not.

A further issue which arose was the fact that women who were approached on the delivery suite were then consented by their care giver. This issue has previously given rise to concern (Cormack 1991), as the 'patient' may feel pressurised to participate for fear of upsetting the person who is then responsible for their care. Although there was no evidence that participating women were made to feel vulnerable, this is an area that needs further exploration.

Some of the women who took part in this study were also involved in other studies. Although women have the right to choose whether or not to participate (Chalmers 1990), multiple research participation is an unexplored area. Not only did this mean that the women gave up more of their valuable time but it also meant that occasionally the women merged the trials within their own minds. For example, one woman wrote on her questionnaire that she liked being part of the study because it meant that she received an additional scan, yet this current study did not include any additional ultrasound scans. Fortunately, the number of women in this present study who took part in simultaneous studies was small. However, with the increase in maternity care research, this is an important ethical area which needs to be addressed.

### ***14.2.3. Randomised Controlled Trial***

To answer the research question a *randomised controlled trial* was conducted in which women were allocated to have their labours managed with the aid of one of three different partograms. Demographic, intrapartum and 'satisfaction' data were collected, analysed and compared between the three trial arms.

There is a growing consensus that the findings from randomised trials provide the most clinically useful evidence about the effects of treatments (Clarke 1998). The great strength of such trials lies in the confidence with which causal relationships can be inferred (Polit & Hungler 1993). However, there are several aspects of the design and interpretation of randomised trials which may be challenged (McPherson & Chalmers 1998). The main criticism of many randomised trials is the poor control of bias and the researchers' reluctance to measure outcomes of interest to the patients (Chalmers 1998). In this current study steps were carried out to minimise bias (see 14.2.8) and the outcomes measured were of clinical value (see 14.2.5). Equal importance was given to the views of the women who participated. The outcomes of interest to the women were particularly highlighted in the open responses when factors such as *support* and *control* were frequently noted. Furthermore, the randomised controlled trial does not enable all interesting variables to be assessed. Human characteristics such as health problems or previous emotional experiences cannot be randomly conferred on people. This means that accidental bias can never be completely excluded. In effect all randomised controlled trials contain some bias because the researcher has chosen the variables that are considered to be important. The postpositivist approach recognises that total objectivity is an unachievable goal.

A further problem encountered in randomised controlled trials is the Hawthorne effect. This was acknowledged by Frigoletto et al. (1995) who suggested that the reduction in caesarean section rate may have occurred because it was this variable which was under investigation. In this current study, it is possible that the midwives, women and obstetricians may have acted differently in the knowledge that they were part of a study. However, this was a pragmatic trial and as such the validity is strengthened. Trials carried out in an unnatural setting are more prone to the Hawthorne effect (Robson 1993). Similarly, the generalizability of the findings is greater in such trials. A manipulation of the environment or management protocols would have resulted in less meaningful findings. For this reason it was reiterated throughout the trial that midwives should manage women's labours according to normal hospital protocol. Local audit data suggests that the Hawthorne effect did not occur in a way that influenced rates of caesarean section. The overall emergency caesarean section rate for the period before during and following the trial was as follows - 1993=11.4%, 1994=13.1%, 1995=12.1%, 1996=13.1% and 1997=12.6%. That being so, the study sample may have differed to the overall population in their knowledge of labour events. Prior to consenting to the trial, most of the participants spent a considerable amount of time (from 20 minutes to 75 minutes) discussing the trial protocol. During this discussion the researcher provided in depth information regarding the normal progress of labour and augmentation, prior to introducing the actual partogram. This was believed necessary to enable the women to fully understand what trial participation would mean to them during labour. Women who were not approached to participate in this trial did not receive this one-to-one information session. This additional information may have contributed to a familiarity with hospital management protocols, maternal expectations and preferences for

certain labour interventions. In reality, the information women receive is variable and also much depends on their own ability to accumulate appropriate information.

The midwives were also 'retrained' in the management of prolonged labour and the use of the partogram through regular trial discussions. As in the World Health Organisation Study (WHO 1994), this may have influenced the study outcomes and reduced the strength of generalizability.

#### ***14.2.4. Choice of action line as study variable***

There is a debate as to whether trials should attempt to assess an active management package as a whole or whether each aspect should be considered separately (Fraser 1993). Active management of labour is not one, but a complex series of interventions and includes selective admission to the delivery suite, early amniotomy, ambulation, continuous support, early use of oxytocin, external auscultation of the fetal heart and selective use of epidural analgesia. With such a variety of management components, an assessment of the whole package would have prevented the determination of which aspect was responsible for a particular effect, for example caesarean section. As stated by Fraser (1993), policy makers would lack essential information as to which elements should be accepted or rejected into clinical practice.

However, the reductionist approach also has its limitations, as can be demonstrated by looking at a previous study (Blanche et al. 1998). This study aimed to assess three different management approaches for women diagnosed as being in prolonged labour. The three trial arms consisted of one group of women who were conservatively managed, one that had amniotomy only and one that received early amniotomy and oxytocin. Although initially it appeared that only one specific aspect of active

management was being explored, the effect on other elements of labour was also great. The women in the early oxytocin arm, for example, were more likely to have a constant support person, would have been continually monitored and had continuous electronic fetal monitoring. Despite the limitations of this approach, however, it was decided that in this current study, only one element was to be explored, the position of the action line being the focus of interest.

#### *14.2.5. Choice of study outcome*

Although the partogram is in widespread use, there is no consensus regarding its most appropriate design. The specific components of the partogram are under evaluated. In particular, little research has been undertaken in the form of randomised controlled trials to assess the efficacy of different placement of the action line. This current study is an important phase in the evaluation of the partogram and the assessment of labour management. Therefore, the main aim of this investigation was to examine the effect on maternity outcome of altering the position of the partogram action line. The main outcomes of interest were caesarean section rate and level of maternal satisfaction. Unlike many previous trials, caesarean section rate was considered the most important obstetric outcome. Earlier trials (O'Driscoll et al. 1969; Franks 1990; Fraser 1992; Thornton 1992; Moldin 1996) have focused on the length of labour and have shown a reduction in labour duration following a management package which advocated early intervention. However, the clinical and maternal relevance of reducing labour by a relatively short period of time (1-2 hours), is uncertain. As there have been no clear advantages highlighted from other trials, in this current study it was anticipated that maternal preferences would be of paramount importance.



Whilst there has been a steady rise in intrapartum studies, most designs have included obstetric outcomes as the primary measure of analysis. Few randomised trials have assessed the maternal perspective. Despite recommendations supporting woman centred care and research into maternal preferences (Department of Health 1993), studies which have assessed maternal views may not be considered sufficient, in their own right, to advance clinical practice. However, as stated in the Charter compiled by the Association for Improvements in the Maternity Services and National Childbirth Trust (1997), social research should be an integral part of clinical research, not an afterthought. It is interesting to note that the most recent review of active management of labour (Impey & Boylan 1999) urges researchers to ‘focus on maternal satisfaction as the primary outcome in randomised trials’ p186. In this current study, the evaluation of maternal views proved to be particularly important in gaining a comprehensive picture of labour events. Despite the difficulties experienced in determining which outcome should influence practice, the researcher believes that the decision to have two primary outcome measures was appropriate. Although statisticians recommend the use of only one primary outcome in research (Campbell & Machin 1993), the complexities of childbirth make many factors important to a positive experience. Using only one primary outcome relies on a minority of people deciding what is most important. The importance should primarily be for the women, not the midwives, obstetricians or the Trust. Women are in the ideal position to analyse the care that is provided (Delbanco 1996). However, receiving information from those in our care is only useful if health professionals listen and act on what they are being told. Although two primary outcomes were chosen, the surrounding and associated factors affecting labour management were also considered. In particular,

the data received from the open questionnaire responses provided a richer understanding of the individual experiences.

#### ***14.2.6. Sample***

Partograms are used to manage women's labours regardless of factors such as the onset of labour, fetal presentation, number of fetuses or parity. However, in this current study only primigravidae in spontaneous labour with a singleton pregnancy and cephalic presentation were included. This study may therefore be limited in that the findings can not be generalised to all labouring women. To have widened the inclusion criteria may have produced more comprehensive findings. However, to have carried out such a study would have required a much larger sample as the various groups would have had to be stratified for randomisation. Additionally, confounding variables would have to be considered, for example the influence of previous labour experiences in multiparous women. From a clinical perspective, reducing the caesarean section rate for primigravidae has potentially important consequences for future pregnancies and therefore should be the main focus of investigation. As stated by O'Driscoll et al. (1993) 'provide a high standard of care and attention first time round and a woman will require little assistance on the next occasion.'(p23). Furthermore, the incidence of prolonged labour is greater for primigravid women. First labours tend to be longer because inefficient uterine action is common and because the genital tract has not stretched before (O'Driscoll 1993). In contrast, inefficient uterine action is a rare occurrence in multigravidae.

#### ***14.2.7. Randomisation***

Simple randomisation was used to allocate women to the various trial arms. Although randomisation was carried out in batches, block randomisation was not used. This meant that there was a potential for an imbalance in numbers in each trial arm. In fact the trial arms did vary in number (2hrs - 315, 3hrs - 302, 4hrs - 311), but fortunately the imbalance was not great. In hindsight, block randomisation should have been used to minimise the risk of imbalances within the sample.

To ensure all women had the same chance of being allocated to any trial arm, randomisation was imperative. Unfortunately, however, it was not possible to use a centrally controlled approach to randomisation, divorced from the clinical setting, due to the resource implications. There was an imbalance in the percentage of women whose cervix was dilated less than 3 cm at randomisation (although not statistically significant), and, although this probably occurred by chance, it introduces potential bias. However, there were more women in the 4 hour arm whose cervix was less than 3 cm at the point of entry to the study. This bias, given the potential for intervention if labours were misdiagnosed, should have worked in the direction of an increase in caesarean section rate and intervention in the 4 hour arm. As this did not occur, it is not believed to be significant. Furthermore, when a comparison was made between women randomised before their progress had reached 3 cm and those whose progress was 3cm or more (Table 11.5.), no statistically significant differences were found in the number of women who crossed the action line.

#### ***14.2.8. Bias***

In randomised controlled trials the researcher should aim to eliminate or at least minimise bias to ensure that the study findings are reliable (Altman 1991). One way of minimising bias is to blind participants and clinicians to the treatment allocation. However, as stated by Fraser (1993), it is difficult and sometimes impossible to achieve blinding of treatment allocation in most trials of active management. This was the case in this current study. If women had been blinded they may have found it difficult to make informed decisions regarding intrapartum factors such as analgesia. Additionally, informed consent would not have been possible for obstetric procedures such as amniotomy or oxytocin administration. The clinicians could not be blinded because pivotal to the study was how they managed the woman's care in relation to the action line. It must be acknowledged, however, that once a treatment group was revealed, the midwives', women's and obstetricians' preferences may have influenced the probability of occurrence of the outcomes being investigated. However, when using the postpositivist approach (Guba 1990) one accepts these external factors, believing that their influences do not compromise the findings. That being so, this study did assess the potential bias introduced by the midwife and the evidence offered reassurance that any preferences of partogram were equally distributed.

Bias may have been introduced through the trial information sheets. As can be seen in appendix 5, the information regarding the two hour action line commented on the caesarean section rate being lower in Dublin where intervention occurs early. This may have seemed the preferable option to those women who did not want a caesarean section and may have influenced their satisfaction in drawing this arm.

Unlike the trial conducted by Frigoletto et al. (1995), in this present study the women in both study groups were managed in the same delivery suite by the same personnel. This study, like others (Lopez-Zeno et al. 1992), could therefore be criticised for the potential introduction of bias created from staff crossover. A major shortcoming of many trials assessing intrapartum care is the similarity between the control and experimental arms (Fraser, Vendetti & Krauss 1998). In this current study, midwives using all three partograms may have altered their management according to the partogram allocation. For example, a midwife who was simultaneously looking after two women, one who had been allocated a two hour partogram and another a four hour partogram, may have automatically managed their care in the same way. This may in fact account for the number of management protocol violations (discussed further in later section 14.2.10). As suggested by Fraser et al. (1998), future trials may need to consider designs incorporating cluster randomisation. This would enable researchers to optimise compliance while minimising contamination. Midwives and obstetricians caring for one group of women only, would prevent cross contamination thereby reducing the incidence of protocol violations. However, in this current study, attempts to minimise bias by the checking of treatment allocations, accounting for each randomisation envelope and regular discussions with staff appeared to be successful.

#### ***14.2.9. Recruitment***

Researchers have used various methods of recruiting women to intrapartum trials, perhaps recognising the ethical dilemma of consenting women in labour. Although some studies have consented women when in active labour (Cardozo & Pearce 1990; Blanche et al. 1998), there are those who believe that the decision to participate

should be made prior to the commencement of labour (Association for Improvements in the Maternity Services & The National Childbirth Trust 1997). For this reason women were recruited when they attended for their ultrasound scan at around twenty weeks gestation, giving them ample time to discuss the trial and consider their options. This was a period in their pregnancy when women received less additional information than at other antenatal visits. In addition, the researcher could be reassured that there was no obvious fetal abnormality prior to discussing the trial.

Although this approach worked fairly well in terms of accessing a large number of women, there were limitations to this approach. Firstly, a considerable number of women ( $n=38$ ) following their scan were upset due to the detection of choroid plexus cysts. It was not believed to be ethical to approach such women even in the knowledge that most cysts have actually disappeared by the time the woman returns for her next scan (Kirwan & Olah 1997). Excluding these women may have been unnecessary, but, time restraints made it impractical to follow these women through their pregnancy to approach them at a later stage. A further problem of approaching women at the scanning visit was that they would consider it an intrusion. For most women the scan visit was a happy occasion and as such many of the women were keen to leave the hospital to show friends and family their photographs. For this reason, being confronted by a researcher after leaving the scan room was not always welcomed. Similarly, those women who had a further clinic appointment did not wish to be delayed any further. As the women were, on the whole, ecstatic following their scan, sometimes the researcher felt that it was deceitful to approach women whilst in such good mood. As suggested by one of the hospital ultrasonographers 'women will agree to anything when they have just been told that they are going to have a healthy baby'.

Approaching women at twenty weeks gestation also meant that many of the women who had agreed to take part in the study were not in fact eligible by the time they entered the hospital in labour. A large proportion of women who had consented to participate were lost to the trial due to needing an induction of labour, elective caesarean sections or having pre term labour. A smaller number of women were lost to fetal abnormalities and malpresentations.

#### ***14.2.10. Protocol Deviations***

A number of women (n= 98) who consented to participate in the trial were not randomised by the midwives on the labour ward. This raises an ethical issue in that these women were denied their choice of participation. One woman was particularly angry at not being randomised as she had spent time discussing the trial with her husband and General Practitioner. To address this issue individual midwives were sent letters during the trial outlining the importance of complying to the trial protocol and maternal wishes. This approach had the desired effect and minimised the number of consented women not randomised in the latter part of the trial.

Some women (n=4) had been randomised to the trial but could not be traced due to the incorrect recording of demographic data. It was disappointing to find that despite trawling through the notes of all potentially eligible women, these four women could not be identified. If the study had been smaller, losing data on these women could have directly influenced the findings.

A number of women (n= 39) crossed the action line but intervention was not initiated. In some cases the women had reached full dilatation when their progress had crossed

the action line and therefore it was inappropriate to intervene. Similarly, some women whose progress crossed the action line were already contracting regularly and therefore a clinical decision was made not to intervene. Additionally, anecdotal evidence from the midwives suggested that it was believed that these women were going to progress without intervention. In some cases this did occur, however in others the delay in intervention simply prolonged the labour. Similarly, some women (n= 72) received intervention prior to reaching the action line despite there being no obvious clinical reason for doing so. These protocol violations, to some extent, may account for the minimal number of intrapartum differences between the trial arms. Like many other studies (Fraser et al. 1998), protocol compliance has been less than satisfactory. In this current study there was no differences in the number of women who received an amniotomy (2hour - 120, 3 hour - 122, 4hour -121) and there was only a small and insignificant difference in the number of women who received a syntocinon infusion (2hour - 144, 3hour - 136, 4 hour - 129). This suggests that midwives and obstetricians preferences played some part in management decisions, regardless of the management or trial protocol.

Some women had their labours incorrectly plotted on the partogram which may have resulted in inappropriate labour management. For example, some women were placed on the partogram prior to being in active labour (as defined in this study) and therefore may have been misdiagnosed as being in prolonged labour. This meant that their progress may have crossed the action line prematurely. However, as discussed in earlier chapters the diagnosis of labour is extremely subjective, therefore, to some extent the midwives were guided by their clinical assessment. If, for example, a woman required analgesia, the midwife may have chosen to commence the partogram



in order to record all intrapartum observations. Similarly, some women were not transferred from the latent phase of the study when they progressed to active labour. This meant that they did not cross the action line at the appropriate time. Fortunately these protocol violations were minimal and not confined to any particular trial arm. However, it does highlight the difficulties of implementing protocols into practice. It was evident from the midwives questioned that some believed the action line to prevent a flexible approach to labour management. This may account for why deviations from the protocol were made.

At the beginning of the trial some midwives appeared confused as to how often vaginal examinations should be performed. Despite receiving verbal and written instructions about the trial, some midwives believed that women should receive vaginal examinations in accordance with the partogram allocated, i.e. women with a 2 hour partogram should receive two hourly vaginal examinations. Midwives said they were particularly influenced by the recommendations of the National Maternity Hospital (O'Driscoll et al. 1993), which several midwives had visited.

On two occasions, at the beginning of the trial, randomisation envelopes were taken randomly from within the box instead of being removed in sequential order. It was apparent that these midwives had misunderstood the randomisation process and had removed the envelopes in a way which they felt achieved the most appropriate method of allocating the women to a trial arm. The researcher reiterated the trial protocol to the midwives concerned and no further problems were encountered.

#### ***14.2.11. Questionnaire***

Many steps have been made to overcome the problems of measuring what is often termed a 'soft' outcome (discussed in methodology chapter) in an attempt to ensure that the findings are a true reflection of the feelings of the women questioned.

As maternal satisfaction was a primary outcome careful consideration went into the tool designed to collect the data. Although it is evident that interviews are the superior method of in-depth data collection (Coolican 1994), questionnaires allowed a large sample to be questioned and a large quantity of data to be produced. This method proved to be acceptable to the women, evident from the healthy response rate (86%). Having developed a relationship with the women in the study gave the researcher confidence that women would respond openly and honestly, thereby enhancing the quality of the data. However, because of the developing relationship with the researcher it is possible that some women did not feel able to give negative comments, although the researcher was not involved in any aspect of clinical care.

In the absence of a reliable theory of maternal satisfaction, the model chosen to underpin the research was that of expectation-fulfilment (Noyes et al. 1974). This model is based on the assumption that a positive attitude to the childbirth experience and care received, results from the women's perceptions that the service/care fulfilled their prior expectations. In this present study the women were questioned about their satisfaction with their labour experience. However, the open responses sometimes related more to women's satisfaction with the service which they had received. This added a further dimension to the study findings by highlighting the important effect that the service has on maternal views. This expectation-fulfilment model has been criticised for several reasons (Avis et al. 1995); firstly, it is difficult to isolate specific

attributes that can be associated with expectations; secondly, there is insufficient empirical support to link expectation-fulfilment with satisfaction; and finally, satisfaction is viewed differently by women when evaluating care. This model has also been criticised for being too narrow, excluding factors that may influence satisfaction outcomes (Avis et al. 1997). However, it has also been suggested that this method of comparing expectations with experience of care to determine satisfaction levels is 'the most obvious method' (Symon 1998). It was certainly evident from the questionnaire responses that women understood how to relate their experiences to this model of evaluation. Furthermore, in maternity care, it has recently been proposed that 'market research' should be introduced to identify expectations and explore consumers' satisfaction and dissatisfaction (Crowley-Murphy 1996). This was not surprising, as women's expectations are developed during pregnancy from many sources, for example, from their communication with other women, reading the literature or even the media. Hallgren et al. (1995) stresses the need to identify individual woman's expectations when planning childbirth education. Yet, there is also a likelihood of disappointment when certain aspects of the experience do not go as planned (Creasy 1997). In this current study this was evident from some of the open responses, for example, some women were not expecting 'after pains' and therefore voiced their disappointment having experienced them. Although the expectation-fulfilment model was believed appropriate for this study, to have questioned women before and after they had delivered their babies may have increased the reliability of the findings. It may have been difficult for women to remember their expectations once the experience was over. However, in this study women's views were assessed as part of a randomised control trial and therefore differences between the groups were as important as individual intrapartum experiences. There is no evidence to suggest that

women in each trial arm were different in their ability to remember or forget their previous expectations.

Having a questionnaire which combined structure with openness provided complementary data and more meaningful findings. Satisfaction questionnaires have previously been criticised for trivialising the views of women by placing the responses into neat numerical packages (Roberts 1992). While quantitative methods have their place in assessing satisfaction, on their own they may not be sufficient to encompass all aspects of the experience. Having structured questions at the beginning of the questionnaire may have influenced the responses to the open question. For example, some women may have discussed their control in labour simply because they were previously questioned about this aspect. However, the women also commented on aspects of their experience on which they were not questioned, for example, postnatal debriefing.

Qualitative trials which incorporate a large sample have their advantages in terms of validity and reliability. In this current study, the open responses added a further dimension to the debate surrounding prolonged labour. To some extent, this data made it possible to explore the individual feelings of a large group of women. However, the size of the sample may also have detracted from the individual experience. For example, in this present study it would have been impractical to produce a personal profile on all women. An exploration of the participants' social and cultural environment would have added a further perspective to the study.

Another problem of the method of data collection used was the fact that it did not allow for the clarification of information supplied by the respondent. It was therefore frustrating, for example, to discover that a woman was satisfied with the 2 hour action line and not to be able to question why she felt this way. Questions which were generated from the responses could therefore not be answered. In particular, questions surrounding the acceptability of intervention were not explored. In hindsight, an in depth interview with a sub group of representative women across the 3 trial arms, may have been informative. As stated by Hodnett (1997), a randomised trial tells one what happened, but not why it happened.

It may be, as stated by Hannah (1999) when reviewing this study, “Perhaps it is time we relied more on the results of these systematic evaluations of women’s views of their birth experiences, using structured questionnaires, to determine how women really feel about their care during labor and birth, rather than assuming that more intervention is bad. p97” On the other hand, it may be that the design of this current study was too structured and therefore may have restricted the answers received.

The questionnaires were administered to only a sub group of all randomised women as it was believed that the first 12 months would provide a more than adequate sample to answer the question. But on reflection, it may have been preferable to have questioned the whole sample. This would have enabled a more definitive exploration of the effect of the various interventions on measures of maternal satisfaction.

As conclusive evidence was not found from the literature to suggest the best time to administer the questionnaires they were given to all participating women on their

second postnatal day. This enabled women who had a difficult labour/delivery to have recovered somewhat, yet maximised the likelihood of recall accuracy. It is well documented (Simkin 1992) that women have extremely clear memories of the birth but that perceptions and memory of events are notoriously selective and subjective (Atkinson et al. 1996).

The study is limited, however, as the women were only questioned on one occasion, in the immediate postnatal period. This meant that feelings which may be related to long term postnatal outcomes were not explored. Maternity care may have long-term effects on bonding, mental and physical health and family relationships (Flint 1986) and therefore a long-term evaluation would have been invaluable. However, for the purpose of this study, the main focus was on the differences between the three groups of women prior to transfer into the community. Although long term follow up may have been beneficial to the study, limited resources made this task not feasible. Previous long-term studies (Abitbol et al. 1996) have shown that prolonged labour and delivery have permanent effects on the female body in terms of both physical and psychological problems.

### **14.3. Interpretation of the Findings**

#### ***14.3.1. Primary outcomes***

The uniqueness of this study lies in the choice of outcomes, the focus on one specific labour component and unexpected findings which did not mirror other studies. As previously reported (Impey & Boylan 1999) the difficulty of comparing trials (particularly for the purpose of meta-analysis) lies in the fact that the methodological qualities vary (discussed previously) and individual protocols differ considerably. The

varying definitions of normal labour within previous studies, for example, makes it difficult to compare the eligibility criteria. In a review of twelve trials carried out by Fraser et al. (1998), for example, the cervical dilatation on admission varied from 2.7 cm (Labrecque, Brisson-Carroll, Fraser & Plourde 1994) to 5.2 cm (Verkuyt, Marks, Munro & Bouwmeester 1986). Additionally, some trials have randomised women only when progress has deviated from the considered norm (Hemminiki et al. 1985; Bidgood & Steer 1987); whereas others (Cohen et al. 1987; Hunter 1993; Lopez-Zeno et al. 1992; Breart et al. 1992, Frigoletto et al. 1995; Cammu & Van Eeckhout) adopted an approach used in this current study whereby women were randomised in normal spontaneous labour. Furthermore, the timing of intervention in the various trial arms assessed in previous studies, ranges from thirty minutes (Cohen et al. 1987) to eight hours (Bidgood & Steer 1987). The type and severity of intervention also differs. In this current study, like others (Frigoletto et al. 1995) amniotomy was performed only if clinically indicated, however, in other trials, for example O'Driscoll and Meagher (1986) amniotomy is performed routinely as part of the admission procedure. The oxytocin regimen also differed between trials with some adhering to a strict high dose regimen (Bidgood & Steer 1987) while others adopted a more clinically driven approach (Frigoletto et al. 1995) as was the case in this current study. The number of vaginal examinations performed also differed between trials as discussed in earlier chapters.

The main similarity, with other studies, lies in the intention to explore labour management issues which surround 'early versus late intervention'. The use of different action lines to trigger augmentation at three different intervals is, however, currently unique. Furthermore, despite the limitations of this study (as discussed in

previous chapters), the emphasis on the individual woman makes this trial superior to many others.

One way that this study appears to differ from others rests in the primary outcome findings. It appears that the 4 hour partogram could reduce both the amount of intervention and the number of caesarean sections performed. This contradicts other studies which have suggested that the optimum time to augment labour is within two hours of deviating from the norm (Hunter et al. 1983; Boylan 1989). A large retrospective study (Saunders & Spiby 1990, plus Spiby, personal communication) discovered that augmentation within 2 hours of the first evidence of delay was associated with a ten percent caesarean section rate, compared with one of twenty eight percent in women treated after a longer interval ( $p < 0.01$ ). Although these findings could be criticised for retrospective bias, the possibility that delay is detrimental to outcome is entertained by many obstetricians and midwives. In particular, the Dublin group (O'Driscoll et al. 1993) would recommend that there is an optimum time for augmentation which is within 1-2 hours of delay. According to the obstetricians at the National Maternity Hospital, failing to intervene at this point may have negative consequences for obstetric outcomes (Foley, personal communication). Others, however have shown that waiting an additional hour before starting an oxytocin infusion can lead to a reduction in caesarean section rate and number of augmentations (Arulkumaran, Michelsen, Ingemarsson & Ratnam 1987). This may account for the lower caesarean section rate in the four hour arm in this current study. However, this study had only around 20% power to detect a difference in caesarean section rate of 3%. Therefore, the impact of various partogram action lines on this outcome remains unanswered. It is interesting to note, however, that



these findings conform to those from the original assessment of the 4hour action line as reported by Philpott and Castle (1972a). Similarly, they support the more recent, although criticised, evaluation of the partogram by the World Health Organisation (WHO 1994). This may suggest that an active approach is unnecessary. Cohen et al. (1987) also arrived at this conclusion when they discovered that the caesarean section rates were similar in the two trial arms despite one group being managed 'aggressively'. In their study, the experimental group had an oxytocin infusion within only thirty minutes of admission and the control group only if they had arrest of dilatation lasting longer than two hours. Both trial arms therefore appeared to be managed more actively than the women in this current study. Data from eighty four free-standing birth centres showed that a caesarean section rate of 4% could be maintained simply by leaving most women alone (Rooks, Weatherby & Ernst 1989). Although it could be argued that this data was derived from a specifically selected population, a similar eligibility criteria was used to that in this current study. It appears from the previous studies that obstetricians, on the whole, always choose to do something rather than nothing (Goer 1995). This fact is highlighted by the number of reported trials which have assessed different types of intervention (see literature review). Interestingly, out of the randomised trials which attempted to reduce the caesarean section rate for dystocia only two compared active management to an approach which offered supportive rather than interventive care (Read et al. 1981; Blanche et al. 1998). Both of these studies were methodologically flawed. In the first of these studies (Read et al. 1981) only 14 women were included therefore conclusions could not be drawn. In the second study (Blanche et al. 1998) women were allowed an epidural which reduced their ability to mobilise and probably increased the intensity of the support received. Furthermore, the 'conservative' group

actually received as much intervention as the 'amniotomy' and 'amniotomy and syntocinon' groups, albeit at a later stage. A further small randomized controlled trial (Bidgood & Steer 1987) of women making poor progress in labour found that those who had oxytocin deferred for eight hours had a higher caesarean section rate (45%) than those who were given oxytocin according to the Dublin regimen (26%). However, seven of the nineteen women in this latter group suffered uterine hyperstimulation. In the current study it was evident from the open responses (discussed later) that many women would not have considered it to be acceptable to defer intervention for a duration of eight hours. There were no reported incidents of hyperstimulation in this current study, perhaps because the oxytocin regimen is guided primarily by the clinical observations as opposed to written instruction. The latest meta-analysis of 12 randomised trials which have assessed the effects of early augmentation in nulliparous women (Fraser et al. 1998) found that there was inadequate support for the hypothesis that early augmentation reduces the risk of caesarean and therefore it does not appear to be more beneficial than a conservative approach. Interestingly, this meta-analysis did not include maternal satisfaction as an outcome. Three of the included studies (Hemminki et al. 1985; Labrecque et al. 1994; Breart, Mlika-Cabane & Kaminski 1992) assessed the women's perceptions of pain during labour. However, it appears that only a superficial assessment was made therefore no firm conclusions can be drawn from the findings. The assessments were made from the findings of a structured questionnaire which did not encourage the women to respond freely. Furthermore, only 'pain' was assessed and other important variables which may relate to the childbirth experience were ignored.

This current study found that the 2 hour partogram, appears to have obvious benefits in terms of psychological outcome. It may therefore be, as suggested by O'Driscoll et al. (1973) that many women do not wish to have long labours, believing that the intervention will in fact reduce the duration. Women in the 2hour arm were more satisfied with their labour experience despite receiving more intervention. These findings contradict other studies which have shown the negative effects of obstetric intervention (Simkin 1986; Crowther et al. 1989). In Simkins survey of 159 mothers, 76% said that oxytocin infusions were stressful and 46% said the same of amniotomy. Similarly, in the study by Crowther et al. (1989) 80% said labour was more painful following augmentation and half said they would not have it again. However, although these studies provide some useful information, there is insufficient evidence from randomised controlled trials to corroborate these findings.

In fact, the most recent evidence from randomised controlled trials support the findings of this current study. For example, the findings supports an earlier randomised study (Blanche et al. 1998) which found that women in dysfunctional labour preferred active management. This trial, which used the Labour Agency Scale (Hodnett & Simmons-Tropea 1987) to assess women's perception of control in prolonged labour, found no evidence to suggest that an increase in intervention led to a decrease in control. In fact the women who were found to perceive themselves as in the greatest control were those whose management involved artificial rupture of the membranes, intravenous oxytocin, continuous monitoring and more caesarean sections (although not statistically significant). Furthermore, a recent evaluation of women's views regarding induction of labour versus expectant management for premature rupture of membranes at term (Hodnett et al. 1997) also showed a preference for early intervention.

However, as noted by Purkiss (1998), high intervention rates may fail to recognise the humane factors that are necessary for many women during childbirth. For this reason, many health professionals may have predicted that women with the most intervention (i.e. 2 hour partogram) would have been the least satisfied because of the 'medicalisation' of the experience. These findings suggest that we can not always be sure of what is important to all women. Churchill (1995) suggested that health professionals view success in terms of low perinatal and maternal mortality and morbidity rates, whereas women value their success in terms of sensitive, personalised and individual care combined with a healthy baby. The women in the 2hour arm may have perceived that the additional midwifery contact that they received which accompanies intervention, contributed to their satisfaction. Additionally, it may be that women have become absorbed in a culture whereby they believe that the midwife should be physically caring for her. It will be interesting to discover the findings of an ongoing randomised controlled trial which is currently assessing labouring in a pool as an alternative intervention for prolonged labour (Cluett, Personal communication). This less invasive 'intervention' will also include continuous midwifery input.

Intervention usually runs parallel to fetal and maternal monitoring which perhaps makes some women feel better tended to and more secure. Some women may in fact prefer a 'medically managed birth' and find relief from someone else taking charge of the situation (Stumpf 1993). Furthermore, some women may have felt more satisfied following intervention because they believed that appropriate action had been taken for the benefit of themselves or their baby. These women may have felt reassured because the intervention, in their minds, had contributed to a positive outcome, i.e. a healthy baby. Kitzinger (1990) disagrees with these arguments, suggesting that the

active management approach has a hidden agenda. In Kitzinger's opinion the medicalization of birth denies and suppresses female sexuality which obstetricians perceive to be dangerous, threatening and disruptive. In her view the greatest obstacle in childbirth is not the intervention but the clock which triggers management. Anecdotal evidence suggests that perhaps to some extent Kitzinger is right. Midwives and obstetricians appear to have become obsessed with the duration of labour, the timing of interventions and the quick delivery of a healthy baby. Prolonged labour has been reported to increase maternal and fetal morbidity and mortality, particularly in the developing countries (WHO 1994). Several further reasons have been offered to suggest why a reduction in labour duration is necessary, for example to assist in the planning of staff rotas (O'Driscoll & Meagher 1986), and to guarantee good infant outcome and therefore protect against being sued (Rosen & Thomas 1989). Some of these ideas may be portrayed to the women who also appear to be caught up in an environment where time is of the essence. Factors such as the media's portrayal of childbirth situations may contribute further to reinforcing these beliefs.

It was interesting to note that the midwives who preferred the two hour action line were those who had been qualified the longest. It may be that these midwives trained and practised midwifery at the height of medicalisation and therefore feel confident that early intervention is the appropriate management. A contributing factor may be that many of these midwives practised prior to the introduction of medical technology and have seen the improvements in maternal and perinatal morbidity and mortality often associated with such interventions. On the other hand, the more recently qualified midwives have come into practice during the development of women-centred care. Many of the midwives questioned were educated on the long programmes for

non nurses and therefore trained in a culture of normality which does not 'pathologise' childbirth. Furthermore, more recently qualified midwives are taught and encouraged to critically analyse midwifery practice and therefore may not accept interventionist practices.

The 3 hour partogram offers no clear benefit in terms of either clinical or psychological outcome and therefore can not be recommended. One explanation for the adverse data produced from this partogram could be that the placement of this action line led to indecisive management i.e. neither aggressive or conservative. This hypothesis equates to that previously suggested by Goer (1995) who suggested that if professionals believe active management works and convince the women of this, the placebo effect and their bias will make it a self-fulfilling prophecy. In this current study the women knew that the three hour partogram was standard practice and because it was being studied may have believed that it had few benefits to offer. Research is often viewed as a tool for change (Lavender 1999) therefore some women may have believed that one of the other two partograms (which were not currently in use) would prove to be the most beneficial. Additionally, because the three hour partogram was the hospital's norm, perhaps midwives and obstetricians felt that cases managed using this chart were observed less rigorously. Some studies have shown dramatic decreases in caesarean section rates when management has been observed as part of a trial ( Lopez-Zeno et al. 1992; Rothman 1993), suggesting that the caesarean section rate may be more of a product of the management of the obstetrician [and midwife] than the management of labour (Goer 1995). An alternative explanation is that the observed difference in caesarean section rates is a chance finding. In view of the fact that the use of the 3hour partogram was the study hospital's normal

management meant that a change in practice was imperative for the potential well being of the women.

### ***14.3.2. Interesting Secondary outcomes***

#### ***14.3.2.1. Obstetric***

This study produced some interesting and unexpected findings amongst the secondary outcomes.

Firstly, it was surprising to discover that in an uncomplicated primigravid population the total number of women whose labour was diagnosed as being prolonged was 44% (ranging from 52% in the 2hour arm to 38% in the 4hour arm). This was similar to that reported by the World Health Organisation (1994), perhaps suggesting that there are inherent problems with our 'normal' clinical definitions and practice. One explanation identified by O'Driscoll (1993) is that labours may have been incorrectly diagnosed. This would lead to progress crossing the action line prematurely and unnecessary intervention being used. Although O'Driscoll doesn't acknowledge a latent phase, Olah and Neilson (1994) suggest that by carefully assessing the state of the cervix in order to diagnose labour, O'Driscoll is dealing with primigravidae in the active phase of labour, the majority of whom would be expected to deliver spontaneously. One hundred and eighty eight women (20.3%) in this present study were in fact randomised when the cervix was less than 3 cm dilated. Although these women could have been considered ineligible and therefore excluded, this being a pragmatic trial, the midwives diagnosis of labour was considered important. As can be seen in table 11.5., there were more women who were admitted when their cervixes were 3cm dilated and their progress crossed the action line in the 2 hour arm than in the other two arms. When the 2 and 4 hour arms were compared, as expected, the

findings were significantly different ( $p=0.006$ ). Interestingly, the dilatation of the cervix at randomisation, in this study, did not appear to have influenced whether or not labour progress crossed the action line (Table 11.6.). This suggests that the midwives' clinical judgement may be more accurate than protocols in diagnosing labour. This is an area for future research

Another explanation for this high proportion of women crossing the action line is that the slope of labour progression, for Caucasian women in the late 1990's, may in fact be different to that defined by Philpott for African women (Philpott & Castle 1972a) in the 1970's. One obvious difference between these populations is the angle of inclination of the pelvic brim (Bennett & Brown 1993). As discussed previously, there has been no formal assessment of labour progress in relation to the partogram on a Caucasian population

A steady increase in birth weight, coupled with the liberal use of epidurals, may offer further explanations of why a physiological labour, particularly for primigravid women, may progress more slowly than previously reported (WHO 1994). Most of the research which contributed to the development and assessment of the partogram occurred in the 1980's at a time when there was a lower mean birth weight, 10<sup>th</sup> and 90<sup>th</sup> percentile (Butler & Bonham 1963; Chamberlain, Chamberlain, Howlett & Claireaux 1975; Alberman 1991). Furthermore, since the 1980's the number of births weighing 3,500 g or more has also steadily increased (Alberman 1991). In Scotland, for example, 34 per cent of births in 1975 weighed 3,500g or more compared with 41 percent in 1991 (Power 1995). However, as highlighted by Impey and Boylan (1999), babies who delivered at the National Maternity Hospital tend to be large



(mean birth weight 3.51kg at term), yet the majority of women continue to deliver vaginally in less than twelve hours. This mean birth weight is not dissimilar to that of the study sample (3.4kg). Further studies also suggest that birth weight does not influence prolonged labour (Sokol, Rosen & Bottoms 1982; Turner, Webb & Gordon 1982).

Cartmill and Thornton (1992) hypothesised that the steepness of the graphic presentation of cervical dilatation affects an obstetrician's perception of the labour progress and thus influences decision making. After recognising the potential impact of Cartmill and Thornton's theory on clinical management, Tay and Yong (1996) decided to test their hypothesis. In their prospective study each partogram design was, in turn, used to manage women's labours, in a study period of two consecutive months. Partograms A, B and C showed a progressively flatter steepness of the curve of labour progression. Nine hundred and ninety women with a singleton pregnancy who presented in spontaneous labour were included in the study. The main study findings were that there was an increase in oxytocin usage in graph C (flattest). Group B and C also showed an increase in 'ominous fetal heart rate pattern' and more depressed Apgar scores at one and five minutes. This study concludes that partograms displaying a flat graph were more often considered to have a slow progress of labour, thus providing some evidence to suggest that the visual display of the chart can also influence decision making. Although this study looked only at one progress line, one could hypothesise that the visual display of the action line may also affect decision making and therefore clinical outcome. In this current study the women's views may also have been influenced by observing the three partograms prior to consent and randomisation.

The number of women, in this study, diagnosed as being in prolonged labour, may in fact highlight the difficulties of defining normality. The timing of intervention is dependent on an initial correct diagnosis of labour and the rapid identification of abnormal progress. However, as mentioned earlier, although practitioners can agree on the management of abnormalities such as placenta praevia, it is not so easy to achieve a consensus for the management of prolonged labour, particularly in the absence of fetal or maternal complications (Downe 1994). The midwives who participated in this study confirmed this view when they wrote about the need for more flexibility, stressing the necessity for a less restrictive, more individualised approach to labour management.

The original intention of active management was to prevent prolonged labour (O'Driscoll, Jackson & Gallagher 1969), and to some extent it appears to be successful (Fraser et al. 1998). However, unlike previous studies (for example, Frigoletto 1995) the more active approach to the management of prolonged labour in this study did not in fact reduce the randomisation to delivery interval. It may be as suggested by Hannah (1999) that the greater use of epidural analgesia in the 2 hour group (38%) versus the 4 hour group (32.6%) resulted in a prolongation of labour, negating the benefits of amniotomy, oxytocin, or both. As can be seen in table 11.7., the study participants who received an epidural had a longer randomisation to delivery to those who used alternative analgesia ( $p=0.0004$ ). However, Rogers et al. (1997), in their randomised study of 405 women, found that those women undergoing active management had shorter labours than those in the control. These differences persisted despite the use of epidural analgesia. In fact, those who had their labour actively

managed and received an epidural had the first stage of labour significantly shortened by an average of 2 hours.

The median number of vaginal examinations in this study was four in each of the three trial arms. This was a surprise finding as it may be considered that more assessments would be made in the later intervention arm. The similarity in vaginal examinations was probably due to the fact that four hourly examinations were ordered for all women until prolonged labour was suspected or diagnosed. The fact that there was no significant difference in duration of labour between the groups offers a further explanation as to why the assessments were comparable. Although it has been reported that febrile morbidity is reduced by active management (Fraser et al. 1998) and that this may be attributed to fewer vaginal examinations (Impey & Boylan 1999), there was no evidence to confirm this in this current study. The mean number of vaginal examinations in the National Maternity hospital (3.7) is similar to that of the study hospital however the frequency with which they are carried out is greater. This similarity in mean number of vaginal examinations is probably due to the shorter duration of labour of women who attend the National Maternity Hospital. Women may want regular reassurance that progress is being made, however others may consider it an invasive, uncomfortable and unwanted procedure. This is an area which needs to be explored further.

Some of the midwives questioned were concerned that later intervention may result in inefficient uterine action with a resulting postpartum haemorrhage. However the study results indicated that in fact there were more women in the 2 hour (n=39) and 3 hour (n=39) arm that had a blood loss more than 500 mls than the 4 hour arm (n=30),

although no statistically significant differences were found. Furthermore, the number of women who received a blood transfusion in each trial arm was similar (2hr - 5, 3hr - 6, 4hr - 4), and probably a more accurate clinical indicator of morbidity. The fact that labour duration was similar in each group may account for these similarities. The amount of blood loss, number of transfusions and need for additional oxytocic drugs is consistent with the number of caesarean sections within each trial arm, a factor which has previously been reported (Duthie, Ghosh, Ng & Ho 1992).

#### ***14.3.2.2. Neonatal***

There is insufficient evidence from previous trials to suggest that active management has an adverse effect on the neonate. Those who are sceptical of this form of management (Goer 1995) have highlighted the neonatal deaths caused through the improper use of oxytocin (Turner et al. 1988). Similarly, it has been suggested that the Dublin doctors 'hang' active management with their own evidence (Goer 1995). In a study conducted by MacDonald et al. (1985), in 19 out of 24 longer labours that resulted in newborn seizures, oxytocin was used.

Although in this current study data were collected on neonatal outcomes, to adequately assess perinatal mortality and morbidity would have required a very large sample of women. Like previous studies Apgar scores (Bottoms et al. 1987; Sheehan 1987), cord blood gas values (Lopez-Zeno et al. 1995) and number of admissions to the special care baby unit (Blanche et al. 1998) were recorded. No significant differences were found between the three trial arms. Furthermore, no trends in the data could be identified. The inadequate sample size may have prevented differences being detected. However, meta-analysis has shown that Apgar scores, special care

baby unit admissions and neonatal neurological abnormalities are not affected by active management of labour (Fraser et al. 1998). Similarly, early use of oxytocin has not been associated with negative neonatal outcomes (Thorp, Boylan, Parisi & Heslin 1988; Cahill, Boylan & O’Herlihy 1992). Therefore, perhaps the timing of intervention, as outlined in this current study, also had no effect on neonatal morbidity and mortality. There were no babies who died in the study and the 2 hour arm provided no evidence to suggest that earlier intervention negatively affected neonatal outcomes.

#### ***14.3.2.3. Maternal***

As mentioned throughout previous chapters, maternal views were pivotal to the study findings and therefore played an important role in defining future practice. The women in this study were asked to comment on what factors they believed contributed to a positive experience of labour. Although their own particular birth conditions may have influenced their responses, they were not always directly related to their own labour experience. For example, a woman may have identified the need for effective pain relief but she may or may not have received it. This tended to support the fact that many women enter labour with particular expectations of standards of care. These may or may not have been met, but the women, post delivery, still consider them to be important. This also may account for the fact that, with regard to the open responses, there were few differences between the three trial arms. The fact that the women often wrote about their experiences in relation to their expectations supported the belief that the *expectation-fulfilment model* used to design the questionnaire was appropriate.

Support by midwives was frequently commented upon, both negatively and positively. The majority of comments were favourable and the women used the questionnaire as an opportunity to highlight and praise individual midwives. The women were satisfied overall, but most questionnaires did identify that certain elements of the women's labours may have been improved. This, supports work carried out by Waldenstrom et al. (1996) who concluded that both positive and negative feelings can coexist.

If the women who were allocated the 2 hour action line received more support due to an increase in intervention, then this may have contributed to their more positive responses to the structured questions. In previous evaluations of a package of active management it is the effect of constant support in labour which appears to herald the most convincing evidence (Hodnett 1997).

Coupled with midwifery support, the presence of a partner was welcomed, yet the data suggested that this support presented itself in many guises as previously reported (Lavender 1997). The help given by the partner stemmed from his mere presence, his verbal encouragement or his active involvement. Support was always mentioned positively by the women, regardless of the form it took.

Many women in this study acknowledged the importance of contributing to making decisions about their labour management, a factor which has previously been associated with a positive experience of labour (Davenport-Slack & Boylan 1974). Also, the Audit commission - First Class Delivery (1997) recently highlighted that women's individual requirements can only be met if they are fully involved in decision making about their labour management. If we accept these points of view, then the

logical conclusion is to assume that women who decided to participate in the study have had a somewhat better experience than normal.

In this study, matters of communication, discussed in the literature by Kirkham (1989), were found to be an issue. Women identified the importance of information, but, did not always feel that they had sought or received it appropriately. The women, who were all primigravidae, commented on the particular lack of information to prepare them for the second stage. Although this aspect of childbirth may be difficult to prepare women for realistically, it does offer a challenge to antenatal educators. It has been reported (Mckay, Barrow & Roberts 1990; Hillan 1992) that women require more realistic information than is often provided. Over the last decade, the issues of choice and informed consent have predominated in the midwifery press, with the policy agenda for maternity care prioritising 'woman-centred' services (Welsh Office 1991; Department of Health 1993). Pivotal to this approach is the provision of appropriate information on which women can base their childbirth decisions. However, supplying women with information which meets their individual needs is not clear cut. Various methods are used in maternity units to disseminate information, namely, education classes, literature, videos and verbal communication. Maternal views on the suitability of this information is inconclusive.

In the postnatal period some women felt deserted by their midwives despite the reported benefits of postnatal debriefing (Charles & Curtis 1994; Ralph & Alexander 1994). This is an issue which needed to be urgently addressed if women are to receive the psychological support they deserve. Furthermore, this process may have the potential to diffuse situations where women's expectations have not been fulfilled and

minimise complaints and litigation. In a large scale survey carried out by Symon (1998) it was reported that an increase in awareness and expectations was largely responsible for an apparent increase in litigation. A randomised controlled trial of postnatal debriefing (Lavender & Walkinshaw 1999) was triggered by the responses made during this study. This study highlighted the significant benefit of providing a debriefing service for women in the postnatal period. These findings have now led to the implementation of a psychological care programme in the study hospital which is currently being audited.

The data support the view of others (Hodnett & Simmons-Tropea 1987) that control is a particularly important element for women in labour, and for some, it is the most important variable of a satisfying childbirth experience (Humenick & Bugen, 1981). Some writers (Oakley 1980; Graham & Oakley 1991; Kitzinger 1980), argue that loss of control is due to the disempowerment of women who strive for normality yet are faced with medicalisation. There was no supporting evidence from this trial that an increase in intervention lead to a lack of control. Previous research has shown that women's views about labour management are clearly related to the procedures they experienced (Jacoby 1987), high obstetric intervention having a direct relationship with maternal dissatisfaction (Brown & Lumley 1994). However, this study offers some support to another randomised controlled trial carried out by members of the same team (Blanche et al. 1998), which discovered that those women who perceived themselves as in the greatest control were those whose management involved the most intervention. Data confirms that the women with intervention are less satisfied than those without (Table 12.12. and 12.13.) However, when intervention did occur, women were more satisfied if it occurred earlier (Tables 12.14.-12.16.). This suggests



that the expectation of intervention and the perception of its appropriateness may directly influence women's levels of satisfaction. Views expressed by the women in this study could be seen to challenge the conventional wisdom that most women perceive obstetric and midwifery intervention as negative. It supports the view that health care professionals and even interested lay groups do not necessarily 'know' what women want. A further example of this was given by the doctors of the National Maternity Hospitals who were 'surprised' when one study (Murphy, Grieg, Garcia & Grant 1986) revealed that women preferred vaginal to rectal examinations to assess labour progress (Goer 1995). Like many practices in obstetrics and midwifery, women's views are very seldom sought.

The evidence suggested that the women welcomed the opportunity to participate in research. However, the research design was one in which informed choice was emphasised. In addition to written information, the trial participants were given an opportunity to discuss the trial at length with a research midwife. Women were not encouraged to make a decision at this point, instead they were given from 20 weeks gestation until the time of delivery to make a decision. This helped women to feel comfortable about refusing to participate (Robinson 1995). The aspect about participation in a trial needs further investigation because it may be that women's awareness of evidence based practice may in fact provide them with reassurance about the care they would receive in labour.

The findings of the midwives questionnaires appeared to reflect the uncertainties of labour management which is highlighted in the literature. The midwives questioned wanted autonomy, yet to a large extent they also welcomed the prescribed guidelines.

This may be because they were influenced by their working environment, labour management being largely directed by protocols. Although the study hospital did not adopt an active management package of care as outlined by O'Driscoll et al. (1973), the protocol did advocate action line triggered intervention. Midwives working in a setting which advocated a more conservative approach may have had different opinions. This study has highlighted the need for maternity units to review their existing guidelines, identify areas that are not based on evidence and encourage midwives to work autonomously. Women deserve to know which practices are based on research and then should be assisted to make decisions based on the findings.

#### **14.4. Implications for future Practice**

The primary research question for this study was: *Are there differences in the caesarean section rate and level of maternal satisfaction when managing labouring primigravid women using a 2hour, 3hour or 4 hour action line?* It was decided that the answers to these questions would guide clinical practice. The partogram action line with the lowest caesarean section rate and the highest maternal satisfaction would be implemented. However, the fact that women preferred the 2 hour action line, despite having the most intervention and having a caesarean section rate higher than the 4 hour arm (although not statistically significant), made the decision less straight forward. On discovering these findings the researcher and clinicians were left with an important dilemma - on which outcome should future practice be based, caesarean section or maternal satisfaction? This question was difficult to answer because at the study outset both outcomes were considered to be of equal importance.

If the obstetric outcome was accepted, this would have ignored the respondents views, thereby failing those women who do not see intervention as a contributor to a negative birth experience. However, if the caesarean section rate was ignored, the potential increase in morbidity had to be considered. The inevitable impact on resources was another factor which could not be ignored in the current financial climate. Caesarean sections are viewed as costly because of the impact on short term resources, but, the cost of long term morbidity is more difficult to assess. Furthermore, although management choice should reflect the individual woman's views, women require information, preferably based on evidence, to guide their decisions.

Following dissemination of the study's findings local changes have been made to clinical protocols. The three hour partogram, appears to provide no obstetric or psychological benefit and therefore cannot be recommended. As such, the study hospital has now withdrawn this partogram.

Following a formal discussion with midwives and obstetricians, the study hospital now uses a partogram with a two hour action line while the evaluation continues. The two hour line was preferred to the four hour line in view of the fact that the difference in caesarean section rate between these two arms was not statistically significant. However, in light of the pressures to reduce caesarean section (Henderson 1996), it is questionable whether other maternity hospitals would have reached the same decision.

The findings of this study have the potential to make a huge impact on the future care of labouring women. The position of the partogram action line appears to have an

impact on both caesarean section rate and maternal satisfaction. However, although caesarean section is a primary outcome in this study it must be remembered that active management of labour was introduced to shorten labours and a reduction of caesarean section was considered an unforeseen but welcome benefit (O'Herlihy 1993). The rate of caesarean section is of huge interest to maternity care providers, primarily because of the maternal morbidity but also because of the resource implications. A woman's mode of delivery not only effects her recovery in the immediate postnatal period but also impinges on future pregnancies.

The issue of woman's choice has predominated in the midwifery press over the last decade and is repeatedly echoed through consumer surveys. It has been reported that women are now beginning to request caesarean sections, often considering them to be a favourable option (Jackson & Irvine 1998). In their study of 276 women, Jackson and Irvine noted that of those women who underwent an elective caesarean section, maternal request was the primary indication in 38% of cases. A further study 102 women (Mould, Chong & Spencer 1996), showed that a caesarean section no longer appears to be an unacceptable mode of delivery to women. If women are adopting this belief then perhaps the findings of this present study are not so surprising. However, a survey of 830 postnatal women in Dublin (Geary et al. 1997) found that only 1.5% had hoped for a caesarean section although 6.3% had received one. More recently, it has been reported that the National Maternity hospital, which has previously been envied for its low caesarean section rate, had a rate of 11.6% for nulliparous women at term in 1997 (Impey & Boylan 1999). One of the factors that they attribute this to is 'changing maternal attitudes'. However, the caesarean section rate for nulliparous with a cephalic presentation at term with a spontaneous labour

remains at only 4.8%. In comparison the mean rate for the same group of women in the study hospital was a less impressive 11.2%. A further study of 308 women in eight participating hospitals (Churchill 1997) found that one in five women had asked for a caesarean section. This represented a significant difference in the data since 1991/2 when only one in eight women said that they had asked to have the operation. A survey of consultants' opinions on why the caesarean section rate is rising also identified maternal request as one of the main reasons (Francome 1994).

Local data (1998) has also shown that almost half of all women, when faced with a post term pregnancy, choose an interventionist approach (i.e. induction of labour) as opposed to conservative management.

It may be that the advancements in medical technology have encouraged women to expect a favourable childbirth outcome. As mortality and morbidity rates have reduced, women may have forgotten the potential dangers of an operative procedure. Alternatively, prior to a caesarean section, some women may not be adequately informed about postnatal complications and discomfort.

Although the qualitative findings of this study presents clearly defined themes, the data suggests that in reality, control, pain, information, decision making and support inter relate. It is therefore important that midwives assess all these aspects to promote a positive experience for individual woman. Each woman will measure her experience of labour differently and therefore it is important that planned individualised care is not neglected. By listening to and acting on the views of women, midwives can assist in promoting odds which are stacked in favour of a fulfilling experience. This can be

achieved, for example, by identifying areas for further research, incorporating findings into care protocols and by communication and collaboration with other health professionals, notably obstetricians and obviously ongoing communication with the women themselves.

However, it may be that individualised care does not allow for a rigid policy of care. In the 19<sup>th</sup> century professionals attempted to achieve uniformity among labouring women (Merriman 1814; Maunsell 1871; Meadows 1871). Their recommendation, that labour should be no longer than 24 hours, was changed in 1970 to 12 hours with little evidence to support this recommendation (Savage 1986). Many women today appear convinced that technology and intervention are essential to guarantee the birth of a healthy baby. But it could be that the patriarchal power of the obstetrician is valued, respected and accepted by society making it difficult for women to reject intervention (Davis-Floyd 1987). The midwives' responses also seemed to suggest that they too found it difficult to reject aspects of labour management which, to some extent were enforced by obstetricians.

A further concern is that professionals may be trying too hard to 'manage' labour. The term 'management' has recently fallen into disrepute, taken by many to indicate a lack of respect for a woman's autonomy (Liston 1995). Instead of managing labour midwives and obstetricians should be working in partnership with the women who they serve. Some women may want a 2 hour action line, however others may wish to adopt a more conservative approach. Some women prefer a medically managed birth and find relief from someone else taking charge, yet others find less interventions more empowering (Stumpf 1993). Therefore, perhaps it should be the women who

choose the timing of intervention once fully informed of the facts. However, whether intervention is required or not, women are individuals and should be treated as such. A small but illuminating phenomenological study (Berg & Dahlberg 1998) addressed this issue when exploring the views of women who had experienced complicated childbirth. Through in-depth interviewing of 12 women they identified that women want to be recognised and affirmed as people in their own right. In seeking this recognition, women expressed their need to be treated as individuals. These findings were similar to those previously reported (Oakley 1979; Green et al. 1998), even though these studies did not concentrate on women who experienced complications. This suggests that women's needs are similar regardless of whether their labour progresses normally or not.

This study highlighted the fact that the study hospital appears to be failing to provide the one component of active management which has proved successful i.e. trained support/companion in labour (Olah & Gee 1996) for some women. The recent report *Towards Safer Childbirth* (RCOG and RCM 1999) has highlighted the importance of one-to-one support stating quite clearly that midwifery staffing should be sufficient to provide a ratio of 1.15:1 midwife to woman in normal labour. In the study hospital it is not unusual for the midwife to care for two or even three women simultaneously. This means that it is often difficult, and sometimes impossible, for her to be a constant companion to each labouring woman. The women acknowledged the need for support throughout their responses adding further weight to its importance as part of an overall package of care. In a recent review of nine trials which assessed support from caregivers (Hodnett 1997), a reduction in the need for analgesia, operative vaginal delivery, caesarean section and a five minute Apgar score of less than seven was

found. Hodnett concludes the review by saying that every effort should be made to ensure that labouring women receive support from specially trained care givers in addition to those close to them. This support should be in the form of continuous presence, the provision of hands-on comfort and encouragement.

A further area of concern was the misdiagnosis of eligibility for commencement of the partogram. As mentioned earlier, one hundred and eighty eight women were placed on a partogram before they were eligible (according to hospital protocol). The misdiagnosis of labour may have major implications for individual women. Hemminiki and Simukka (1986) reported that women with a mean cervical dilatation of 3 cm or less on hospital admission had a longer average length of labour, an increased number of intrapartum interventions, and more diagnoses of abnormal labour. Similarly, Stewart, Dulberg and Chapman (1990) found that 35 per cent of dystocia diagnoses were made in the latent phase and forty percent of caesarean sections for dystocia were performed in this phase. A recent randomised trial assessing the area of labour admissions, confirmed that the admission procedure may influence obstetric outcome (McNiven, Williams, Hodnett, Kaufman & Hannah 1998). In this study of two hundred and nine nulliparous women, participants were randomised to either an early labour assessment group or a direct admissions group. Women in the early labour assessment group were examined, and, if found to be in the latent phase, were encouraged to go home or ambulate before being admitted to the delivery suite. The admissions group were automatically admitted to delivery suite. Significant decreases occurred in duration of labour, use of epidural analgesia and use of oxytocin in the early labour assessment group. These women also evaluated their labour experience more positively. The timing of hospital admissions and subsequent diagnosis of active



labour may therefore affect labour progress and ultimately obstetric outcome. Midwives in the study hospital need to carefully examine their current admission procedure. Additionally parent educators should be informing women of the physiology of labour and advising them appropriately. Perhaps more emphasis should be placed on the benefits of remaining at home until labour is established. There is an implicit assumption that admission to the delivery suite means being confined to bed which in itself is detrimental to the progress and course of labour. Community midwives could have a pivotal role in assessing women at home, offering them reassurance and guidance. The introduction of an assessment system like the one described by McNiven et al. (1998), may be beneficial in other hospitals including the study hospital.

#### **14.5. Implications for Further Research**

The discussion of the findings of this present study highlighted several issues which might be addressed in designing future studies into the evaluation of the partogram and the assessment of intervention. Additionally, several further research questions have arisen relating to various aspects of the childbirth experience.

As addressed by Olah and Gee (1996), evidence has shown that the introduction of innovative approaches to patient management should be subjected to scientific scrutiny before they are widely implemented. This has not been the case with either the use of the partogram or the introduction of active management. The issues surrounding late versus early intervention remain unclear and the evidence to decide the correct positioning of the partogram action line is inconclusive. Whilst the debate between active and expectant management of prolonged labour continues, the

fundamental issue of defining what actually constitutes a prolonged labour has been neglected. Until evidence is provided to indicate the best time to intervene when labour becomes dysfunctional our knowledge will remain deficient. Perhaps the most appropriate starting point is to re-define normal labour. As discussed earlier, current partograms are based on designs from the 1970's and on different populations. It is probably time to re-examine the normal progress of labour by recording the mean progress from admission to full dilatation. It may be that the gradient of the line affects obstetric outcomes as suggested by Tay and Yong (1996). Furthermore, the normal progress of labour may follow a curved, not a straight line. This would account for why such a large percentage of women (44%) actually crossed the action line.

Although the partogram has been in widespread use for over 20 years, thorough evaluation is just beginning. There are currently studies being carried out across the world looking at the different aspects of the partogram. For example, in South Africa (Pattinson, Personal Communication) an ongoing multi-centred trial is currently comparing an aggressively managed group (with only an alert line) with an expectantly managed group (using an alert and action line). Trials such as this highlight the wide interest in this tool and the potential impact on maternal outcomes. Furthermore, a Cochrane protocol has recently been published (Buchmann, Gulmezoglu & Nikodem 1998) which outlines a forthcoming review in which management of women using a partogram will be compared to management of women without using a partogram. The objective of this review is to assess the benefits and risks of partogram use on maternal, obstetric and fetal outcomes. It is reassuring to note that the measurement of maternal views will be an integral part of

this review. There is already in progress in a North American teaching hospital a randomised trial of the management of labour with and without a partogram (Knox-Richie, personal communication).

As mentioned earlier, there are many controversies surrounding labour. One of these controversies is whether or not a latent phase should be acknowledged on the partogram. There is no evidence from randomised controlled trials as to whether the presence of an identified latent phase influences clinical outcomes. Such a trial would greatly contribute to the existing body of knowledge.

This study neither supports or rejects active management of labour as the evidence is inconclusive. In the light of the conflict between clinical and emotional outcome, it is important to carry out a two arm trial to compare management of labour using the 2 hour and 4 hour action line. In order to proceed with such a study approximately 1500 women are needed in each trial arm to detect a 3% difference (8% versus 11%, as in this study), in caesarean section rate with 80% power (alpha 0.05). A collaborative, multi - centred approach would be favourable to complete such a study in a reasonable length of time. The study hospital has continued with a two arm trial to continue evaluating the partogram and is seeking collaborating centres.

This new study has the potential to confirm the previous findings thus providing a definitive answer. It will provide an opportunity to carry out an in-depth exploration of women's views and feelings. This current study was limited in that although it identified that the women in the two hour arm were most satisfied, the rationale for this is unconfirmed. This current study adopted the enhancement model of the role of

qualitative research (Popay & Williams 1998). This meant that it was strongly linked to the quantitative aspects. However, qualitative research can be independently important and sometimes the only approach to answer particular questions. In the follow-up study to this current one a piece of research will be undertaken using only a qualitative approach. Through unstructured but focused interviews an assessment will be made of the woman's perception of the support she received in labour which could be related to her overall level of satisfaction. It might then be possible to answer the question of whether women with more/earlier intervention are more satisfied only because they received the most support. Additionally, it may be possible to explore whether it was the anticipation of the intervention or the intervention per se which influenced women's level of satisfaction. Clinical governance will be introduced in the year 2000. As outlined in the white paper, *The New NHS: Modern, Dependable* (Dept. of Health 1997), each Trust and individual will be responsible for ensuring that the quality, effectiveness and outcome of care are given equal priority to quantity and cost. Research will play an important part in ensuring that this occurs. Following the implementation of Clinical Governance more quality issues will be explored within maternity care and perhaps other researchers will acknowledge the importance of qualitative research in its own right.

This present study took place in the hospital's delivery suite which has a relatively high intervention rate. Recently, at the study hospital, a midwifery led unit has opened where the philosophy of care emphasises normality and adopts a more individualised approach to care. In light of the midwives' previous comments regarding autonomy and individuality, it would be interesting to assess the timing of intervention in this unit. It may be, as previously suggested, that the physical environment contributes to

the level of maternal satisfaction (Drew, Salmon & Webb 1992; Ogden, Shaw & Zander 1998). Although the midwives welcomed the practicalities of the partogram, they did comment on its inflexibility. An important point made was the fact that the partogram action line is one of many components that assists in managing labour, for example descent of the head. Perhaps this tool has contributed to midwives and obstetricians failing to use their clinical skills in assessing labour progress. Additionally, it would be of benefit to compare intrapartum outcomes between the two units as well as maternal and midwifery satisfaction.

This study highlighted several aspects of care which need further exploration. Firstly, it was evident from the findings that the information provided does not always meet the individual needs of women either prior to, during or following labour. One hundred and fifty four women expressed their dissatisfaction with the information received. A careful assessment of information provision throughout the maternity system needs to be carried out. The Report *Changing Childbirth* (Department of Health 1993) raised awareness of pregnant women's needs for information. This issue was subsequently highlighted in the national survey - First Class Delivery (Audit Commission 1997). In this survey, practitioners were warned not to underestimate the value that pregnant women place on information about their own and their babies' well being. It was also acknowledged that there is always more that can be done to improve information provision.

A further area that needs investigation is an exploration of the prevalence and management of afterpains. Traditionally, it is reported that mainly multiparous women suffer from afterpains (Manning 1997). However in this study a considerable

proportion of women (all of whom were primiparous) (n=60, 14.6%), complained of this symptom. Women were not always prepared for these pains, adding further to the evidence of insufficient information. A study conducted by Murray and Holdcroft (1989) found that 30% of primiparous women had severe and moderate pain compared to 58% of multiparous women. But what was alarming was that up to 10% of women who had experienced pain had a total pain rating index score of above 30, which is as severe as that recorded in labour. Afterpains are an area of maternity care which urgently needs to be explored. Any investigation should include the prevalence, severity, relationship to obstetric outcome and management.

Furthermore, it would be of benefit to carry out a long term follow-up of participants to discover whether the position of the action line and subsequent timing of intervention affects postnatal morbidity. A trial of 734 women in Jamaica (Abitbol, Taylor & Karimi 1996) provided some evidence that prolonged labour was associated with persistent complaints, particularly when the labour was terminated with a caesarean section. These complaints included backache, tiredness, urinary disorders, chronic cervicitis, changes in body image, sexual dysfunction, permanent weight gain and negative feeling about previous birth as well as about future pregnancies. The long term sequelae of prolonged labour needs further investigation to provide practitioners with a wider perspective of the consequences of labour events.

## **Chapter 15**

### **Final Conclusion**

The starting point for this study was to determine the impact of altering the position of the partogram action line when managing labouring women. It was believed that altering this line would affect obstetric outcome and possibly influence maternal satisfaction. In fact the evidence to support maternal preferences was more convincing than that of any of the obstetric outcomes measured. In particular, it was surprising to discover that the expectation of early intervention appeared to have influenced the level of satisfaction experienced.

Throughout the study, there has been evidence of inconsistencies surrounding labour management. This study has highlighted the complexities of labour for individual women as well as the difficulties experienced by practitioners, who, in their attempt to provide appropriate care, strive to answer important questions.

The evidence provided by this study enabled the primary research question to be only partially answered. There were differences in the caesarean section rate and level of maternal satisfaction when managing labouring primigravid women using a 2hour, 3hour or 4 hour action line. However, the lack of statistical significance between the 2 and 4 hour action line in terms of caesarean section rate made the answer incomplete. The evidence provided to answer the secondary research question (Are there differences in intrapartum and neonatal outcomes when managing labouring primigravid women using a 2hour, 3hour or 4 hour action line?) was weak but demonstrated the urgent need for further research into this area.

This study identified a wide range of areas which need further investigation. Although it was an aspect of intrapartum care which was being explored, problems were also identified in antenatal and postnatal care. This, in itself highlights the complexities of the childbirth experience and demonstrates the difficulties, and perhaps inappropriateness, of exploring one area in isolation.

This study adds to the current body of knowledge and reinforces issues which have already been discussed. In particular it adds a further dimension to the debate surrounding active management of labour. Furthermore, it highlights the need for ascertaining maternal views. As we enter the millennium it is essential that practitioners appreciate that the views of women are vitally important. The ongoing re-evaluation of issues pivotal to women must be carried out if midwives and obstetricians are to provide truly women centred care. It is no longer acceptable to pay lip service to the views of women in either practice or research.



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# APPENDICES



## Appendices

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## Appendix 1: Ethical Approval

# Royal Liverpool and Broadgreen University Hospitals NHS Trust

PRESCOTT STREET LIVERPOOL L7 8XP TEL: 0151-706 2000 FAX: 0151-706 5806

---

Your Ref:

Our Ref: GMB/ARM/95/122

If telephoning please ask for: 3158

Please quote our reference

16th November 1995

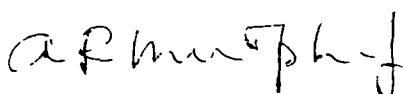
Mr. S. A. Walkinshaw,  
Consultant in Fetomaternal Medicine,  
Liverpool Women's Hospital,  
Crown Street,  
Liverpool,  
L8 7SS.

Dear Mr. Walkinshaw,

## RANDOMISED TRIAL OF ALTERING PARTOGRAM ACTION LINE

Thank you for your letter of 31st October 1995. The Ethics Committee formally approves the abovementioned protocol.

Yours sincerely,



G. M. Bell,  
Chairman, Ethics Committee



**Liverpool John Moores University**

Graduate School

LO.DB

17 October 1996

Ms T Lavender  
School of Health  
Tithebarn Street

Dear Ms T Lavender

I am pleased to inform you that the Ethics Committee has now considered your application for approval of the project entitled:

**Partogram Action Line Study**

and I am happy to confirm that it was approved.

The Ethics Committee approval is given on the understanding that:

- (i) any adverse reactions/events which take place during the course of the project will be reported to the Committee immediately;
- (ii) any unforeseen ethical issues arising during the course of the project will be reported to the Committee immediately;
- (iii) any change in the protocol will be reported to the Committee immediately.

Please note that ethical approval is given for a period of five years from the date granted and therefore the expiry date for this project will be October 2001. An application for extension of approval must be submitted if the project continues after this date.

I am enclosing form EC5 and would be grateful if you could spare the time to complete the questionnaire and return it to me.

Yours sincerely

Lisa Olsen  
Secretary, Ethics Committee  
0151 231 3365

Encs.

Copy to Supervisor - Mrs I Walton

## **Appendix 2**

### **PARTOGRAM ACTION LINE STUDY (P.A.L.S.)**

#### **DATA SHEET NO.**

##### **BASELINE DATA**

2. Surname -----

3. Maternal unit no.

4. Group allocation 2 3 4

5. Age yr.

6. Gestation wk. = days.

7. Date of randomisation / / 8. Time of randomisation :

##### **LABOUR PRIOR TO RANDOMISATION**

9. Cervical dilatation prior to randomisation :-

- |    |               |                          |
|----|---------------|--------------------------|
| 1. | < 3cms        | <input type="checkbox"/> |
| 2. | 3-10 cm       | <input type="checkbox"/> |
| 3. | fully dilated | <input type="checkbox"/> |

10. Is the cervix fully effaced:-

- |    |     |                          |
|----|-----|--------------------------|
| 0. | yes | <input type="checkbox"/> |
| 1. | no  | <input type="checkbox"/> |

11. Membranes

- |    |                  |                          |
|----|------------------|--------------------------|
| 0. | Intact           | <input type="checkbox"/> |
| 1. | Ruptured         | <input type="checkbox"/> |
| 2. | Meconium stained | <input type="checkbox"/> |

**LABOUR AFTER RANDOMISATION**

12. Date of delivery      /      /      13. Time of delivery :

14. Randomisation - delivery interval      hr.      min. = min.

15. Action line reached or crossed

0.      no      ☐
1.      yes      ☐

16. Syntocinon used

0.      No      ☐
1.      Yes without reaching max. dose      ☐
2.      Yes, reaching max. dose      ☐

17. Time on syntocinon

0.      No synto.      ☐
1.      < 4 hours      ☐
2.      4- 8 hours      ☐
3.      8-12 hours      ☐
4.      12-16 hours      ☐
5.      > 16 hours      ☐

18. Rupture of membranes -

1.      S.R.O.M. with clear liquor      ☐
2.      S.R.O.M. with meconium      ☐
3.      S.R.O.M. with clear liquor and mec. later      ☐
4.      A.R.M. with clear liquor      ☐
5.      A.R.M. with meconium      ☐
6.      A.R.M. with clear liquor and mec later      ☐
7.      Other      ☐

19.

0.      Not blood stained      ☐
1.      Blood stained      ☐
2.      Frank blood      ☐

20. C.T.G. monitoring

- |    |                          |                          |
|----|--------------------------|--------------------------|
| 1. | Intermittent C.T.G       | <input type="checkbox"/> |
| 2. | Continuous with external | <input type="checkbox"/> |
| 3. | Continuous with internal | <input type="checkbox"/> |
| 4. | Auscultation only        | <input type="checkbox"/> |

21. Was fetal blood sampling performed?

- |    |                                      |                          |
|----|--------------------------------------|--------------------------|
| 0. | No                                   | <input type="checkbox"/> |
| 1. | Normal in 1st stage                  | <input type="checkbox"/> |
| 2. | Normal in 2nd stage                  | <input type="checkbox"/> |
| 3. | Abnormal requiring del. in 1st stage | <input type="checkbox"/> |
| 4. | Abnormal requiring del. in 2nd stage | <input type="checkbox"/> |

22. How many F.B S. were performed

23. Was internal pressure catheter used during labour?

- |    |     |                          |
|----|-----|--------------------------|
| 0. | no  | <input type="checkbox"/> |
| 1. | yes | <input type="checkbox"/> |

24. Was amniocentesis used?

- |    |     |                          |
|----|-----|--------------------------|
| 0. | no  | <input type="checkbox"/> |
| 1. | yes | <input type="checkbox"/> |

25. Number of vaginal examinations performed after randomisation

- |                 |                         |
|-----------------|-------------------------|
| 26. Anaesthesia | 0-none                  |
|                 | 1-local                 |
|                 | 2-opiates               |
|                 | 3-epidural (top-ups)    |
|                 | 4-epidural (continuous) |
|                 | 5-spinal                |
|                 | 6-general               |
|                 | 7-nitrous oxide         |
|                 | 8-other                 |

27. Mode of delivery

- |    |  |                          |
|----|--|--------------------------|
| 1. | Spontaneous vaginal delivery               | <input type="checkbox"/> |
| 2. | Instrumental delivery for delay            | <input type="checkbox"/> |
| 3. | Instrumental delivery for distress         | <input type="checkbox"/> |
| 4. | Caesarean section for delay (1st stage)    | <input type="checkbox"/> |
| 5. | Caesarean section for delay (2nd stage)    | <input type="checkbox"/> |
| 6. | Caesarean section for distress (1st stage) | <input type="checkbox"/> |
| 7. | Caesarean section for distress (2nd stage) | <input type="checkbox"/> |

**3RD STAGE**

28.

- |    |                              |                          |
|----|------------------------------|--------------------------|
| 0. | Intact perineum              | <input type="checkbox"/> |
| 1. | 1st degree tear              | <input type="checkbox"/> |
| 2. | 2nd degree tear              | <input type="checkbox"/> |
| 3. | 3rd degree tear              | <input type="checkbox"/> |
| 4. | Episiotomy                   | <input type="checkbox"/> |
| 5. | Episiotomy + tear            | <input type="checkbox"/> |
| 6. | Episiotomy + 3rd degree tear | <input type="checkbox"/> |

29. Blood loss .....ml.

30. Blood transfusion

- |    |     |                          |
|----|-----|--------------------------|
| 0. | no  | <input type="checkbox"/> |
| 1. | yes | <input type="checkbox"/> |

31. Oxytocin

- |    |                                      |
|----|--------------------------------------|
| 0. | Not given                            |
| 1. | Syntometrine or syntocinon i.m. only |
| 2. | Additional oxytocic drugs            |
| 3. | Other                                |

32. Placenta retained

- |    |     |                          |
|----|-----|--------------------------|
| 0. | no  | <input type="checkbox"/> |
| 1. | yes | <input type="checkbox"/> |



**BABY**

33. Hospital number

34. Weight                      g                      35. Apgar 1min.                      36. Apgar 5min.

37. Admission to S.C.B.U.

0.                      no                      ☐  
1.                      yes                      ☐

38. Cord blood gas - Arterial P.H.                      .

Arterial B.E

Venous P.H.                      .

Venous BE.

## Appendix 3

# Liverpool Women's Hospital NHS Trust

## PALS STUDY

UNIT NO.

STUDY GROUP - 2. 3. 4.

An important part of the study, which you have taken part in, is discovering how women feel about their experience of labour. It would therefore be of great help if you would spend a few minutes completing this confidential questionnaire.

Please compare your **actual** experience of labour with how you had thought it would be and tick the appropriate response. Please tick one box only.

### **A. The control I felt in labour was:**

- |  |       |
|--|-------|
| 1. I did not know what to expect       | ..... |
| 2. Much worse than I expected          | ..... |
| 3. Somewhat worse than what I expected | ..... |
| 4. About what I expected               | ..... |
| 5. Somewhat better than expected       | ..... |
| 6. Much better than I had expected     | ..... |

### **B. The length of my labour was:**

- |                                     |       |
|-------------------------------------|-------|
| 1. I did not know what to expect    | ..... |
| 2. Much longer than I expected      | ..... |
| 3. Somewhat longer than I expected  | ..... |
| 4. About what I expected            | ..... |
| 5. Somewhat shorter than I expected | ..... |
| 6. Much shorter than I expected     | ..... |

**C. The pain I experienced was:**

1. I did not know what to expect .....
2. Much worse than I expected .....
3. Somewhat worse than I expected .....
4. About what I expected .....
5. Somewhat better than I expected .....
6. Much better than I expected .....

**D. All things considered, my childbirth experience was:**

1. I did not know what to expect .....
2. Much worse than I expected .....
3. Somewhat worse than I expected .....
4. About what I expected .....
5. Somewhat better than expected .....
6. Much better than I expected .....

**E. If time suddenly went backwards and you had to do it all over again, would you take part in this study?**

1. Definitely not .....
2. Probably not .....
3. I'm not sure .....
4. Probably yes .....
5. Definitely .....

**F. If the study group I was allocated to became the normal practice for this hospital, I would be:**

1. Very disappointed .....
2. Slightly disappointed .....
3. Not sure .....
4. Fairly pleased .....
5. Very pleased .....

**G. Please write any comments about your childbirth experience which you think may be of benefit to this study.**

Thank you for taking the time to complete this questionnaire.

## Appendix 4: Permission to carry out the study



Liverpool  
Women's  
Hospital

---

.. Liverpool Women's Hospital  
Crown Street  
Liverpool L8 7SS  
Tel: 0151 708 9988  
Fax: 0151 702 4028

---

Your ref: JR/CM  
Our ref:  
If telephoning please ask for:  
..... EXT: 1019. ....  
Direct Line: 0151 702 1019

---

5<sup>th</sup> May 1995

## To: Whom it may concern

Dear Sir/Madam

**re Ms T Lavender - Midwife**

I write to inform you that the above Midwife has my permission to undertake a Partogram Action Line Study here at The Liverpool Women's Hospital.

I hope this information is useful.

Yours faithfully

**Julie Riley (Mrs)**  
**Obstetric Directorate Manager**

## Appendix 5

### **LIVERPOOL WOMEN'S HOSPITAL NHS TRUST**

## Partogram Action Line Study (PALS)

### Information sheet

Every woman in our hospital has her labour recorded on a chart called a partogram so that her labour can be carefully monitored. One of the most important parts of this chart is where we record how the cervix is dilating.

On our charts there are two lines - one defines normal progress and the second tries to define when labour is becoming slow. It is where the second line should go that causes the argument. If this line is too early then many women may need further management. If it is too late then some women will labour for too long. Different groups have claimed that doing things early may eventually reduce the risk of caesarean section. Others think that too many women end up having “medical” labours.

We are carrying out a study at Liverpool Women's Hospital to try to answer this question in 2 ways.

Firstly, if you change where the line is, will it change (i.e. reduce) the number of caesarean sections? Secondly, what do women feel about the different treatments?

To do this women need to be allocated at random (by chance) to get a certain treatment. This is called a randomised trial and is the best way to answer the question.

If you agree to help, you will be randomly chosen to have your progress charted on one of 3 different partograms when you come into the hospital in labour. In partogram A the line will be early (2 hours as they do in Ireland), in partogram B the line will be in the middle (3 hours - what we do now), in partogram C, the line will be late (4 hours - the World Health Organisation guidelines).

The actual way your labour is handled will be as you want it with the guidance from the midwife and doctor if necessary. The only difference is that our normal treatment of “slow labour” will be triggered at either 2, 3 or 4 hours on the partogram.

When you come for your scan a research midwife will give you more details and ask for your written permission. You will have another opportunity to talk about it then and will be free to withdraw at any stage.

If you need extra information please call Tina Lavender (research midwife) - tel. (0151) 708 9988 and ask switch board to contact bleep no.225, or Mr. S. Walkinshaw - tel. (0151) 702 4072.

## Appendix 6

# LIVERPOOL WOMEN'S HOSPITAL NHS TRUST

## PARTOGRAM ACTION LINE STUDY CONSENT FORM

Have you read the information sheet provided? Yes/No

Have you had an opportunity to ask questions and discuss the study? Yes/No

Do you understand the information that has been given to you? Yes/No

Do you understand that you are free to withdraw from the study-  
- at any time?  
- Without effecting your future care? Yes/No

Do you agree to take part in the study? Yes/No

Signed (patient)..... Date.....

Signed (research..... Date.....  
midwife)



## Appendix 7

### 2 hour partogram

## PARTOGRAM

[illegible]

HOSPITAL No. \_\_\_\_\_

NAME

ADDRESSOGRAM

DATE \_\_\_\_\_

## BLOOD GROUP

### DURATION OF LABOUR PRIOR TO CHART

## SPECIAL INSTRUCTIONS

## GESTATION

9H

hrs.

## PARITY

## DURATION OF RUPTURE OF MEMBRANES

[illegible]

TIME

[illegible]

PRESENTATION POSITION

10 9 8 7 6 5 4 3 2 1 0

10 9 8 7 6 5 4 3 2 1 0

A B D O M I N A L

V E N A

X

[illegible]



## Appendix 8

### 3 hour partogram

[illegible]

Rhodes Ref. 922916

ADDRESSOGRAPH

## SPECIAL INSTRUCTIONS

### DURATION OF LABOUR PRIOR TO CHART

**BLOOD GROUP**

DATE \_\_\_\_\_

GESTATION	Hb	hrs

911

hrs.

### DURATION OF RUPTURE OF MEMBRANES

**PARITY**

1

1

[illegible]

TIME

[illegible][illegible][illegible]





## Appendix 9

### 4 hour partogram

[illegible]

ADDRESSOGRAPH

DATE

BLOOD GROUP

DURATION OF LABOUR  
PRIOR TO CHART

## SPECIAL INSTRUCTIONS

## GESTATION

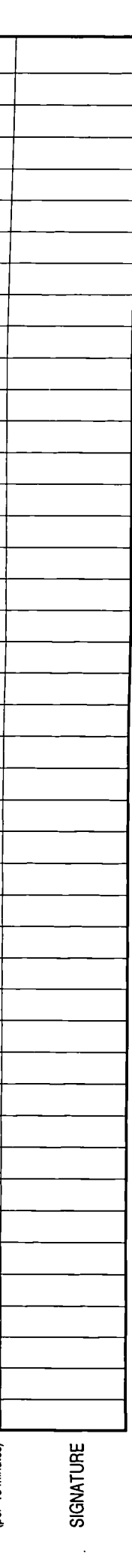
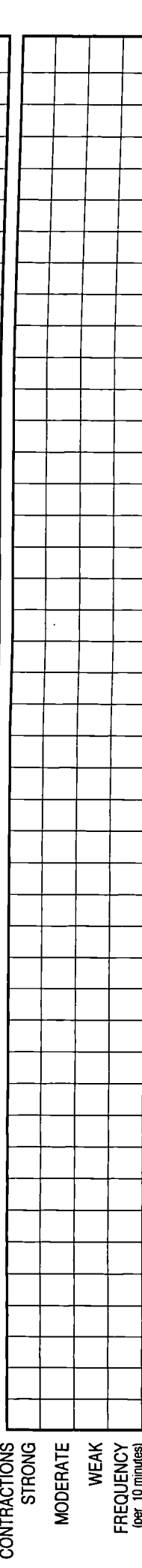
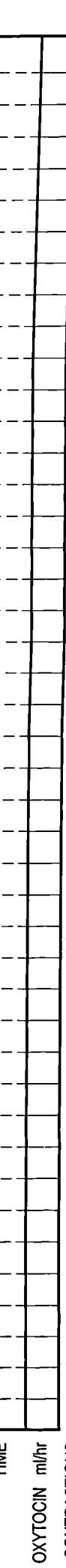
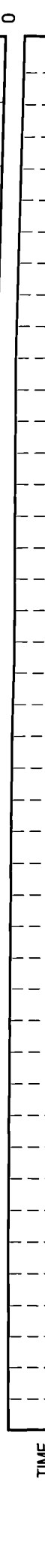
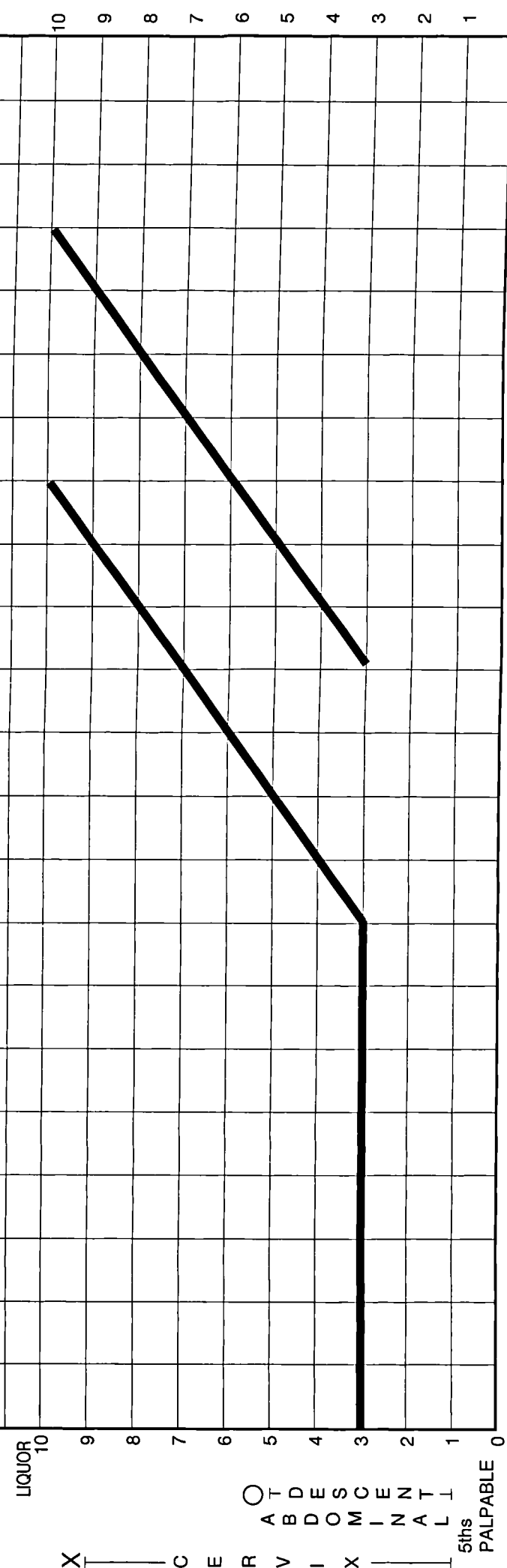
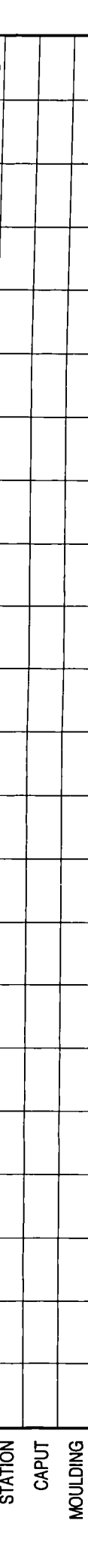
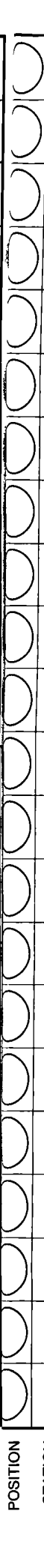
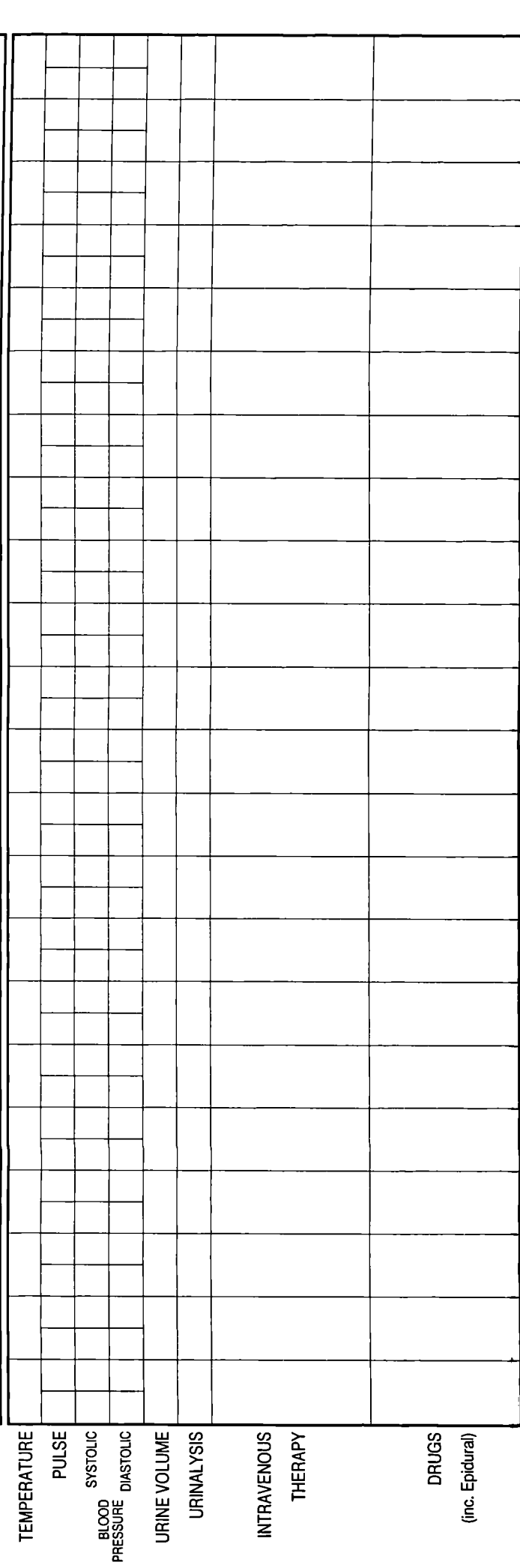
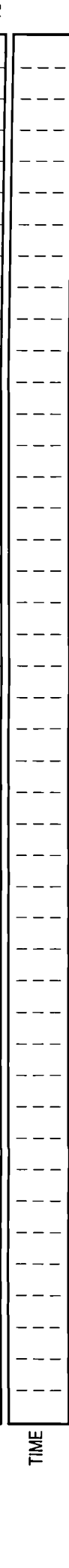
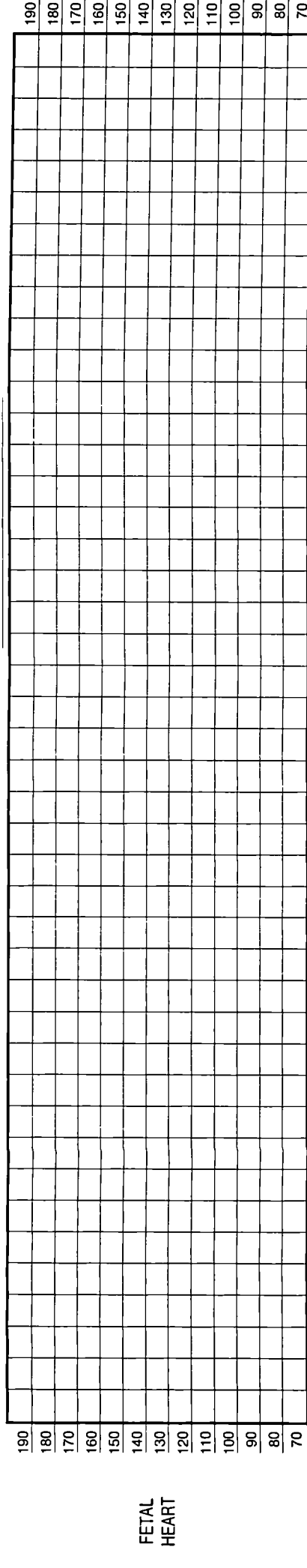
9H

hrs.

PARITY

### DURATION OF RUPTURE OF MEMBRANES

hrs.





## **Appendix 10: Management protocol**

### **Management of Dysfunctional Labour**

Correct use of the partogram will facilitate the recognition of dysfunctional labour. All assessments should include a note of cervical dilatation, gestation and the abdominal findings.

If, on the partogram, progress is approaching the action line and where progress is less than half a centimetre per hour, re-examination should follow after 2 hours rather than 4 hours to provide early diagnosis of dysfunctional labour.

If progress reaches across the action line the Senior House Officer should be summoned to assess the clinical situation. If labour is not already augmented and there are no maternal or fetal contraindications then syntocinon infusion is recommended.

#### **Primigravidae in spontaneous labour**

Oxytocin infusion should be initiated as per regime and reviewed after 3 hours maximum. (Vaginal examinations may be by the midwife or medical staff).

If, on assessment, progress has returned to the normal range the continue.

If progress continues to deviate, the registrar must be informed. If still off the partograph, a decision must be made as to whether to use an intrauterine catheter to assess pressures accurately or perform a caesarean section.

The preferred option is to use an intrauterine catheter and observe pressures for 30 minutes unless other factors contraindicate this. Any reason not to use an intrauterine catheter when indicated should be clearly documented.

If pressures are proven to be between 60-70 mm above the baseline pressure then a caesarean section should be performed. If below this level then augmentation of labour should be increased to achieve these pressures *within 1 hour*. The mother should then be reassessed after 2 hours of achieving these pressures.

Intrauterine catheter pressures should be measured in Montevideo units. (Strength of contraction x frequency in 10 minutes) and recorded on the partogram.

Unless adequate progress has been made a caesarean section should then be performed.

August 1992  
Revised March 94

## Appendix 11

# **GUIDELINES QUESTIONNAIRE**



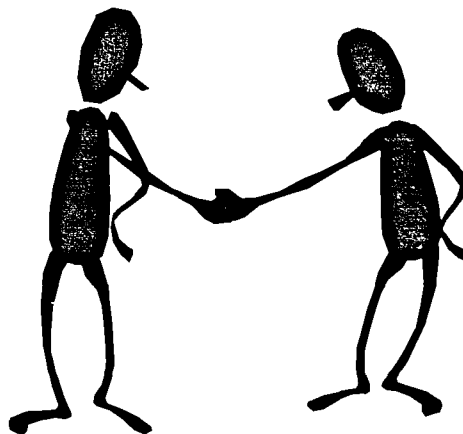
Dear midwife,

I am currently undertaking a study to assess how midwives feel about guidelines for labouring women.

I would be very grateful if you would spend a few minutes completing this anonymous and confidential questionnaire.

Please answer as honestly as possible and feel free to write any additional comments.

The questionnaires can be returned to me personally, via the box in the delivery suite coffee room or via the internal mail.



Many thanks for your co-operation

TINA

**A)How many years have you been qualified as a midwife?**

1. < 1 Year.....
2. 1-5 Years.....
3. 6-10 Years.....
4. 11-15 Years.....
5. >15 years.....

**B) Have you worked on the delivery suite in the last 5 years?**

1. Yes.....
2. No.....

**C) Do you think written guidelines are necessary on the delivery suite?**

1. Yes.....
2. No.....

**D) What are your general views about guidelines for labouring women?**

.....

.....

.....

.....

.....

.....

.....

**E) Do you think it is necessary to use a partogram for labouring women?**

1. Yes.....
2. No.....

**F) What are your views about the use of the partogram for managing women in labour?**

.....

.....

.....

.....

.....

.....

.....

**G) What are your views about using the graph on the partogram to plot cervical dilatation?**

.....

.....

.....

.....

.....

.....

.....

**H) Have you used partograms without an action line?**

1. Yes.....
2. No.....

**I) Do you think it is necessary to have an action line on the partogram?**

1. Yes.....
2. No.....

**J) Please give reasons for your response to the above question**

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....



**K) Which action line do you think proves to be the most beneficial to a labouring primigravid woman?**

1. 2hr
2. 3hr
3. 4hr

**L) Please give reasons for your response to the above question**

.....

.....

.....

.....

.....

**M) Do you think it is necessary to have a defined latent phase on the partogram?**

1. Yes.....
2. No.....

**N) Please give reasons for your response to the above question**

.....

.....

.....

.....

.....

**O) If guidelines for delivery suite did not exist, which of the following would you choose to manage an uncomplicated labouring woman?**

1. No partogram.....
2. Partogram without alert or action line.....
3. Partogram with an alert line only.....
4. Partogram with alert and action line:.....

**P) Please give reasons for your response to the above question**

.....

.....

.....

.....

.....

*Thank you for taking the time to complete this questionnaire.*

## Appendix 12

### Publications

# A conflict of outcomes

By Tina Lavender and Steve Walkinshaw

While there has been a steady rise in intrapartum studies, most designs have included obstetric outcomes as the primary measure of analysis. Few randomized trials have assessed the maternal perspective on various treatments or interventions. Despite recommendations supporting women centred care and research into maternal preferences (DoH, 1993), studies which have assessed maternal views have usually placed them as a secondary outcome. This suggests that these views may not be considered sufficient in their own right to advance clinical practice.

When we carried out a randomized trial to assess the effect of different timing of intervention using different partogram action lines (Lavender et al, 1997), it was decided that maternal satisfaction was a primary outcome, alongside the rate of caesarean section. A decision was made by the investigators that the partogram that would influence practice would be the one that had the lowest caesarean section rate or the one that the women preferred.

The results of the study showed that the women whose labours were managed using the 2 hour partogram action line and receiving the most intrapartum intervention were the most satisfied. Women whose labours were managed with a 4 hour partogram action line were the least satisfied, but had the lowest caesarean section rate and received the least intrapartum intervention. The difference in caesarean section rate was 3%.

On discovering these findings, the investigators have been left with an important dilemma. On which outcome should future preference be based — caesarean section or maternal satisfaction?

If we accept the obstetric outcome we will be ignoring the respondents' views. Thereby failing those women who do not see intervention as a contributor to a negative birth experience. We say that we acknowledge the right for women to choose their options for care but is this only when it suits the health professional?

If we ignore the caesarean section rate, we

must accept the implications of a potential increase in morbidity. The inevitable impact on resources is another factor, which cannot be ignored in the current financial climate.

Although it is true that management choice should reflect the individual woman's views, women require information, preferably based on evidence, to guide their decisions.

The future management has been debated among midwives and obstetricians at the study hospital with a consensus that the women's views should predominate while we continue evaluating the partogram. In light of the pressures to reduce caesarean section (Henderson, 1996), it is questionable whether other hospitals would have reached the same decision.

The study discussed provides one example of the dilemma of deciding which outcome should influence practice. Although statisticians will recommend the use of only one primary outcome in a study, the complexities of childbirth make many factors important to a positive experience. Using only one primary outcome relies on a minority of people deciding what is most important. Surely the importance should primarily be for the women, not the midwives, obstetricians or the Trust.

Women are in the ideal position to analyse the care that is provided (Delbanco, 1996). However, receiving information from those in our care is only useful if we actually listen to it. Health professionals need to decide how important the maternal views really are. Will they influence change? Where do they stand in relation to other outcomes? How much choice do we really give the women? It is no longer acceptable to pay lip service to the views of women in either practice or research. **BJM**

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## Partogram action line study: a randomised trial

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**Objective** To assess the effect of three different partograms on caesarean section and maternal satisfaction.

**Design** Prospective randomised clinical trial.

**Setting** Regional teaching hospital in North West of England.

**Participants** Nine hundred and twenty-eight primigravid women with uncomplicated pregnancies who presented in spontaneous labour at term.

**Interventions** The women were randomised to have their progress of labour recorded on a partogram with an action line 2, 3 or 4 hours to the right of the alert line. If the progress reached the action line, a diagnosis of prolonged labour was made. Prolonged labour was managed according to the standard ward protocol.

**Main outcome measures** Primary: Caesarean section rate and maternal satisfaction; secondary: need for augmentation, duration of labour, analgesia, cord blood gas analysis, postpartum haemorrhage, number of vaginal examinations, Apgar score and admission to special care baby unit.

**Results** Caesarean section rate was lowest when labour was managed using a partogram with a 4-hour action line. The difference between the 3- and 4-hour partograms was statistically significant (OR 1.8, 95% CI 1.1–3.2), but the difference between 2 and 4 hours was not (OR 1.4, 95% CI 0.8–2.4). The women in the 2-hour arm were more satisfied with their labour when compared to the women in the 3-hour ( $P < 0.0001$ ) and 4-hour ( $P < 0.0001$ ) arm.

**Conclusion** Our data suggest that women prefer active management of labour. It is possible that partograms which favour earlier intervention are associated with higher caesarean section rate. As the evidence on which to base the choice of partograms remains inconclusive further research is required.

### INTRODUCTION

The partogram is considered a valuable tool in the improvement of maternity services by allowing midwives and obstetricians to display intrapartum details in a pictorial manner. A number of common partogram designs follow the work of Philpott and Castle<sup>1</sup> and most incorporate an action line. An action line allows unambiguous diagnosis of prolonged labour, enabling the timing of intervention to be based on the rate of cervical dilatation. It is conventionally placed a number of hours to the right of another line, the alert line<sup>2</sup>, which describes the rate of cervical dilatation of the slowest 10% of primigravidae<sup>3</sup>.

The timing of intrapartum interventions which may correct prolonged labour and include amnio-

tomy, intravenous hydration, analgesia, oxytocic infusion and operative delivery<sup>4</sup>, has not been subjected to rigorous evaluation. The Dublin group<sup>5,6</sup> have proposed that an active management package which relies on early identification of prolonged labour with early correction by oxytocin reduces caesarean section rate. Despite inclusion of all the components of the National Maternity Hospital protocol for active management of labour, a more recent randomised study of 1934 nulliparous women<sup>7</sup> failed to provide evidence that such a protocol reduces the caesarean section rate. Most other studies of various forms of early intervention have shown reductions in duration of labour but not in caesarean section outcome<sup>8</sup>.

Philpott and Castle<sup>1</sup>, who were the first to provide specific guidelines on the timing of intervention for prolonged labour, recommended an action line 4 hours to the right of the alert line. This recommenda-

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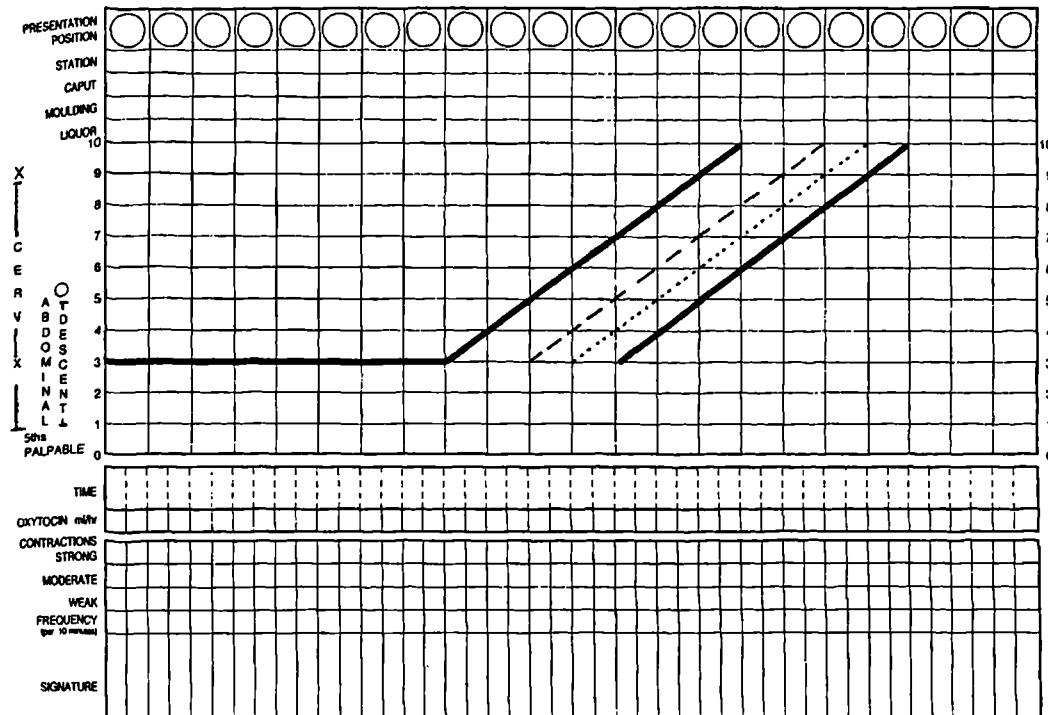


Fig. 1. Partograms used in this study included an alert line and either 2 hour (---), 3 hour (.....) or 4 hour (—) action line. Cervical dilatation at the first vaginal examination in the active phase ( $\geq 3$  cm) was plotted on the alert line.

tion was to enable adequate time to transfer women from peripheral units to a central unit when labour became prolonged. This design has been adequately evaluated only recently, when the World Health Organisation carried out a large multicentre trial of 35484 women in south east Asia<sup>9</sup>. They achieved caesarean section rates of 10% in primigravidae in labour and have therefore recommended the widespread use of a partogram with a 4 hour action line.

However, as the evidence to support either a 2 or 4 hour action line was inconclusive in 1992, a consensus was reached among senior medical and midwifery staff at the Liverpool Women's Hospital that the partogram in Liverpool would contain a 3 hour action line. This adaptation to the WHO partogram has been used by others<sup>10</sup> who believe that partograms have not been sufficiently evaluated.

A neglected aspect of the debate over timing of intrapartum intervention is the view of women themselves. Both early and late interventions may have many unwanted sequelae: limitation of maternal mobility, increased use of epidural analgesia, increased incidence of fetal heart rate abnormalities, uterine hypertonus and caesarean section. Unfortunately, no information is available on women's views of the relative merits of these differing approaches.

The issue of timing of obstetric intervention during spontaneous labour thus needs to be addressed and should include women's views. Therefore, we

carried out a randomised trial to evaluate the null hypothesis that there are no differences in caesarean section rate and maternal views in women whose labour is managed using partograms with a 2 hour, 3 hour or 4 hour action line.

## METHODS

This study was conducted in an inner city teaching hospital in Liverpool over an 18 month period following approval from the ethical committee. Potentially eligible women were given the opportunity to discuss the study at the time of the 20 week ultrasound scan to ensure informed consent.

The eligibility criteria consisted of primigravid women who presented in spontaneous labour, at term with a live, singleton, cephalic presentation. Exclusions were women with diabetes, pregnancies complicated by fetal malformations and women requiring high dependency intrapartum care. Women were also excluded if they had an unsatisfactory admission cardiotocograph.

On admission in spontaneous labour, women were randomly allocated to one of three trial arms – a partogram with 2 hour, 3 hour or 4 hour action line (Fig. 1), using consecutively numbered sealed opaque envelopes. The partogram was contained inside the randomisation envelope to make the process efficient and to ensure that the women received their allocated

management. The randomisation sequence was generated using a table of random numbers. Given the type of intervention, blinding of clinicians or women to the allocation was not possible.

Eligible women were randomised to the trial once established labour had been confirmed by digital examination. Labour was confirmed if 1. the cervix was effaced; 2. the cervix was dilated at least 3 cm; and 3. regular uterine contractions at least every 5 minutes, lasting a minimum of 20 seconds, were present.

The management of randomised women was unaffected if labour followed the expected rate of progress. However, if cervical dilatation crossed the allocated action line, a clinical assessment was made and delivery suite guidelines for the management of prolonged labour were followed. Where augmentation was required, this involved oxytocin alone when membranes were ruptured or amniotomy followed by oxytocin in the presence of intact membranes. The oxytocin infusion rate commenced at 2 mU/min and was doubled every 30 minutes until effective regular uterine contractions were achieved, the maximum rate of syntocinon being 32 mU/min.

Women with oxytocin infusion or with epidural analgesia had continuous external fetal monitoring.

All women randomised in the first 12 months (615 women) were administered specifically designed questionnaires on the second postnatal day to ascertain their level of satisfaction with labour. An *expectation-fulfilment model*<sup>11</sup> was used in the design of the questionnaire, which was presented in the form of a rating scale followed by an open question. The women were asked to mark on the scale, the point which best described the fulfilment of their expectation with regard to control in labour, effectiveness of pain relief, duration of labour and overall experience. Two supporting questions were also included asking whether if time suddenly went backwards, they would take part in the study again and how they would feel if their allocated group became normal practice. A factor analysis using principal component analysis with varimax rotation<sup>12</sup> was carried out and the six items (eg, control, length, pain, experience, repeat and practice) were entered. The items all loaded on 1 factor suggesting the tool was unidimensional. It was therefore possible to calculate an overall satisfaction score. The six items were then entered to establish the reliability using Cronbach's alpha<sup>13</sup>. Alpha was 0.8 which suggests that the questionnaire has internal consistency.

Primary outcome measures were caesarean section rate and maternal satisfaction. Secondary outcomes were need for augmentation, duration of labour, use of analgesia, postpartum haemorrhage, number of

vaginal examinations, admission to SCBU and Apgar score.

### Data analysis

Demographic and intrapartum information were extracted from electronic records, with any discrepancies being double checked with the hospital case records. Data sheets were completed for all randomised women prior to inputting the information on a computer database. Prior to analysis, data were double entered to maximise the accuracy of the information collected.

### Statistics

Fisher's exact test was used to calculate the odds ratio and 95% confidence intervals for categorical data. The unpaired *t* test and Mann-Whitney *U* test were used to compare the difference in means/medians between the groups. The maternal satisfaction data were analysed using a one-way ANOVA, followed by the Sheffé multiple comparison test.

As there was little available evidence to allow precise sample size calculations, a large pilot study was needed to assess feasibility of a definitive trial on this subject. The sample size of 300 per group was chosen to enable detection of differences as large as 5% between groups and to give 95% confidence intervals of approximately  $\pm 3.5\%$  assuming an observed rate of 10% under then current standard treatment. The sample size of 200 per group was sufficiently large to detect differences in the satisfaction score of  $<1$  with the  $>95\%$  power. The differences in the satisfaction score of less than 1 are unlikely to be of any clinical significance, therefore, the decision was made to stop administering the questionnaire after 12 months.

### RESULTS

The study took place between January 1996 and August 1997 in a single obstetric unit with 10,189 deliveries during this period. Of these total deliveries, 3717 were to primigravid women. Out of 1633 eligible women at term, 429 declined participation, 171 were never approached, 98 consented women were not randomised, and three consented women withdrew before randomisation. This left a total of 932 randomised women. However, four randomised women could not be traced due to the inaccurate recording of demographic details. This meant that data were collected on a total of 928 women.

The demographic details and cervical state at randomisation are given in Table 1. As there was no difference with respect to maternal age, gestational age,

**Table 1.** Baseline information. Values are given as *n* (%) or mean [SD].

	2 h <i>n</i> = 315	3 h <i>n</i> = 302	4 h <i>n</i> = 311
Maternal age (years)	25.1 [5.1]	24.8 [5.4]	25 [5.1]
Gestation (days)	280.2 [7.9]	279.7 [8.2]	280.2 [8.1]
Cervix 3–10 cm	256 (81.3)	243 (80.5)	241 (77.7)
Cervix effaced	270 (85.7)	245 (81.1)	259 (83.5)
Membranes intact	196 (62.2)	203 (67.2)	197 (63.5)

cervical dilatation, cervical effacement or presence of membranes it can be confirmed that the randomisation process was successful.

The intrapartum details (Table 2) show that more women in the 2-hour arm crossed the partogram action line, compared with the 4-hour arm, and therefore received more interventions to augment labour (OR 1.6, 95% CI 1.1–2.2). This offers reassurance that the research protocol was adhered to.

The study does show differences in caesarean section rates in the three arms: 2 hours 11.1% (CI 8%–15.2%), 3 hours 14.2% (CI 10.6%–18.8%), 4 hours 8.3% (CI 5.6%–12.2%), as shown in Table 3. However, only when the 3 and 4 hour arms were

compared did the difference reach statistical significance (OR 1.8, 95% CI 1.1–3.2).

When a one-way ANOVA was performed on the maternal satisfaction data, highly significant differences were found ( $P < 0.0001$ ). The Sheffé test identified that the women in the 2-hour arm were more satisfied, compared with women allocated to the 3-hour ( $P < 0.0001$ ) and 4-hour arms of the trial ( $P < 0.0001$ ) (Table 3). All other secondary outcomes showed no significant differences among the three trial arms.

## DISCUSSION

Although partograms are in widespread use, little research has been undertaken in the form of randomised control trials to assess the efficacy of different placement of the action line. Whilst the debate between active and expectant management of prolonged labour continues, the fundamental issue of defining what actually constitutes a prolonged labour has been neglected. Until evidence is provided to indicate the best time to intervene when labour becomes dysfunctional our knowledge will remain deficient.

It was surprising to discover that in an uncomplicated primigravid population 44% of women had

**Table 2.** Intrapartum details. Results are expressed as *n* (%) or median [interquartile range]. Differences between groups are given as odds ratios (95% CI) or difference in medians (95% CI).

	2 h <i>n</i> = 315	3 h <i>n</i> = 302	4 h <i>n</i> = 311	2 h vs 3 h	3 h vs 4 h	2 h vs 4 h
Randomisation–delivery (min)	516 [330–737]	532.5 [332.5–739.3]	517 [302–734]	–7 [–52, 36]	17 [–28, 60]	10 [–35, 54]
Vaginal examination	4 [3–6]	4 [3–6]	4 [3–6]			
Action line crossed	163 (51.7)	124 (41)	118 (38.1)	1.5 (1.2–2.1)	1.1 (0.8–1.6)	1.7 (1.3–2.4)
Action taken	146 (46)	119 (39)	110 (35.5)	1.3 (0.9–1.9)	1.2 (0.8–1.7)	1.6 (1.1–2.2)
Amniotomy only	120 (38)	122 (40.4)	121 (39)	0.9 (0.6–1.3)	1.1 (0.8–1.5)	1.0 (0.7–1.4)
Syntocinon used	144 (45.7)	136 (45)	129 (41.6)	1.0 (0.7–1.4)	1.1 (0.8–1.6)	1.2 (0.9–1.6)
Epidural	120 (38)	99 (32.8)	101 (32.6)	1.3 (0.9–1.8)	1.0 (0.7–1.4)	1.3 (1.0–1.8)
Blood loss > 500 mls	39 (12.4)	39 (12.9)	39 (12.6)	1.0 (0.6–1.6)	1.4 (0.8–2.4)	1.0 (0.6–1.6)

**Table 3.** Outcomes. Results are expressed as *n* (%) or mean [SD]. Differences between groups are given as odds ratios (95% CI) or difference in means (95% CI). CS = caesarean section; SCBU = special care baby unit.

	2 h <i>n</i> = 315	3 h <i>n</i> = 302	4 h <i>n</i> = 311	2 h vs 3 h	3 h vs 4 h	2 h vs 4 h
Satisfaction score	23.5 [5.9]	21.4 [6.1]	19.3 [5.6]	3.5 [1.7–5.3]	1.7 [0.8–3.5]	5.2 [3.4–7.0]
CS (total)	35 (11.1)	43 (14.2)	26 (8.4)	0.8 (0.5–1.2)	1.8 (1.1–3.2)	1.4 (0.8–2.4)
Fetal distress	12 (3.8)	12 (3.9)	7 (2.3)	1.0 (0.4–2.4)	1.8 (0.6–5.5)	1.7 (0.6–5.2)
Failure to progress	23 (7.3)	31 (10.3)	19 (6.1)	0.7 (0.4–1.3)	1.8 (0.9–3.4)	1.2 (0.6–2.4)
Instrumental delivery	66 (20.9)	68 (22.5)	73 (23.5)	0.9 (0.6–1.4)	0.9 (0.6–1.4)	0.9 (0.6–1.3)
Cord pH	7.3 [0.07]	7.3 [0.07]	7.3 [0.07]			
Apgar < 7 at 5 min	6 (1.9)	4 (1.3)	5 (1.6)	1.5 (0.4–7.3)	0.8 (0.2–3.9)	1.2 (0.3–5.0)
SCBU admission	4 (1.3)	1 (0.3)	2 (0.6)	3.9 (0.4–191.2)	0.5 (0.009–9.9)	2.0 (0.3–22.0)



prolonged labour (ranging from 52% in the 2-hour arm to 38% in the 4-hour arm). One explanation for this high proportion of women crossing the action line is that the slope of labour progression, for caucasian women in the late 1990s, may in fact be different to that defined by Philpott and Castle<sup>1</sup> for African women in the early 1970s. A steady increase in birthweight at term, coupled with the liberal use of epidurals, may offer further explanations of why normal labour, particularly for primigravid women, may progress more slowly than previously reported<sup>14</sup>.

This pilot study had only around 20% power to detect a difference in caesarean section rate of 3%. Therefore, the impact of various partograms on this outcome remains unanswered.

The 2-hour partogram had obvious benefits in terms of psychological outcome. Women allocated to the 2-hour arm were more satisfied with their labour experience despite receiving more intervention. These findings support earlier randomised studies<sup>15,16</sup> which found that pregnant women in high risk situations preferred active management.

The 3-hour partogram offers no clear benefit in terms of either clinical or psychological outcome. One explanation for the unfavourable results in this group could be that the 3-hour partogram led to indecisive management: neither aggressive or conservative. An alternative explanation is that the observed difference in caesarean section rates is a chance finding.

This study does not provide enough evidence to support either early or delayed diagnosis of prolonged labour. In the light of the conflict between clinical and emotional outcome between the two groups, it would be important to carry out a two arm trial to compare management of labour using the 2-hour and 4-hour action lines. In order to proceed with such a study 1500 women would need to be recruited in each trial arm to detect a 3% difference (8% vs 11%, as in the pilot study), in caesarean section rate with 80% power (alpha 0.05). A collaborative, multi-centred approach is therefore required.

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# A prospective study of women's views of factors contributing to a positive birth experience

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**Objective:** to explore the aspects of a woman's childbirth experience which she perceived as being important.

**Design:** as part of a large randomised trial, which assessed the timing of intervention in prolonged labour, women's views were explored using a specifically-designed questionnaire. The questionnaire, which was administered on the second postnatal day, incorporated a rating scale followed by an open question. The responses to the open question are presented in this paper.

**Setting:** regional teaching hospital in the north west of England.

**Sample:** 615 primigravid women received a copy of the questionnaire. Of the 519 women who returned the questionnaire, 412 women answered the relevant section, the findings of which are presented in this paper.

**Analysis:** the responses to the open-ended question were analysed by the generation of themes from the most frequently occurring responses.

**Main findings:** the main themes which emerged were support, information, intervention, decision making, control, pain relief and trial participation.

**Key conclusions and implications for practice:** most women are able to identify important contributors to a positive intrapartum experience. Midwives have an important role in identifying these contributors and supporting women to fulfil their individual needs.

## INTRODUCTION

In the 1980s a number of reports from the House of Commons Social Services Committee focused attention on the issues which surround perinatal and infant mortality (1980, 1984, 1989). However, while maternity services have concentrated on mortality rates, women's views, experiences and preferences have tended to be neglected (Martin 1990).

In 1992, a different approach was adopted by the all party select committee chaired by Nicholas Winterton MP (House of Commons Health Committee (1991–1992)). This report expressed concern about hospitalisation of 'normal' healthy women and the unnecessary use of routine intervention. It strongly supported the need to assess women's views on childbirth issues and contained a vision of a maternity service which offered both safety and

satisfaction. Many of the recommendations in this report were addressed in *Changing Childbirth* (Department of Health 1993), which offered guidance for health professionals in an attempt to improve the service offered to women and their families, giving more choice to consumers.

The reduction in mortality rates has led to higher expectations of the childbirth experience (Gibb 1994). Many women now enter labour expecting a positive and personally-rewarding experience (Brucker & MacMullen 1987). Most women will have these expectations confirmed by the reality of their experience, but others will not (Stolte 1987). This may be due to unexpected factors such as obstetric intervention (Brown & Lumley 1994), or to unrealistic expectations (Szczepinska 1995).

By using mortality markers in isolation, many professionals fail to understand the sense of disappointment that some women experience following

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potential to nurture and empower parents to birth as they choose. The sharing of power and decision-making, discussed by the parents, presents a challenge for midwives concerning who has the right to manage birth. In order to meet this challenge, individual midwives must examine their own birth beliefs and practices, and ensure that these are congruent with those of the birthing parents. This sharing relationship between midwife and couples can also be fostered by the profession constantly reviewing the education and socialisation of midwives.

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delivery, even when the outcome is a healthy baby (Churchill 1995). What is considered a criterion of success by health professionals may not always correspond with the women's criterion.

If health professionals are to view women holistically they need to explore both the physical and psychological aspects which contribute to the overall experience of labour. The view taken in this study is that health professionals might not necessarily know what women want. Instead, the views of recently-delivered women are explored to discover what they perceive as being important contributors to a positive experience of labour.

We have, therefore, taken the opportunity to assess the views of a large cohort of normal primigravidae who had a spontaneous onset of labour. These women were already participating in a randomised trial into the timing of intervention in labour. They were cared for in labour by midwives and the intervention of amniotomy and/or oxytocin infusion was determined by a partogram action line, which was either two, three or four hours to the right of the alert line. The three-hour action line was the norm for the study hospital.

## METHOD

### Design

Eligible women were primigravidae who presented in spontaneous labour with a longitudinal lie, cephalic presentation and live singleton fetus. All had consented to participate in the Partogram Action Study (PALS), a randomised controlled trial investigating timing of intervention in spontaneous labour (Lavender et al. 1998). If a woman's labour was progressing within normal limits (i.e. approximate cervical dilation of 1 cm/hour) then her labour management was to be unaffected, but if the action line was crossed then intervention was triggered.

One of the primary outcomes of the trial was the level of satisfaction as scored in a category rating scale. The opportunity was taken to explore the views of these women in more depth by the inclusion of an open question. As pointed out by Guba (1990) when referring to the basic belief of positivism, the ultimate aim of science is to predict and control natural phenomena. However, the fact that the sample is very much subject centred makes it difficult and inappropriate to predict or control those under investigation. It is well recognised that the implicit adoption of tenets of science, based in a positivistic paradigm, gives rise to conflicts with humanistic philosophy (Playle 1995). The approach to this study, therefore, aimed to 'humanise' the research by exploring and giving equal precedence to both 'soft' and 'hard' outcomes. So, therefore, a postpositivist approach was adopted, which has an advantage in that it recognises the need for as many

sources of data, theories and methods as possible (Guba 1990).

### Procedure

Permission to conduct the study was obtained from the NHS Trust and Local Research Ethics Committee. Women were informed about the study through written information and a discussion with the research midwife in the antenatal period. Written consent was obtained from all participating women. Women were randomised using the sealed opaque envelope method to one of three trial arms when established labour was confirmed. Postnatal questionnaires were administered to all women randomised over a 12-month period. Six hundred and fifteen women were given questionnaires on the second postnatal day with an additional two sheets of A4 paper. The women were asked to comment on both positive and negative aspects of their experience, and to discuss what they believed were the most important aspects of their labour. The questionnaires were returned by a method of their choice. This included postal boxes, hospital reception, members of staff or through the post.

### Analysis

The responses to the open-ended question were analysed using a qualitative method proposed by Norris (1981), whereby the data were systematically indexed to facilitate the development of themes and conceptual frameworks from the most frequently recurring topics. The data were viewed by two researchers who independently generated categories from the responses. One of the researchers was not involved in the project in any way. The categories were then collated and individually discussed until a consensus was reached.

## FINDINGS

Of the 519 (86%) women who returned the questionnaire, 412 (79%) expressed their views in a narrative way. These women represented 50% of those eligible over the recruitment period of 12 months. The responses of women were consistent, with agreement about aspects which they considered important contributors to a positive labour experience. The women's responses did not appear to relate to whether or not they had received intervention or to which trial arm they were allocated to. Unless indicated, the findings, therefore, represent the views of the group as a whole.

The main intrapartum themes, which emerged from the analysis were support, information, intervention, decision making, control and pain relief. In addition, many women made comments regarding their experience of participating in a trial. The experience of being a trial participant seemed to

have enhanced some women's labour experience, and so the authors believe this theme to be equally relevant.

### Support

The responses showed clearly that women in each trial arm agreed that one of the most important aspects of their labour was support. The support of the midwives and that of a partner/friend were both considered crucial to having had a fulfilling experience. The midwife was often praised by the women for being 'attentive', 'a great comfort' or 'a real friend.' All women in the study were accompanied by a partner, friend or family member throughout the labour and this was perceived as beneficial by the women. One woman articulated the views of 119 (28.9%) women by saying that:

I felt that the care I received throughout a long labour was appropriate and I felt I was treated excellently by all I came in contact with. These were the factors that were most significant to my well-being throughout the birth rather than the protocols regarding clinical intervention.

Thirty-two (8%) women reminisced about previous maternity care as told to them by older relatives, being reassured that advancements have been made for the benefit of women:

My mum said it (the birth) was a nightmare in her day . . . . My dad wasn't allowed in and my mum said she felt so alone. I am so glad that things have changed because I don't think I could have coped if I'd of been alone . . . .

Partners and family members supported the women in various ways, for example, one woman reported that:

My boyfriend was great because he was really nervous before I went into labour but he ended up getting really involved and he even cut the cord. I was so proud of him and it made it all so special.

However, 78 (19%) of women said that their partners wanted to 'just be there in the labour room', which was perceived as equally special.

### Control

The concept of 'control' has been considered by several writers and many meanings have been reported (Green et al. 1990). This being so, the authors of this article did not attempt to provide a definition of control, thinking it more relevant to consider women who used this term and explore what it meant to them. The women talked about both self control and external control.

Being in control was seen as a positive aspect of labour, with 124 (30%) women stating that it was

necessary to maintain personal 'dignity during labour.'

I was pleased that I felt I had a lot of control during labour. If I had lost control I would have felt really embarrassed. I thought I might of let myself down by screaming or swearing but I'm so glad to say I never.

Although 61 (15%) women acknowledged that they had maintained control during the intrapartum period, they also stressed the difficulty of achieving this aim:

Childbirth is really difficult and it is very hard to stay in control even when all is normal. My labour was normal but I still found it extremely difficult to remain calm and listen to the midwife and make decisions.

Unfortunately, not all women felt they were in control. One woman suggested that the control was taken away from her:

I did not feel in control – the hospital are in control. A lot of the time, probably due to pain relief I felt I did not know exactly what was going on. There seemed to be a lot of people milling around, but nobody actually explaining everything that was going on.

Regardless of the way women defined control, they identified that their expectations played a part in whether they considered their experience to be a fulfilling one or not. The views of one woman were echoed by many when she wrote about the importance of knowing that the staff were in control:

I felt at all times that the midwives and doctors were in control of the situation, which was reassuring as I was high risk. My progress was slow, the baby had had his bowels open (meconium) and the heart trace was dipping but everyone knew exactly what to do so I was pleased with the way things went.

### Decision making

One hundred and eight (26%) women acknowledged the fact that they wanted to participate in decision making. However, the desired degree of involvement differed greatly between individuals. One woman's account of her second stage of labour difficulties shows clearly the importance of involving women when important decisions are to be made:

When I was not getting anywhere pushing, the doctor asked if I wanted help. I was pleased that I was asked and that it was not forced on me. I feel that it was my decision.

In the above quote, the respondent had underlined the word 'asked' in her attempt to emphasise the importance of her own contribution to her labour management. Participation in decision making can

only occur if effective communication between woman and midwife is achieved. One woman was clearly denied the opportunity to make a decision regarding her pain relief:

The midwife did not have enough time for me. I knew that the right pain relief was important and I said I had an open mind, but she interpreted that as an immediate request for diamorphine – I was given it so quickly as it was more convenient for the midwife.

Of the 108 women who acknowledged the fact that they wanted to participate in decision making, 89 (82%) commented on the importance of both them and their partners being involved in deciding on various aspects of care. The main decisions women wanted to make were choices regarding who should be present at the delivery, which method of pain relief they should have and what position they should adopt at delivery.

### Information

One hundred and fifty-four (37.4%) women felt unprepared for labour, which they attributed to either lack of information or their own unrealistic expectations. Some women considered themselves to blame for this lack of information:

I wish I had more information antenatally, I didn't really know what to expect regarding pain and delivery etc. I also wish I'd practised the breathing exercises more frequently as during the labour I found it hard to breath properly. I'll know next time!

A few women attributed their lack of information to the insensitivity of the staff:

I felt that the reasoning for my being left so long was not explained properly.

The most distressing account was one from a woman who had been in labour for 16 hours which resulted in an assisted delivery:

The actual birth of my child had to be assisted by having an episiotomy and forceps delivery which was not explained beforehand and no pain killing injection given. The actual delivery has left me feeling quite traumatised for the moment. I understand my baby was in distress and the course of action had to be taken, I just feel it could have been carried out more sympathetically.

One area which 60 (15%) women felt unprepared for was the second stage of labour. Comments included, for example that they 'didn't expect it to be so difficult' and they 'did not know how to push.'

Those women who felt prepared, responded more positively than those who did not. Similarly, those who believed they had required adequate and

accurate information throughout their labour were less likely to view their labour negatively:

They (midwives) explained everything that was happening which was great because when they explained things I felt a lot calmer.

Reception of information was perceived by 112 women (27%) as being a contributor to the sense of control:

The midwife explained what was going on as I was in labour and this meant I felt I was in control.

Many women commented on the lack of information they received following the delivery of their baby. Although the women were questioned on the second post natal day they were already seeking answers to questions regarding their intrapartum experience. Amongst the 87 (21%) women who commented about postnatal information, a consensus was reached which acknowledged that postnatal support was lacking:

Someone should talk to you after you have had your baby because although my midwife was very good when I was in labour I would have liked to have asked her about what went on. My labour went fine, I think, because I had a normal delivery but it would have just been nice to have talked to the midwife about the labour.

### Pain

Eight-five women (21%) mentioned pain or pain relief, highlighting its importance as a contributor to intrapartum well-being. There did not appear to be any differences between women randomised to the different trial arms. Fifty-five women across the three trial arms, commented that their chosen method of pain relief was ineffective, whilst 30 women believed their pain to have been managed in an appropriate way to meet their individual needs. Although some women said that the pain was 'unbearable' or 'a lot worse than expected', there were others who believed that the pain was 'not so bad' or 'a lot better than expected'.

Women in the study had various methods of pain relief for their individual needs. While some women commented that they were 'very happy to be able to manage with very little pain relief' there were others who 'wanted everything for the pain'. The following accounts of two women's chosen pain relief demonstrates their individuality:

I enjoyed being in the pool. The warm water helped with the pain and helped me to be more mobile. The aromatherapy was enjoyable. It helped build a more relaxed atmosphere and made me feel in control.

The epidural was extremely effective. I would definitely recommend it to other women. Being

pain free meant I could sleep which meant my labour seemed shorter and I wasn't too tired to push the baby out.

### Intervention

Probably the most interesting theme generated was intervention. The fact that these women were taking part in a study assessing intervention may have heightened their awareness of intervention, thereby influencing the generation of this theme. However, most women did not perceive intervention as a negative aspect of labour, instead 102 (25%) women saw it as a positive contributor to their experience when abnormal labour patterns developed. Women felt reassured when allocated to the two-hour action line, knowing that intervention would occur promptly if indicated:

Although no intervention was needed I was happy to know that after 2 hours I would be helped along rather than left.

Surprisingly, only one woman believed that she had unnecessary intervention, however, 41 (10%) women believed that they either waited too long for intervention or did not feel they were given the intervention they required:

I think earlier intervention (if needed) would be more welcome, as it offers the patient more reassurance and choice.

I didn't seem to be making any progress and would not have liked to go much longer without assistance.

The number of women in the four-hour arm ( $n = 23$ ) who said that they waited too long for intervention was double that of those in the other two trial arms (two hours:  $n = 8$ , Odds Ratio 0.32 (0.19–0.77),  $p = 0.008$ ; three hours:  $n = 10$ , Odds Ratio 0.42 (0.17–0.98),  $p = 0.04$ :

After 5 cms I was pleased to be checked (vaginal examination). After the length of time it was taking I was very glad when the registrar said I could have the drip. From the time that the drip was put up to the birth, I could not believe how quickly it went, I wish I'd of had it earlier.

A minority of women suggested that intervention should be used with caution, identifying the negative aspects of its use:

The point to make is that intervening earlier may just tip the balance and may cause more problems when perhaps the idea is to make it easier. Unnecessary intervention in my opinion only adds to the load that a woman has to cope with. Labour in itself is very demanding and personally I was glad that I required no intervention.

### Trial participation

It was encouraging to note that 134 (32%) women acknowledged the need for research, recognising the positive effects to maternity care:

I think the study is good as it keeps up with new ideas of improving things for childbirth.

It was evident that women accept and welcome research into maternity care, being aware of the benefits to themselves and their families:

I think it is very important to do studies about childbirth and how new mothers cope with the birth of their baby so they improve techniques to make mother, fathers and babies more confident in this emotional experience.

Another said:

As long as the protocols are based on sound medical/clinical evidence then I would be happy with whatever was adopted as the hospital policy.

It was welcoming to read some women saying, 'I was pleasantly surprised when I was approached about the PALS study', and, 'Thanks so much for telling me about the PALS'. Women apparently did not feel coerced into participating in the trial, instead they felt that they were given an additional choice:

When I was approached about the study I was very pleased because improvements can only be made if people like me take part. I did not feel that I had to take part because I went home to think about it. I was allowed to choose whether I wanted to take part which made me think very hard about the study.

### DISCUSSION

Unusually, the trial was used as a method of accessing a large group of women with normal pregnancies and spontaneous labours. Using a trial to access women early in pregnancy was considered to be the most ethical approach to recruitment. All too often women are bombarded with questionnaires to complete without receiving any preliminary information.

Although the themes were examined by trial arm, to ensure that negative views were not concentrated in any one group, only the theme of intervention showed any differences. The data have, therefore, been presented as a single group.

Although it is generally considered (Burns & Grove 1995) that interviews are a superior method for in-depth data collection, the use of questionnaires does allow a large sample to be questioned yet still allow a large quantity of data to be produced. Because a relationship had developed between the women in the study and herself, the researcher felt confident that women would respond openly and honestly, thus enhancing the quality of the data.

However, because of this developing relationship there was a possibility that some women did not feel able to give negative comments, despite the researcher's lack of involvement in any aspects of clinical care. The postpositivist approach acknowledges external influences, recognising the 'absurdity of assuming that it is possible for a human inquirer to step outside the pale of humanness while conducting inquiry' (Guba 1990, p. 20).

As conclusive evidence was not found from the literature to suggest the best time to administer the questionnaires, they were administered to all participating women on their second postnatal day. This enable women who had a difficult labour/delivery to have recovered somewhat, yet maximised the likelihood of recall accuracy. It is well documented (Simkin 1992) that women have extremely clear memories of the birth, but also that people's perceptions and memory of events are notoriously selective and subjective (Atkinson et al. 1996).

The study is limited, however, as the women were only questioned on one occasion, in the immediate postnatal period. This means that feelings which may be related to long-term postnatal outcomes were not explored.

The women in this study were asked to comment on what factors they believed contributed to a positive experience of labour. Although their own particular birth conditions had influenced their responses, these were not always directly related to their own labour experience. For example, a woman may have identified the need for effective pain relief, but she may or may not have received it. This tended to support the fact that many women enter labour with particular expectations of standards of care. These may or may not have been met, but the women, post delivery, still considered them to be important. This may also account for the fact that there were few differences between the three trial arms.

Support by midwives was frequently commented upon, both negatively and positively. The majority of comments were favourable and the women used the questionnaire as an opportunity to highlight and praise individual midwives. The women were satisfied overall, but most questionnaires did identify that certain elements of the women's labours may have been improved. This supports work carried out by Waldenstrom et al. (1996) who concluded that both positive and negative feelings can coexist.

Coupled with midwifery support, the presence of a partner was welcomed, yet the data suggested that this support presented itself in many guises as previously reported (Lavender 1997). The help given by the partner stemmed from his mere presence, his verbal encouragement or his active involvement. However, whichever form this support took it was always mentioned positively by the women.

Many women in this study welcomed the opportunity to contribute to making decisions about

their labour management, a factor which has previously been associated with a positive experience of labour (Davenport-Slack & Boylan 1974). Also, the Audit Commission (1997) recently highlighted the fact that women's individual requirements can only be met if they are fully involved in decisions about their labour management. If we accept these points of view, then the logical conclusion is to assume that women who have decided to participate in the study have a somewhat better experience.

In this work, matters of communication, discussed in the literature by Kirkham (1989), were found to be an issue. Women identified the importance of information, but did not always feel that they had sought or received it appropriately. The amount, content and manner of delivery were commented upon. The women, who were all primigravidae, commented on the particular lack of information to prepare them for the second stage. Although this aspect of childbirth may be difficult to realistically prepare women for, it does offer a challenge to antenatal educators.

In the period following delivery some women felt deserted by their midwives despite reported benefits of postnatal debriefing (Charles & Curtis 1994, Ralph & Alexander 1994). This is an issue which needs to be urgently addressed if women are to receive the psychological support they deserve.

The data supported the view of others (Hodnett & Simmons-Tropea 1987) that control is a particularly important element for women in labour, and for some, it is the most important variable to having a satisfying childbirth experience (Humenick & Bugen 1981). Some writers (Kitzinger 1980, Oakley 1980, Graham & Oakley 1981) argue that loss of control is due to the disempowerment of women who strive for normality yet are faced with medicalisation. There was no supporting evidence for that point of view in this study. An increase in intervention did not lead to the women saying that they had a lack of control. Previous research has shown that women's views about labour management are clearly related to the procedures they experience (Jacoby 1987), high obstetric intervention having a direct relationship with maternal dissatisfaction (Brown & Lumley 1994). However, findings from this study offer support to findings from another randomised controlled trial carried out by members of the same team (Blanche et al. 1998), which discovered that those women who were found to perceive themselves as in the greatest control were those whose management involved the most intervention. Views expressed by the women in this study challenge the conventional wisdom that most women perceive obstetric and midwifery intervention as negative. It reinforces the view that health care professionals and even interested lay groups do not necessarily 'know' what women want.

The evidence suggested that the women welcomed the opportunity to participate in research and



the research design was one in which informed choice was emphasised. In addition to written information, the trial participants were given an opportunity to discuss the trial at length with a research midwife. Women were not encouraged to make a decision at this point, instead they were given from 20 weeks' gestation until the time of delivery to make a decision. This enabled women to feel comfortable about refusing to participate (Robson 1995). The area of trial participation needs further investigation as women's awareness of evidence-based practice may, in fact, provide them with reassurance about the care they would receive in labour.

Although clearly-defined themes are presented here, the data suggest that in reality, control, pain, information, decision making and support interrelate. It is, therefore, important that midwives assess all these aspects to promote a positive experience for each individual woman. Each woman will measure her experience of labour differently and, therefore, it is important that planned individualised care is not neglected. Childbirth has previously been described as 'a gamble' and a 'lottery in which there will, sadly, be losers' (Szczipinska 1995, p. 574). Yet, by listening to the views of women, midwives can assist in promoting odds which are stacked in favour of a fulfilling experience. This can be achieved, for example, by identifying areas for further research, incorporating findings into care protocols and by communication and collaboration with other health professionals, notably obstetricians, and obviously ongoing communication with the women themselves.

Although no revolutionary ideas are presented here, the findings add to the current body of knowledge and reinforce issues which have already been discussed. As we enter the millennium we must appreciate that the views of women are vitally important. The ongoing re-evaluation of issues pivotal to women must be carried out if midwives are to provide women-centred care.

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## Managing Labor Using Partograms with Different Action Lines: A Prospective Study of Women's Views

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**ABSTRACT:** **Background:** *The precise timing of medical intervention for women in prolonged labor is the subject of considerable debate. The partogram action line is a tool to assist practitioners in the correct diagnosis of prolonged labor. Despite its widespread use, the precise timing of the action line has not been rigorously studied, and women's views have rarely been sought. The aim of this study was to assess the effect on maternal satisfaction of managing labor using partograms with action lines drawn at 2, 3, or 4 hours to the right of the alert line. Methods:* *As part of a large pilot randomized controlled trial, women's views were explored using a specifically designed questionnaire that was completed by 615 primiparas 2 days after giving birth. The quantifiable data were analyzed by comparing means using ANOVA followed by the Scheffe test. Results:* *Women in the 2-hour arm were significantly more satisfied than those in the other two arms ( $p < 0.001$ ), despite having the most obstetric intervention. Conclusions:* *For women in prolonged labor, obstetric intervention can be an acceptable or even favorable option. Midwives and obstetricians need to provide labor management that takes into account the preferences of the women to whom they give care. (BIRTH 26:2 June 1999)*

It is accepted midwifery practice that obstetric intervention should not be used unless clinically indicated (1). The recent national government report, *First Class Delivery* (2), of 2376 women, confirmed that consumers also hold this view, recognizing the negative effect of many procedures. Although evidence (3,4) exists to suggest that women do not want unnecessary routine intervention when labor is progressing normally, few data are available that assess maternal views of abnormal labor.

Prolonged labor contributes to maternal and fetal mortality and morbidity (5). One measure introduced to improve the outcomes of laboring women was

the partogram (6). This tool is considered to be valuable because it allows midwives and obstetricians to display intrapartum details in a pictorial manner, enabling rapid identification of abnormal labor patterns (Fig. 1). , ,

Common partogram designs follow the work of Philpott, and most incorporate an action line (7), which denotes the timing of intervention based on cervical dilation. It is conventionally placed a number of hours to the right of another line, the alert line, which describes the rate of cervical dilation of the slowest 10 percent of primigravidas (8). The use of the partogram itself has only recently been evaluated in an appropriate way, demonstrating clear benefits in terms of obstetric outcome (9).

However, the precise timing of the intervention remains a source of considerable debate. Early and aggressive intervention may reduce cesarean delivery rates, as argued by the Dublin group (10), although recent trials have not supported this (11,12). Later intervention may result in fewer women having procedures, but may prolong labor or increase operative intervention. The views of women themselves have rarely been sought in such complex clinical scenarios.

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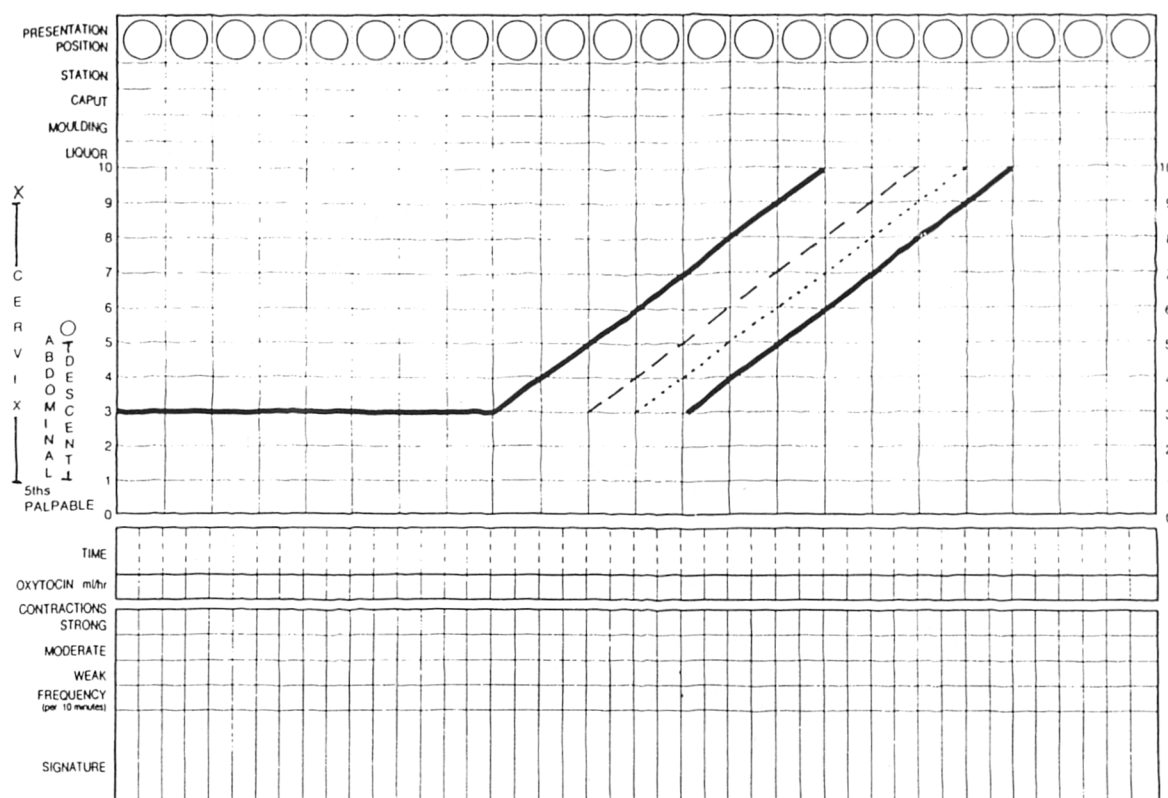


Fig. 1 Partograms used in this study included an alert line and 2-hour (---), 3-hour (.....), or 4-hour (—) action line. Cervical dilation at the first vaginal examination in the active phase ( $\geq 3$  cm) was plotted on the alert line.

From the woman's perspective, therefore, advantages and disadvantages of different approaches to abnormal labor may exist. What groups of women think about the relative merit of these approaches has yet to be evaluated.

Despite its widespread use, the precise timing of the action line has not been rigorously defined in appropriate trials. This may be important, since the timing of intervention will determine the proportion of women undergoing procedures, such as amniotomy, intravenous infusion, and continuous electronic fetal monitoring. The evidence for the efficacy of many of these procedures has been debated (11).

We conducted a large pilot randomized controlled trial of the outcome of spontaneous labor in normal primiparous women. The randomization was to a partogram with an action line at 2, 3, or 4 hours. The primary outcome measures were cesarean section rate and level of maternal satisfaction. As a primary outcome measure in this phase, we assessed women's views of labor using two methods of qualitative assessment, one with a rating scale and the other with a more open approach. We report here on the results of the rating scale analysis.

The overall study of 928 women showed a clinically

interesting difference in cesarean section rate, and statistically significant differences in overall satisfaction (13). This current paper provides more detailed information on the development of the questionnaire and on the individual items that were assessed.

## Methods

### Sample

The study was carried out in an inner city maternity hospital in Liverpool between January 1996 and August 1997. Women included in the trial were primigravidas with uncomplicated pregnancies, who presented in spontaneous labor at term and had a live singleton cephalic presentation.

Women were randomized to one of the three trial arms by a computer-generated random number sequence. Trial allocation was with a sealed opaque envelope. Given the type of intervention, blinding of clinicians or women to the allocation was not possible. Based on previous hospital delivery data and recruitment rates from previous trials, we anticipated that 600 women would be randomized to the study in one year. Since little evidence was available to allow pre-

cise sample size calculations, a large pilot study was needed to assess the feasibility of a definitive trial. The overall number of recruited women in this study was therefore determined by the duration of the research post. Consultation with a statistician and psychologist suggested that 600 women would provide an adequate sample and that this part of the study was unlikely to be underpowered. A sample size of 200 women per group was sufficiently large to detect differences in the satisfaction score of less than 1 with more than 95 percent power. Since differences in a satisfaction score of less than 1 are unlikely to be of any clinical significance, it was believed unnecessary to obtain a larger sample.

### *Procedure*

Permission to carry out the study was obtained from the local research ethics committee. Information leaflets were given to primigravid women at the booking visit to ensure that they received and had time to absorb the information before discussing the trial. At the 20-week ultrasound visit all eligible women were invited to discuss the trial with the researcher. For those who decided to take part, written consent was obtained.

After the women's eligibility was confirmed, the delivery unit midwives carried out the randomization using the sealed opaque envelope method. Management of labor followed the current delivery unit protocol, whereby obstetric intervention was triggered according to the action line of the partogram. Intervention was either amniotomy in the presence of intact membranes and the commencement of a standard oxytocin regimen, or oxytocin alone if spontaneous rupture of the membranes had occurred.

Specifically designed questionnaires were administered by the research midwife to all participating women on their second postnatal day. They were completed at a time convenient to the women, usually before transfer to the community. The questionnaires were returned by any method chosen by the individuals (including postal) in an attempt to reassure them that their responses were confidential.

A questionnaire was considered to be the most appropriate tool for the study since it allowed a relatively large sample of women to be questioned quickly and cheaply yet generated a good volume of data. The questionnaire was specifically designed for this study, because when previous tools were piloted they were either unacceptable to respondents or did not measure desired areas of childbirth.

An expectation-fulfillment model (14) in the form of a category rating scale was used in which women were asked whether or not their expectations had been met. The main themes that were explored through the questionnaire were control, pain, length of labor, and

overall experience. Two supporting questions were also included that asked whether, if time suddenly went backwards, women would take part in the study again, and how they would feel if the group to which they were allocated became normal practice. The themes were incorporated into six items, the respondents being allowed to check only one option for each question.

Content validity was achieved by asking primigravidae in the antenatal and postnatal period, "What worries you most about labor?" The responses to this question were consistent, and the literature supports these themes.

Construct validity was achieved when 20 questionnaires, identical to those in the study, were administered to women after the delivery of their first baby. Using the "known groups technique" (15), one-half of the questionnaires were administered to women after an uncomplicated labor and birth, and the other half were administered to women after an emergency cesarean delivery. The test results supported the hypothesis that the latter group would show less satisfaction (mean scores for each question showing > 1 point difference). These findings offered reassurance that the instrument was capable of detecting psychological differences based on labor experience.

### *Data Analysis*

The precoded responses from the questionnaires were entered onto a database alongside the demographic and intrapartum information. Data were analyzed using SPSS for Windows, version 6.1.

Odds ratios and 95% confidence intervals were calculated for the nominal/categorical data. The Fisher's exact test was used for 2 by 2 tables. For non-normally distributed continuous data, the significance of the difference between the three groups was determined by the Kruskal Wallis test. Normally distributed data were analyzed by a comparison of means using a one-way analysis of variance (ANOVA).

Although the satisfaction data were categorical, the sample size made it appropriate to perform a one-way ANOVA to determine whether or not differences existed between the groups. The Scheffe (16) multiple range test was then performed to establish specific differences between the groups. The Scheffé test, being conservative, would reduce the possibility of a type one error in a relatively large sample. The overall score was also analyzed using a one-way ANOVA followed by the Scheffe test.

### **Results**

A total of 615 women were randomly allocated to one of three trial arms during 12 months in a single obstetric unit that had 6067 deliveries over this period. Of these

deliveries, 1763 were to primigravidas. Of 1178 eligible women at term, 314 declined to participate, 171 were never approached, 72 consenting women were not randomized, and 3 consenting women withdrew before randomization, leaving 618 randomized women. Since 3 randomized women could not be traced due to the inaccurate recording of demographic details, data were collected for 615 women.

The response rate was 86.5 percent ( $n = 519$ ), with fairly equal numbers of women responding in each trial arm (2 hr 89%, 3 hr 80%, 4 hr 84%). A small number of women, evenly distributed across the three arms, responded that they did not know what to expect in answer to questions on some items (control, 12.3%; length of labor, 6.2%; pain, 7.7%; experience, 5.8%). This response was difficult to code because it could be interpreted as being positive, negative, or neutral. These data were not considered to be part of the rating scale and therefore were not included in this analysis. Omitting this option altogether may have forced some women to respond in a way that did not truly reflect their feelings.

The demographic information in terms of maternal

age, gestation, cervical dilation, cervical effacement, and condition of membranes showed no significant differences among the trial arms (Table 1). The obstetric outcomes for women whose data were analyzed are described in Table 2. No statistically significant differences occurred with respect to age, gestation, epidural analgesia rate, and cesarean delivery rate between women who participated and those who declined.

Data for nonresponders were as follows: mean age 24.6 (SD 5.3); mean gestation 28.1 (SD 8.2); percentage of women randomized whose cervix was 3 cm or more 75 percent; mean randomization to delivery interval 536.8 (SD 5.3); epidural analgesia rate 35.4 percent; and spontaneous vaginal delivery rate 64.6 percent. These findings are similar to those for the respondents.

The satisfaction data are presented in categorical form in Table 3. This table demonstrates the frequency of responses to each question.

### Questionnaire Reliability

To identify which questionnaire variables could be combined as unified concepts, a factor analysis using

Table 1. Description of Women at Randomization to Trial Arms

Characteristic	2 Hours ( $n = 179$ )		3 Hours ( $n = 169$ )		4 Hours ( $n = 171$ )	
	No.	(%)	No.	(%)	No.	(%)
Maternal age, mean (SD)	25.1	(5.1)	25	(5.3)	24.8	(4.8)
Gestation, mean (SD)	281.4	(8.2)	280.9	(8.5)	281.5	(9.1)
Cervix < 3 cm	28	(16)	32	(19)	37	(22)
Cervix 3–10 cm	151	(84)	137	(81)	157	(78)
Cervix effaced	149	(83)	139	(82)	166	(85)
Membranes intact	113	(63)	119	(70)	112	(65)

No statistical differences were found.

Table 2. Intrapartum Outcomes

Outcomes	2 Hours ( $n = 179$ )		3 Hours ( $n = 169$ )		4 Hours ( $n = 171$ )	
	No.	(%)	No.	(%)	No.	(%)
Action line crossed*	90	(50)	73	(43)	64	(37)
Action line-triggered intervention† (ARM, Syntocinon, or both)	83	(46)	66	(39)	57	(33)
Randomization-delivery interval (min), mean (SD)	531	(282)	534	(265)	542	(281)
Epidural analgesia	69	(39)	48	(28)	50	(29)
Vaginal examinations, median (IQR)	4	(3–5)	4	(3–6)	4	(3–6)
Spontaneous vaginal delivery	117	(65)	110	(65)	114	(67)
Instrumental delivery	42	(23)	34	(20)	41	(24)
Cesarean delivery (overall)	21	(12)	24	(14)	16	(9)
Cesarean delivery (delay)	12	(7)	18	(11)	13	(8)
Cesarean delivery (distress)	9	(5)	6	(3)	3	(1)

\* When 2 and 4 hours were compared using Fisher's exact test,  $p = 0.02$ .

† When 2 and 4 hours were compared using Fisher's exact test,  $p = 0.02$ .

ARM = amniotomy.

IQR = interquartile range.

No further statistical differences were found.

**Table 3. Categorical Satisfaction Data**

Items	2 Hours (n = 179)		3 Hours (n = 169)		4 Hours (n = 171)	
	No.	(%)	No.	(%)	No.	(%)
<b>Control</b>						
I did not know what to expect	22	(12.3)	20	(11.8)	27	(15.8)
Much worse/somewhat worse than expected	35	(19.6)	66	(39.1)	75	(43.9)
About what I expected	44	(24.6)	41	(24.3)	34	(19.9)
Somewhat/much better than expected	78	(43.6)	42	(24.9)	35	(20.5)
Missing data	0		0		0	
<b>Length of labor</b>						
I did not know what to expect	8	(4.5)	9	(5.3)	16	(9.4)
Much longer/somewhat longer than I expected	55	(30.7)	65	(38.5)	95	(55.6)
About what I expected	63	(35.2)	47	(27.8)	29	(17.0)
Somewhat shorter/much shorter than I expected	53	(29.6)	47	(27.8)	31	(18.1)
Missing data	0		1	(0.6)	0	
<b>Pain</b>						
I did not know what to expect	11	(6.1)	14	(8.3)	12	(7.0)
Much worse/somewhat worse than I expected	51	(28.5)	61	(36.1)	101	(59.1)
About what I expected	51	(28.5)	52	(30.8)	34	(19.9)
Somewhat better/much better than expected	65	(36.3)	41	(24.3)	24	(14.0)
Missing data	1	(0.6)	1	(0.6)	0	
<b>Experience</b>						
I did not know what to expect	11	(6.1)	10	(5.9)	12	(7.0)
Much worse/somewhat worse than I expected	52	(29.1)	61	(36.1)	82	(48.0)
About what I expected	48	(26.8)	46	(27.2)	37	(21.6)
Somewhat better/much better than expected	68	(38.0)	51	(30.2)	39	(22.8)
Missing data	0		1	(0.6)	1	(0.6)
<b>Taking part in the study again</b>						
Definitely/probably not	14	(7.8)	23	(13.6)	46	(26.9)
I'm not sure	30	(16.7)	29	(17.2)	26	(15.2)
Probably/definitely yes	135	(75.4)	117	(69.2)	99	(57.9)
Missing data	0		0		0	
<b>Study group becoming normal practice</b>						
Very/slightly disappointed	13	(7.3)	28	(16.6)	60	(35.1)
Not sure	51	(28.5)	50	(29.6)	51	(29.8)
Fairly/very pleased	114	(63.7)	85	(50.3)	57	(33.3)
Missing data	1	(0.6)	6	(3.6)	3	(1.8)

Principal Component Analysis with varimax rotation (16) was performed by entering the six items (control, length of labor, pain, experience, repeat participation in the study, practice). The items all loaded on one factor (Table 4), suggesting that the questionnaire was

unidimensional; that is, all factors related to satisfaction with the labor experience.

After data were collected for 519 women, the internal consistency of the six questions was examined by calculating correlations between each item using Pearson's correlation coefficient. When a positive correlation ( $p < 0.001$ ) was discovered among all six items (control, experience, length of labor, pain, practice, repeat participation), they were then entered to establish the reliability and internal consistency using Cronbach's alpha; alpha was 0.82, which suggests that the questionnaire had internal consistency.

#### Comparison of Means

A one-way ANOVA was calculated, significant results for all variables were obtained ( $p < 0.001$ ), and com-

**Table 4. Factor Matrix to Identify Variables That Could Be Combined as Unified Concepts**

Items	Factor 1	Factor 2
Control	0.74056	-0.18489
Experience	0.67439	-0.27764
Length of labor	0.68899	-0.34124
Pain	0.74499	-0.39115
Practice	0.67716	0.62992
Repeat study participation	0.68519	0.61897

parisons were performed using the Scheffé multiple range test (Tables 5 and 6). In the overall satisfaction score the Scheffé test showed that women in the 2-hour arm were significantly more satisfied than those in the 3- or 4-hour arms ( $p = 0.0001$ ). In all six questions a post hoc Scheffé test at  $p < 0.05$  showed a significant difference between 2 and 4 hours. With respect to the items of control, pain, and practice, the post hoc Scheffé test at  $p < 0.05$  showed a significant difference between 2 and 3 hours, and with respect to the item of repeating the study, a significant difference was found between 3 and 4 hours (Table 6).

### Discussion

The difficulties of defining and measuring satisfaction have been widely reported (17–21), with little consensus about the best way to conduct investigations. The complexities of childbirth and the individuality of each woman's experience make it extremely difficult to measure such an ill-defined outcome with confidence. During labor a woman has a wide range of emotions, from the pain and distress of the first and second stages to the happiness and relief felt after the birth of a healthy baby (22). This study acknowledges the difficulties of measuring satisfaction. The importance of assessing maternal views cannot be ignored, however, if a full picture of the effects of care is to emerge.

Although the expectation-fulfillment model was recently criticized (23), evidence suggests that satisfac-

tion relates to the level of expectations (24–26), and has been considered an "obvious method" for use in maternity care (27). Since it was reported that overall "satisfaction scores" tended to underestimate the extent of dissatisfaction with particular aspects of care (18,21,28,29), the items were also individually reported. An important part of the questionnaire was to identify the individual variables that affected satisfaction in each trial arm, in addition to indicating the level of satisfaction.

The results of our study appear to be generalizable to other populations, with only 10 percent of eligible women who were never approached about participating in the trial. In large pragmatic trials, recruitment rates of 50 percent or more are generally regarded as excellent. Failure to approach only 10 percent of eligible women, which occurred as a consequence of multiple factors such as lack of available resources, increase in work load, and human error, is considered acceptable by the authors.

As can be seen from Table 2, differences occurred in both intervention and cesarean delivery rates among the trial arms. Although these differences did not reach statistical significance, the results were interesting from a clinical standpoint.

The results of this study showed that women allocated to the 2-hour arm were significantly more satisfied than those in the other two arms, despite having the most action line-triggered intervention. These findings support an earlier study (30) of dysfunctional labor

**Table 5. Overall Satisfaction Score**

Statistical Test	2 Hours	3 Hours	4 Hours	2 vs 3 Hours p	3 vs 4 Hours p	2 vs 4 Hours p
Mean (SD)	23.5 (5.9)	21.4 (6.1)	19.3 (5.6)	<0.0001	<0.064	<0.0001

**Table 6. Satisfaction Outcomes for Questionnaire Items**

Items		2 Hours	3 Hours	4 Hours	F (df)	p
Control	Mean	4.45	3.57	3.27	28.01	<0.0001
	SD	1.26	1.29	1.27	(2,468)	
Length of labor	Mean	3.96	3.50	3.10	14.44	<0.0001
	SD	1.19	1.37	1.33	(2,510)	
Pain	Mean	4.11	3.43	3.11	21.22	<0.0001
	SD	1.27	1.34	1.15	(2,504)	
Experience	Mean	4.23	3.61	3.37	15.7	<0.0001
	SD	1.3	1.3	1.25	(2,501)	
Repeat study participation	Mean	3.94	3.5	3.2	13.75	<0.0001
	SD	0.99	1.1	1.3	(2,537)	
Practice	Mean	3.88	3.17	2.82	28.66	<0.0001
	SD	1.15	1.5	1.52	(2,531)	

Questions 1–4 scale = 2–6, questions 5 and 6 scale = 1–5.

which reported that women whose labors were managed by amniotomy and oxytocin solution (Syntocinon) were more satisfied than those who had amniotomy only or expectant management. Although the satisfaction scores are statistically significant, the practitioner must determine their clinical significance. We believe that because of the lack of statistically significant differences in other outcomes, a relatively small difference in overall satisfaction score (3 points) may influence changes in practice.

Surprisingly, the group with the lowest cesarean delivery rate (4 hr) was the least satisfied in all the outcomes explored (control, pain, length of labor, overall experience). Similarly, the women in this group were more likely to say they would "definitely not" take part in the study again, if time suddenly went backwards. Furthermore, these women were more likely to say they would be "very disappointed" if the allocated management became normal practice. These results suggest that the fear of a longer labor without intervention may cause greater dissatisfaction to a woman when compared with early identification of abnormal labor patterns with corrective interventions. When the women were questioned, however, they were not aware of the other intrapartum outcomes. Previous knowledge of the different cesarean delivery rate, for example, could have led to different responses.

The results of the satisfaction phase of this study alone are extremely important. They highlight the fact that if a diagnosis of possible prolonged labor is made, many women may choose early obstetric intervention. Even those women whose labor progresses normally may actually feel more satisfied knowing that intervention will occur earlier if progress deviates from the norm.

The study is limited in that women were questioned on one occasion only, and therefore their responses reflected their level of satisfaction at a single time period. Longitudinal studies may discover a variation of feeling throughout the postnatal period. A further study limitation is that the tool used, that is, the questionnaire, did not enable an in-depth discussion, which may have discovered why women responded in different ways. Although this study identifies which group of women was more satisfied, we can only hypothesize about reasons. Even though all women were given the same information by the researcher before randomization, it must be acknowledged that participating in a trial may have heightened the women's awareness of labor events, thereby influencing their responses. This study does not ignore the individualism of each woman, but it suggests that a more flexible approach should be used for the timing of intervention in labor. By encouraging women to express their views of labor and combining these findings with the intrapartum

data, a holistic picture has emerged that enables women to make informed choices about their labor management. These findings are probably not what many midwives and obstetricians would have anticipated, which highlights the importance of encouraging women to express their preferences, rather than health caregivers making assumptions about what women want.

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## Commentary: Managing Labor: What Do Women Really Want?

Mary E. Hannah, MDCM, MSc

It was with great interest that I read the report by Tina Lavender and her colleagues from Liverpool in this issue of *Birth* (1). It describes their randomized controlled trial on the use of different action lines for the management of labor with a partogram, and reports on the results for women randomized during the first 12 months of the study. The primary focus of the paper is on women's satisfaction with their childbirth experience and with their participation in the study itself. The full report of the trial was published earlier in the *British Journal of Obstetrics and Gynaecology* (2).

In this trial, normally laboring primigravidas were randomized to management of labor with a partogram in which the action line was at 2 hours (2-hr group), 3 hours (3-hr group), or 4 hours (4-hr group). If the action line was crossed, labor was managed more actively (an oxytocin infusion if membranes were ruptured, and amniotomy followed by oxytocin if membranes were intact). Women who enrolled during the first part of the study were asked to complete a questionnaire at 2 days postpartum to rate their experiences. Compared with what had been expected, they were asked to comment on the control they felt in labor, the length of labor, the pain experienced, and their overall experience. They were also asked to comment on their willingness to participate in the study again and whether they would be disappointed if the treatment they received became standard practice.

In the study overall a total of 928 women were randomized. Statistically significant differences were found for the rates of cesarean delivery among the

groups, which according to the original report were 11.1 percent for the 2-hour group, 14.2 percent for the 3-hour group, and 8.4 percent for the 4-hour group; the differences between the 3- and 4-hour groups were statistically significant (2). Among the subset of women who completed questionnaires postpartum, no statistically significant differences occurred in rates of cesarean section (ranging from a low of 9% for the 4-hr group to a high of 14% for the 3-hr group).

As the authors point out, it is generally assumed that women are more satisfied with their care if there is less intervention. Thus to find the opposite, as was the case with the Lavender study, makes one stop and think. A previous multicenter trial of induction of labor for women with prelabor rupture of membranes at term (PROM) also found that earlier intervention (induction of labor) was associated with greater maternal satisfaction (3). Perhaps it is time we relied more on the results of these systematic evaluations of women's views of their birth experiences, using structured questionnaires, to determine how women really feel about their care during labor and birth, rather than assuming that more intervention is bad.

Few randomized controlled trials are perfectly designed, conducted, and analyzed. Thus what are the limitations of the Lavender study? The authors did not use a centrally controlled approach to randomization (divorced from the clinical setting). In addition, although not statistically significant, an imbalance was present among the three groups in the percentage of women whose cervix was dilated less than 3 cm at randomization (16% vs 19% vs 22%). I suspect this imbalance was due to chance, but I would be more confident about that if randomization (using consecutively numbered opaque sealed envelopes) had not been left in the hands of the midwives in the labor and delivery unit. It is curious that the women allocated to the 2-hour group did not give birth earlier than those allocated to the 4-hour group, if one accepts that amniotomy and oxytocin, if nothing else, do speed up labor. Perhaps the greater use of epidural analgesia in

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the 2-hour group (39%) versus the 4-hour group (29%) resulted in a prolongation of labor, negating the benefits of amniotomy, oxytocin, or both. Since all of these interventions can have an impact on maternal satisfaction, I would have preferred that the results of the maternal questionnaire had been on the whole sample rather than a subset. Hopefully the authors will undertake secondary analyses to explore further the effect of the various interventions on measures of maternal satisfaction.

The finding of statistically significant differences in mean scores of measures of maternal satisfaction, favoring the 2-hour group, is important new information that should be used in counseling women about approaches to the management of labor. When the results were reported as categorical data, women were consistently more likely to rate their outcomes as much worse or somewhat worse than expected if they were in the 4-hour group compared with the 3-hour group, and they were least likely to report these unfavorable ratings if they were in the 2-hour group.

The issue cannot yet be put to rest, however, as we do not know if a 2-hour action line will result in a higher or lower rate of cesarean section than a 4-hour action line. Many women might accept "feeling control during labor," "pain," or "a birth experience" that is worse than expected or labor that is longer than

expected if the ultimate result would be a lower risk of a cesarean section and less need for epidural analgesia. The sample size of this study was too small to address these important outcomes adequately, as the authors concede in the discussion section of their primary paper. Hopefully, Lavender and colleagues will consider mounting an appropriately sized multicenter trial to evaluate the 2-hour versus the 4-hour action line formally. The study should examine rates of cesarean section, operative vaginal delivery, and other important obstetric and neonatal outcomes for those primigravid women who are undecided, based on current information, as to how they would like their labor managed. Should such a trial go forward, I would strongly encourage the investigators to ask all women enrolled to rate their childbirth experiences.

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