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# Clinical trials and their tribulations: the midwife's perspective

Helen Spiby

A thesis submitted in partial fulfilment of the requirements of Sheffield Hallam University for the degree of Master of Philosophy

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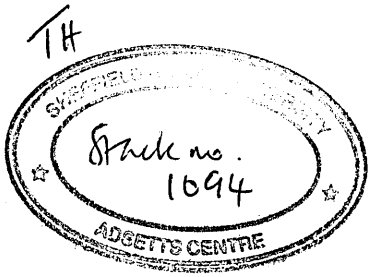
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## Abstract

From the late 1970's, there was an increasing criticism of hospital maternity care. Conventional practices were challenged, including that of recumbency for birth.

Professionals responded to these criticisms in a variety of ways: more homelike decoration in labour wards, information for women through birth plans and new equipment to use in labour. Some obstetricians utilised the randomised controlled trial to evaluate new methods of management. Inevitably, midwives attending women in labour came into contact with these trials. This thesis utilises the experiences of one such clinical trial.

A case study methodology was used to identify the impact of the trial on the work and experiences of midwives attending women in labour. The effects on midwives' work include changes of philosophy, changes to practice, increased work, exacerbation of existing inter-disciplinary tensions and difficulties with communication. The effect of the presence of a midwife research assistant has been explored. Midwives' contact with research at the time of the trial is also included.

This programme of research has added to the body of knowledge by demonstrating the extent of the impact of clinical trials on the work and experiences of midwives attending women in labour. The appropriateness of the case study approach for use by midwifery researchers has also been demonstrated. Issues arising from the case study have been further reviewed in the light of contemporary midwifery practice, education and research and related to the wider research agenda.

Recommendations are made for the conduct of clinical trials in the labour ward and for future avenues of enquiry.

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**APPENDICES**

# CHAPTER ONE: INTRODUCTION

## 1.1 Background

"I had no experience of clinical research and of the hazards that lay in store for me." (Houston 1981, page 99).

Like Houston, the author was appointed to the post of Midwifery Research Sister having little previous experience of research. The responsibilities of the post included the day-to-day running of a randomised controlled trial to evaluate the upright position for delivery. The upright position was to be effected using prototype equipment. The randomised controlled trial will be referred to as "the trial".

Two years of working on one randomised controlled trial might discourage further consideration of that particular exercise. However, several reasons existed for selecting the trial for the purpose of study at higher degree.

This chapter will start by giving the reasons why the trial was chosen and suitable for further study and the focus of the investigation (sections 1.2.1 and 1.2.2). The next sections will address language and terminology (section 1.3) and will progress to a plan of the subsequent chapters of the thesis (section 1.4). Section 1.5 describes the method chosen for presentation of the case report. The case report comprises the final section (1.5.1) and this sets the scene for the subsequent analysis. Following

this, the content of the thesis will immediately follow the pattern described in section 1.4.

### 1.2.1 Reasons for studying the trial

At the time of the trial, few midwives in the United Kingdom had the opportunity to become involved in clinical research, especially in a dynamic area of practice, in which they had a personal interest. The author was fortunate to have such an opportunity. Whilst some of the experiences of working on the trial were difficult, it seemed important to try to learn from those both on an individual level and for the profession to gain from them, as it appeared likely that other trials of intrapartum care would take place.

When conducting the literature search for the trial, the research midwife noted descriptions of professional attendants' views on the acceptability of new methods of care or management (Williams et al 1980; Flynn et al 1978). However, it is the labouring woman who is subject to new developments of clinical care or management and the professional attendants who are there to provide the service, so why were such views included? The reason appeared to be to offer reassurance that midwives and obstetricians could still do their job when new practices were adopted. These accounts were quite perfunctory and related to the practicalities, for example, of accomplishing monitoring (Williams et al 1980) and did not give a complete picture of the experiences of those whose

work was most greatly affected by the trial. At the time of carrying out the literature search, the author was unsure about the inclusion of such views. Perhaps such reports were included due to the experiences of changing practice encountered in earlier trials.

Several issues emerged during the trial. These included some which might be expected in clinical research such as ethical issues, but also others which were unexpected. Whilst professional naivety could have been a factor, the research midwife was, nevertheless, surprised by the number of difficulties associated with the trial. It seemed appropriate to try to determine whether the issues were specific to that setting and, more importantly, why these might occur.

The study of this case offered an opportunity to use a qualitative approach to look into issues arising from a quantitative research programme. Whilst these two research approaches are usually regarded as representing different ends of the investigative spectrum (Corner 1991), use of the case study widens the research perspective of the individual whose work had previously been mainly in the experimental domain. It would also allow new theories to emerge which could subsequently be tested in quantitative approaches.

### 1.2.2 The focus of the investigation

In considering the focus of the investigation, the author considered various options, for example, a detailed appraisal of the ethical issues related to research and care in labour or issues related to designing and conducting intrapartum clinical trials. Through all of the possible avenues of research two features occurred: the labouring woman and her attending midwife.

Midwives attend the majority of women in labour in the United Kingdom, sometimes with responsibility for overall care planning and provision or for providing midwifery care for women with complicated pregnancies and labours (House of Commons Health Committee Report 1992). Thus of those whose professional work takes place on the labour ward, it is midwives whose work is most greatly affected by additional activities such as research or audit. The effects of additional demands on midwives' work are inadequately described: thus this also triggered the focus of the case.

The midwife is key as she co-ordinates the work of the labour ward, communications and the educational experiences of trainees, in addition to providing clinical care and thus affecting women's experiences of their labours.

The labour ward is a high risk area for medico-legal claim.

Midwives attending women in labour carry heavy responsibilities for ensuring a safe outcome and of facilitating a positive emotional experience. The consequences of a midwife's actions are far reaching in terms of the health of the woman or her child if problems such as handicap or trauma are attributed to care in labour. It is therefore important that anything which may impact on the midwife's work and the quality of such care should be both identified and understood. The primary focus of the investigation was therefore defined as the work and experiences of midwives attending the labours of women who participated in the trial. It seemed likely that if midwives' experiences in such situations were better understood, then this would indirectly benefit women in their care.

Other considerations which informed the focus of the investigation included the need to maintain a manageable scope to allow the detailed analysis appropriate for this level of work (Stake 1995). Whilst it might be difficult to explore challenging experiences, the identification of such difficulties and their causes then become useful for other researchers .

The rationale for the study was, therefore, developed from the following perspectives: the case and potential sources of data were easily accessible to the researcher due to her continuation in post and the case itself was of inherent interest. Exploration of the case would allow understanding of midwives' experiences of working in the

trial and acknowledge the emic perspective (Stake 1995). New theories would emerge from study of the case. An increasing amount of obstetric and midwifery research meant that the issues identified and explored might be of relevance for other similar trials.

This study will, therefore, be of value to the following: midwives attending women in labour, future instigators of clinical research in intrapartum care, and women who take part in research. In respect of the latter, the emphasis in this work will be to consider the effects on women which also had an impact on their attending midwives.

### 1.3 Language and terminology

There is a growing body of literature on issues related to language and terminology in the maternity services (Shirley and Mander 1996; Coppen 1995; Leap 1992; Bastian 1992). Although still commonly termed "patients" in the early to mid 1980's and in trial documentation, those who participated in the trial are referred to as "labouring women". The midwifery staff working in the labour ward, whose role was to provide clinical care and to attend women in labour are termed the "attending midwives".

Whilst women give birth, midwives deliver them. This case study has as its focus, the attending midwives, thus the term delivery will be used as it was in common usage at the time. Its use should not be held to imply that the midwives' experiences of delivery was of more importance

than the labouring women's experience of giving birth (Leap 1992).

There are perhaps several reasons why it may be argued that the first person could be used in presentation and analysis of case study material. Firstly, as the researcher is the key instrument and was personally involved in the case, this could support the use of the personal pronoun. There is support for the use of the first person in academic writing in the nursing literature (Webb 1992). However, the most important reason for not using the first person is that the writer is most comfortable with use of the third person.

### 1.4 Plan of the thesis

Following this introductory chapter, the content proceeds with a description of the methodology used (Chapter Two) and an exploration of key issues related to conducting randomised controlled trials of intrapartum care (Chapter Three). This will be followed by an analysis of what it means to be a midwife and defines the midwifery role in the first stage of labour (Chapter Four). The role of the attending midwife in the second and third stages of labour are then considered together (Chapter Five). The impact of the trial on the work of the attending midwives is identified. The thesis concludes (Chapter Six) with a discussion of the case study both in terms of it as a methodological approach and as a personal reflection. Theories generated will be reviewed in the light of

contemporary midwifery practice and the wider research agenda. Recommendations will then be made for the conduct of future clinical trials of intrapartum care and for new avenues of research.

### 1.5 Presentation of the Case Report

Whilst various options are reported for the presentation of case studies, the method used relies most closely on that described by Patton (1980). This choice was formed on the basis that it appeared to offer the reader the greatest insight into the case.

A chronological narrative was developed incorporating both descriptive aspects of the case and issues which arose from the data: this formed the case report, which forms section 1.5.1. The aim of this approach was to achieve the requirement of "thick description" identified by Stake (1994) and to provide the reader with an interesting and descriptive account (Patton 1980). The content and method of presentation of the case report are considered further in section 2.7.

### 1.5.1 The Case Report

The case report commences with detail about the clinical trial, which was the trigger for the case. There are then six sections to the case report. These cover the following areas :

a. The case study site
b. Preparatory work prior to the trial
c. The trial protocol and participants
d. The work of the research midwife
e. Changes to the protocol
f. Issues related to the progress, results and reporting of the trial

## The Trial

A randomised controlled trial in which labouring women were allocated to the upright position using prototype equipment for the second stage of labour and delivery or to the conventional semi-recumbent position in bed. This trial took place in the early to mid 1980s. Entry of women to the trial took place over a 21 month period.

The purpose of the randomised controlled trial in the case study was to evaluate the upright position for the second stage of labour and delivery using a prototype design of equipment. Outcomes of especial interest were the effect on delivery when epidural anaesthetic was used, postpartum bleeding and the condition of the baby at birth. There had been an increase in interest nationally in the upright position and few well-controlled studies had been carried out. The management of women in the trial was to include the use of spontaneous bearing down efforts during the second stage of labour.

### a. The case study site

The consultant maternity unit was situated in northern England on a large District General Hospital site. Whilst not a new building, the labour suite had recently been redecorated internally with the aim of creating a more homelike appearance to what were termed the delivery and first stage rooms. Its catchment area served a mainly inner city population to the north and east of the city

centre, with areas of significant social deprivation. The area also included some new housing developments and a small proportion of women from adjacent rural areas. Women attending the unit came from an ethnically diverse population, including the Asian and Afro-Caribbean communities.

The maternity unit was a site for the clinical training of students of midwifery, nursing and medicine. It had an affiliated midwifery training school which also served one of the other units in the city and student midwives, at that time, worked between both units. Four consultant obstetricians were in post.

The midwifery work force was fairly stable. Many of the unit's midwifery staff were local people and had trained in the area and remained there on qualification. Midwives who worked in the clinical areas comprised both midwifery sisters and staff midwives. Both full and part-time posts were available and the unit had a small core of permanent night staff. The labour and delivery suite had a large number of experienced midwifery sisters and a hierarchical structure existed. Night duty was covered by the permanent night staff, augmented by the unit's other midwives who worked a pattern of internal rotation between day and night duty. A traditional pattern of rotation between areas occurred for non-night duty midwives. Staff midwives rotated more frequently than the midwifery sisters.

The unit's policies and practices reflected a fairly active

approach to the management of labour, although formal documentation on these was scanty. A routine package of shave, enema and shower was carried out on women's admission to the labour ward. Vaginal examinations were carried out at no longer than four hourly intervals, amniotomy was carried out at three centimetres cervical dilatation and fetal scalp electrodes used quite frequently. Continuous cardiotocograph monitoring was used universally. Women, with few exceptions, gave birth in bed in a slightly propped position. The third stage of labour was managed actively.

**b. Preparation for the trial**

The trial was preceded by a similar study led by an obstetrician. Several clinical outcomes from the earlier study warranted further consideration, in particular the effect of posture on epidural anaesthesia and the issue of postpartum haemorrhage. It was considered important to study the upright position further using different equipment in case any particular design contributed to negative clinical outcomes. Women in the earlier study had received significant amounts of obstetric intervention in their labours and it was important to study the effects of posture for women in normal patterns of labour.

Liaison took place between the principal investigator and senior midwifery managers about the creation and resourcing of a post of Labour Ward Research Sister to work on the trial. The post was advertised both internally and in the nursing press. Funding was obtained to support the trial, including the salary of the research midwife. Ethics Committee approval was obtained for the research.

The Nursing Mirror carried an advertisement for a post of Labour Ward Research Sister. The advertisement stated that, although some research experience would be advantageous, a genuine interest in project work and the aims of this trial were most important. A willingness to work flexible hours was considered essential. A two year fixed term contract was provided. The purpose of the post was to have day-to-day responsibility for the running of the randomised trial.

The midwife appointed had previously worked as a Labour Ward Sister at a different consultant maternity unit and had developed an interest in the use of a range of postures for labour and delivery.

The research midwife's responsibilities included the provision of information about the trial to women at antenatal clinics, classes and on the antenatal ward. The research midwife was also to offer information to both labouring women and midwives about the technique of limited bearing down during the expulsive phase of the second stage

of labour, deliver as many women as possible in the study, maintain labour ward equipment used in the study, collect and analyse fetal and maternal blood samples and collect data.

The post of research midwife was new to the unit and not a part of the unit's midwifery establishment, outside the ward complement of staff and not rostered on the off-duty.

No formal orientation was provided and thus it fell to the research midwife to make her own introductions. Several midwives expressed surprise that the research midwife appeared in a midwifery sister's uniform, despite the fact that the job description had been available on wards prior to her arrival. Anecdotal information suggested that there had been little encouragement from midwifery managers for local midwives to apply for the post which, being of a fixed term nature, had been viewed rather dubiously. Further attempts to achieve an orientation to the labour suite met with resistance from some of the more senior ward staff, who felt that they had no responsibility to facilitate entry to the clinical area. The research midwife visited all wards and departments during the various shifts and introduced herself to staff in the unit, explaining her role and offering information about the research. The lack of formal orientation meant there was no official introduction to each area and no formal stamp of approval or support for the post or the post-holder.

There appeared to be a clear hierarchy amongst the labour

suite midwifery staff. The research midwife, although designated at sister grade and having previously held a sister's post, was not a part of the local culture and could not be easily slotted in to the hierarchy.

Support was offered by the clinical midwifery manager in gaining entry to the labour suite, but it was felt more appropriate to persist and gain entry by one's own efforts.

**c. The trial protocol and participants**

Women would be offered information about the trial prior to labour onset. Pain relief would be offered according to unit practice. Continuous monitoring of the fetal heart would be carried out and radio telemetry was available, if women wished to remain mobile.

Random allocation between the two positions for birth would be effected at the end of the first stage of labour.

All deliveries would be carried out by a small number of experienced midwives in an attempt to ensure uniformity of technique. The prototype equipment was to be kept at a set angle of inclination. During the second stage of labour, women would be encouraged to use spontaneous expulsive efforts, rather than the traditional prolonged breath-holding efforts. If instrumental delivery was required, this and perineal repair would take place in the allocated delivery position.

The following clinical observations and measurements were to be made:-

1. At full cervical dilatation, an accurate assessment would be made of the fetal station and position in the pelvis. Fetal scalp and maternal venous blood samples would be obtained for estimation of pH and $pO_2$.

2. Immediately after delivery of the baby, maternal venous and umbilical arterial blood samples, for estimation of pH and $pO_2$ as before.

3. Blood loss at delivery was to be determined using a dilution technique.

The protocol designed by an obstetrician had several elements where midwifery practice was being changed and where a different management was being imposed. The elements of the different management were those of both changes to practice, for example, through the change of birth position and also the overt encouragement of a less restrictive approach to care in labour. The fact that the protocol was inflexible, medically imposed and even its very existence were all concerns to midwives.

Women eligible for the trial were those having their first to fifth child, in a cephalic presentation at term and with no apparent contra-indications to vaginal delivery.

**d. The work of the Research Midwife**

The literature search included the following areas :-

1. Previous obstetric and midwifery research of posture for labour and birth
2. Historical and cross-cultural perspectives of birth positions
3. Information available to women about the use of similar birthing equipment
4. Research related to the use of limited bearing down expulsive efforts
5. Dilution techniques for assessment of blood lost at delivery

Pilot work was carried out to assess the suitability of using limited bearing down and in techniques for estimation of blood loss. Time was also spent receiving training in techniques of blood sampling and analysis, appropriate to the study and training in use and care of the blood gas analyzer.

To try to prepare midwives for the change in delivery position, a video showing births in a number of postures was obtained. This did not appear to engender much

enthusiasm for alternative delivery positions as it bore no resemblance to local practice.

The protocol required five hundred women to take part during a two year period of study. It therefore appeared important to assess the likely interest in the use of the upright birth position. A survey was carried out amongst women attending the antenatal clinic. This revealed an interest in the upright position for birth to the order of 50% in a sample where 50% responded. This suggested that an extensive campaign of information and recruitment was required.

The research midwife spent time in the antenatal clinic each day to offer information to women attending for their thirty-two week appointment. All women meeting the study criteria were invited to meet the research midwife, see the equipment, discuss the trial protocol and ask questions about participation in the research.

The research midwife attended all hospital based antenatal classes. On the occasion of the visit to the labour suite, midwives running the classes would ask the research midwife to talk about the equipment and to discuss the trial. The research midwife was also invited to two of the antenatal classes held by community midwives and discussed the trial at those. Posters were used to advertise the trial. Women who were in-patients were visited on the antenatal ward and the trial explained.

Consent to participation in the trial and clinical suitability for inclusion were confirmed when the woman was in labour. This was the role of the research midwife and required a high level of monitoring. During periods of annual leave, it was hoped that labour ward midwives would carry out this function.

Random allocation was effected using opaque sealed envelopes, which the protocol stated should be opened towards the end of the first stage of labour.

During the research midwife's annual leave, few women had a discussion about the trial and the rate of entry of participants fell dramatically.

There was also the perception that discussing the trial of posture in labour increased the requests for alternative positions. This was generally perceived as a more negative than positive side effect of the trial.

This high level of input and the research midwife's often lengthy shifts and "on-call" commitment served to emphasize the different nature of her work. She worked outside the normal midwifery structure, followed her own programme and worked ostensibly with medical staff in research, which was itself seen as academic and theoretical rather than practical, despite the fact that this was a clinical investigation. Several midwives questioned the purpose and the motives of becoming involved in research and

acknowledged their lack of understanding of and interest in it.

The different goals of research and clinical work came into sharp focus: adding to the body of generalisable knowledge versus the care of individuals. The attending midwives, concerned about the success of individual labours, could often not understand the research midwife's concerns about recruitment and the loss of potential participants.

A prototype design of equipment was used for the trial. The first prototype was in a maternity unit in North London and the second model used in the trial. The equipment was only available for use by women participating in the trial. The equipment was covered in anti-static black and comprised several adjustable and removable parts, hydraulic workings and powered by the mains electricity supply. Fabric covers were created by the hospital's linen room to mask the black anti-static cushions. When deployed in a horizontal position with the addition of an extension, the equipment could be used as a couch and allowed a woman to assume a horizontal position, if required. Foot rests allowed for the feet to be braced and supported. Portions of the seat were removable and the handgrips and an overhead rail could also be adjusted or removed. The equipment supported women in an upright position with their back reclined fifteen to twenty degrees from the upright. Both midwives and women often considered the equipment an unattractive contraption, with unpleasant connotations.

A further component of the research midwife's role was to contribute to the evaluation of the prototype equipment. The views of trial participants and attending midwives were also obtained. This part of the work falls outside the boundaries of the case study as it was not reported as having an impact on the attending midwives' work.

**e. Changes to the trial protocol**

Four significant changes occurred to the original trial protocol. The stipulation that deliveries would be carried out by a small number of midwifery sisters was abandoned on the request of the senior midwife (education). The removal of five hundred deliveries from the experience available to students over a two year period was considered unacceptable. An accommodation was reached where student midwives could still achieve their required experience by delivering women allocated to the control arm of the trial.

The above stipulation also raised negative comments from the senior midwifery sisters. This encroachment on the midwife's territory of allocating the labour ward staff was not appreciated. It not only encroached but also gave the midwives one more demand to fit in to an already difficult situation. It did not reflect the existing system of allocation where junior midwives were first allocated followed by more senior midwives. This allocation continued during the trial, with some concern to junior midwives.

Further logistical difficulties in terms of access to equipment also rendered it impossible for deliveries to be restricted to either the research midwife or any specified group.

When discussing the trial with women, concerns became apparent about the inclusion of the technique of fetal blood sampling as a part of the trial protocol. This invasive test, whilst performed in cases of suspected fetal distress on cardiotocograph monitoring, was unacceptable to women when presented as part of a research project. This became optional rather than mandatory. Midwives viewed this test as an unnecessarily invasive procedure, unacceptable when carried out for research rather than clinical indication.

Equipment which had been expected for estimation of blood loss did not become available. Thus the new and more accurate technique could not be a part of the study.

It had been intended that women receiving epidural anaesthesia would be included in the trial. Concerns voiced by key members of staff resulted in this only being possible when anaesthetists of the most senior grade were on duty. This resulted in many women being excluded and a key area remained unexplored.

The project appeared to suffer many reversals in that several changes from the original protocol had to be incorporated. This raised questions about the value of the

project.

**f. Issues related to the progress, results and reporting of the trial**

The trial commenced immediately on receipt of the equipment, after a considerable delay. The proportion of women participating in the trial increased to a certain extent during the course of the study, although it was necessary to maintain a high level of information and active recruitment throughout the trial.

The research midwife was responsible for collection of blood samples and their analysis. This required her attendance at as many deliveries as possible (80% women in the study). Whilst responsible for some of the deliveries herself, she was also available to support midwives new to the equipment and to clarify points in the protocol.

The research midwife had met the woman prior to labour but the attending midwife, in the vast majority of cases, had not. The attending midwives were not present at the discussion of the trial and, despite having the content of the discussion explained, still felt at a disadvantage. Whilst some liked having another midwife to work with and an extra pair of hands, some felt uncomfortable about the

presence of another midwife. A new role was also imposed on the attending midwives: that of gate-keepers to research.

The research midwife, keen not to lose potential participants, attempted to identify them at the ward reports. This was necessary as information about a woman's participation was not always communicated and if so, often in a less than positive manner. Similarly, when women were being transferred from the care of one midwife to another, communications about expected progress and outcome were altered by participation in the trial. The trial was considered to cause the midwife disruption to her usual clinical care and routines: this sometimes caused considerable concern. The trial was also deemed additional work.

The trial raised ethical questions for some midwives. Restriction of the equipment for use by women participating in the study concerned some. The disappointment for some women caused by random allocation was a difficult experience for their midwives. If events did not proceed optimally in a delivery, it was sometimes suggested that things would have gone better if traditional methods had been used.

During the course of the trial, regular sessions were held to offer progress reports to midwives and obstetricians. The results of an interim data analysis were presented at an in-house meeting. Several of the results appeared less than encouraging and this caused further scepticism.

By the end of the trial, nine hundred and eighty women had

demonstrated a definite interest in the trial during their pregnancy. A sample size two hundred less than that originally planned was obtained. Data was collected on an on-going basis. Advice on statistical techniques indicated that analysis should be effected on the "intention to treat" basis.

Briefly, the upright position was found to be associated with an increase in average blood loss at delivery and in the incidence of postpartum haemorrhage. No difference was found between the two positions in the incidence of instrumental delivery or perineal trauma. Women allocated to the upright position for delivery were more likely to report their position as comfortable for the second stage and were more likely to indicate a preference for the upright position for their next delivery than women allocated to give birth in bed.

The trial was reported in a refereed obstetric journal, subsequently picked up by a women's magazine. Information from the trial was included in meta-analyses of the effect of the upright position on delivery. Presentations were made at the case study site, numerous midwifery Study Days, Midwives' Refresher Courses and branch meetings of the Royal College of Midwives.

The next sections will describe and support the choice of research approach and reasons for the choice of research method (sections 2.1 and 2.1.1) and will define the boundaries and focus of the investigation (section 2.1.2) Section 2.1.3 expands on the choice of method and 2.1.4 addresses the issue of rigour in qualitative research. Ethical concerns related to case study approach are introduced in section 2.2. Sections 2.3 - 2.3.2 relate to data collection and 2.4.1 and 2.4.2 to the analytic strategy. Sections 2.5, 2.6 and 2.7 offer themes arising from the data, understanding the case and further information on the presentation and content of the case, respectively.

## 2.1. The research approach

A method was required which would allow exploration of issues at a sufficient level of analysis and which would allow study of the trial as it existed, in its totality and without manipulation. The purpose of the study is to generate hypotheses which can subsequently be tested. A naturalistic and holistic approach was necessary to generate theory (Burns and Grove 1997).

### 2.1.1 The research method

Alternative methods such as the survey, widely used to describe maternity practices or midwifery knowledge and

attitudes would not necessarily identify all of the areas where the trial impacted on the work of the attending midwife (Mays and Pope 1996). A survey would also not permit the detailed analysis required to determine reasons for that impact. Experimental methods are essentially concerned with theory testing rather than theory generation and utilise a prescriptive and controlling approach in the development of knowledge about cause and effect (Woods and Cantanzaro 1988). There appears no scope for the latter when the object of the investigation is not amenable to manipulation or control and when the components are both closely related and interactive. The single case study appeared the suitable research approach as it is suggested that any phenomenon can constitute a case, including "people, groups, critical events, communities, project sites or subparts of a programme" (Patton 1987, page 147).

The case study allows relationships between variables to be examined (Polit and Hungler 1995) and has two functions. Firstly, to arrive at a comprehensive understanding of the subject under scrutiny. Secondly to generate theory about the processes within the unit studied (Becker 1971).

There are various definitions of the case study (Yin 1994; Stake 1994; Hutchinson 1990). Here, the approach is that of a case study which falls within the definition of explanatory (Yin 1994) and intrinsic (Stake 1994). It is a rigorous investigation carried out by a researcher who lived and breathed the case over a period of time, although Holloway and Wheeler describe this more formally as

"immersion in the setting" (1996, page 4)!

### 2.1.2 The boundaries and focus of the investigation

The case includes all aspects of the randomised controlled trial of posture in labour, the setting, the professionals and their relationships. For the reasons stated in section 1.2.2, the unit of analysis is the work of the attending midwife (Woods and Cantanzaro 1988), illustrating the observation made by Stake that

> "Case study is not a methodological choice but a choice of object to be studied "(1994, page 236).

In selecting all aspects of the trial for the investigation, Holloway and Wheeler's assertion is supported: that nurses (here a midwife) are familiar with the case and its context before commencing the investigation (1996). At the start of the investigation, the limits or boundaries of the case were unclear, again reinforcing the appropriateness of the case study approach (Mays and Pope 1996).

The fundamental research question is to determine *how* and *why* the trial caused difficulties in the work of the attending midwives. There is, however, an important issue here: the case is the vehicle to develop our understanding of a particular situation (Stake 1994). Whilst of intrinsic interest, otherwise it would not stimulate enquiry, the case is the means to an end; that of increasing understanding and determining meaning. The case

study is therefore both the means and outcome of the learning (Stake 1994).

It is the intention that this study will allow detailed insight into the case and allow theories to emerge.

### 2.1.3 Further justification for the choice of method

This method appeals because it allows a comprehensive analysis of the issues which arose during the process of the study and the opportunity to make sense of those and to learn from them. This is described by Patton who suggests that, in some instances, it is perplexity which triggers use of a case (1980). Some of the issues caused concern at the time: the case study approach does not discount such aspects of the experience and their inclusion will, it is hoped, render it more understandable and interesting (Reed and Robbins 1991).

The case study is also a reassuring method for the research student with a nursing background, as it is by no means unknown. The case history has long been used as a teaching exemplar for students in the health care professions (Hutchinson 1990; Treece and Treece 1986). Whilst Hutchinson differentiates between case histories and case study in relation to their theoretical and analytical bases, the scope of the topic is common to both (1990). Both the case study and the case history allow use of a single example to gain new understanding of the subject with which to inform future practice.

Whilst working on the trial, the author was, like other midwives, "busy doing" (Hunt 1993, page 177) with little time for reflection. A further reason for using the single case study is associated with the emphasis, in the nursing and midwifery professions, on reflective practice using critical incident techniques. Many of the issues which arose during the process of the trial fulfil the criteria for critical incidents in that they were occurrences which were clearly recalled and of particular importance to the individual (Brookfield 1990). It appears entirely appropriate to utilise those incidents in both a research context and in fulfilling the current professional ethos of reflective practice (English National Board 1997).

It is also hoped that this work will raise the profile of the case study approach within the midwifery profession. Sleep called for qualitative studies in midwifery (1992) but in a recent analysis of research methods used by midwives, the case study approach is reported less frequently than surveys, randomised controlled trials, ethnography and phenomenology (McCormick and Renfrew 1997).

### 2.1.4 Rigour in qualitative research : application to the case study approach

Mays and Pope correctly cite the common criticism of qualitative research as being too concerned with personal account, lacking the potential for application to the wider population and of being subjective in nature (1996). These are the concerns of those used to positivist methods. Qualitative research, used to generate theory, cannot be conceived or critiqued in the same manner as methods which test theories. It must, however, still be a rigorous and disciplined enquiry.

The strength of the case study approach is that a number of methods of data collection can be used within the one investigation (Yin 1994: Woods and Cantanzaro 1988). Use of multiple data sources confirms information and thus allows construct validity to be achieved (Yin 1994). It is considered that the researcher is the main tool in the enquiry (Holloway and Wheeler 1996), as it is they who decide on patterns found and interpretations made. Within any one case, the investigation may become unwieldy if too many issues are explored. It is, therefore, necessary to study only the issues which are key to the informants (Becker 1971).

## 2.2 Ethical concerns

There is concern about ethical issues in case study literature (Stake 1994; Yin 1994). These relate to both

protection of the site and of individuals, as it is important to avoid harm (Becker 1971). Permission was obtained from the professional lead and other key individuals to embark on this research and for access to departmental documents. All informants gave permission prior to interview. They are not described further to prevent identification. Care has been taken that individuals cannot be linked with observed incidences. To maintain confidentiality, published reports of the trial are not cited in this thesis. Further ethical considerations will be included in section 2.3.2.

## 2.3 Methods of data collection

Issues related to documentary and interview data are described in the following sections.

### 2.3.1 Documentary data

Documentary sources included all communications and papers related to the trial including the research midwife's post, reports of the trial including pilot work, administrative and departmental documents, correspondence, minutes of meetings and memoranda, literature searches and publications.

One further specific source of data was a log recorded by the research midwife during the trial. This had commenced as a diary record of the development and progress of the trial, including issues which arose during the day to day

running of the trial and their resolution. This record had been kept from taking up post to eventual publication of the report of the trial. The log thus included both fieldnotes and significant milestones or events. It offered a rich source of data, albeit from one perspective, that of the research midwife, and it flagged issues which could be pursued during the case study investigation.

Documentary sources of data were used to obtain information of a descriptive nature about the setting for the research and to understand its unique nature and working practices. These sources also provided time frames and details of those parts of the trial with which the case study researcher had not been involved. Individual documents confirmed observations noted in the log and flagged particular issues to be followed up using other sources.

Some documentary material was obtained but discounted as being outside the boundaries of the case. This comprised information related to the prototype equipment used in the trial.

The strengths of documentary sources relevant to their use in case studies are detailed by Yin (1994) in that the data is stable over time, it can be collected without calling attention to the process, it is exact and can cover a wide range of topics. Documentary evidence also enables verification of information from other sources. However, access can be difficult, reporting bias may occur within the original composition and documents may be of such poor

quality that extrapolating information is impossible. One of the shortcomings of using documentary sources of data is the lack of certainty that all sources have been identified and accessed (Treece and Treece 1986). However, as far as could be determined through questioning individuals and archival searching, it appeared that a complete set of documentation was collected and there were no difficulties with access or accuracy (Treece and Treece 1986).

### 2.3.2 Interview data

As the focus of the investigation developed to the attending midwives, it became clear that their views should be sought. Following permission from the Head of Department, a sample of qualified midwives were approached to take part in interviews.

A purposive sampling strategy was used to involve certain individuals in the study (Holloway and Wheeler 1996). The criterion applied were that the respondents were qualified midwives who had cared for women in both arms of the trial, they had previously offered a range of comments about the trial and were likely to be good informants (Patton 1986). The midwives were of varying seniority and had all worked at the unit both before and during the trial. The posts held will not be described further to avoid identification of individuals.

Of the ten midwives approached, eight agreed to be interviewed. This was an arbitrary number based on the

presumption that it was manageable and would allow for decliners. During the planning of the interviews, consideration was given to the use of tape-recording to minimise disruption to the conversation and to obtain a complete record. Some midwives expressed serious reservations about this process, thus a speed-writing technique was used to capture information.

A semi-structured interview was used because the researcher had already identified the areas in which further information was sought and because it allowed freedom to probe further (Woods and Cantanzaro 1988). The topic areas within the interview were shaped by the issues identified in the preliminary analysis of documentary material.

Interviewing colleagues brings particular dilemmas (Holloway and Wheeler 1996). A preliminary verbal approach was made to each midwife to introduce the purpose of the study and time given for consideration of the request and to ask any questions about the process. It was made clear that the project was course work and that there was no obligation to participate. When potential respondents had agreed verbally to the interview, the researcher arranged the interviews discreetly to maintain confidentiality in a location acceptable to the participant within the workplace but away from public view. Prior training in interview skills had been taken, including video-taping of technique. One issue in interviewing is that of establishing rapport with participants and assuming an air of unbiased interest (Polit and Hungler 1995). Whilst establishing rapport is

not so great an issue if the interviewer and respondent know each other, the researcher was aware that respondents may find it difficult to raise some points which were critical of the trial and thus offered reassurance that all views were acceptable (Polit and Hungler 1995). The researcher was acutely aware of her own experiences of the trial, referred to by Wilde as "luggage" (1992, page 239) and felt that it was important that this did not encroach on the interview as her perceptions of the trial may not have been the same as the respondents' (Holloway and Wheeler 1996). The plan for the face to face interview was for it to last approximately 45 minutes to prevent fatigue and also to avoid disruption to the clinical area. The fundamental principles of courtesy to respondents (Polit and Hungler 1995) and achieving an appropriate atmosphere were followed (Kidder 1981).

The interview schedule commenced with a "grand tour" type of question, and the question order followed a chronological approach to the trial, in order to facilitate a logical flow of ideas for respondents. The aim of the interview was to enable respondents to recount their experiences of the trial and any impact on their work as a midwife attending women in labour. The interview schedule included the areas of preparation for and notice of the trial, issues related to the process and progress of the trial, the impact of the trial on the work of labour ward midwives and issues related to completion of the trial (Appendix 1). A number of non-leading probes were available to ensure that all required areas were covered

(Polit and Hungler 1995) but it was seldom necessary to use these as the respondents spoke freely on all of the areas. Most interviews lasted approximately forty-five minutes with a maximum duration of slightly over one hour. The researcher was concerned about the potential for difficulties with recall. However, whilst respondents acknowledged that time had elapsed since the trial and that other research had taken place on the labour suite, they remembered the trial very clearly.

Two midwives declined participation on the grounds that the trial had caused enough concern at the time and they did not wish to consider it further. The remaining midwives appeared willing to be interviewed. The interviews took place at pre-arranged times when this could be fitted in with clinical duties. On completion of the interviews, respondents were thanked and two emphasised that they had enjoyed the opportunity to talk about the issues raised. None of the respondents appeared discomforted by the experience. On completion of the interview, short notes were made to supplement the interview data. These comprised observations of the non-verbal parts of the interview. Following typing of the interview questions and responses, achieved within 48 hours in all cases, these were offered to participants as an opportunity to confirm that they were happy with the data and to check for accuracy and as a part of the validation process. The majority of midwives declined reading the transcripts for various reasons, including time, embarrassment and a predominant view that, by now, the trial really had taken

up enough of their effort and concern. All interview material was held securely in a location accessed only by the researcher. As the majority of midwives declined reading the interview, efforts at validation included asking midwives involved in the trial to read the case report, some of whom had also been interviewed.

### 2.4.1 Analytic Strategy

Yin suggests that the strategy appropriate for analysing case study data is that of explanation building (1994). The purpose of this approach is to develop an explanation of the case, which may include critical consideration of policies, processes or theory. This process may be iterative and include consideration of alternative explanations of certain issues (Yin 1994). Stake's view is that, as the main task is to understand the case, then the focus of the effort should be on interpretation of the issues encountered (1994). These tenets were followed in the analysis of case data and methods uses described in section 2.4.2.

### 2.4.2 Methods of data analysis

The first step on the pathway of analysis was to use the log kept by the research midwife in which issues related to the work of midwives on the labour suite were identified. In the first instance, this included areas of concern for both the attending midwives and the research midwife. This identified midwives' preparation for the trial, ethics and communications amongst the areas to be pursued in the subsequent investigation. Confirmation of the issues identified in the log was carried out by verification from other sources. These sources included, as stated in sections 2.3.1 and 2.3.2, documentary sources and interviews with midwives involved with the trial.

Documentary sources were searched for information which either offered material describing the unit, its working practices or the organisation of care in the case study setting. Information was sought which could either confirm or refute observations made in the log and which could cast light on whether differences to midwives' work had occurred because of the trial.

Information obtained in the interviews was subjected to content analysis (Patton 1990). This process involved reading the complete transcript several times and manual coding of the data. Following this, the coded information was collated within categories (Woods and Cantanzaro 1988). When issues were identified for the first time in the

interviews, the log and documentary sources were re-visited for further information. All of the analysis was carried out by a single researcher.

From this range of sources, therefore, a composite picture emerged both describing the setting and its working practices and also identifying issues related to the clinical trial and its impact on the work of the attending midwives.

## 2.5 Themes

Nine main categories or themes emerged from the data. These categories appeared to meet the requirements suggested by Woods and Cantanzaro that items are grouped appropriately within one category and that the categories are distinct (1988).

These themes related to communication, changes to ward organisation and clinical care, ethical issues, lack of fit, changes to the culture, more work for attending midwives, questions about why particular events had occurred and issues about research and midwives. These will be amplified in the following section and quotations from the midwives' interviews to support the categories are included in appendix 2. The use of a selection of quotations fulfils Polit and Hungler's requirement that the sense of the primary sources is not discarded (1995) and fulfils the requirements of confirmability (Holloway and Wheeler 1996).

Issues which contributed to the theme of communication included the fact that attending midwives had little involvement during the planning phase of the trial, the extra information which was required due to the trial and associated uncertainties, differences in the attending midwife's communication with the labouring woman, the lack of involvement of attending midwives in the information and consent process, patients being better informed and, on completion of the trial, the publication of results in an obstetric rather than midwifery journal.

The trial required changes to the allocation of staff in the labour ward and the trial protocol stipulated care and required that midwives practice differently in some of the most fundamental and important areas of practice. Midwives had a new role, that of research gate-keeper placed upon them and were faced with more women asking to give birth in different ways and uncertainty and concerns about how deliveries would go in the upright position.

Midwives' concerns on ethical issues related to restriction of use of the prototype equipment to women in the trial, the disappointment caused by the randomization process and concerns about interim findings.

The feeling emerged from the data that some things related to the trial did not fit into the existing system. These included the information about the research which did not fit into ward handovers and the research midwife who was working in a different way, new to the unit and who did not

immediately fit into the hierarchy.

Cultural changes included research on the labour ward, a midwife working in a different way, concerns about the overt encouragement of a less restrictive approach and changes from the position for birth used most frequently in the unit.

The trial was also considered to cause more work for the attending midwives due to the equipment and issues related to information and communications.

The eighth category comprised questions about why the research was necessary and this particular project. The changes from the original protocol raised questions and certain elements within the protocol, such as the blood samples, appeared to be at variance with an investigation of a more natural approach to delivery.

The final category related to research and midwives. Research was a new activity for a midwife to be involved in and had different goals. The research midwife was seen to be allied to doctors rather than midwives and was not perceived as an integral part of the midwifery team. The trial was held to be only the research midwife's job and was a non-essential activity.

## 2.6 Understanding the case

As stated above (section 2.4.1), the most important aspect of case study research is to develop an understanding of the case. The next step in the analytic strategy was, therefore, to examine, in detail, the issues from all aspects of the trial which had an impact on the attending midwives.

This examination included the following elements:-

1 Existing factors affecting midwives' work.
2 Identification of the impact of the trial on the work of the attending midwives.
3 Difficulties for the attending midwife arising from the trial.
4 Difficulties for the labouring woman, which also impacted on the work of the attending midwife.

This work is included in chapter three which explores the use of randomised controlled trials in intrapartum research and the consequences for midwives. This examination continues as the focus of chapters four and five where the issues are examined in groups which relate to the existing organisation and components of midwifery work on the labour ward. These groups also follow the conventions of the standard midwifery texts. From this examination, theories will be developed and alternative explanations considered where possible: thus achieving internal validity (Patton 1980).

## 2.7 Presentation and Content of the Case

Case studies may be presented in a variety of ways. These include chronological or topical or with the use of vignettes to describe the typical or extreme (Yin 1995; Patton 1990; Stake 1995). The report should be organized and must reveal the case clearly to the reader but also include the issues which will subsequently be further explored (Patton 1990). It must achieve the level of thick description required by Stake (1995) and be both interesting and informative.

The use of the vignette was rejected as it seemed inappropriate to classify any observation related to a woman's labour as either typical or extreme and selection of incidents may allow individuals to be identified.

In this case report, the chronological approach was used to reflect, in a narrative, the experience of those involved in the trial and the pace of the impact of the trial upon them. The case report included both a description of the setting for the trial but also included, within the narrative, the issues of concern to midwives which had been revealed through the data collection and analysis. These were woven into the narrative to allow the attending midwives' voices to be heard within the case report as it was the impact of the trial on their work which was the focus of the case. This approach would also complement that used in later chapters to examine the reasons why the

trial had such an impact on the work of the attending midwives. Appendix 3 offers a summary of the research process using one example of an issue encountered and investigated using the case study approach.

# CHAPTER THREE : THE RANDOMISED CONTROLLED TRIAL IN THE LABOUR WARD

## 3.1 Introduction

This chapter will present an overview of the rationale for and history of the use of randomised controlled trials (sections 3.2 and 3.3), with particular reference to aspects of methodology (sections 3.4.1, 3.4.2, 3.4.3, 3.4.4) and ethics (section 3.5) applied to investigations of intrapartum care. This chapter will demonstrate that the labour ward is a unique area for controlled clinical trials involving several key groups (sections 3.6 and 3.7) and will explore issues related to the planning of such research (sections 3.8.1, 3.8.2 and 3.8.3). Key issues related to randomised controlled trials in the Labour Ward and their planning will be summarized in section 3.9.

## 3.2 The purpose and definition of the Controlled Clinical Trial

Petrie defines clinical trials as

> " planned experiments comparing the efficacy of different medical treatments when they are administered to patients " (1987, page 187).

The randomised controlled trial is one form of experiment, which is used to avoid systematic errors of allocation and measurement and to act as a basis for statistical testing.

The investigation should be conducted systematically and the aim is that results of treatment from a limited sample will allow inferences about effect in a wider population (Pocock 1983). The term "controlled" is used to signify the manipulation or control of the independent variable (Goode and Hatt 1952). Randomisation acts as a matching procedure to achieve equal distribution of characteristics between the experimental and control groups (Goode and Hatt 1952); guarding against bias in the allocation of treatments.

## 3.3. Clinical Trials : a brief history with particular reference to the Labour Ward

Clinical trials to evaluate the merits and hazards of various therapies are a feature of the post 1950's in most areas of medical practice.

Labour Ward is an area where two groups of clinicians practice their craft: midwives and obstetricians. Cochrane took obstetricians to task for their poor record in well-designed controlled evaluation (1979). Chalmers supported this by commenting on the paucity of scientific evidence on which obstetric practice is based (1983).

Obstetricians have used a range of designs in their research into the management of labour and the merits of various designs have been debated. (Lilford 1987; Hawkins 1989). Randomised controlled trials have been suggested to be the method for generating the best quality of

information on which to base clinical decisions, although they do not demonstrate the optimal management for individual patients (Lilford 1987). Whilst most texts focus on drug trials when discussing experimental methods, Pocock advocates their use for evaluation of non-drug therapy (1983). However, the appropriateness of using randomised controlled trials to investigate aspects of labour management has been challenged due to the continuing nature of the labour process and the difficulty or wisdom of trying to separate out the various aspects of the labour experience (McNabb 1989).

Labour is a unique time to do research because it is a life event of great social and psychological significance to the woman and her family (Boyd and Sellars 1982). Sheila Kitzinger, an anthropologist and childbirth activist, acknowledged the highly individual nature of the labour and birth experience and each woman's right to that (1983).

At the time of the trial, labour and childbirth were associated with lower levels of both maternal and perinatal mortality and morbidity than formerly (Macfarlane and Mugford 1984; Baird 1960). Reduced family size meant that childbirth was experienced on fewer occasions by individual women and therefore the experience was more precious.

The labour ward is unique as a setting for conducting randomised controlled trials for another reason in that those in receipt of services are not usually ill, even though they may be treated as such. Users of maternity

services were becoming increasingly well-informed from the late 1970's and had higher expectations of their care. Research into methods of managing labour must therefore be examined against such a background. This will be further explored in section 3.6.

The following sections will discuss the key features in trial design.

### 3.4.1 Minimising bias

A comparison of treatments may be affected or biased by a factor unrelated to the treatment itself. Pocock identifies the three factors which may effect a difference in outcomes: the method of treatment, chance variation and bias due to other factors (1983). Several sources of bias exist in quantitative research.

The key aim of the randomised controlled trial is to avoid or minimise the effects of bias when different treatments are compared. Random allocation prevents the investigator predicting the next treatment option and guards against accidental bias in the treatment group. This technique usually results in groups which tend to be matched for a variety of demographic and other variables. Random allocation can be effected in a variety of ways, some more resistant to manipulation than others. Methods used to effect random allocation include telephone randomization and the use of opaque sealed envelopes. Chalmers and Grant

advise that random allocation should be organised by someone not directly involved with the clinical part of the trial (1985). Stratification may be employed if the population consists of distinct subgroups with particular prognostic features.

There is a further cause of bias which can be affected by the preferences of clinicians. This relates to the selection of participants for entry in to the trial: all eligible patients, who consent, should be entered. This bias is more likely to occur when, despite the stipulations of trial protocols, entry of participants may be in the hands of attending clinicians rather than researchers (Crowley et al 1991).

Measurement or observer bias is a further concern in the evaluation of new methods of care or treatment. Subjectivity may enter into the measuring of response to treatment, including a patient offering a "good" response. If treatment allocation is known to the participant, then this may have one of several effects. Allocation to the new treatment may be seen as interesting and convey optimism and the old treatment may be viewed unfavourably. Other participants may view the new with suspicion and the standard treatment as reassuring (Pocock 1983). If treatment allocation is known by the clinician, then a subjective measurement of effect will be made.

Various strategies exist for the reduction of observer bias. Use of single or double blind techniques avoids

knowledge of treatment group by either recipient or by both observer and recipient. To achieve the latter technique, treatments should be indistinguishable at the point of administration. Use of blinding can brings its own difficulties in disturbance of the patient-clinician relationship and the need for increased vigilance for side effects.

In the context of controlled experimentation in the labour suite, the potential for bias exists at several points. Sources of bias in intrapartum research will be further developed in the sections 3.4.2 and 3.4.4

### 3.4.2 Issues of outcome measurement and sample size

The main emphasis of clinical trials is usually on the measurement of the so-called "hard" outcomes, related to morbidity or mortality and on physical measures of health or disease. The trials of labour management have usually reported outcomes such as neonatal death, the observed duration of various stages of labour, types of delivery or Apgar Scores (evaluation of the infant's condition at birth). This preference for measuring mortality and other quantifiable endpoints can lead to an exclusion of the psychosocial or "soft" outcomes, which are of interest to women (Oakley 1983). Choice of outcome measures will also impact on sample size.

Prior calculation of sample size is suggested (Gore and Altman 1992). The numbers of participants needed depends

on the incidence of the outcomes under investigation, the change considered clinically significant and the power to detect a statistically significant difference between treatments. Use of statistical techniques allows the likelihood of chance variation in determining effect to be identified (Pocock 1983). Trials of inadequate size do not detect true differences in treatments (Lilford 1987). Once entered in to the trial, all participants should be included in the analysis. Analysis of results on the "intention to treat" basis allows a pragmatic interpretation of findings rather than an "explanatory" approach which deals with compliers only (Pocock 1983, page 182).

In many investigations of intrapartum care, it is impossible to blind clinicians to treatment allocation. The difference between birth in the upright position or in bed is obvious. In addition, when outcomes such as instrumental delivery are being measured, which clinicians also initiate, the potential for bias is obvious. To address this, it is suggested that, where possible, surrogate measures of outcome could be used (Lilford 1987) such as measuring a baby's condition at birth in terms of rates of admission to Special Care Baby Units. However, it is impossible to obtain surrogate measures for all outcomes.

A further issue in clinical trials is the availability of participants. This issue will be addressed in section

3.8.2 related to planning the trial.

### 3.4.3 The clinical trial protocol

This is the key document in a trial. Pocock suggests that the protocol is an operations manual in its description of how the trial affects individual patients and the scientific basis of the study (1983).

### 3.4.4 Compliance with treatment and deviations from protocol

Much of the discussion of treatment compliance in clinical trials has related to pharmaceutical research, ensuring that medication is taken on schedule and how this can be verified. Calendar packs can be employed, unused drugs collected and blood and urine levels monitored. Pocock advises that it is better to anticipate protocol deviations rather than to simply wait until they occur (1983).

There are two sources of deviations from research protocols: professional attendants and those in receipt of care. Whilst perhaps there has been a tendency for under-reporting of this issue, midwives tampered with the randomization procedures in Crowley's study of delivery position and obstetricians did not adhere to the random allocation (1991). Thomson also described midwives' interference with the allocation of women between treatments in three controlled trials (1988). There may be other reasons for protocol deviations, including perhaps an

unwillingness to work in a way which may not seem to be in the woman's best interests.

### 3.5 Ethical issues

It is suggested that it is the random allocation of patients between treatments which gives clinicians the greatest angst in clinical trials (Gore and Altman 1982). There is a trade-off between the individual and collective benefit when this method is employed (Pocock 1983). It has also been argued that the alternative, of introducing a new treatment into practice without first conducting a controlled trial, lacks merit (Gore and Altman 1982).

Potential participants require a full description of options both within and outside of the trial to enable informed decisions to be made. The research participant has a right to be treated fairly, information held in confidence and the right to participate or decline as they chose, without fear of detriment to their treatment.

Clinical experimentation in the labour ward has particular concerns. There are two individuals affected by the trial but one key participant and one or more people involved in the decision-making process. Whilst acknowledging the need for research, women do not wish to put their babies at risk or to subject the fetus in utero to invasive techniques. Advice from user groups to prospective parents about participation in clinical research appeared in the late 1980s (National Childbirth Trust 1988) and now

comprehensive guidance exists (Association for Improvements in the Maternity Services 1997).

### 3.6 Personnel involved in clinical trials

Gore and Altman advocate strongly for the inclusion of statisticians in the design of the clinical trial (1982). The convening of Advisory or Steering groups can support researchers, allow stake holders to be involved and may reduce barriers to the project.

The importance of having informed and enthusiastic participants amongst the clinical and nursing staff has been noted by Pocock (1983). Each clinician will, according to Pocock, need to resolve his or her own concerns about randomization (1983). Gore and Altman view this matter even more strongly (1982). They suggest that the three groups of patients who should not be entered into a trial are those for whom the treatment is contra-indicated, where response to treatment may be biased and any patient whose doctor has a particular treatment preference. In this case study, it is the midwives who are in such a position: this impact of the trial on the attending midwives will be considered in section 4.6.

### 3.7 Issues related to service users in labour ward research

In this section, service users will be considered as

groups, of which there are several, rather than on an individual basis.

From the 1970's the management of labour was a subject of intense consumer and media interest. In the mid 1970's Leboyer propounded the approach of birth without violence (Leboyer 1975). Dissatisfaction with the management of labour at one London hospital led to demonstrations on Hampstead Heath in 1982. The Active Birth movement formed shortly afterwards and held its ground-breaking conference in 1982.

The support groups gained recognition for their work in challenging health care providers on issues such as insufficient choice about place of birth, poor hospital conditions and overuse of technology (Oakley and Houd 1990). They also worked to share information between professionals and service users, counsel, raise funds and provide advice on specific issues such as access and choice.

Groups which supported alternative approaches to the main stream of care were, however, observed as having the tendency to "incline towards their own orthodoxies" (Oakley and Houd 1990, page 113). Critical of traditional care and its lack of evaluation, consumer groups appeared to welcome alternative approaches without calling for their evaluation. The concern was on providing choice and getting away from the old routines.

## 3.8 Planning randomised controlled trials in the Labour Ward

In planning randomised controlled trials, several considerations are important. Firstly, selection of outcomes and how these can be measured. Sample size can then be calculated using statistical techniques. When these have been determined, it is necessary to check that there are sufficient potential participants locally.

The trial was designed by a consultant obstetrician and followed on from earlier work. Various obstetric outcomes were to be investigated and a sample size of five hundred women planned for a two year period. Information from an earlier trial was the main influence rather than local knowledge. Ethics Committee approval and funding were obtained to support the salary of the research midwife and equipment.

There were two groups most affected by the clinical trial: the attending midwives and labouring women. The extent to which these groups were involved in the development of this trial will be explored.

### 3.8.1 The involvement of midwives

The involvement of midwifery managers in the trial was peripheral rather than central. Whilst involved in the

appointment of the research midwife and supportive of the concept of natural childbirth and exploring new ideas, this held little sway with other midwives. It did not result in support for the study as a key manager's views were not those of the clinical midwives. Whilst offering no opposition, managers appeared to treat the trial as an incidental issue, as it was outside their control.

The attitudes of midwifery managers to studies have been found to be crucial to their success (Renfrew and McCandlish 1992; McHaffie 1990). Negative attitudes to research due to the potential drain on resources have been reported as a concern for managers (Renfrew and McCandlish 1992).

Midwives working on the labour ward were not involved in the planning of the trial. Many midwives were sceptical about the whole project and questioned the extent to which women would wish to become involved.

Attending midwives had no influence on either the choice of topic for research nor on the choice of methodology. The beneficial effects of engendering ownership amongst clinical staff by their involvement in the planning of studies has been described (McHaffie 1990). It has been demonstrated that midwives offer greater support to (Hicks 1992) and interest in (Renfrew and McCandlish 1992) research associated with obstetricians rather than midwives: this should have worked in the favour of the trial's acceptance.

The trial of the upright position was concerned with an aspect of midwifery care. It can be argued that midwives should initiate such research. However, this would be difficult to achieve when midwives had little understanding of research (Thomson 1988) and, with the exception of one or two individuals, at that time, were not taking a lead role.

### 3.8.2 The involvement of women

There was no formal involvement of service users, either as a group or as individuals, at the planning stages of the trial. Interest amongst women in using the upright position for delivery was not determined formally prior to obtaining the research funding. The planned sample size was based on successful recruitment in the earlier study and the figure of five hundred proved over-optimistic for the case study unit. Approximately twenty-five percent of women were interested in the upright position for delivery. Procedures of concern to women in the trial protocol did not emerge until the research midwife commenced recruitment. The involvement of service users at the planning stage may yield useful information about the acceptability of particular components of an investigation.

In the case study, the attending midwives and the women were the two groups most affected by the trial of the upright position and they were not involved at the planning stage. In the labour ward setting, the labouring woman has

an opportunity to decline participation but the midwife, due to her position in a hierarchical structure, may have difficulty in voicing her concerns.

### 3.8.3 Choosing the subject of research

In the case study unit, a professional's interest triggered the trial rather than local demand for the new method of care.

However, at a wider level is there any relationship between consumers of maternity services and health care professionals in the identification of topics for research? Gardosi and colleagues cited women's wishes to be more active in labour and to use more upright positions for birth as reasons for conducting their research (1989). Flynn and Kelly's early study of ambulation cited patient complaints about confinement in bed as a trigger for their trial (1978).

Intrapartum research where midwives are the prime movers reflect a concern with traditional parts of practice: episiotomy and enemas (Sleep et al 1984 ; Romney and Gordon 1981). There are midwifery led investigations of birth position (Beardsell 1983; Kesby 1982). The latter reports reflect the provision of these alternatives in response to consumer demand and used non-randomised comparisons to determine suitability.

Some aspects of intrapartum care have been investigated by

both consumer groups and professionals but a causal relationship cannot be established between the two. Examples of subjects which have received the attention of both include the survey by Kitzinger and Walters of women's experiences of episiotomy (1981) and Sleep's trial of perineal management (1984). Epidurals and amniotomy have also been subject to both consumer and professional interest (Kitzinger and Walters 1984; MacArthur et al 1990; National Childbirth Trust 1989; Stewart et al 1982).

There may be other explanations for professional initiation of research beside that of obtaining information for women about new options. An alternative view is that to conduct research on the newer methods of birth can be seen as consumer friendly whilst still allowing professionals to retain control over labour. It may be that if a unit wishes to be seen as a centre of excellence, research is one way of achieving this.

The relationship between professionals and users of the service in this area appears a spiral. Clinicians require information derived from research to provide a safe service and to provide the information with which women can make choices about birth.

### 3.9 Summary

The issues related to the design and planning of randomised controlled trials have been detailed in the preceding sections, with particular application to the labour and

delivery suite. It has been argued that this clinical area is a unique and challenging setting in which to attempt to conduct the "planned experiments" described by Petrie (1987, page 187).

For the trial to proceed in a way which is both scientifically rigorous, clinically safe and ethically acceptable, the following requirements will have an impact on the attending midwife and the woman. The attending midwife needs to understand the trial protocol and have access to a source of information. The woman needs access to information to make an informed decision on participation and to have the opportunity to participate in the trial, if she wishes.

There are also obligations for those employed on the research to maximise recruitment of women to the trial and to ensure adherence to trial protocol. The impact of these issues will be explored in chapters four and five.

The lack of involvement of midwives in developing the trial meant that no feeling of ownership was engendered. Failure to involve women in planning resulted in an over optimistic sample size and issues of concern to women did not emerge until recruitment commenced. The involvement of both midwives and women in the planning stages may help to avoid difficulties in the subsequent progress of such trials.

# CHAPTER FOUR : MIDWIFERY CARE FOR WOMEN IN THE FIRST STAGE OF LABOUR AND THE CLINICAL TRIAL

## 4.1 Introduction

There are only four categories of people who can attend a woman in labour: a midwife or student midwife in training or a medical practitioner or medical student (Nurses, Midwives and Health Visitors Act 1979). Midwives have a duty to attend and the responsibility cannot be delegated to anyone other than those previously described.

This chapter will commence with the origins of the title "midwife" and official definitions of this role (section 4.2). The purposes and components of midwifery care for women in the first stage of their labours will then be defined (sections 4.3.1-7), as these are the midwife's prime concern in her work on the labour ward. The chapter will proceed with an exploration of professional issues (section 4.4), characteristics required of the midwife (section 4.4.1), routes into midwifery, professional regulation and control (section 4.4.3). This chapter will then develop factors which affect the provision of midwifery care (section 4.5.1-6). The impact of the trial on the work and experiences of the attending midwife will be identified and analysed (section 4.6.1-6 and 4.7). Section 4.8 will summarise the issues identified in this chapter and make recommendations for future intrapartum research.

## 4.2 What it means to be a midwife

The term midwife is Anglo-Saxon in origin: the components of which are "mid" meaning together with and "wif" or woman, The origin of this term and its interpretation of an attendant who provided companionship for the labouring woman are widely described in the professional literature (Myles 1982; Schwarz 1990).

The definition of the term midwife used currently in the United Kingdom is that ratified by the International Confederation of Midwives, the International Federation of Gynaecologists and Obstetricians and the World Health Organisation. The part of the definition concerning intrapartum care is pertinent to this case study and is as follows:-

The midwife

> "must be able to give necessary supervision, care and advice to women during labour, to conduct deliveries on her own responsibility" (UKCC 1994, page 4). The activities of a midwife, defined as appropriate in the European Community Midwives Directive Article 4, are as follows:-
>
> "to care for and assist the mother during labour and to monitor the condition of the fetus in utero by the appropriate clinical and technical means
>
> to conduct spontaneous deliveries including where required an episiotomy and in urgent cases a breech delivery

recognise warning signs of abnormality in the mother or infant which necessitate referral to a doctor"
(UKCC 1994, page 5).

Whilst minor changes to the Statutory Instruments for midwifery have taken place since the 1980's, the fundamental nature of the midwives' responsibilities have been unchanged. Normal pregnancy, labour and birth is the province of the midwife. There is significant responsibility in the midwife's role in attending women in labour. The primary activity of midwives attending labouring women is the provision of direct clinical care.

The midwife's role in labour is described in detail in the midwifery textbooks (Myles 1982; Sweet 1982). Myles' Textbook for Midwives was used widely in the teaching of midwifery students prior to the time of the trial. In her ninth edition, Myles stated that the principles of good care in labour are to

"Give comfort; relieve pain
Maintain cleanliness
Exercise vigilant observation " (1982, page 256).

Traditional midwifery teaching also acknowledges that care related to labour should commence in the antenatal period. One of the aims of antenatal care being the detection and treatment of physical illness which might cause difficulties in labour (Myles 1982). Emotional preparation for labour has, for many years, centred on the provision of information to allay anxiety and training in techniques to deal with physical discomfort. Such preparation needs to

be complemented appropriately on the day of labour by care from the midwife (Shearer 1990).

## 4.3 Midwifery care in the first stage of labour : its purpose and components at the time of the trial

The over-riding purpose of care in labour was to deliver a live healthy mother of a live, healthy baby (Sweet 1982). The experience should also be emotionally fulfilling (Sweet 1982).

From the perspective of midwives attending women in labour, Myles describes the fundamental principles on which care in labour is based (1982). These, it is suggested, fall into the categories of close and careful observation, the relief of pain and assistance to achieve comfort and the prevention of infection (Myles 1982). The midwife must also be able to recognise and deal with any complications which may arise (Myles 1982).

The key elements for midwives in providing care for women in the first stage of labour in hospital were:-

1. To welcome and admit the woman to the hospital labour ward
2. Observations and monitoring
3. Mobility
4. Attention to hygiene needs
5. Relief of pain
6. Emotional care and support

### 4.3.1 The admission process

The midwifery texts describe the need for a warm welcome for the woman arriving at the door of the labour suite (Myles 1982; Sweet 1982). The woman was entering an environment which was almost entirely unknown to her. For a woman having her first child, this was perhaps her first experience of hospital, which she may have visited briefly, at most, during antenatal classes. The woman's concerns were on adjusting to this new setting and to dealing with what lay ahead in her labour.

However, the midwife had certain tasks to carry out and documentation to complete. The attending midwife assessed the labouring woman's condition and obtained a history of the labour through examination, observation and listening. The examination which took place when the woman was admitted was also repeated at intervals throughout the labour and was carried out each time for the same reason: to assess progress and detect abnormality. The components were abdominal examination, vaginal examination (unless contra-indicated) and palpation of uterine activity, recording of cardiovascular vital signs and inspection for oedema. Recording of these observations was also a requisite midwifery activity. Some of the documentation formed part of the clinical record and some was required by the organisation.

At the time of the trial, a further component of the admission process concerned the physical procedures carried out in the mistaken belief that infection could be prevented by extensive local preparation and cleansing. This was the rationale for the administration of enemas and for perineal shaving, which were present in 50% of English Maternity units in the mid 1980's (Garforth and Garcia 1987). A fine welcome to the hospital labour ward, guarantied to reassure the labouring woman! Women were, however, more fortunate in the case study unit than in some other maternity hospitals in not being obliged to don a white hospital gown for labour.

### 4.3.2 Observation and Monitoring

Midwifery care during the first stage of labour must meet the aims of detecting abnormality for the woman or her baby and referring in such cases to medical aid.

This took place by virtue of a relatively fixed regime of observations of temperature, pulse and blood pressure which were documented on the woman's labour record or partogram. The fetal condition was assessed by various means and both with and without the use of technology. Use of the Pinnards' stethoscope was a non-technological method but from the late 1960's, the cardiotocograph had played a significant role in the monitoring of fetal well-being in labour. Although introduced following minimal research and subsequently found to be of little value in the detection of complications in a low risk labour, its use was

widespread. However, the use of this equipment, with its own needs, and interpretation of its graphic recordings were a universal feature of midwifery practice in the hospital setting.

The institution of electronic monitoring was prompted by factors such as unit policy; the effects of such policies and protocols will be discussed later. The care of women for whom this equipment was used posed challenges for the midwife in achieving the woman's comfort due to restriction of position and discomfort from the apparatus itself.

The abdominal examination, first carried out on admission (section 4.3.2), was repeated at intervals during labour. It allowed assessment of the descent of the baby into the maternal pelvis and this latter observation was verified by internal examination. These usually occurred at intervals of no greater than four hours apart.

Observation of vital signs such as fetal heart and maternal pulse and blood pressure measurement, palpation of contractions and inspection of liquor amnii were half hourly events and the woman's temperature taken every few hours. The midwife had several activities to perform, which all generally increased in frequency as labour progressed. The aim of carrying out these observations was to detect any abnormality in the maternal or fetal condition or the progress of labour.

### 4.3.3 Mobility

At the time of the trial, labour was commonly spent on a delivery bed. For the woman experiencing a straightforward pattern of labour, there was no reason why a range of postures could not be adopted and a range of furniture used for support. The midwife would be engaged in arranging these props.

Walking around can help to both increase the efficiency of contractions and to assist the woman to cope with them. For the woman who laboured in bed, then attention still had to be given to posture to avoid complications such as supine hypotension.

### 4.3.4 Attention to hygiene needs, nutrition and hydration

Attention to hygiene, nutrition and hydration, offering opportunities for privacy with the birth companion, rest and conservation of energy were all aspects of the further physical care provided by midwives to labouring women. Assistance with elimination and the associated measurements and testing also formed a part of the midwife's work.

### 4.3.5 Emotional support

In addition to monitoring physical parameters to achieve a safe outcome, there were psychological needs to be met in labour. There was a need for compassion in dealing with a

woman who may be anxious or distressed and support from the midwife was vital in this area. Women anticipating labour have many concerns about giving birth and how they will cope with the experience (Raphael-Leff 1993). For some women, these concerns include a fear of death itself (Odent 1991). It was the midwife's role to support the woman through these concerns. Companionship was suggested as a means of counteracting the impersonality within the maternity system of that era (Prince and Adams 1987). Information was a part of this support and has been found to contribute to the woman's ability to retain a sense of control in labour (Crowe and van Baeyer 1989) and satisfaction with the process (Boyd and Sellars 1982).

Emotional support, at the time of the trial, was provided through information, involvement of the woman's companion, time spent in explanations, kindness and encouragement. Preparation for labour should begin in the antenatal period (Myles 1982). Whilst antenatal classes and birth planning contributed to the process of providing information, not all women participated in these activities. Whilst time spent in supporting the woman will improve her experience of the first stage of labour, it is also setting the scene for the woman and midwife's working together in the second stage. These will be explored in section 5.2.4.

### 4.3.6 Relief of pain

The provision of emotional support is closely linked with helping a woman to cope with the pain of labour. Assisting the woman with alleviating pain in labour and administering analgesic agents were further components of the midwife's role.

The midwife had a range of methods of pain relief to draw on. Simple methods such as back massage involved the midwife herself or in coaching the woman's birth companion. Strategies learned in parentcraft classes could be engaged, with help from the midwife, such as relaxation and breathing exercises. Flint advocates that midwives work to maintain the woman's morale (1986), offering reassurance and information to achieve this and to reduce tension which may lead to a greater experience of pain.

Narcotic drugs were administered to relieve pain and gaseous compounds self-administered by inhalation. The decision to administer these was made by the midwife, in consultation with the woman. The introduction of epidural anaesthesia in the 1970s added the possibility of labouring with minimal discomfort, albeit with the attendant costs of immobility and increased need for instrumental delivery.

With all of the methods detailed above, the midwife was responsible for advising on their appropriateness. The midwife may also administer some of the methods or augment them and must monitor effectiveness and observe for side

effects. Myles states that the safety and success of pain relief depend on the use of the most appropriate method for the circumstance, the appropriate dosage, timing and correct administration : such were the midwife's activities and responsibilities (1982).

It can be seen that midwives had a great deal of responsibility for an optimal experience for women in labour. So, what should a midwife be like?

### 4.4 Professional issues

The following sections deal with issues related to the characteristics of the midwife, training, regulation and control pertinent to midwifery at the time of the randomised controlled trial.

#### 4.4.1 The appropriate person to be "with woman"

This concerned John Maubray, an eighteenth century physician who lectured at his home on midwifery and defined a curriculum of preparation for assuming the midwife's role. Maubray (1724, cited in Towler and Bramall 1986) described the physical and temperamental characteristics of the ordinary midwife.

These included the need to be

> "patient and pleasant, soft, meek and mild in her Temper, in order to encourage and comfort the labouring woman. She should pass by and forgive her small Failings and Peevish faults; instructing her gently when she does and says amiss.. In the like manner, as she ought to be faithful and silent; always on her guard to conceal those things which ought not to be spoken of" (Maubray 1724, cited in Towler and Bramall 1986, page 107)

Many of Maubray's recommendations are still pertinent. The Code of Professional Conduct for Nurses, Midwives and Health Visitors stipulates the need for confidentiality (1992). Myles speaks of the need for a

> "calm, optimistic temperament" (1982, page 257) and that the midwife may have to exercise firmness with kindness.
>
> Flint more recently described a further skill, that of being patient and suggests that
>
> "an atmosphere of loving, caring and involved support" is required (1986, page 59).

The Central Midwives Board, which until the early 1980s was the professional body which regulated midwifery practice, required that a midwife be over twenty years of age and of good character (1980).

Neither Maubray nor Myles mention information giving as part of the role. However, an ideal midwife was described

as one who offered information with which women could orientate themselves to the likely events and progress of labour (Kirkham 1983b).

### 4.4.2 Becoming the ideal midwife

At the time of the trial, many State Registered Nurses had prepared to become midwives through a one year period of training, although this was being extended to come into line with European Directives. A course combining theoretical and practical experience concluded with both State and Hospital examinations. Following this the midwife's name was entered on the Roll held by the Central Midwives Board for England and Wales and the individual became a practitioner with its responsibilities.

The majority of entrants to the nursing profession prior to the 1980's were women around the age of 18 -19, i.e. school leavers. The youthfulness and lack of life experience meant that student nurses were held to be malleable and subservient to the male dominated profession of medicine. Some nurses immediately went on to midwifery training after their initial qualification.

The educational requirement for admission to the role of student Midwives was a minimum of five General Certificate of Education passes at Ordinary level or equivalent (Central Midwives Board 1980), markedly different from that of medicine which required Advanced Level passes. Midwifery was for many entrants something to be done after

nursing, to round off the experience. Some stayed after qualifying and did not return to general nursing for various reasons. Whilst vocation played a part for some, job security, an enjoyment in dealing with the well instead of the sick and a route into health visiting with an accelerated prospect for promotion all played a part.

A further entry gate had operated in England. A three year course prepared non-nurses to become midwives: this had developed following a national shortage of midwives in the 1960's (Donnison 1988). On completion of the training programmes and success with examinations, all became midwives of equal status and equal responsibility.

The majority of midwives were nurses, used to following both medical and managerial instruction, with little question. Training and post-qualification midwifery were geared towards the clinically competent practitioner. Since 1936, midwives had been obliged to participate in a system of mandatory continuing education to maintain eligibility to practice (Towler and Bramall 1986).

Entry to the profession was restricted to women until challenges under the Sexual Discrimination Act of 1973 allowed the entry of men into the profession (Donnison 1988). The Trades Union specifically aiming to represent the needs of midwives had its origins in the upper middle classes with strong links to both the medical establishment and social reformers (Cowell and Wainwright 1981; Rivers 1981). At the time of the trial, the Trades Union to which

the majority of midwives belonged was not affiliated to the Trades' Union Congress and had a staid image.

The profession thus comprised many who would conform and not question issues related to practice or the work situation and who had been brought up to obey rules.

### 4.4.3 Regulation and control

The activities of a midwife attending a woman in labour were detailed in the previous sections (4.3.1 - 4.3.7). The reason for these activities are statutory in that in the United Kingdom, midwives have a duty to attend a woman in childbirth. This statutory obligation arose in the Nurses, Midwives and Health Visitors Act (1979).

At the case study unit, midwives worked in the National Health Service and were employees of the Health Authority. Midwives had an obligation to work in a way considered acceptable by their employer: this was enforced by their senior colleagues, the midwifery managers. Unacceptable working practices could be subjected to managerial and disciplinary sanctions. Midwives' behaviour was, therefore, shaped by adherence to conditions of employment and a wish to avoid disciplinary action with a range of punitive sanctions including dismissal.

Midwifery in the United Kingdom has an almost unique system of self-regulation, again enshrined in the Statutory

Instruments and known as midwifery supervision. In this, each midwife is subject to the sanction of a supervisor whose responsibility is to ensure a high standard of care and professional practice. At the time of the trial, supervision had a punitive image. A midwife perceived not to be functioning appropriately could be subjected to professional sanction through investigation of practice, suspension and referral ultimately to the profession's statutory body.

Midwifery was a highly regulated and unquestioning profession. Rules governed the components of practice, Codes and Rules prescribed the behaviour which the public could expect and policies or protocols stipulated individual's work in units. The latter issue will be explored in section 4.5.2.

## 4.5 Factors affecting midwifery care provided to women in the first stage of their labours

In sections 4.5.1 - 4.5.4, factors affecting the provision of midwifery care at the time of the trial will be described and explored. These include the midwives' working patterns, the range of midwives' responsibilities and the role of policies and protocols.

### 4.5.1 The organisation of midwives

This section will include midwives' working patterns and the information systems to which the midwife had access at the time of the trial or in which she participated.

At the time of the trial, midwifery working followed a traditional pattern with hospital midwives moving between clinical areas. Community midwives provided the majority of the ante and postnatal care and communication between the two parts of the midwifery service took place through the community midwifery office, in the majority of cases.

This system was not confined to the case study unit and was widespread in the midwifery services until the late 1980's when Team Midwifery schemes developed. The advantages and disadvantages of the previous systems have been discussed (English National Board 1997). At that time, women had rarely met, prior to labour, the midwife who provided their intrapartum care and who delivered their baby (House of Commons Health Committee 1992).

To provide care, midwives needed information about the woman. The woman also had considerable information needs as described in section 4.3.6. The ability to exchange that information depended on a shared understanding of the language and terms used. This applied both between professional groups and between professionals and those in receipt of care.

At the time of the trial, information about the woman preceded her arrival on labour ward in the form of clinical notes which were retained throughout the pregnancy at the hospital. Information in the women's own possession consisted of the Maternity Co-operation card which acted as a means of communication between the hospital and primary care elements of the shared care partnership and which was also available for professionals in case medical advice was required in an emergency.

Information was given through the "handover" or ward report, which occurred at the start of each span of duty and which was an established part of the midwifery routine. The aim of this report is that the information given will provide an accurate and sound basis for care, although the extent to which this is achieved has been challenged (Hunt and Symonds 1995). Handovers fell into a routine of abbreviations familiar to all but students and information about women was transmitted in a pre-set but limited pattern. Lengthy reports were met with calls to speed up the process. This typology of handovers was instantly recognisable to midwives when presented at a national conference by Sheila Hunt and thus common to labour wards around the United Kingdom (Hunt 1989).

The ward report was followed by the allocation of labouring women to their attending midwives. Following this, more detailed information about each labouring woman would be passed from the midwife relinquishing care to the one

taking over that responsibility. The relinquishing midwife would then leave with good wishes and assurances to the woman of a successful outcome. Women were encouraged to follow the new midwife's directions: this pattern was also observed in other units (Hunt and Symonds 1995).

At the time of the trial, the allocation of women to attending midwives had certain underlying, if unspoken, principles. Midwifery was organised along hierarchical lines with all midwives very aware of their position in the hierarchy. The allocation of midwives came within the jurisdiction of the senior sisters. Every effort was made to ensure that student midwives were allocated to care for women who appeared likely to deliver that shift. Following allocation of students and their accompanying midwives, allocation of women to midwives would take place starting with allocation to the most junior staff midwives and then the midwifery sisters.

Additional communications took place about the labouring woman. The "ward round" was a further regular information exchange between the midwife and obstetricians. This involved the senior midwife on duty and obstetricians with responsibility for the labour suite over the next 12 - 24 hours. The consultant or their senior registrar were accompanied by a retinue of junior staff, medical students and the senior midwife. Each labouring woman was visited by this entourage and, usually a brief examination was carried out. Instructions for the attending midwife were documented in the clinical notes. Midwives were also

obliged to communicate with medical colleagues in emergency situations, that is any deviation from a state of normal in the maternal health or in the process of labour (Central Midwives Board 1980).

Birth plans also provided a means of exchanging information between labouring women and their attending midwives. These had been introduced in the unit shortly before starting the clinical trial by a senior midwife, who fostered a "go ahead" view to the service. Birth plans have been demonstrated to have an empowering effect on women (Moore and Hopper 1995). Their introduction had not been universally well received.

The midwife must be a team player (Opuku 1992; Warwick 1986). Training occurs in groups, practice requires involvement with both professionals, women and their families, so communication skills are paramount. However, whilst being team members, midwives on the labour ward could never be the captain. Relationships in the labour ward were such that the obstetrician was always considered the most senior professional (Donnison 1988).

It has been demonstrated that set patterns existed in midwives' working practices and in the ways through which information was exchanged. One significant change, the introduction of birth planning, had been introduced into the unit. Midwives' work already brought them into contact with many people: other health professionals, students,

women and their families.

### 4.5.2 The midwife's other responsibilities: teaching and administration

In addition to providing direct clinical care, midwives working on the labour suite had other responsibilities. These included administration and organisation of the ward and the educational responsibility for ensuring that learners from various professions had appropriate learning opportunities. At the time of the trial, learners were becoming more assertive in their attainment of clinical experience and competition for "cases" occurred. Thus, when faced with students requiring learning opportunities, the attending midwife had to balance the needs of the woman with the need to provide educational experience for the student. Such interruptions slowed down the midwife's work, interrupted clinical care and disrupted communication with the woman (Schott 1995). Midwives also often had to function as domestic assistants, orderlies and clerical officers, when none of the latter were available.

Midwives were pivotal to the running of the labour ward. Whilst needing to juggle the many clinical demands as well as being able to prioritise information, they had to make sure that all of the jobs were done and everyone's needs met.

Midwives also had considerable influence over communications, for example, in the handling of telephone

enquiries about individual women. Such enquiries interrupted and disturbed the midwife, who would either give a message to be transmitted to the caller or who left the woman to speak to the caller in the labour ward office. Families were requested to keep phone calls to a minimum and a "party-line" was adopted where the birth companion was asked to keep other parties informed of progress. This was not unique to that unit. In summary, telephone calls were an interruption for the midwife and deflected her attention from other more important work, as reported elsewhere (Hunt and Symonds 1995).

### 4.5.3 Factors affecting the provision of emotional support in labour

An optimal aim was to provide the woman with close support, where the midwife could spend time and give the attention required. This required adequate staffing and time free of interruptions. Rapport between the two parties was important and information must be readily available, in a form which was understood.

The issues described in section 4.4.2 relating to the interruptions experienced by attending midwives have a bearing here. Staffing levels were also an issue. Uneven workloads are a characteristic of delivery suites and this unit was no exception. Associations have been reported between midwives' accounts of staff shortages and their inability to extend emotional support to women (Robinson, Golden and Bradley 1983). Midwives, who had not met the

woman before, had a relatively short time to establish rapport due to the combination of a progressing labour and the traditional shift system.

Information must be presented in a way which can be understandable. Information must also be transmitted rather than blocked or deflected to other sources. These behaviours are reported in both the nursing and midwifery literature. Nursing sources suggest that such behaviour occurs because nurses wish to avoid giving conflicting information and because there is certain information which the system does not allow them to give (MacLeod Clark 1981). This behaviour is unhelpful and, in the context of labour, has been ascribed to midwives needing to retain power over a situation (Hunt and Symonds 1995), although alternative explanations exist.

The establishing of a rapport between the attending midwife and labouring woman may take various methods. The discussion of shared life experiences can contribute to this (Duggan 1981). Such information provides the labouring woman with a further source of non-medical knowledge and may support that of her own family and friends. A sharing of experience will obviously not be available to all labouring women, but sharing personal experience has also been found to be helpful by midwifery researchers (McHaffie 1988).

### 4.5.4 The influence of litigation

The role of litigation in shaping practice requires acknowledgement. At the time of the study, midwives had concerns about litigation, albeit not to the extent that this shapes practice to-day. Concerns were manifested about the need "to cover oneself". This was at variance with the official professional ethos of midwives having responsibility for their own actions, rather than through referred authority, as in nursing. This awareness often manifested itself at the time as a defensive and rather inflexible approach to practice coupled with a hesitancy about whether one's position was safeguarded if practising in any way outside the main stream. This confusion stemmed from the contradictions of the professional ethos, the lack of opportunity to practice the full range of midwifery skills and the restrictions on practice at that time (Robinson, Golden and Bradley 1983). This, coupled with the expectation of a safe outcome for mother and baby, put certain pressures on the midwife.

### 4.5.5 Policies and protocols in the labour ward

At the time of the trial, midwifery actions were regulated by the unit's rules. Whilst not always accessible in hard copy, there was a widely held belief that certain aspects of care were unit policy, for example, rupturing the membranes at three centimetres cervical dilatation. The authors of these policies were considered to be the medical staff.

Information from two large surveys carried out around the time of the trial provides information about the extent to which policies and protocols affected midwifery practice on labour wards.

Robinson and her colleagues' survey of midwives revealed that complete midwifery autonomy over practice was rarely experienced (1983). Whilst 82% of midwives reported that labouring women were cared for by a midwife and not examined routinely by a doctor, Robinson found that midwives' actions were usually directed by medical involvement or by policies. If some of the key elements of midwifery care are considered, in 50% of units a policy defined the timing of vaginal examinations, 29% of units had policies stipulating the timing of intramuscular analgesics, despite the fact that these activities fall within the midwife's sphere of practice.

Consultant units, including the case study site, were more likely to have policies stipulating labour management compared to either isolated or integrated GP units. Midwives in teaching hospitals were less likely than those in non-teaching settings to be responsible for decision-making (Robinson et al 1983). Midwives and obstetricians also differed on the extent to which they perceived that midwives could take responsibility for decision-making over fetal monitoring (Robinson et al 1983). Robinson's study revealed that the involvement of medical staff in determining unit policy had resulted in the erosion of midwives' skill (1983). Thus at the time of the trial, the

skills of midwives practicing in England had been eroded through lack of use and increasing medical involvement in intrapartum care.

The protocol driven approach was reinforced by a Report on Intrapartum Care from the Maternity Services Advisory Committee which stipulated that all maternity units should develop operational policies to ensure a consistent standard of care (1984). However, the Advisory Committee had also recommended that all disciplines should be involved in the creation of these policies to ensure their understanding of them (1984). It is the latter part of the Advisory Committee's recommendations which had not been evident from Robinson's survey.

Similarly, a survey of maternity unit policies was carried out in 1984 by Garcia and Garforth. This survey of labour and delivery routines in English consultant maternity units identified interesting variations in policies and factors which affected these.

Unit size, geographical location in the country and the presence of learner staff all affected routines (Garcia and Garforth 1989). Larger units were more likely to have policies stipulating action when labour progress was deemed slow. "Northern" units were more likely to prohibit women from eating during labour and to have fixed regimes for vaginal examination in labour. Midwives in Northern units were less likely to "top up" epidurals or to suture the perineum and were more likely to subject women to policies

related to bowel preparation and perineal shaving (Garcia and Garforth 1989). If medical students received education in the unit, then policies of timing of amniotomy and electronic fetal monitoring for all women were more likely in that unit. Midwives were then more likely to apply fetal scalp electrodes, to suture the perineum themselves and to allow more than just the husband as a companion for the labouring woman.

Like Kirkham (1983), Garcia and Garforth became aware of different priorities for women and midwives during the admission process. However, it was commonly unit policy rather than the woman's preference which dictated whether the partner or a birth companion could be with the woman at this time (Garcia and Garforth 1989).

Midwives were reported to feel constrained by policies related to vaginal examinations and in some units, policies even varied between consultants over the practices of bowel and skin preparation. The findings of both surveys concur: midwifery involvement in decision-making was less in consultant than in GP units (Garcia and Garforth 1989; Robinson, Golden and Bradley 1983).

Thus, from both of these surveys it is evident at the time of the trial that labour ward practices around the United Kingdom were dominated by policies which were usually medically led. This had affected midwives' practices, reduced their skills, eroded their confidence and diminished their role. This can become a self-fulfilling

prophesy. Further decline becomes inevitable with midwifery autonomy so compromised and midwives feel incapable of providing independent care (Oakley and Houd 1990). More recently, Hunt's ethnographic research in the labour ward found similar problems for midwives. Medical control over labour was exercised by policies of continuous electronic monitoring and of doctors needing to be seen to make the final decision, even when suggestions came from the midwives (Hunt and Symonds 1995).

The existence of protocols regulating midwifery practice demonstrates that there was a disparity between the autonomy espoused by the profession and supported by various definitions of midwives' activities and the reality of life on labour suites in English consultant maternity units in the early 1980's.

## 4.6. The impact of the trial on the work and experiences of midwives in the care of women in the first stage of their labours

The clinical trial impacted on the attending midwives' work in calling for changes to the allocation of midwives to labouring women, a different approach to care in the first stage of labour and on aspects of communication. All of these points of impact occurred due to the trial protocol and for this reason issues related to policies and protocols will be explored first.

#### 4.6.1.1 Policies and protocols in labour ward work

The trial protocol was the vehicle through which an inflexible regime of management was imposed on areas of practice, which were under the jurisdiction of the midwife.

It has already been argued in section 4.5.5 that midwives' work, at the time of the trial, was restricted by policies. There was also a disparity between midwives' claims about being practitioners in their own right and the reality of working in the National Health Service maternity units. Whilst the randomised controlled trial added restrictions, the imposition of a protocol was, in itself, not an unusual circumstance. An obstetrician-led trial protocol reflected the medical domination of labour ward policies described in section 4.5.5. Whilst midwives were used to policy and protocols, questions arise about the extent to which these were welcome and why they were used: these issues will now be explored.

Bryar was concerned about the extent to which a unit's policies limited midwives from providing individualised care (1988). The issue is perhaps whether midwives *really* support individualised care. One midwife appeared to prefer a rigid framework as she liked "the discipline and order of her job" (Hunt and Symonds 1995, page 123). The processing of women through areas such as antenatal clinic in the 1970's and 1980's and through the labour ward at night (Hunt and Symonds 1995) all reflect little attention to psychological needs or individualised care. Midwives

appear to like rituals and routines. Different rituals offer a means of unwinding and light relief after the responsibility of delivering a woman of her baby and draw the attention of others to the completed task (Hunt and Symonds 1995).

Other reasons for engaging in routines exist. For newcomers, engaging in routines can be comforting (Davies and Atkinson 1991). For the majority of midwives working in hospital at the time of the trial, two other issues are pertinent. Firstly that the majority of their experience was in hospital practice and thus an institutional setting, where a "normal in retrospect" approach to labour and birth was prevalent and where women were treated as patients. This treatment of women as patients was reinforced by the fact that many midwives had also previously been nurses, again with a focus on nursing the sick in institutions, where a task orientated approach to work had been prevalent. In such settings, rituals and routines have been found to have a major effect on clinical practice (Walsh and Ford 1989).

Sleep has identified a further reason for developing policies (1992). These are well known to clinicians and relate to the often apparently knee-jerk reaction to one adverse event. Sleep argued that policies are useful for the teaching of students (1992), although it is unclear how an effect is achieved or whether it is easier for the busy clinical teacher who can offer the policy manual to the student as a time-saving exercise.

Menzies suggested that policy documents are a defence mechanism against professionals' distress and the need to form new relationships with patients (1970). Whilst this was true of midwives on the labour suite at the time of the study, who were meeting and providing care for a new set of women each shift, it does not appear to be the reason why such documents existed. Concerns about getting to know a woman prior to her labour have only more recently become more widely acknowledged within the profession (Flint 1993). The reason for policy documents appeared to be far more closely related to regulation of practice and professionals by the organisation, professional leaders or obstetricians. They served a controlling rather than an emotionally supportive function.

Midwives cope with the situation of providing care for women they have not previously met by a different ritual. Stereotyping of childbearing women is used widely (Green et al 1990) but this practice is not without its dangers. It can be a substitute for appropriate communication and may result in hostility or disrespect (Green et al 1990; Hunt and Symonds 1995).

Women who expressed a willingness to enter this particular clinical trial were sometimes viewed by midwives as being interested in "natural childbirth": a new fashion at the time and not highly favoured in the unit. Women could thus be perceived as going against the norms of the unit and of upsetting certain aspects of the labour which were within

the midwife's control. Midwives have defined the criteria for good relationships with their clients as when the midwife is in full control over a situation (McCrea and Crute 1992): the research disturbed this.

#### 4.6.1.2 Policies and protocols : effects on midwives' and women's experiences

Hospital policies played a key role in midwives' views of their working experiences. They resulted in midwives leaving NHS practice (Weig 1990, cited in Oakley and Houd 1990), when birth became medically led. However, some midwives appreciate their existence whilst others feel that they confer a professional "strait-jacket" and inhibit midwives from offering individual care (Bailey and Robertshaw 1991). If the hospital policy conflicts with the midwife's view of what is good practice, then this can upset the development of a therapeutic relationship (McCrae and Crute 1992). In section 4.6.1.1, it was established that the randomised trial upset the midwife's control over practice, thus also potentially upsetting the therapeutic relationship.

Whilst midwives view policies and protocols in a variety of ways and these documents exist for a variety of reasons, such documents also impact on the experiences of women.

They

> "are sometimes dated, occasionally signed, rarely referenced, yet, written in tablets of stone, they dictate countless women's experiences of pregnancy and childbirth" (Sleep 1992).

The application of policies to a situation may be inappropriate or inadequately thought through (Lewison 1995) resulting also in negative effects for midwives themselves and for the care they offer.

At the time of the trial, the use of protocols was widespread. Midwives were tolerant of protocols to the extent that they accepted different ones when moving to practice in different geographical areas (Garcia and Garforth 1989).

It can be concluded from sections 4.6.1 and 4.6.2 that the imposition of a protocol itself was not new. Various reasons have been identified about why policies and protocols might be used. However, whilst midwives have mixed views on their use, negative impacts on the experiences of both midwives and women cannot be discounted.

#### 4.6.1.3 The randomised controlled trial: a different protocol

Randomization was where the trial protocol differed from other policy and protocol documents and which also impacted on the midwife's practice. Key issues which emerged in the trial were restricting the use of equipment to women in the trial and the random allocation between treatment groups. Randomised controlled trials have brought moral dilemmas for midwives elsewhere (Oakley 1994). Midwives in the Social Support and Pregnancy Outcome trial experienced this due to the restriction of their provision of social support intervention to half of the women in the study. Thus, whilst these midwives are reported as having enjoyed the autonomy of their work, they disliked the obligation of working within the constraints or rules of the protocol (Oakley 1994). Attempts to influence the randomization process have been recorded in several trials where midwives were involved (Oakley 1994; Crowley 1991). In Oakley's trial the use of randomization meant that women perceived by midwives as being at risk were not allocated to the package of additional support: this resulted in dilemmas for the midwives (1994).

Oakley used the rationale of needing to produce high quality scientific information as a support for use of the randomised controlled trial. This may not change all midwives' views. It assumes an understanding of research, which is not present amongst all midwives (Thomson 1988)

and also, a utilitarian approach to the acquisition of knowledge which runs counter to the importance of the individual as espoused in the Code of Professional Conduct (UKCC 1992).

Midwives' difficulties in working within a framework of randomization have also been reported by McCandlish and Renfrew (1991). They suggest that difficulties arise from midwives' views on the merits of existing treatment options (usually preferable to anything new) and the extent to which chance should be allowed to determine treatment method. Midwives are not alone. Doctors also have difficulty in this area and tampered with randomization procedures in what was also a trial of posture in labour (Crowley 1991).

Clinicians are in a difficult position when new techniques are introduced. Women have been known to relinquish choice and take the midwife's advice (Bluff and Holloway 1994) in the belief that the latter's experience is greater. The midwife providing care for an unquestioning or unassertive population may then be faced with greater concerns. As an advocate for the woman how can the midwife meet all of these different needs or concerns? In the trial, midwives faced with questions about birth position took a variety of approaches to such discussion. Some used personal experience of birth. Other midwives emphasised their flexibility or declined to become involved in discussion and referred all questions to the research midwife.

Lilford discussed the issue of professional equipoise or strength of belief in treatment efficacy in relation to conducting clinical trials (1992). For trials of birth position, it is impossible for clinicians to be in the state of clinical equipoise described by Lilford. Clinicians have experience of traditional management and beliefs in its efficacy.

Thus, there is a difference between how a randomised controlled trial protocol impacts on the work of an attending midwife in comparison to the effects of other protocols. Midwives had ethical concerns associated with restricting the equipment to use only by women in the trial and imposing random allocation proved difficult and unpopular. Further, the reasons for using random allocation were not understood by all midwives. Midwives have a responsibility to do their best for the labouring woman. This will usually involve working in the way in which they have the greatest experience. To work within the bounds of randomised controlled trials runs counter to this.

#### 4.6.1.4 Frictions between midwives and obstetricians are emphasised by clinical trials

In the case study unit, a recently appointed consultant had introduced the randomised controlled trial and also other policies and research into other aspects of labour ward practice, such as induction of labour. Thus around the

same time, midwives had to cope with several changes related to the obstetric management of labour but which also impacted upon their practice. Similarly, midwives did not appear to relish increased consultant involvement on the labour ward as observed in other units with three tiers of medical staffing (Kitzinger et al 1990).

The historical relationship between midwives and obstetricians is one of tension and friction (Donnison 1988). In any one maternity unit, consultants may have a range of approaches to one condition and the extent to which the midwife can be responsible for dealing with them (Hunt and Symonds 1995). Kitzinger and her colleagues have described the two ways in which midwives and obstetricians cross paths as being through clinical contact and by the development of policies (1990). Even if the consultant is absent from the labour suite, through the latter they will affect midwives' practice. Midwives may agree or disagree with the protocols and view the consultant accordingly (Kitzinger 1990).

The obstetrician designed protocol exacerbated tensions in the case study unit between midwives and obstetricians. The clinical trial protocol impacted on midwifery practice around delivery, and to a lessor extent around other subtler but important ways in the first stage.

There was also a strong sense of what was usual in that unit, through the citing of certain practices as being policy in certain situations. The perception of the

research midwife, new to the unit, was that policies were often quoted by midwives to their colleagues who might appear to be considering deviation from the usual approaches. The reason for this appeared to be related to not encouraging flexibility of practice and concerns about not wishing to be implicated if any untoward event occurred.

In terms of inter-disciplinary relationships, clinical midwives were at a difficult period. Working practices were usually determined by obstetricians or by their midwifery managers with little consultation. The trial took place in a "Northern" teaching hospital, as defined by Garcia and Garforth (1989) and contained many of the practices associated with such units.

In conclusion, a group of workers who were very used to practices being imposed and inflexible received a variety of upsets. These included birth planning and changes to long-standing policies on the labour ward through the appointment of a new consultant, even before the addition of the trial. Thus, whilst working within a medically - led protocol was not new, the trial imposed new methods on to what was fundamentally midwives' work and introduced ethical difficulties for the attending midwives.

### 4.6.2 Changes to the allocation of midwives

The clinical trial protocol stipulated care for women participating in the research. It also stated who should be involved in caring for women in the trial. It had been intended that the deliveries of women participating in the research would be carried out by the research midwife and a small number of senior midwifery sisters to ensure a certain level of experience and technique. This immediately proved unpopular. The allocation of midwives to labouring women on the labour ward was one of the few remaining areas where midwives retained control: the trial protocol encroached on this.

The stipulation in the protocol about who would provide care to women in the trial met with fierce opposition from the Head of Midwifery Education who did not wish to see a reduction in the clinical experience available to student midwives. A compromise was reached whereby student midwives delivered women allocated to the " bed" arm of the trial and qualified midwives delivered women allocated to birth in the upright position. In terms of scientific rigour, this compromise appears to have little merit.

Junior midwives were also affected by the protocol. The unwritten rules of the allocation of attending midwives to labouring women was described in section 4.5.1. Junior midwives who were not supervising a student would be allocated to provide care for trial participants without

discussion of the midwife's preference or experience. Junior midwives were expected to deliver women in a position different from that in which they had experience and where, if difficulties arose, they were the least experienced to deal with them. Following the allocation of juniors, more senior midwives were allocated to care for women in the trial. The fact that a less experienced midwife then felt under pressure in that situation was surely not in her best interests nor those of the woman. This situation has been observed more recently with the addition of water to the range of options available to women in labour (Chapman 1994).

In summary, the trial protocol threatened to impact on one of the few aspects of life on the labour ward where the midwife retained control. It is hardly surprising that this stipulation in the trial protocol was unmet. The midwives needed to retain control over one of the few remaining aspects of their work.

### 4.6.3 Changes to clinical care

The trial protocol made few differences to the attending midwife's care in the first stage of labour. No changes to the admission procedures were required by the research proposal and the schedule of observation and monitoring remained unchanged. Hygiene and other needs were met in the usual manner and women continued to have an unrestricted choice of pain relief, although choice of epidural excluded women from the trial.

### 4.6.4 Changes to philosophy

Whilst the schedule of monitoring remained unchanged by the trial protocol, some impact was felt in the issue of mobility. The difference was quite subtle and occurred because the protocol stated that women in the trial could remain ambulant with the use of radio-telemetry to effect continuous fetal heart recording. The fact that mobility became a definite option brought a more flexible approach to care in labour. This emphasis on flexibility, coming hard on the heels of the introduction of birth plans, served to emphasise that a new era was dawning. Both of these changes affected the work of the attending midwives and were imposed on them, rather than originating from them. The midwife had little time to become used to this change in her practice and had no official opportunities to voice any concerns.

### 4.6.5 Issues related to communication

The midwives became aware of the trial because women would mention their interest, often as soon as they arrived on the labour suite. For a midwife unhappy about the trial, then this was a cause of discomfort for her during the first stage of the woman's labour. Women had received information about the trial from the research midwife and thus appeared well-informed. Discussion of other positions for birth, in addition to the options within the trial, was perceived to increase women's knowledge and their requests

for these alternatives. The attending midwife's work was altered again by the trial. Women interested in the trial had also met the research midwife before: some attending midwives felt disadvantaged by that existing rapport. The attending midwives also reported their difficulties and hesitancy in discussing the trial with women. A variety of reasons contributed to this. The terminology of the trial protocol reflected contemporary research terms. The attending midwives were unused to the language of research and concerned about giving incorrect information. Midwives' lack of familiarity with the principles of research has been described by Thomson (1988). There was also the feeling that everything to do with the trial was the research midwife's job and that they should therefore not become involved with it.

These were all difficulties for the attending midwives and resulted in further feelings of disadvantage.

#### 4.6.6.1 Impacts due to the work of the research midwife

The trial also impacted on the attending midwives through the work of the research midwife. Keen not to lose potential participants in the trial, the research midwife attended ward handovers to identify women involved in the research. This was necessary because information about the research was not always shared with staff coming on duty and, if included, was often done in a negative manner. Research did not fit into the existing packages of

information at the ward reports and "stuck out like a sore thumb"!

The research midwife also enquired regularly about potential trial participants in order that eligibility for the trial could be verified and consent re-checked. The attending midwives thus had a new role imposed upon them: that of gate-keepers to a research sample.

#### 4.6.6.2 Gate-keeping

Whilst used to controlling the access of students, gate-keeping for research was a new situation and again uncertainty about this role was experienced. Issues of status contributed to this problem. Students of any discipline are inevitably junior in the hospital hierarchy to qualified midwives. The research midwife was employed at sister grade and so was of at least equal seniority within the organisation, if not within the culture, to some of the midwives and was senior to the staff midwives.

Attempts by the research midwife to seek information about a woman's progress or to offer information about the research appropriate to that stage of labour was met with responses which suggested that such enquiries were sometimes unwelcome, despite endeavouring to pick a convenient time. Reactions from the attending midwives indicated that the research was an irritation, too inconvenient or unimportant. It was one more concern to

fit into an already difficult situation with many pressing priorities. Subsequently, it became apparent that concerns existed about what was going to be required of the attending midwife by the research. In addition to issues of hierarchy amongst midwives, the attending midwives were aware that the study had been devised by a consultant obstetrician, perceived as having seniority in the hospital hierarchy to themselves. There was always the issue then of having little choice but to comply.

In terms of the "hand over" of individual women, the trial also brought about changes to communications at this time. Midwives' usual confidence about satisfactory outcome wavered with knowledge of participation in the trial, which was mentioned with hesitancy. Midwives acknowledged that they were uncertain about what to say in the face of research participation. If the second stage of labour was approaching and the random allocation to the upright delivery position had been effected, then little discussion took place and the imminent delivery was not anticipated so keenly as if semi-recumbency had been allocated. This is in contrast to the encouragement that women usually received from the midwife relinquishing care, indicating confidence in the new midwife, encouragement to follow her instructions and that all will be well (Hunt and Symonds 1995).

## 4.7. The impact of the trial on the experiences of labouring women which also affected the attending midwives

Women have a considerable need and desire for information about the labour and birth process. Information was available through antenatal classes, birth planning and through antenatal care from the midwife. The trial added to the information available to women due to the requirement that the research midwife provided information during pregnancy. Women therefore met the research midwife in addition to midwives in the hospital and community antenatal clinics.

Through discussion of the clinical trial, inevitably other questions arose about care in labour. Discussion of these issues suggested that choice was available. Women had a further source of information, which at the time appeared to be welcomed, although the potential for conflicting information existed. Research information also had the potential to add to women's distress if terminology used was poorly explained. It may also have given the woman certain expectations, which then the attending midwife had to deliver. The extent to which the research midwife offering information and answering questions might be perceived as professionally unethical is open to debate. Midwives are very possessive of *their* women. However, if women needed information and it was available at that time from an appropriately qualified source, then it appeared unethical to withhold it.

As stated in section 4.6.5, women admitted to the labour ward usually offered information to the attending staff that they were a part of the trial. This was greeted in a variety of ways. Some women encountered a rather half-hearted response and consequently felt diffident about raising the subject again unless they saw the research midwife on the labour suite. They were told that it was too early in the labour to consider the second stage and that a lot might change or occur to make it impossible and not to worry as the research midwife would be on duty soon! This was not encouraging for the woman, as at a key time, she was receiving different messages to those previously received and which reduced the likelihood of her raising the issue again. Kirkham reported that women quickly learn to modify their behaviour to that perceived as required by the midwife (1983). It has been suggested that the "not to worry" approach can hardly be deemed reassuring (MacIntyre 1982).

It is also difficult to pursue a topic when the language associated with it was new. Women were generally unfamiliar with the language of research and commented on the difficulty of introducing this topic. If their hesitant introduction met with a less than enthusiastic response, then this must have been disappointing and difficult at a stage in labour when the woman was trying to establish trust in attending staff and needed to be seen as not difficult or different. The fact that some midwives were also unsure about discussing the research made for a

difficult time for both parties, when there are already different perceptions of terms around childbearing (Garcia and Garforth 1989). Obtaining information through the vehicle of research was less demeaning for a woman than many of the methods observed in other studies such as self-denigration and jokes about herself or her partner (Kirkham 1983b). The potential for empowerment exists but this may be restricted to women who could deal with the terminology and who could integrate that with other information.

Issues for women of communications and information also had an impact on the attending midwife. Even if the midwife did not raise the subject of the trial, a labouring woman might: thus, for the attending midwife, the trial was difficult to avoid.

### 4.8 Conclusions and Recommendations

Torn between various demands, the attending midwife was trying to do her best in a difficult situation. Concerned about going out of line, the midwife had to keep within the parameters laid out for her and try to meet the needs of the organisation, her colleagues, the woman and her family. Sympathetic to her colleague involved in research, she had far too much to do herself than to be any more than politely interested. She had her job and it isn't the research. That is the research midwife's job! She already had many interruptions to her care of the woman - research was just one more. Her primary purpose was, after all, to provide clinical care to labouring women.

It was unfortunate that a major piece of research came at a time of other changes to the philosophy and practices of one, already highly charged, clinical area. Whilst a medically led approach to management was not new, the randomised controlled trial reinforced tensions between midwives and obstetricians. It introduced new ethical dilemmas and undermined the midwife's position. It was also unsurprising that midwives avoided one of the stipulations in the protocol, when this related to one of the few areas where they retained control.

Struggling to establish rapport with women going through a crucial life event when she had not met them before, the attending midwife was in some ways usurped and wrong-footed: the woman knew the research midwife already. When trying to offer information, some of it had already been provided, perhaps with a different emphasis or perspective to her own: thus her position was undermined and she felt unsettled.

Concerned about the individual woman, the thought of involving her in an experiment for the greater good proved ethically difficult when the midwife is advised, in her professional code, to work always in the individual woman's best interests. This usually means providing care in the way that the midwife knows best. Equally, for a midwife convinced of the benefits of the new alternative, to subject the woman to a trial was again difficult, although as Thomson suggested (1988), this approach to practice does

not have a scientific base. The trial had several impacts on communications. Midwives had more interruptions in their work, women's expectations were raised, they were better informed and there was the potential for disappointment on several issues. Research had a different language, it did not fit easily into systems of the time and raised doubts for the midwives and reduced their certainty about outcome.

Research proposals are often pared down to maximise the chances of obtaining funding. The constraint of time is considerable and there is often little time available at the planning stage to involve all who may be affected by the research. There are many valid reasons why this happens but not to do so is false economy, in terms of goodwill and the integrity of the research. It is especially important when the research of one discipline impacts on the work of another. During the development of a trial, after receipt of funding, it is in the interests of all parties for the research team to conduct seminars to discuss the proposed research in terms of both subject matter and methodology. This would enable clinical staff to be better informed about both the purposes of the trial and the research design, develop ownership of the research topic and feel more confident in discussing it. Such meetings may allow misconceptions to be dispelled and ethical issues explored. This type of development work would be a professional courtesy and acknowledgement of the vital importance of the clinician's contribution.

The research funding supported a midwife to be responsible for day-to-day running of the trial, including provision of information and recruitment of women to the study, delivery of some women in the trial, collection and processing of clinical samples and data collection. Additional work was therefore not imposed on the attending midwives. With few exceptions information about the trial was provided by the research midwife, despite invitations and assurances that the involvement of colleagues was welcome. Thus the separate nature of the work was established. Should such activity be incorporated within the mainstream midwifery role and become a part of normal unit life? This approach will be explored further in chapter five.

The service, which is the product of its workers, should not suffer when research is being conducted. Care should not be compromised because health care professionals feel uncomfortable about research. Disruption to the service must be minimised and midwives must feel supported when research is going on which affects their practice. This support could come from Supervisors of Midwives.

What can midwives gain from involvement in research ? So far, it appears little. Midwives have appreciated the opportunity to practice in alternative ways and to consider traditional parts of their practice (Harding 1988). Some larger scale trials offer tangible incentives such as mugs or tee-shirts when units are progressing well with research. However, should incentives be necessary in a professional group? There appears to be few immediate

incentives when the goals of clinical care and research are so different. The benefits of research to womankind do not take precedence for the midwife working always on a one-to-one basis with an individual.

# CHAPTER FIVE: MIDWIFERY CARE FOR WOMEN IN THE SECOND AND THIRD STAGES OF LABOUR AND THE CLINICAL TRIAL

## 5.1 Introduction

The second stage of labour is the time of greatest concern for the midwife about the rate of progress and fetal well being, with the third stage of labour causing the greatest concern about the woman's health. For the fetus, this is the time of greatest risk of hypoxia and the woman may suffer haemorrhage following the birth. Whilst consideration was given to addressing these two stages of labour in separate chapters within this thesis, they will be considered within the same chapter. This is because similar issues have arisen from the two stages of labour. In addition, as labour is a continuum (McNabb 1989) with little temporal distinction between the second and third stages, to consider them separately would cause an artificial and unhelpful division.

This chapter will describe the midwife's care in the second and third stages of labour (section 5.2.1-7 and 5.3.1-6). Care provided after birth, relevant to the trial, is described in section 5.4. Factors that affect care (5.5.1-6) and the impact of the trial on the work of the attending midwives are identified (section 5.6). Difficulties caused by the trial are explored in sections 5.7, 5.8 and 5.9. Finally, the chapter is summarised and findings discussed (section 5.10).

### 5.2.1 Midwifery care for the second stage of labour: definitions and purpose

The second stage of labour lasts from full dilatation of the uterine cervix until and including the birth of the baby. The duration of the second stage of labour is very variable from a few minutes and one or two contractions to three hours or longer.

During the second stage of labour, the nature of the woman's experience changed, in that she was required to play a more active part in the birth process. In the first stage the contractions, although known to be fulfilling a purpose, were something which the woman had to cope with as best she could. During the second stage of labour, both primary and secondary powers are brought in to play during the expulsive phase. The primary powers of involuntary uterine contractions are assisted by the secondary powers of voluntary maternal expulsive efforts. The second stage of labour thus requires the woman to work extremely hard but she usually feels that something is being accomplished from the pain experienced.

Whilst the midwife's activities will be detailed below, in summary, the second stage was a time when the midwife's duties are increased due to the pace of progress and the woman's different needs. The extent of the midwife's responsibilities during this stage of labour are detailed in the European Community Midwives Directive and are as follows:-

"5.6 to conduct spontaneous deliveries including where required an episiotomy"

"5.7 to recognise the warning signs of abnormality in the mother or infant which necessitate referral to a doctor and to assist the latter where appropriate" (UKCC 1994, page 5).

The attending midwife's responsibilities of the first stage of labour of assisting the woman and monitoring the fetus continued during the second stage. Care given during the second stage must be documented, as well as observations and treatment.

The ultimate purpose, however, of the midwife's care was to accomplish the delivery of a healthy woman of a healthy baby, with minimal trauma to both parties. Whilst the latter has long been acknowledged as an aim of midwifery care, there was also the hope that giving birth could be a positive experience for the woman and one from which she would emerge mentally unscathed (Myles 1982).

The following sections will identify the components of care.

### 5.2.2 Observations and Monitoring

There was generally an increased pace of midwifery activity during the second stage of labour. Contractions occurred every two to three minutes thus leaving the woman only a minute's rest in between. The contractions were also of

longer duration, lasting up to one minute and stronger, bringing with them the sensation of needing to bear down. The time between contractions was filled with, for the woman, trying to rest, gather strength for the next effort and to obtain information. The midwife was carrying out the care of the woman and observing the condition of mother and fetus.

Monitoring of both maternal and fetal condition and of the progress of labour took place more frequently than in the first stage. The fetal heart was either monitored continuously using a cardiotocograph or auscultated after each contraction using a Pinnard's stethoscope and the colour of the liquor amnii observed. The reason for this schedule of observation was due to the increased risk to the fetus of hypoxia at this stage of labour (Sweet 1982). The woman's pulse and blood pressure were noted more frequently than in the first stage to detect signs of physical distress or exhaustion. The rate of progress of the baby towards delivery was also key. Delay beyond a certain point necessitated seeking medical opinion, as excessive delay could be detrimental for the woman or baby. Progress was judged by a variety of means including the woman's behaviour, abdominal and vaginal examination, as in the first stage and observation of the rate of advance of the presenting part.

The midwife was therefore continuing with an increased schedule of observation at a time when the woman needed even more help and encouragement. The midwife's anxieties

were usually at their greatest, generally at the time of the trial, being grounded in a medical model of pregnancy. This model hinged on the belief that labour could be normal only in retrospect, that professional attendants were working towards the prevention of physical complications and to achieve healthy outcomes a doctor or midwife must be in charge of the event. The contrasting model of pregnancy is of a normal life event, unique to the woman, where the woman takes part in decision making and where not only a healthy outcome is expected but also an emotionally satisfying one (Bryar 1988).

### 5.2.3 Pain relief

Support through and relief of pain remained an issue at this stage of labour. Whilst, as stated above, the woman may feel the second stage was easier than the first as she could work actively with the contractions, the latter were still painful and other new sources of discomfort occurred. As delivery approached, considerable distension of the soft tissues takes place and extremely uncomfortable sensations experienced as the baby's head emerged. At this stage the midwife gave constant encouragement, using clinical skills and judgement to ensure that this stage of labour proceeded as smoothly as possible. It was also sometimes necessary to administer local anaesthetics at this stage, if episiotomy (a surgical incision of the perineum) is required.

### 5.2.4 Emotional support

Women needed emotional support at this stage of labour. This was provided by the continuous support of the midwife, encouragement for the woman's efforts, feedback about progress and reassurance that all was progressing well. In addition to support from the midwife, this was a part of the birth companion's role.

### 5.2.5 Attention to hygiene, comfort and hydration

The second stage of labour was hard physical work for the woman. The work of pushing made the woman perspire more and she needed to be as refreshed as possible. The mouth became dry from pushing and sips of ice or cool water were needed between contractions. To avoid delay and complications during the second and third stages of labour, it was considered optimal that the woman's bladder was not full and the midwife needed to assist the woman to achieve this.

In addition to achieving basic hygiene and comfort, there was a need to minimise the risk of infection to the woman and her baby. This routine started, as described in the previous chapter, on the woman's admission to the labour ward with cleansing of the perineal area with the shave, enema and shower routine, albeit in the mistaken hope that infection might be avoided and the baby delivered into a clean area. As the actual birth approached, further cleansing took place to prepare a sterile field for

instruments and into which the baby could emerge. This swabbing and draping followed a set pattern for each maternity unit and needed to be achieved, if at all possible, at each delivery. Great importance was accorded to the correct placement of sterile drapes. Achieving correct application of drapes was a landmark in a student midwife's training and was a ritual which midwives moving between units had to achieve to be considered by colleagues to be practising in an acceptable way.

### 5.2.6 Position and Pushing

At the time of the case study, birth took place in most units in the United Kingdom in the semi-recumbent position with a minority of units admitting that they actually *stipulated* the position which women should use for birth (Garcia and Garforth 1989). Twenty -eight percent of units surveyed in the Confidential Enquiry into Facilities available at the Place of Birth were reported to have equipment similar to that used in this trial and, in several units, research into their use was in progress (Chamberlain and Gunn 1987). The semi-recumbent position was, however, perceived as the norm by women and their midwives at the study site.

Most women adopted a semi-recumbent position in bed, supported by pillows. As the delivery approached, women were encouraged to place their feet against the midwives' hips to achieve a brace against which to push a position not without discomfort (Grierson 1983). The position of

propped up semi-recumbency was difficult to maintain as women often slid down the bed due to use of plastic undersheets. Between contractions, the woman moving back up the bed to where she had started from used precious energy.

This position was adopted when the woman was encouraged to commence with active expulsive efforts. Whilst position was stipulated, so too was the way in which women were encouraged to push. The convention at the time was for three long pushes to be accomplished with each contraction to maximise the progress of the fetus towards delivery. Women were exhorted to make considerable efforts at this stage and to hold their breath for prolonged periods of time, taking only a quick breath in between expulsive efforts. Whilst some small differences existed between midwives, certain elements were common to the package. The instructions given by the midwife at this stage often took the form of a chant and were a further ritual of midwifery practice. Some information was given on how events were progressing, encouragement to greater effort was usually advocated, but generally, the information followed preset patterns and dealt with the matter in hand. Whilst standard practice at that time, this method of pushing was unwelcome to some women (Grierson 1983).

At the time of delivery of the baby's head, instructions changed to encourage the woman to pant to slow down the emergence of the baby's head with the aim of minimising trauma to mother or baby.

### 5.2.7 Delivery techniques

As delivery approached, certain rituals were used to try to achieve a sterile field for delivery (as described in section 5.2.5).

At the time of the trial, set techniques were used in the delivery of the baby. The principles underlying these techniques were considered to be the delivery of the smallest diameters of the baby across the perineum to reduce the risk of perineal lacerations, although these fundamental beliefs have been challenged recently (Myrfield, Brook and Creedy 1997). Whilst assisting with delivery of the baby's head, the midwife would use set positions of her hands to apply gentle pressure to the baby's head and to slow down the rate of delivery, for the reason previously described and also to prevent trauma to the baby. Certain techniques were used to detect and deal with nuchal cord (the umbilical cord being wound around the baby's neck). To assist delivery of the baby's trunk then further set hand positions and techniques were used, again with the aim of minimising trauma and the baby placed, in most cases, on the woman's abdomen. Following this, the baby was separated from his mother by the midwife or occasionally the woman's partner clamping and cutting the umbilical cord.

### 5.3.1 Midwifery care in the third stage of labour: definitions and purpose

The third stage of labour lasts from delivery of the baby until, and including, delivery of the placenta and membranes. It is usually the shortest stage of labour and lasted in most cases five to seven minutes. During the third stage of labour, again in the majority of instances, the woman resumed the role of passive recipient of treatment. The method of management most commonly practised at the time of the trial was known as active management.

The midwife's responsibilities at this stage of labour are detailed in the European Community Midwives Directive and those relevant to the third stage of labour are as previously stated. The birth of the baby brings the additional responsibility as follows:-

> "5.8 to examine and care for the newborn infant; to take all initiatives which are necessary in care of need and to carry out where necessary immediate resuscitation" (UKCC 1994, page 6).

This demonstrates that after delivery of the baby, the midwife had two separate recipients of her care. The woman's well-being remained a cause of concern and the baby's health also required monitoring.

### 5.3.2 Observations and monitoring

Whilst the third stage of labour was shorter, there remained a need to monitor the woman's condition. Potential problems included inability to deliver the placenta, uterine inversion and the risk of postpartum haemorrhage. Thus the midwife remained vigilant until this stage was completed and in the hour following, as this was the time of greatest risk of primary postpartum haemorrhage.

### 5.3.3 Pain relief

The third stage of labour was usually less uncomfortable for the woman. Contraction of the uterus was felt and some rectal pressure as the placenta delivered. Explanation of the sensations was usually adequate support, unless complications occurred.

### 5.3.4 Attention to hygiene, comfort and hydration

The short duration of the third stage rendered it unnecessary to make especial efforts to prevent dehydration. Thirst was easily relieved by sips of water.

Prior to delivery of the placenta further cleansing took place with the aim of avoiding the introduction of infection to the raw area within the uterus from which the placenta had separated. A sterile field was also used to minimise the risk of infection to any perineal trauma which

was awaiting suturing. It was difficult to achieve comfort at this stage of labour when an uncomfortable position must be maintained. The woman was tired from the exertion of the baby's birth. There was also not the emotional satisfaction associated with achieving placental delivery as with the previous stage of labour. Thus the third stage of labour was usually endured with few women, at that time, expressing interest in inspection of the placenta.

### 5.3.5 Position

The woman's position during delivery of the placenta and membranes was also subject to little variation. A semi-recumbent position was used and the midwife palpated the abdomen to detect satisfactory progress in separation of the placenta from the uterus.

### 5.3.6 Techniques

The technique known as active management involved administration of an oxytocic drug into the muscle of the woman's leg during the birth of the baby's body. Placental delivery would then be accomplished by a technique known as controlled cord traction, used following contraction of the uterus. This required a bracing of the midwife's hand behind the symphysis pubis, whilst the placenta was delivered. Blood lost was collected, measured and all necessary information documented.

## 5.4 Care after birth

The second midwife attending the birth had the responsibility of assessing the condition of the newborn baby and of providing immediate care. The prime concern was that the baby was in a satisfactory condition in terms of heart beat, colour, respiratory effort, muscle tone and response to stimulus. A standard scoring technique, known as the Apgar Score, was used at one and five minutes after birth to assess the newborn's condition and to trigger resuscitation measures. The initiation of such measures was the responsibility of the second midwife, who would summon paediatric assistance, if required. Further activities in care of the newborn were the drying and wrapping of the baby to prevent heat loss and application of an umbilical cord clamp. At the time of the study, cleansing of the eyes with normal saline solution was also carried out and the baby weighed within a few minutes of birth. Identity bands were written, checked by the parents for accuracy and applied to the baby's limbs. Parents wanted to know their baby's weight and to know that there are no apparent problems or congenital anomalies: thus the second midwife carried out the first examination of the baby and relayed this information to the parents. The second midwife would carry out the first recording of baby's temperature. Temperature was subsequently recorded hourly for the first three hours of life to detect hypothermia. The umbilical cord was also observed for signs of haemorrhage. The second midwife obtained permission from the parents to administer an intramuscular

injection of vitamin K. The baby was then dressed in a hospital issue napkin and baby gown.

The newly delivered woman was then presented with a dressed and tightly wrapped baby on completion of the remainder of the delivery procedures. These activities took place immediately after the birth and could all be accomplished within five minutes, following a brief opportunity for the woman to hold and look at her baby. If the mother wished to breastfeed, the attending midwife would assist with the first breastfeed within an hour of birth. If bottle-feeding, the first feed was given by a midwife or a nursing auxiliary.

The next necessary step was the repair of perineal trauma, which in all but the most minor cases, at the time of the trial, involved the junior medical staff. The midwife prepared certain sterile equipment, then the doctor scrubbed up as if for surgery and with the woman in the uncomfortable lithotomy position (legs secured in stirrups) sutured any lacerations.

In addition to the first, second and third stages of labour, there is also an unofficial fourth stage of labour. This lasts for the first hour following the birth, when the midwife remained in close observation of the woman in case of complications such as haemorrhage.

In the time immediately after birth, some women experienced discomfort from uterine contractions or "afterpains". Such

discomfort, which was quite severe for some women, especially multiparae, was usually treated with simple oral analgesics. Pain from the perineum was treated with local application of ice, bathing and simple analgesics.

Following the above activities, if all was well, the NHS rewarded the mother with tea and toast and the opportunity for a shower! Women remained on the labour suite for at least an hour following birth during which time the above activities took place, documentation was completed and the woman and her baby transferred together to a postnatal ward.

## 5.5. Factors affecting midwifery care in the second and third stages of labour

The following issues already affected midwives' work in the second and third stages of labour:- the organisation of midwives, time limits and administrative duties. In addition, the role of midwifery training, cultural norms and research will all be explored.

### 5.5.1 The organisation of midwives

During the second and third stages of labour, the midwife was in constant attendance on the woman. During the allocation of midwives to labouring women detailed in the previous chapter, a woman's stage of labour was taken into account. If a woman was approaching the second stage, then a midwife would be busy for some time and unable to provide

much care for other women, although variations in workload often meant that midwives had to provide care for more than one woman at a time. Interruptions could still occur whilst midwives were caring for women in the second stage of labour.

At the time of the actual birth, a second midwife was called to the delivery room, whose responsibility was to provide immediate care for the newborn, as detailed in section 4.4. The allocation of the second midwife was not usually pre-arranged. As the birth became imminent, the attending midwife asked the partner to ring the bell in a certain manner. The activities carried out by this second midwife were usually accomplished quite speedily. This was because the second midwife would usually have left unattended a labouring woman for whom she was providing care.

It is also important to remember that the attending midwife, responsible for the delivery, may also have been responsible for the care of another woman throughout this period, so she had concerns about that woman's welfare. If the attending midwife had not previously been allocated to care for another woman, news of the delivery was often greeted with the allocation to an impending arrival on the labour ward. This would often be another labouring woman. Thus considerable pressures existed for the midwife to complete one case in order to move on to the next.

### 5.5.2 Beat the clock !

Policies and protocols shaped midwives' work in the second and third stages of labour, just as they did for the first stage. Standing orders stipulated drug dosage and methods of administration. Policies, even if unwritten, formed the basis for much of practice. One particular issue of great relevance to midwifery practice was the time allowed for expulsive efforts and during which delivery should be accomplished.

The rules of the unit stated that delivery of the baby should be accomplished within certain time limits: one hour of active pushing for women expecting their first baby, and thirty minutes for women expecting a second or subsequent baby. This was by no means confined to the study unit with sixty percent of units in England and Wales reporting time limits for the second stage of labour (Garcia and Garforth 1989). Failure to achieve delivery within this time would necessitate the woman's referral to a junior doctor, who would then discuss the case with a registrar with a view to instrumental delivery.

Whilst some midwives were happy with having clear policies for when to refer patients, the one hour time limit was not universally supported. Mechanisms by which midwives could buy some time for women to progress normally were well known, as described by Rothman in a study of New York nurse-midwives (1983).

The existing tensions between midwives and obstetricians were exacerbated by the inappropriateness of the above referral mechanism. Not only did an experienced professional, the midwife, have to refer to a less experienced professional, the Senior House Officer, but the midwife usually had a very clear idea of what needed to be done and who should do this - an assisted delivery by the registrar.

In relation to the third stage of labour, the midwife's management was stipulated by a unit policy and drug standing orders which stipulated active management of the third stage of labour.

### 5.5.3 Midwifery education

Training as a midwife had a large part to play in defining a midwife's care and methods. Midwifery work comprised to a large part clinical skill. The theory of the mechanisms of labour (the process of the accommodation and passage of the baby through the mother's pelvis) was taught in the classroom and often learned by rote.

Classroom instruction was supported by the use of textbooks, some written by midwives. Midwifery textbooks of the time contained very detailed instructions about every aspect of care in labour. The mechanisms of labour were described and then every aspect of care in labour was specified, even where the midwife had to stand to conduct the delivery (Myles 1982).

Examples from the midwifery texts of that time will illustrate the approach

> "Encouragement should be given and a word of commendation after each effort is opportune. Praise is a good stimulus to continued endeavour" (Myles 1982, page 310).

Whilst being instructed very clearly on how to encourage the woman to push and how to conduct delivery, Myles left her reader in no doubt over who was in charge of the event

> "Some prefer patients to be propped up on three pillows or two foam wedges" (Myles 1982, page 308).

The *woman's* preference was not commented on nor was the midwife instructed to obtain it, despite being instructed on everything else. The prevailing view was that it was the midwife who was in charge.

Another key feature of the midwifery texts of the time was in their exhortations about the importance of midwifery care and the "intensive vigilance" which should be exercised over every aspect of labour (Myles 1982, page 309). The second stage of labour was

> "Fraught with danger to the mother and child" (Myles 1982, page 307)

The third stage of labour was the

> "most hazardous for the mother" (Sweet 1982, page 209), requiring skilled care to avoid complications.

Elsewhere, in relation to the midwives' conduct of the second stage of labour, a more reverential view of the midwife's care is shown

"It is now that the true value of the midwife is revealed" (Sweet 1982, page 207).

Such advice put pressure on the midwife. The approach of Myles and Sweet appeared to be a mixture of didactic instruction and reverential awe. Perhaps their aim was to give midwives unswerving confidence in their ability and the knowledge that they were taking the correct course of action in each circumstance. The teaching was, in clinical terms, entirely sound for its day and considered the best in the world. It may appear inappropriate to criticise but it quite clearly had limitations. Both Myles and Sweet were products of an era where nursing, a precursor to midwifery for many practitioners, had been entered as a vocation rather than a job. The midwife was advised, quite correctly, to demonstrate a respectful and reverential attitude to attending birth (Myles 1982). Myles had practised at a time when avoiding prolonged labour was even more important due to poorer maternal health. The need to avoid the disasters of postpartum haemorrhage or obstructed labour was paramount. It can be debated, however, whether these approaches really engendered confidence in the midwife or simply induced an inflexible approach to providing care to a woman whom, some authors appeared to consider, should be grateful for such professional expertise (Myles 1982).

Clinical placements allowed experience to be gained from observation of and instructions from qualified colleagues. During training, student midwives in England were required to perform 40 normal deliveries, considered the minimum to achieve competence in delivery technique. Much of learning the skills of midwifery practice consisted of making use of the handed down perceived wisdom of experienced colleagues. Despite their didactic tone, the midwifery texts acknowledged that clinical techniques could only be learned through experience (Sweet 1982).

### 5.5.4 Cultural norms

Contemporary midwifery culture had considerable influence on several issues. These included women's position for birth and other aspects of behaviour considered appropriate for women in labour. This did not include the use of alternative positions for birth, which were considered unnatural. Midwives in another unit described them as

> "too animal and degrading" (Griffiths and Hare 1985).

How did semi-recumbency come to be the position most commonly used at the beginning of the 1980's? The historical influences on birth position have been described in detail elsewhere, as have cultural differences in birth practices and birth position (Jordan 1978; Englemann 1882). Thus, only a brief summary will be included here.

It appears that accoucheur convenience played a key role in maintaining the status quo of semi-recumbency. The

semi-recumbent position was really a modification of the previously used lithotomy position. Semi-recumbency achieved a token improvement in raising the woman's head and lifting her back from the mattress and avoided fixing her feet in stirrups. However, semi-recumbency still achieved excellent access and visibility of the perineum for the attendant and scope for cleansing and draping and creation of a sterile field, as if for surgery.

Birthing chairs and stools had been hallmarks of the midwife's repertoire of previous centuries. Such equipment had taken over the physical support role previously performed by fathers and thus contributed to the banishment of the latter from birth rooms. They had provided

> "an artificial means of placing the woman in the semi-recumbent position." (Englemann 1882).

Sitting had been the most frequently used position for birth since the sixteenth century, despite the disadvantages of contamination of the midwife with bodily fluids and perineal damage for the woman (Gélis 1991). Furniture was used to avoid the fatigue of the woman and her attendants in maintaining her in an upright position (Giron 1906-7, cited in Gélis 1991).

However, the stark appearance of some of the equipment, coupled with the unnatural nature of an inanimate object in contrast with the warmth of human support, became synonymous with the pain that women of earlier centuries could expect in labour (Gélis 1991). The often quoted

historical landmarks of the introduction of obstetric forceps and of the means of reducing the pain of childbirth through the use of chloroform and ether also contributed to the banishment of upright positions, especially from institutional birth. The former, due to accoucheur access and the latter due to the woman being rendered insensible.

Many midwives working at the time of the trial had previously delivered women in the left lateral position. Thus they were not totally unused to some variation in this aspect of practice. However, despite this and the fact that a few units still utilised other positions for birth, the most commonly used position and one perceived as culturally normal at the case study unit was birth in bed in a semi-recumbent position.

The unit had many very experienced midwives who had worked there for much of their professional career. Low staff turnover is a positive feature within a working environment. However, it may result in little introduction of new ideas. If, in addition, midwives were unchallenged by requests from women for alternative approaches to birth, then the same methods of practice perpetuated and new methods were often not introduced or used.

### 5.5.5 Research

Whilst there is currently an acknowledgement of the need for practice to be evidence-based (Renfrew 1997), this has not always been the case in midwifery. In the early

1980's, many midwifery and obstetric practices were based on custom and professional preference such as routine perineal shaving and administration of enemas.

However, the foundations for some practices may have been based, originally, in some small and somewhat remote part on research. One example was the time limit commonly accepted in English Consultant maternity units to accomplish delivery of the baby, that is the permissible length of the second stage. The origins of limiting the second stage appear to be from a paper by Wood et al in 1973. This research had methodological shortcomings in terms of a small sample size, lack of blinding of observers involved in measuring outcomes and included practices different from those used in the early 1980's. Thus the research foundation was both shallow and an inappropriate base to practice. Yet the practice of limiting the second stage was, as previously discussed, widespread and fairly absolute.

In terms of care in the third stage of labour, the policy of active management was widespread in the United Kingdom in the early 1980's. Its appropriateness as a policy for all women went unchallenged by midwives with few exceptions. The foundation for the policy arose from the work of Spencer, amongst others, who determined that the use of controlled cord traction in conjunction with administration of oxytocin would reduce haemorrhage following placental delivery (Spencer 1962), although this was not without some side effects.

Thus research had contributed, in a small way, to the foundations of management and care for the second and third stages of labour at the time of the trial. However, the research foundation was usually unacknowledged by midwives and unknown to the majority. Very little *midwifery* research per se existed at that time thus only obstetric research influenced practice on the labour and delivery suit. This was shortly to change with the work of midwifery researchers such as Romney. However, at the time of the trial, midwives had the research findings of another discipline, imposed upon them.

Midwifery did not see itself as an academic profession in need of a research base to its knowledge until some time later. Sheila Hunt has written that midwifery has traditionally been a profession characterised by action, whereas "scholarship is a rigorous, demanding disciplined unhurried activity" (1993, page 177). Research carried out by obstetricians was usually published in medical journals, often not accessed by midwives. Some research of posture for labour had been conducted outside the United Kingdom and again, published in journals not easily available to British midwives.

Hunt explored the reasons why research findings were not implemented by practitioners (1981). In addition to the difficulties, firstly of access identified above and secondly, in interpretation of the findings, Hunt also identified scepticism as a reason why research findings may

lack relevance to practitioners. Whilst Hunt's study included nurses, her findings apply to midwives. Many midwives questioned the value of research as an activity and the appropriateness of the posture research to the local population.

In general, research and midwives did not mix (Thomson 1988). It was something usually designed and carried out by doctors with minimal midwifery involvement. Research was not a part of midwifery training or the contemporary midwifery culture.

The trial came, therefore, as a significant new addition to the labour ward situation.

## 5.6 The impact of the trial on the work and experiences of the attending midwife

Thus, into the cultural norm of a set position for birth, a second stage restricted in length, with the woman's expulsive efforts directed by a midwife, came the trial.

The aim of the trial was to assess the effect of using the upright position for the second stage of labour and delivery on several obstetric outcomes. The randomised controlled trial impacted on the work of the attending midwives in key ways in the second and third stages of labour.

The protocol stipulated that a Fetal Scalp Blood Sampling

test would be performed at the start of the second stage of labour. In this procedure a sample of blood is obtained for testing for pH levels. In labour ward practice at that time, fetal scalp pH was the best marker for detecting acidosis in the fetus. At the time of the study, this procedure was used to determine fetal well-being when cardiotocograph traces appeared suspicious of fetal distress. The procedure was invasive for both the woman and fetus and, in the case of the trial, uncomfortable for the woman at a crucial stage of labour. At the time of the trial, it was used infrequently. The fetal scalp pH was to be accompanied by obtaining a sample of maternal venous blood, again for pH estimation. These readings would form a baseline measurement against which samples of maternal and umbilical cord blood obtained after the birth, could be compared and would allow between position comparisons of the acidotic change in the fetus and maternal-fetal differential.

A further change to the midwife's working practices came with the inclusion within the trial protocol of a new technique for maternal expulsive efforts. This technique, known as limited bearing down, was introduced by an obstetrician from Uruguay as part of a package aimed at achieving a normal labour and birth (Caldeyro-Barcia 1979). This package challenged several of the practices in common usage at that time: routine amniotomy, the recumbent position for delivery and prolonged breath-holding with expulsive efforts during the second stage of labour.

The third and most obvious change for the midwife was in the woman's position for birth. Half of the women in the study were allocated at random to spend the second stage of labour and deliver in the upright position. This was a change for all midwives in the study unit, as the equipment was new and had been purchased through research funding. It was also expected that the placenta and membranes would be delivered and perineal suturing take place in the allocated delivery position.

If the research midwife was unavailable, then it was hoped that labour ward midwives or junior obstetric staff would collect blood samples after delivery for pH analysis.

### 5.7 Difficulties for midwives

The additional difficulties caused for midwives by the randomised controlled trial fall into several themes, which will subsequently be explored. These are :-

1. Increased work
2. A change to practice
3. What value research ?

#### 5.7.1 Increased work

The first change imposed by the study was the use of Fetal Scalp Blood Sampling at the onset of the second stage of labour. The inclusion of this technique as part of the research, whilst obviously familiar as a diagnostic tool in

cases of suspected fetal distress, did not endear the protocol to the midwives. It was considered additional work, too invasive to be used purely for research purposes and unlikely to be welcome to women in advanced labour. The latter turned out to be completely accurate.

The opportunity for this additional screening of fetal well-being at that stage of labour was not supported by the midwives. They felt that if there was no indication to carry out the test on clinical grounds, then that argument appeared spurious. In the event, the concerns expressed by the midwives were valid, as it soon became obvious that women did not wish to have the test performed and it would be impossible to complete the research if the fetal blood test remained mandatory. Thus, the fetal blood sample and maternal sample at the start of the second stage of labour became optional.

Some midwives suggested that the use of the prototype equipment comprised additional work for them. The equipment had to be moved between delivery rooms, often at a time when the woman was advancing in labour, sheets placed on it and thorough cleaning was required afterwards. This was extra work as the prototype was used in addition to a bed, which the woman used earlier in labour and to which she returned after the birth. Two pieces of equipment were used, where usually only one was needed and extra work ensued also in helping women to transfer between the two.

As previously described in section 5.6, if the research midwife was unavailable, it was hoped that ward midwives or junior doctors would be involved in collecting and analysing blood samples after delivery. This was rarely accomplished and was unwelcome. Whilst at the time the strength of feeling was difficult to understand, on reflection, that position is entirely reasonable. At the start of the trial, the blood gas machine was situated in the theatre complex distant from the labour ward area. It required a five minute walk in each direction, time awaiting analysis and permission from staff in that area and thus proved more work when staffing levels were often stretched. It was therefore impossible to spare midwives for such an activity. Even when the blood gas analyser was situated on the labour suite, it was considered unacceptable for the midwife delivering the woman to carry out the research function, as she was expected to remain with the woman in the period immediately following delivery (Central Midwives Board 1980) and not to abandon her to carry out purely research procedures. Similarly, the second midwife was keen to return to the woman she was attending in labour, on completion of the immediate care of the baby. No spare capacity existed to take on the research activity from within the existing staff resources during the research midwife's annual leave.

During the second stage of labour, the atmosphere in the delivery room altered. Midwives were engrossed in their work. However, additional communications were sometimes needed because of the research. These were a further

interruption for the attending midwife, just as those related to students (Hunt and Symonds 1995).

At the time, it was easy to interpret the midwives' position as an unwillingness to help with the research. However, it has been demonstrated that the trial caused additional work for the midwife, whose priority was the provision of clinical care.

### 5.7.2 Changes to practice

The next significant change was in asking midwives to change their technique when encouraging women with expulsive efforts during the second stage of labour. Traditional practice and that included in the midwifery texts of the time has been described above (see section 5.2.6).

In the trial, the use of the technique of "limited bearing down" was to be encouraged. This involved encouraging the woman to follow her own instincts about pushing and not to receive breath-holding instructions. Adams wrote of the almost chant-like way in which the midwife's encouragement proceeded during the second stage of labour (1989). The midwife had to learn the ability to give encouragement without direction and how to inform on progress without encouraging further effort: features of the usual method. The midwife had to change the habits of a professional lifetime!

Besides being a change in a fundamental midwifery practice, the apparently slower rate of progress of the baby towards delivery impacted on the midwife's other concerns about how long she and the woman had to achieve delivery without medical intervention. Whilst the trial protocol allowed for this and encouraged the midwife to consider progress and maternal and fetal well-being, rather than a one hour time limit, this proved unsettling as the midwife was without another of her usual parameters. Whilst for some midwives this proved a positive experience and a useful dimension to practice, many felt uncertain and uncomfortable in the face of a lack of upper limit of labour duration.

The third and most obvious change to practice was in being expected to deliver women in the upright position. This new and aesthetically unappealing piece of equipment was purchased through research funds for use by women in the trial. Several midwives expressed concerns about where to stand to perform the delivery, where the drapes and instruments could be placed, their ability to control the delivery and reduced visibility of the perineum. These concerns remained vivid some time after the trial.

A further component of the attending midwife's concern was about when to help a women to transfer into the upright position. The purpose of the study was to evaluate the effects of the upright position during the second stage. Its use was not intended for the first stage of labour. Midwives were concerned that a woman transferred too early would become uncomfortable and subsequently suffer

perineal oedema: a side effect already reported (Goodlin and Frederick 1983). However, for a woman experiencing her second or subsequent birth, the first stage of labour might progress rapidly and the second stage last only a few minutes. If transfer was left too late, then the woman's opportunity and her participation in the research were lost.

The physical relationship of the woman and midwife was also different when using the upright position rather than the bed. The woman was upright and usually at the midwife's eye level. This was completely different from their usual spatial relationship and, in some cases, reduced the physical distance between them. It has been suggested that an upright position helps women to ask questions, make requests and to have these met (Sherr 1995).

Further practical concerns about using the upright position related to immediate care of the baby. The absence of a relatively flat surface on which to place baby, and the different method of collecting blood lost at the delivery were significant concerns for some midwives.

Midwifery practice of that era did not generally include the former practice of delivering the baby into the midwife's apron (Leap and Hunter 1993), favoured by domiciliary midwives earlier this century. Thus short umbilical cords or a mother's preference not to have the baby placed on her abdomen provided some technical difficulty for the midwife.

The different and possibly more accurate method of collection of blood loss was also a concern. When birth takes place on a bed, there is a certain amount of contamination of bed linen. This results, it is generally agreed, in an underassessment of the amount of blood actually lost. The collection of blood into a receptacle from births in the upright position avoided this. Pilot work carried out in another unit, albeit using a different type of equipment, found a higher rate of postpartum haemorrhage. Postpartum haemorrhage was always a concern to midwives and could be detrimental to the woman's condition. In addition, midwives did not want to be associated with deliveries where haemorrhage occurred, lest it be considered their poor management. When considered against a background of the tone and authority of the teaching described previously from the contemporary midwifery texts, the midwives' concerns were valid. They had been instructed in no uncertain terms about the methods which should be used to attend labouring women. Conducting the trial was, in itself, a challenge to traditional practices and to some a criticism. Such concerns can leave the professional emotionally vulnerable (Harding 1988).

The change in position also increased the likelihood of contamination of the midwife by the woman's body fluids at delivery. This obviously proved unpopular and appears a justified concern. Some midwives chose to change into theatre clothing and wellingtons to conduct deliveries in the upright position.

Pressures were put on the attending midwives as they were caught between the research team and the concerns of junior medical staff in relation to perineal repair. The research protocol stated that perineal repair would take place, where possible, in the allocated delivery position. The research midwife tried to ensure that this occurred. Here, the practice and working experiences of the medical staff were changed. They were also sometimes faced with a situation clinically different and technically more difficult to the one with which they were accustomed.

In addition to the differences imposed by the trial identified in sections 4.6.1-4 and 5.6, there are fundamental differences between conducting other controlled clinical trials and those which involve midwives. The midwife, as described in sections 5.2.1 and 5.3.1 carried the responsibility for ensuring a safe outcome to the birth for both the woman and baby. The midwife was herself the instrument in care in normal labour and had only one chance to do her job correctly.

This was different to clinical trials of other aspects of medical care. Whilst some drugs may cause extreme reactions, antidotes are often available and other pharmacology may reverse side effects. Problems occurring from a midwife's care cannot always be reversed. The midwife is conscious that inappropriate management on her part may result in a brain-damaged infant or a woman with enduring morbidity from the delivery. These are irreversible and, in addition, may lead to complaint or

litigation, which every practitioner dreads. In addition, there is a relationship between the woman and her midwife, even if only during the labour, which was not a feature of, for example, pharmaceutical trials. These are the underlying reasons why the changes to midwifery practice caused such a concern for the midwife. There was a great deal at stake.

#### 5.7.2.1 Cultural norms

There was also the issue of cultural norms. Although some midwives had experience of delivering in the left lateral position, that was a different situation to that of the upright position. The left lateral position was seen as an *official* position, as it remained a part of the current midwifery culture, albeit in a small number of units and it had previously been used by some of the unit's midwives. There was also written instruction available in some contemporary texts of how birth in the left lateral position should be conducted (Sweet 1982). It was therefore acceptable, if slightly unusual, whereas the use of equipment to facilitate the upright position for birth was completely outside the local midwifery culture.

Despite the historical precedents, the upright position was not viewed as a normal part of practice and thus received little support from the midwives. Modern practice used more sophisticated technology. Modern midwives were proud of their professional status. The historical association was an unpopular image. These modern practitioners did not

wish to be associated with their professional predecessors who caught babies with women seated in armchairs, surrounded by numerous others and when many women died in childbirth.

Due to the delay in receiving the equipment, there could be no further delay and the trial started immediately on arrival of the equipment. Change is generally accomplished more slowly in clinical practice and the immediate start of the trial allowed no time for acclimatisation.

For the research midwife, the proper start of the trial could not come quickly enough, after a five month delay. However, the fact that even after this delay, attending midwives were still surprised at having to start the trial suggests that the process of helping midwives to acclimatise to the change could have been handled better. This leads on to the consideration of how midwives were prepared for delivering women in the trial.

#### 5.7.2.2 Preparing midwives

So, how were midwives prepared prior to delivering women in the trial? The acquisition of such training is, and always has been, a requirement of the Statutory Instruments (UKCC 1994).

There is a need for pilot work in controlled clinical trials. A small pilot study to familiarise midwives with the technique of limited bearing down was carried out

whilst the equipment was awaited. This proved useful for those midwives involved but left many still uninitiated into the technique. Considerable selection bias operated in choosing the sample, thus not preparing midwives adequately for the reality of using a new technique with women experiencing labours which progressed very differently.

Whilst the trial received considerable support from one senior midwife and efforts were made to provide opportunities for midwives to discuss the technique of delivery in the upright position, concerns persisted. A minority of units had experience of such equipment and none locally: thus midwives with such expertise were unavailable. A video was obtained, which purported to show births in a variety of postures, including that of sitting and this was shown to midwives in the unit. A rather stony silence descended as the practices within the video bore little resemblance to local practice and did nothing to reassure. The attending midwives therefore had no means of observing colleagues conducting such deliveries prior to the trial, which is, after all, how the majority of delivery techniques are learned and nothing was available in the midwifery texts. Coming at a time when midwives had suffered a de-skilling and erosion of their role, it is hardly surprising that such a radical addition was unwelcome.

Assisting women to give birth in a range of positions was an area of practice which, at the start of the trial,

received little attention in the midwifery texts. It was not until 1986 that Flint's textbook suggested that deliveries in positions other than semi-recumbency were easy (Flint 1986). Her book also included illustrations to assist the midwife in preparing for this task.

#### 5.7.2.3 The question of normality

A major question appears to be around the definition of "normal" in the context of midwifery practice. The use of the upright position theoretically remained within the parameters of normality, when a woman was progressing in labour with no apparent problems with her condition or her baby's. Alternative delivery positions were viewed by midwives as different, if not frankly abnormal. The woman remained in normal labour and the midwife is the expert trained in normal childbirth. Yet the strength of midwives' concerns suggests that either they did not entirely believe this or that there must be other causes for their concern. It was all a great upheaval to many midwives as it went against the practices of a professional lifetime and was not culturally normal. The midwife was being asked to make this trip into the unknown at the stage of labour when her responsibilities were most acute. At that time, there was an ethos of labour being normal only in retrospect, so the midwife had enough uncertainties about outcome and well-being, without adding the clinical trial.

### 5.7.2.4 Midwives and ways of learning

Why was being asked to deliver in the upright position such a trial for the attending midwives? The development of clinical skills in midwifery will now be considered more closely. Whilst theory is introduced in the classroom setting, clinical skills are gained initially through observation of qualified midwives, through the guiding hands of another midwife placed over the student's in the early stages of learning to deliver and through closely supervised practice in a requisite number of births during training.

At the time of the study, forty deliveries formed the minimum number which needed to be achieved to qualify as a midwife and by which safe delivery technique could be learned. There are shortcomings in having a finite number of times to achieve competence in a task, when clinical experiences vary and when individuals learn at different rates. The pressure on students and their mentors to obtain the requisite number of deliveries meant that whilst these were achieved, it was at the expense of other aspects of care (West and Thompson 1995). Some junior midwives asked the research midwife to put sterile gloves on to guide them with the delivery. These concerns about conducting the delivery were still recalled by the attending midwives sometime later. From this, midwifery training does not appear to have prepared the less experienced attending midwives to apply their skills in different situations.

As previously stated, a midwife

> "must be able to give necessary supervision, care and advice to women during labour, to conduct deliveries on her own responsibility " (UKCC, 1994).

The training programme should prepare her for that. However, it seems that it did not. If midwives' confidence is shaken by considering birth in positions other than semi-recumbency, then the training of the time must be considered inadequate, perhaps due to the inflexibility of approach.

Midwives learn in a variety of ways. Recently there has been acknowledgement of the value of story telling as an educational tool. Information is absorbed because the situation recounted is real (Kirkham 1994).

When the trial started, an early participant allocated to the experimental group required an assisted delivery: this was seen by the midwives as condemnation of the upright position. If women wished to leave the upright position or their labour did not progress well in that position, the research midwife soon knew about it! Harding described how being associated with a randomised clinical trial meant that she was held responsible for all of a woman's subsequent problems, whether or not they were associated with the management under review (1988). As this trial progressed, positive accounts did emerge, albeit still overshadowed by the negative cloud hanging over the upright position. Positive accounts were offered in an apologetic tone by midwives who realised that they were challenging

the cultural norms and preferences of the majority of their colleagues. In discussions amongst colleagues or with labouring women, the attending midwives' personal experiences were also shared and these usually related to accounts of giving birth in bed as being acceptable.

#### 5.7.2.5 Midwives and decision-making

Whilst the experiences of the more junior midwives have been described above, consideration must be given to the more experienced midwife. This section will explore the effect of introducing a new technique on midwives' decision-making.

There is a growing literature on the decision-making process for practitioners of nursing and midwifery. Most acknowledge the work of Dreyfus and Dreyfus who identified the five steps through which a practitioner moves from novice to expert (1986). Benner and Tanner applied this to nursing (1987) and, more recently, decision-making has been addressed in the context of midwifery (Price 1995).
According to Cioffi and Markham (1997), midwives use the cognitive process known as heuristics in their decision-making. Whilst there are several components, representativeness is one key component of decision-making, which requires exploration. The term representativeness is used to reflect the fact that a certain set of signs may indicate a particular clinical condition (Cioffi and Markham 1997). As the clinical signs are the same with the use of the upright position, there is no difference with

the representative element of the decision-making process. However, the "availability" component or ease with which similar situations come to mind is altered. In the case of the trial, availability was not present. Due to the introduction of this new equipment, such situations were not available for use in the decision-making process.

Thus, just as midwives were unable to access knowledge from midwifery texts or from colleagues' oral reports, their decision-making process was also affected by the trial.

#### 5.7.2.6 Manifestations of concern

Midwives' concerns about the trial manifested in a variety of ways. Conversations between midwives or a sharing of their opinions with antenatal and labouring women made their concerns clear and overt. The reluctant involvement of some midwives with the trial was a further manifestation of unease. Some women who had previously been recruited were not entered into the trial, despite apparent clinical eligibility and willingness to take part. The incidence of this was particularly high when the research midwife was on holiday.

The midwives affected by this trial were not alone in their concerns and the local situation of not getting the correct participants into a trial was not unique. In the Dublin trial, Crowley reported an entry into the trial of women ineligible for the study (1991). It was suggested that this was in the hope of getting the trial completed as soon

as possible, once the target sample size became known. There are alternative explanations for the entry of ineligible women into Crowley's trial. It may be that the midwives were unhappy to restrict use of the equipment and thus broke the rules to provide women with that choice. A further explanation relates to Thomson's observation about midwives' lack of understanding of research protocols (1988). Forgetfulness and pressure of work also contributed to the failure to enter some women into the local study, just as with the MAIN trial (McCandlish and Renfrew 1991).

One manifestation of concern about the trial was a questioning of the necessity of the research enterprise.

### 5.8 Issues related to research

In the following sections, issues related to both midwives' experiences and association with research will be explored.

#### 5.8.1 Research: a necessary activity

The research midwife provided information to colleagues from published papers related to the upright position for birth: this was not all favourable (Beardsell 1983). This met with some interesting responses. Further questions were raised about the necessity of carrying out the local study, concerns about negative findings (Goodlin and Frederick 1983) and a doubting of the whole exercise. The attending midwife was placed in a dilemma. Being obliged

to participate in the local research, then she was being asked to practice in a way which had already been demonstrated as having some shortcomings and which may possibly not be in the best interests of her patient, which is the stipulation in the Code of Professional Conduct (1992).

It also reinforced the view of some midwives that research findings were not taken notice of and research as an activity lacked usefulness and thus credibility. Whilst it was generally agreed that the enterprise should be completed, there was a general feeling of doubt about undertaking research.

As described in section 3.4.1, the avoidance of selection bias is a key component of the randomised controlled trial. The method of random allocation to treatment options used in the trial was of opaque sealed envelopes. This produced some amusement amongst both women and attending midwives as it appeared to resemble a lottery. It appeared difficult to associate such an apparently trivial method with a serious investigation.

Several other issues gave the trial a less than sure foundation: the delay in starting the trial due to awaiting the arrival of the equipment, the changes to protocol and the exclusion of a significant part of the potential study population.

This trial was, for many, the first time when attending midwives had come into contact with research, especially that which affected their practice. It was also the first time that the post of research midwife had been appointed in that unit.

On conclusion of the trial, no publications were submitted to the midwifery journals: a shortcoming on the part of the research midwife. Thus the research just disappeared from the scene. Midwives' history of involvement in research and their views about research workers will now be explored.

### 5.8.2 Midwives and research

The Report of the Committee on Nursing (Chairman Professor Briggs 1972) recommended that nursing and midwifery should become research-based professions. Despite this, at the time of the trial, midwives had little involvement, either during or after qualification, with research. Research-awareness appeared in the midwifery training syllabus in September 1980 (Central Midwives' Board 1977) and the one English research-based Statutory Refresher Course commenced in 1977 (Towler and Bramall 1986). However, thirteen years after the Briggs' Report, there was little evidence of systematic evaluation in midwifery and midwives still lacked training in research (Oakley and Houd 1990).

A clinician affected in any way by research needs to be in a state of clinical equipoise (Lilford 1992) about the

relative merits of the treatments under review. This may be easy for some disciplines used to the experiment to achieve new knowledge. However, midwives based their practice and decision-making on elements beside research such as tradition and intuition (Rees 1997).

Hicks explored midwives' views of midwifery clinicians and researchers (1995). Hicks found that midwives associate different characteristics with being a good researcher rather than a good clinician. Midwives associated greater ambition, poorer communication skills, being less kind, stronger, more logical, less emotional, more confident, less popular, less compassionate, more rational, more organised and more analytical with being a good researcher rather than with being a good clinician (Hicks 1995). When these characteristics are compared with those required of a midwife in section 4.4.1, divergent views emerge. It appears difficult to reconcile the caring and compassionate midwifery image with an involvement in research.

It has been demonstrated that, in the labour suite, attending professionals are affected by and can themselves affect the research. To be involved in randomised controlled trials, an experimenter is needed. Experiments require a systematic approach with the steps of the experiment repeated exactly on each occasion: labour may not allow this to happen.

## 5.9 Difficulties for women which also impacted on the work of the attending midwife

One obvious difference for women participating in the trial was the presence of additional staff during the second stage of labour and at the delivery. The reason for this was to ensure that the trial protocol was followed and that blood samples were collected for analysis. The research midwife attended the births of women in both arms of the study. She tried to be useful, not interfere with the attending midwife's care unless requested and keep in the background, offering only thanks and congratulations to the woman and her family. The presence of additional staff immediately appears sub-optimal for the woman and her birth companion (Hunt and Symonds 1995). However, that was not uniformly the experience within the trial. Several women and their partners expressed pleasure at meeting someone whom they had met before. It offered a known face at a key time, when the woman was in a new environment and many women appreciated this form of continuity. This was particularly welcome to women if their attending midwife was called away, as they still felt supported (East and Colditz 1996) and this was also appreciated by some midwives.

Several women were very disappointed at their allocation to use of the labour bed, despite thorough explanations about the random allocation. This disappointment can be understood and has been reported in other randomised controlled trials of maternity care (Waldenstrom and Nilson

1993). As previously stated in section 3.3, women had fewer experiences of childbearing in the 1980's than earlier this century. In addition to delivering a healthy baby, the woman also hoped to have a satisfactory birth experience and opportunities to achieve this were fewer. Whilst some women were, at the time, unconcerned with their allocated position, the disappointment of some women supports McNabb's view that it is inappropriate to subject such important topics as birth position to random allocation within a controlled trial (1989). The disappointment expressed by women of all parities runs counter to the claims of Gupta and Lilford that multiparous women are more sanguine about the benefits of different delivery positions (1987). All of the above experiences affected the attending midwives as they, in addition, to the research midwife had to support the woman and her partner with any disappointment and distress.

Women participating in the trial were attended by midwives who were practising in ways with which they were unfamiliar. It was described in section 5.7.2.2 that midwives expressed concerns about how to conduct delivery in the upright position. On some occasions, women became aware of the midwives' concerns. Harding observed that the prejudices of professional staff may spread to women resulting in a lack of confidence in the trial (1988). Women trust midwives because of their expertise and usually believe that the midwife knows best (McCrae and Crute 1988) but they are sensitive to the emotional tension around them during labour (McKay and Smith 1993; Raphael-

Leff 1991). The trial contributed to increasing that tension.

### 5.9.1 Women's knowledge of the midwives' views

When discussing the trial, women asked the research midwife about her colleagues' views. Her response was honest and indicated midwives' very mixed views about one of the options within the trial.

At the time of the trial, the research team did not attempt to formally assess and quantify midwives' support or opposition to the new method of management. However, Lilford suggests that potential participants become uncomfortable about taking part in a trial if two thirds of clinicians are against it (1992). Further, that a trial is unethical if aggregated clinician preference falls outside that ratio. The optimal situation is for the clinician to be uncommitted to either treatment option, to make his or her own preference clear to the patient or to have obtained the patient's consent not to do that (Lilford 1992).

Is it appropriate to place women in a situation of uncertainty when the birth experience is so precious? Simkin has demonstrated that women have accurate long-term recall of events around the birth of their children (1991). Is it acceptable to ask the midwife to do anything different from her current practice and anything less than her best, which is usually the method she has practised most? When the significance attached to negative events

may increase over time and the only recourse for dissatisfaction at the time of the trial was via the complaints procedure or litigation, then changing practice has significant implications for all parties.

Whilst these are primarily issues of concern to the pregnant or labouring woman, they also impact on the attending midwife due to the additional tensions which may arise in the short but vital relationship between the two.

### 5.9.2. The impact of the research midwife

The research midwife met almost all of the women who entered the study during the antenatal period and was present at the majority of births. This offered a continuity not available generally in the maternity system at that time. Many women were pleased to have the opportunity to discuss the labour after the event with someone who was there: this again was not usually available. This took place when the research midwife sought their views about birth position and thanked them for their help with the research. Many women thanked the researcher for the opportunity to take part and were pleased to contribute to the research. They also thanked the research midwife for her help; an experience also reported by Oakley (1994). In some cases, the contact after the trial of birth position continued at the women's instigation for several years after the birth. The research midwife was privileged to receive Christmas cards enclosing photographs of the children. Difficulties in

terminating the researcher-participant relationship have been reported elsewhere (Oakley 1994; Davis 1986). Research midwives should aim to work in a way which does not foster dependency.

The effects on women of participation in clinical trials of care in labour are only partially understood, although there is a changing trend in reports. From a brief mention of women's experiences, almost as an afterthought in obstetric papers (Flynn and Kelly 1978), more recently separate papers have included both midwives' and women's views (Harding et al 1989). These papers have usually concentrated on views on the methods of management and issues such as comfort and acceptability. There are mixed messages from separation of the obstetric from the psychosocial and the relegation of women's and midwives' experiences to less mainstream journals. More recently women's views on their actual participation in clinical trials have been reported including the effect on privacy, the approach of the research midwife and information received about the trial (East and Colditz 1996).

Researchers need to consider this issue. The satisfaction questionnaire is a frequent component of maternity service provision and evaluation. Yet the effects of research participation and satisfaction with that experience are not usually included in such surveys. Researchers should consider the use of such methods as standard feedback for the planning of future clinical trials of maternity care

and as an essential element in units where research is a frequent activity.

## 5.10 Where does that leave the attending midwife? Conclusions and Recommendations

Overnight, the attending midwife was asked to change several of the practices of her professional lifetime. These were also important practices at a key stage of labour, when the midwife was already working at full capacity. Not only did the attending midwife have to change practice but she also had additional work to accommodate at this stage of labour. Placing this in the context where the cultural norm was also being challenged, then there is no surprise that the midwives were concerned. The midwife had no reassurance that the way in which she was being asked to work was one which would be in the interests of the woman. Midwives were not prepared nor did they have access to information from other midwives about this new method. Clinical decision-making was altered.

Alternative ways must be considered to prepare practitioners for future trials. From experiences in this clinical trial, it appears that first hand experiences are important. Harding, in describing the preparation of midwives for the Bristol Third Stage trial, sought advice about physiological management from midwives experienced in its use (1988). She then transmitted this information to her colleagues. From Kirkham's work (1994), it appears important to cut out the middleman and present the sharing

of skills as personal experiences. Midwives appear to like information "straight from the horse's mouth". This could be supplemented by the involvement of a midwifery educationalist to facilitate workshops to revisit anatomy and physiology and the mechanisms of labour. Use of anatomical models or clinical simulators and appropriate audio-visual material might also be helpful, although nothing will replace practice. One thing is certain, women should be looked after by confident practitioners, especially at such a key stage of labour.

Whilst the means of practical preparation have been outlined above, there is also the need to consider other preparation. Whilst conscious that her colleagues may have concerns about the project, the research midwife was surprised by the strength of feeling. Knowledge of the theory behind the change process and support in achieving acceptance of the trial in a more structured way may have been helpful to her and her colleagues. The research midwife worked to provide information to colleagues, listening to concerns, offering frequent project updates and being available almost all of the time to deal with the trial. This was clearly not enough, or, for whatever reason, ineffective.

Midwives' concerns about this trial manifested in a variety of ways. In future studies, a different approach is necessary. Midwives' views on both the treatment methods and the process of the research could be collected as an integral part of the investigation. These views would then

be seen as being taken seriously and being of equal value to those of participants. Whilst completing the research picture, the effects of this approach on the incidence of deviations from protocol could then be measured.

Midwives were also receiving mixed messages on the value of research and were left with many questions about research as an activity. Lack of involvement and education in research methods undoubtedly contributed to this. The research midwife, a novice to research herself, was perhaps unconvincing or unreassuring. These issues should be addressed in future research during the development and pilot phase of the trial.

The effects of research staff on the outcomes under investigation must be considered in this type of research. It has been demonstrated that the research midwives in this and other studies have been an additional interaction for the women receiving services. They are another variable in the experiment whose effects pass unmonitored. Research staff should take care to minimise the effects of their presence on the process under investigation. Whilst they may ensure a standardisation of technique and ensure that a protocol is followed, it may also become difficult to separate the effects of the individual from the effects of the intervention. It is important to avoid disrupting important therapeutic relationships, for example, between women and their attending midwives. Research workers must take care not to encourage dependency amongst participants, as the former are usually a transient phenomenon.

## 6.1 Final reflections

This chapter will review the case study of the trial of the upright posture for labour and delivery. The chapter content will begin with a reflection on the use of the case study as a research approach (section 6.2). This will be followed by a summary of the impact of the trial on the work of attending midwives (section 6.3.1) and the issues which emerged (section 6.3.2). The findings of the research programme will then be applied to present day midwifery and the wider research agenda (section 6.4.1, 2 and 3). Recommendations will then be made both for the conduct of future intrapartum research (section 6.5.1-6) which affects midwifery practice and for the direction of future research (section 6.6.1-5). This chapter will conclude with a summary of the benefits of undertaking this programme of research (section 6.7).

## 6.2 Reflections on the use of the case study approach with particular emphasis on midwifery

One of Platt's criticisms of the case study approach is that easily available cases seldom lead to good research (1988). The trial and its setting could be held to be an example of the easily available. However, easily available does not mean easily achievable for either data collection or analysis. Platt's implication that the convenient should be avoided can be challenged on the grounds that its

use avoids the need for additional resources. It also maximises the use of background knowledge, essential for the case study researcher and also allow exploration of issues. This ensures that the concerns of all parties involved are regarded as important, dealt with sympathetically and difficulties which occurred are better understood.

A further criticism of case studies relates to the confusion between case study as a method of teaching and research. However, when the case has cast new light on a situation and learning has taken place, such criticisms appear misplaced. Stake argues that the researcher who uses case studies is in fact a teacher who uses a range of approaches but to whose account the reader can relate (1994).

The case study presented as a chronological narrative offers the story-telling approach suggested by Kirkham to be a vital learning method for midwifery (1994). Thus, this approach in a piece of midwifery research reflects a way of sharing knowledge used in other aspects of midwifery practice. For midwives, use of the case study avoids manipulation and separation of an entity and studies the totality as advocated by Bates (1995).

In presenting the case, the organisation of material was considered very carefully and alternatives considered. The presentation and analysis of issues has taken place according to the stages of labour. Firstly, it is a

chronological approach in line with that chosen for the presentation of the case narrative. Secondly, it is an approach which will be familiar to at least part of the intended audience (midwives) and thus hopefully more easy to relate to their own experience. Thirdly, it has been used to reflect the increasing pace of the impact of the trial as labours progressed and midwives' concerns increased.

In case study literature, it is suggested that internal validity can be established by posing rival explanations (Hutchinson 1990). This approach was particularly useful in considering which issues related to the protocol caused the most concern for midwives (see sections 4.6.1-3). However, the purpose of a naturalistic enquiry is to allow understanding of a situation in order that theory can be generated for subsequent further exploration. In this case, concerns arose from a variety of different and sometimes related reasons. Thus, whilst this was useful, in a naturalistic enquiry such an approach alone is insufficient.

Some authorities challenge the use of terms such as validity and reliability in the context of qualitative research (Lincoln and Guba 1985) and suggest alternatives such as truth values. The difficulty with these terms is that they are used by experienced qualitative methodologists in specialist texts. The term validity is used here as it is the one which appears more frequently in texts related to research methods used by midwives (Rees

1997). The components of validity will be investigated. Whilst each component of the data collection has its own strengths and weaknesses, the use of a range of approaches to data collection allows construct validity to be achieved; this is a strength of the case study approach. The case narrative and issues which emerged from the data collection have been reviewed by midwives who took part in the trial and are held as a true account. Thus face validity has been confirmed (Mays and Pope 1996).

It was stated earlier that the investigator is a key element in the case and thus potentially one of the greatest weaknesses. The requirements of case study researchers are that they must be able to respond to issues which arise and also to have a comprehensive grasp of the situation and issues, ask the correct questions and be open to the information received (Yin 1994, Stake 1994). These are also skills which midwives use in clinical practice. Lest the reader should feel that it is only skills of story telling which are required, this is not so. The investigator is responsible for the interpretation made and must make the decision about the findings of the case study (Mays and Pope 1996).

In conclusion, whilst there are shortcomings to the use of the case study approach, including the tendency to dwell on negative experiences (Treece and Treece 1986), case studies have human interest (Platt 1988). Case studies allow, not just the reflection cited in section 2.1.3, but also the opportunity to acknowledge concerns beyond those of the

researcher and to treat such concerns empathetically (Stake 1994). They offer a non-manipulative approach well-suited to the midwifery researcher and offer a similarity to other aspects of midwifery practice in that they can incorporate the activities of teaching, advocacy, evaluation and reporting (Stake 1995).

## 6.3 A summary of the findings

The following sections will briefly summarize the findings of the investigation identifying the impact of the trial and analysis of the issues from the perspective of the attending midwife.

### 6.3.1 A summary of the impact of the trial on the work of the attending midwives

It has been demonstrated that the labour ward is a unique setting for conducting clinical trials. The trial impacted on the work of attending midwives in several ways. It affected care and the philosophy of care in the first stage of labour. It altered communications and added further interruptions to those already experienced by midwives. Its impact was most pronounced at the period of labour of greatest concern to midwives and an additional player was added to the scene. This brought with it a resulting increase in and change to interactions between the attending midwife and labouring woman. The trial caused more work and changed fundamental aspects of midwifery practice. It attempted to encroach on the midwife's

deployment of staff. Existing professional tensions were exacerbated and midwives had a new role placed on them: that of gate-keepers to a research sample. Midwives were also caught between researchers, the woman and medical staff.

Midwives' concerns manifested in a variety of ways. The research midwife appointed to co-ordinate the trial was new to the unit. Whilst possessing some understanding of research and the enthusiasm essential for midwives working on projects, she was unversed in the theory behind the change process, suggested to be an essential pre-requisite to such work (Washbrook 1991).

As stated in section 1.3.2, the case study is both the means and outcome of the learning. Analysis of the case revealed issues which have contributed to the understanding of the midwives' concerns and of the difficulties encountered in running the trial.

### 6.3.2 A summary of the analysis of issues

Lack of involvement at the planning stages of those subsequently affected by the research is detrimental to the progress of such trials. The trial demanded changes of approach. Midwifery training of that time relied on fairly traditional methods in classroom teaching, authoritative texts which stipulated one approach and passing clinical skills down the midwifery generations. The method used to prepare midwives for the trial was inadequate and various

aspects of the trial undermined confidence and raised questions about what comprised normal in the context of midwifery practice and local culture. Several issues contributed to tensions surrounding the trial. Other changes to the ward's philosophy and practices had taken place within a short period of time. These had all impacted on the work of the midwives. The midwives' perception of a lack of consultation about the introduction of the trial meant that no feeling of ownership was engendered. Ethical dilemmas emerged.

The trial took place at a time of change in both maternity care and midwifery practice. A new era had dawned in maternity care with the advent of consumerism. Midwives, whose role had been eroded and closely regulated, were meeting several new challenges but were still, themselves, within a model of subordination to obstetrics and the systems imposed by their profession and their employers. For wrong-doers, there were threats of disciplinary action. The trial raised several questions about research activity and midwives' involvement in that.

For midwives, the primacy of interests were those related to the well-being of the individual labouring woman and her baby with only one chance to get things right in the care of a woman in labour.

## 6.4 Application to the present day

Prior to making recommendations for the conduct of future trials of intra-partum care and direction for research, the contemporary situation will be reviewed.

### 6.4.1 Maternity care and the care setting

Maternity care has received considerable attention from central government in the past six years. Two key reports, from a House of Commons Select Committee (1992) and the Expert Maternity Group (1993), both acknowledged the pivotal role of the midwife in maternity care. Philosophies of providing women with choice, continuity and control in her experience of maternity care are now considered desirable. The philosophy of continuity is achieved through the various new ways in which midwives are organised. One aim of current patterns of care is particularly important in the light of the case study and that is to reduce the number of professionals with whom the woman comes into contact.

The geographical base of care has also altered. The previous shared care arrangements, even for women in normal patterns of pregnancy, meant that several visits were made to the hospital antenatal clinic. Now women may attend for an ultrasound scan and the remaining antenatal care is provided in the community. Thus opportunities to approach all women about research at a given stage at a hospital antenatal clinic do not exist now, as they did in the early

1980s.

Labour ward is, however, to many extents unchanged. It remains a stressful area for midwives to work in (Mackin and Sinclair 1998). These researchers found that 78% midwives felt that they had insufficient time to perform duties to their own satisfaction. A perceived inability to affect the work place agenda also contributed to their stress. Midwives are still dealing with students, telephone enquiries and other administrative issues. It remains an area where workload may vary widely. The fundamental nature of the work and midwives' responsibilities remain virtually unchanged.

### 6.4.2 Midwifery: education, practice and research

Since the trial, the midwifery profession has undergone several changes. Training has been incorporated into higher education thus becoming geographically distant from its service link (Silverton 1996). Education is now provided at a minimum of diploma level and there are considerable changes in the resources available to midwives. There are several refereed journals and a far wider range of basic and specialist midwifery texts. Midwifery has moved on. It encourages flexibility and the provision of informed choice. There is also academic interest in models and philosophies of midwifery care (Bryar 1995).

As stated in section 4.5.5, at the time of the trial, midwives had suffered from an erosion of role. Many positive changes have occurred since the trial and these have offered opportunities to midwives. However, significant threats to the profession continue, although they may be different to the role erosion of the 1970s.

The clinical grading exercise of 1988 brought significant concerns. The current approach within the National Health Service is that of efficiency through managerialism (Symonds and Hunt 1997). The removal and downgrading of midwifery management posts has resulted in a weaker voice for midwives. There are also concerns about the potential for devaluing basic midwifery skills (Price 1994) and the possible consequences for women and midwives of academic success (Downe 1990). Some feel that a two tier system may develop from tensions between experienced clinical practitioners and those with academic achievements (Sidebotham 1993). Midwives do not always demonstrate respect for each other (Mander 1997) and there are concerns that midwifery may again be dominated by men. It is suggested that this will come from within the profession (Edwards 1994) rather than, as in the past, from obstetrics (Donnison 1988). Thus, working as a midwife remains a challenging and far from comfortable option.

Many of the tenets of practice held sacred for so long have been overturned. The time limited second stage, prolonged breath-holding and fasting during labour have all been challenged. However, policies and protocols remain very

much in evidence. Litigation is even more of a concern for both individual practitioners and the Trusts which provide their vicarious liability. There are new constraints on the work of the attending midwives. Initiatives such as Risk Management and the Confidential Enquiry into Stillbirths and Deaths in Infancy ensure that policies will persist. Tensions still exist in the midwife-obstetrician relationship (Hunt and Symonds 1995). If anything, regulations in the workplace are increasing. The research described in the trial would be unpopular for different reasons to-day. Changes to working position have to be considered carefully in the light of Health and Safety regulations and universal precautions used to avoid contamination with body fluids.

As Hunt stated, in the 1980s, few midwives were carrying out research without depending on other disciplines (1993) but the database dedicated to midwifery research (MIRIAD) is now expanding at an encouraging rate (McCormick and Renfrew 1997). Midwifery's research involvement and capability has developed significantly over the past ten to fifteen years (Mead 1996). Many midwives now pursue graduate and higher degree programmes. There are several Chairs in Midwifery in England and several midwives capable of leading programmes of research into midwifery practice. The Report of the Task Force on Research in Nursing, Midwifery and Health Visiting was entirely supportive of midwifery research. It encouraged the provision of research funding, training and the establishment of centres of excellence (1993). Research

remains high on the list of priorities in continuing education requirements for midwives and their Supervisors (Pope et al 1998).

The International Confederation of Midwives' statement on midwifery research (1990) advised that all midwives should be able to appraise and critically apply research findings. However, despite the progress cited above, some issues remain unchanged. There are still many midwives for whom research was not an integral part of their training. The current emphasis on evidence based practice is a useful experience for some but research is still not viewed as a necessary activity by all members of the profession.

Renfrew and McCandlish noted the lack of incentive for midwives to become involved, as research is included only in the criteria for clinical grading at grades H and I (1992). This does not encourage the incorporation of research into the role of practitioners working at clinical grades. For those interested in a career in research, there is a lack of career structure (Department of Health 1993). There is also a need to continue to strengthen the links between the component parts of midwifery: education, research and practice (Report of the Standing Nursing and Midwifery Committee 1998).

### 6.4.3 The wider research agenda

The National Health Service Research and Development programme launched in 1991 includes the evaluation of health technologies. The randomised controlled trial is the cornerstone of the Health Technology Assessment programme (Ashcroft et al 1997). Future research seeking to explore cause and effect will continue to utilise controlled clinical trials. Entries in the MIRIAD database demonstrate that midwives are using the randomised trial in researching their own practice. It appears certain that midwives will continue to come into contact with this research method. However, in some of these contacts the trials may be initiated by a midwife.

## 6.5 Discussion and Recommendations for the conduct of future research which affects midwives' intrapartum care and discussion of alternative approaches

### 6.5.1 Planning

All parties affected by a trial of labour management must be involved in the planning. Examples of this have been reported (Rogers et al 1998). This may allow identification of serious difficulties such as procedures unacceptable to midwives and women. A collaborative approach would also allow a range of outcome measures to be included, which meet the interests of all parties.

Aspects of care which fall within the midwifery remit should not be altered without consultation and it appears counter-productive to change too many practices within a short space of time. Given the constant change occurring within the NHS, midwives have many initiatives and changes to cope with beside research.

It has been suggested that research likely to receive the support of staff is that which respects the woman as an individual, allows partner participation and which is easy (Power et al 1989). Involving an existing member of staff may be seen as less contentious than appointing an outsider who is not a part of the local culture. It may also ease access via midwifery managers, if the researcher is known from previous work (Mander 1992).

### 6.5.2 Training needs

The Supervisor of Midwives is a key individual whose responsibility is to support midwives in their practice and to ensure a high quality service (ENB 1997). Whilst the former focus of this role was on discipline, a new emphasis emerged in the early 1990s. The Supervisor of Midwives is now encouraged to adopt a proactive approach to supporting midwives in their practice. This should be accomplished as a guide and mentor to the midwife rather than as an arbiter over practice and punisher of misdemeanours. A key area for which the Supervisor has responsibility is in helping midwives to access the necessary training requirements when new tasks are used (UKCC 1994). Thus midwives have access

to a source of support when new practices are considered.

As stated in section 5.9, the involvement of midwifery lecturers may be considered, if fundamental aspects of midwifery practice are to be altered. The potential problem of this is that midwifery lecturers are considered to lack clinical credibility (Hindley 1997). They are also often not researchers (Kirkham 1994) so would need information themselves before harnessing their support for the research. Time should be spent in seminars on both the aspect of care being researched and on research methodology.

One part of the approach suggested above was reported recently (Rogers et al 1998) Midwives were surveyed to assess confidence in two methods of third stage management and training was offered where required. Several meetings were held to prepare staff for their roles in the trial. This trial of third stage management achieved a higher compliance with the treatment allocation than in the Bristol trial, less surprising when this unit was using expectant management more than Bristol. This demonstrates the importance of staff attitudes on the progress and integrity of the research.

### 6.5.3 Avoid disruptions

There are already enough interruptions to midwives' work. Like biases, the potential for disruptions to midwives' work must be minimised. Future research should include

midwives' views of treatment options (see section 6.5.1 and 6.5.2) and their experiences of the research process. This evaluation could be linked to monitoring trial progress and deviations from protocol. Problems associated with randomised controlled trials may, of course, be subject related.

On the labour suite, increasing establishment to support the research would reduce the interruptions to midwives' work and remove the additional player from the scene. It would, however, put all of the onus onto attending midwives who are already juggling many demands. Midwives would need preparation for such a role. This approach would be time-consuming in view of the shift system and would lose the focal point of information and co-ordination. The merit of trying this system would depend on the local system of midwifery working.

### 6.5.4 The change process

The person with responsibility for introducing the new project must have an understanding of the change process and be able to deal appropriately with the reactions and rejections which may be encountered (Washbrook 1991). This individual should also have a source of guidance and support.

### 6.5.5 Consent

For future trials, serious consideration must be given to how information can be provided to women during the antenatal period (AIMS 1997) and consent confirmed in labour. Alternative ways of providing information and recruitment have been tried in other research. However, difficulties in recruitment have been reported when this is left to clinical staff and selection bias has operated. However, continuity is not disrupted and there are no additional professionals involved. Further, any approach should not disrupt the process of care, for example, in the antenatal clinic. In the light of Patients' Charter standards on waiting times, causing delays in the system would be unacceptable.

All of this must take place in a way which considers the trade off between disturbing continuity of care or carer but also avoids compromising the quality of research information. New approaches to fulfilling the ethical obligations of information and consent require evaluation.

### 6.5.6 Consider alternative methodologies

Despite the higher profile of research in midwifery and wider exposure to it, some midwives are unhappy with the randomised controlled trial. The question is, therefore, how can rigorous research into cause and effect be conducted in a way which is more acceptable to midwives? An alternative approach is the randomised preference trial.

This approach has been criticised for requiring additional resources and offering little methodological advantage over traditional randomised controlled trials (Brocklehurst 1998). It may, however, offer a more ethically acceptable option for midwives in that women's choice and access to all options would be supported, including the woman's right to enter the trial.

## 6.6 Recommendations for new directions in research

The following sections will outline possible avenues for future research of relevance to midwives, consumers and researchers.

### 6.6.1 Providing information and gaining consent

Several areas warrant further investigation. New methods of providing women with information about research must be evaluated to determine women's perceptions of the quality of the information provided and the impact on the woman's experience of pregnancy and labour. Midwives' views on assuming that responsibility should also be assessed.

### 6.6.2 Midwife research assistants

Further work is required to map the experiences of research assistants who are midwives. Many midwives have now had such experience and this research would allow information on appropriate training, support and supervision. Nurses employed in research posts have reported isolation

(Carpenter 1990). Research midwives have been held to account for all of a unit's problems (Harding 1988) and have found working in research to be an unsettling experience (Oakley 1994). Difficulties of access (Patton 1980), role confusion (Wilde 1992) and denigration of the value of the role by others (Woodward and Chisholm 1988) are among the experiences of research assistants from the social sciences and nursing. However, as the author would stress, there are benefits to the work. Oakley reported greater understanding of the problems in the system and better insight into women's perceptions of the service (1994).

Identifying appropriate ways of monitoring the work of research assistants and their effects on the research are important. Whilst experimental research focuses on minimising bias and maintaining objectivity, there is still interaction. Good and Schuler confirm that research nurses have a key role in recruitment and retention of participants in trials (1997). They suggested that researchers working with experimental methodologies must individualise their approaches to retain patients in trials, whilst still maintaining a uniformity of technique. Methods of achieving this should be shared and areas of difficulty for research workers debated more openly.

### 6.6.3 The involvement of service users

Further work on methods of collaboration in research between professionals and lay groups is needed to identify

the components of best practice. The need to avoid tokenism or exploitation of lay groups or to use them as a "rubber stamp" is important. Similarly, mechanisms to inform participants about the outcome of trials and to provide them with reports needs acknowledgement as a necessary trial activity, both in terms of time and expense (Roberts 1990). Whilst various ways have been tried (Kenyon 1997), appropriate methods need to be identified.

### 6.6.4 Midwives and research

The nursing and midwifery professions have considerable problems when their own members become involved in research. Jordan has observed that there are no single definitions of the role, ward nurses view the research nurse with suspicion, managers consider research as a soft option, chosen by those seeking an easy life away from the wards (1990). Further work is required to determine the reason for midwives' attitudes to research (Hicks 1995) and to see whether any of these are amenable to change. It will also be interesting to note whether midwives continue to respect the research conducted by other disciplines above that of their own (Hicks 1992).

Can incentives be found to encourage midwives to engage in research activity? However, should incentives be required for a professional, or even a semi-professional group (Etzioni 1969)? Midwives see clinical care and research as completely different activities with no shared theme, although it has been suggested that there are commonalities

(Kirkham 1994). Similarly, Hillier and Shisto suggest that if midwives engage in reflection, then they become researchers of practice and contribute to the body of knowledge (1993).

The conventional midwifery career does not include the almost mandatory year in research which is a part of careers in some branches of medicine. Whilst Chalmers questioned whether experience in research offers appropriate experience for those who wish to return to pursue clinical practice (1991), at least this approach allows research to be a part of the mainstream experience. Research opportunities are increasing for midwives but not to the extent that significant increases in demand would be met. Research is pursued more frequently as a component of course work, rather than as a clinical activity.

### 6.6.5 Midwives, ethics and the Code of Professional Conduct

The fundamental role of the Code of Professional Conduct is to enshrine accountability for practice (Hillan 1992). In an analysis of the different purposes of Codes, charters and mission statements, Henry suggests that codes are enforceable by the profession (1995). Codes go further than charters in that they provide the professions with the means of regulating their members' conduct. The principles in codes are intended to generate positive outcomes. Nurses' knowledge of the Code of Professional Conduct is incomplete (Haywood Jones 1990). However, there has been

little investigation of midwives' understanding and application of the Code of Professional Conduct to their practice.

There is now a growing body of texts which apply moral philosophy to midwifery practice, for example Jones (1994). These offer an introductory approach to ethical theory and deal with important issues such as consent and confidentiality. Some texts do not address other midwifery concerns related to research. Midwives remain unprepared for the disappointment which women feel on random allocation and their own feelings in that and other research-related situations.

Henry explored the subject of professional ethics in the context of organisations (1995). Ethical decision-making in midwifery has received little attention until recently (Siddiqui 1997), although both the Royal College of Midwives and International Confederation of Midwives (1993) have issued guidance documents. Differences have been identified in ethical decision-making between members of different professional groups (Grundstein-Amado 1992). It is possible that midwives apply ethical theory differently to other health carers. Midwives need to spend more time in debate and investigation of these issues.

### 6.7 Benefits from this research

The case study has allowed a detailed exploration of what goes on beneath the surface when a randomised controlled

trial is conducted and the impact of such a trial on the work of the attending midwife. For the individual, it has proved a unique method of reflection, albeit in the context of a lack of definite evidence of the benefits of reflection. Important lessons have been learned for conducting future research. It has offered experience in qualitative research methods, complementing that gained in the quantitative and experimental approach of the trial. It has developed understanding of the difficulties encountered during the trial of birth position.

It has added to the body of case study research conducted by and related to midwives. It has also generated new theories for subsequent investigation and made recommendations for the conduct and direction of future research. There is a considerable body of information related to the impact of researchers on, for example, participant observation and interviews. This has contributed information about researchers engaged on experimental work. It has also raised questions about the appropriate preparation of such researchers, although it may be that this was a poor appointment and some of the difficulties would have been avoided by others.

The investigation has demonstrated that controlled clinical trials have a profound impact on midwives' experience of providing care. Neither midwives nor research should suffer when the two come into contact. This thesis has identified how and why problems occurred in one case study. Whilst analytic rather than statistical generalization is

possible from the case study approach, it has been demonstrated through using other research, that difficulties are not confined to one setting and issues of importance to the wider midwifery and research communities have emerged.

Recommendations have been made which aim to improve midwives' experience of research and to maintain the integrity of intrapartum clinical trials. Future investigators of intra-partum care should remember the advice of one health promotion research group (Power et al 1989):

> "Women must like the intervention but so too must staff for however effective an intervention may appear, it is unlikely to become part of practice unless and until midwives feel comfortable with it".

Appendix 1

## INTERVIEW SCHEDULE

As I discussed with you before, I am carrying out some research as part of a course. I wonder whether you would be able to help me by taking part in an interview. This will probably take up to an hour.

I would like to ask you about your experiences as a midwife working on the labour suite during the trial of birth position which was carried out here a few years ago. There are no right or wrong answers to the questions. Please just be honest and give as much information as you can from your own views.

I have obtained permission to approach midwives from the Head of Midwifery. However, you are not obliged to take part and no one will be informed of who agrees. Your name will not be recorded and you will not be identified in any reports.

Would you be willing to help me with this? Thank you.

Are you comfortable?

1 First of all, can you tell me what immediately comes back to you about the trial?

2 How did you get to hear that the trial would take place?

3 How did you feel when you heard about the trial?

4 What did you think about how midwives were prepared for the trial?

5 Are there any issues or events which you remember particularly from working on the labour ward whilst the trial was in progress?

6 To what extent did the trial being run on the labour ward have an effect on your work as a midwife?

7 Were there any aspects of the trial which had a particular impact on your work or experiences as a midwife on the labour ward - both positive and negative?

8 There are various ways of providing information and obtaining consent to clinical trials. You may remember that women were told about the trial and shown the equipment when they came to the hospital for their 32 week visit. Do you have any views about this?

9 I was usually around to check women's consent in labour and take bloods at delivery. Do you have any views about this?

10 When the trial came to an end and we'd finished recruiting women to the study, do you have any views about this part of the trial?

11 Are there any other issues related to the trial and your work as a midwife on the labour ward that you would like to tell me about?

Thank you for your time and the information.

Appendix 2

## THEMES ARISING FROM THE DATA

A selection of quotations from interviews with midwives demonstrated how themes were identified.

1. Issues related to communication

"It made them question the midwife more. I think I found that difficult at the time and I know other people were unhappy about it with you but you weren't telling them anything which they shouldn't have known really." (MW1)

"Women were getting more information from you." (MW2)

"You told us the results but the report went into a medical journal and I didn't think when it was the midwives that was fair."(MW5)

"We had to let you know or talk to you about what stage Mrs so and so was at, for the consenting." (MW7)

"I think we always wondered what you said." (MW8)

2. Changes to ward organisation

"It did affect things because we had to think about who would deliver them and then the students were affected." (MW3)

"I do remember it was difficult with the students they couldn't deliver in the chair and then at the beginning X had wanted just certain people involved well that wasn't on - especially as some of them didn't want to be." (MW5).

3. Changes to clinical care

"It was just so different delivering like that .. It's a confidence issue, you don't want to do it wrong. It's a confidence issue to do it the first few times and you don't want to do something wrong which will affect the woman." (MW1)

"A lot of people thought how am I going to deliver in it." (MW2)

"Also getting used to sitting down to deliver - took some trying using your lap to catch the baby on, if you needed it." (MW3)

"You had to be aware to follow protocols, there's a lot of do's and don'ts." (MW7)

4. Ethical issues

"The randomisation for the clients, especially the ones who didn't get to use it. Sometimes you felt disappointed for them … Midwives found it difficult to support someone when you know that they are disappointed with that outcome." (MW1)

"Well I suppose the lucky dip was difficult for some of them and then you'd feel bad as well." (MW2)

"They were disappointed if they wanted the upright position and got the bed." (MW3)

5. Lack of fit

"You were there all of the time but on the fringes - I don't know whether that's positive or negative but you didn't fit in - the way you worked I mean, that's not meant to be rude … also you worked with the doctors." (MW5)

"I suppose it was all new and I just wasn't sure where it all fitted in." (MW7)

"I remember you being around at report and trying to get a word in about the trial but it didn't seem to fit in." (MW8)

6. Changes to the culture

"Walking round wasn't normal for us." (MW3)

"... but at the time we were just starting to get research and I wasn't so keen then." (MW2)

"There were other things going on. A new obstetric theatre … Birth Plans, etc. All of a sudden, all these new things." (MW4)

"It was all so different - the research, the upright position … You as well, we hadn't had a research sister before so you as well." (MW4)

"It was just a whole new way of life." (MW5)

7. More work

"Generally though, I think it makes more work for the midwife to make it a good experience for the woman with the trial." (MW1)

"I remember dragging that monstrosity down the corridor, moving it, cleaning it, the comments women made." (MW1)

"People wanted support and we needed to be more supportive to the juniors and so we had to give them more time .. we had to give more input to that woman so it was more work."(MW2)

"The trial took a lot of time and effort. At the time it was a bind and a right hassle. Nowt but a bind." (MW2)

8. Why?

"Oh yes wasn't there the FBS - if it was about normal labour why do that? (MW4)

"I think also there were lots of changes with the research - like the epidurals were in and out of it. That seemed odd so it was difficult to understand." (MW5)

9. Research and midwives

"In the research, I was just glad it wasn't me, it's full-time, it's intense, the questions, the criticisms, a lot for someone to shoulder and I think we all wondered what you'd taken the job for. (MW1)

"It wasn't what I thought had to be done compared to other things - it was a bit on the edge of midwifery." (MW5)

Appendix 3

## THE RESEARCH PROCESS

1. The researcher had encountered certain issues when working as a research midwife on a trial of the upright position for birth.

2. A case study approach was selected as it offered the opportunity to explore, in depth, one case in its context.

3. The aim of the case study was to identify the effects of one randomised controlled trial on the work of midwives attending the labours of women participating in the trial.

4. A literature search commenced and continued throughout the investigation. This literature came from a range of disciplines and related to the midwifery profession, practice, education and research, randomised controlled trials and ethics, amongst other areas.

5. A log recorded during the trial allowed a preliminary identification of issues of concern to midwives associated with the trial, for example, the impact on midwives and women of the random allocation process.

6. All documentary sources of data related to the trial were identified and subjected to content analysis.

7. A purposive sample of midwives involved in the trial were interviewed to ensure that the focus of the investigation was on the work of the attending midwives.

8. Data from the interviews was subjected to content analysis and issues identified. In the case of the random allocation process, this confirmed the log entries that midwives had been unhappy with the random allocation and its effects on women's experiences and their own.

9. The researcher used the multiple sources of data to achieve validity.

10. A case report was constructed using a narrative and chronological approach, including both information about the setting for the trial and issues identified by midwives.

11. The remainder of the investigation focussed on analysing the reasons for the impact of the trial on the work of midwives attending women in labour. This was achieved by consideration of other literature from a wide range of sources.

12. The thesis closes with recommendations for midwifery practice, future research of intrapartum care and the wider research agenda.

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